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415-26

Approval report – Application A1341

Cell-cultured duck (*Anas platyrhynchos domesticus*) biomass

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Suprême SAS (Gourmey) to amend the Australia New Zealand Food Standards Code to permit the use of cell-cultured duck biomass as a food ingredient.

On 24 June 2026 FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 17 submissions.

FSANZ approved the draft variation on 6 October 2026. The Food Ministers' Meeting was notified of FSANZ's decision on 13 October 2026.

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

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Supporting document

The following document which informed the assessment of this application are available on the A1341 page on the [FSANZ website](#):

SD Risk and technical assessment (at Approval)

The published submissions from the call for submissions can be found on the [A1341 Consultation Hub](#) page.

Executive summary

In August 2025, Food Standards Australia New Zealand (FSANZ) received an application from Suprême SAS (Gourmey) to vary the Australia New Zealand Food Standards Code (the Code) to permit the use of cell-cultured duck biomass as a food ingredient.

The cell-cultured duck biomass is made from embryonic stem cells sourced from *Anas platyrhynchos domesticus* (Pekin duck). The biomass would be mixed with other ingredients to be used in products such as 'cell-cultured foie gras' and 'cell-cultured duck pâté'.

The application was assessed under FSANZ's recently developed regulatory framework for cell-cultured foods in accordance with established risk analysis principles and international best practice. In applying these principles, FSANZ adopted a cautious approach that recognises cell-cultured foods are an emerging and innovative food, and regulatory experience assessing these foods is still developing. This ensures a strong focus on safety is maintained as regulatory experience is gained, while also providing a clear and predictable pathway to market for cell-cultured foods assessed as safe.

FSANZ conducted a comprehensive safety assessment of cell-cultured duck biomass, including the cell line used in its production, using the best available scientific evidence. The assessment identified no public health or safety concerns associated with either the production cell line or the resulting biomass. The application was assessed under FSANZ's general procedure.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 24 June to 22 July 2026. Seventeen submissions were received and considered as part of our assessment.

For reasons set out in this report, FSANZ has approved the draft variation proposed at the call for submissions.

The approved draft variation includes:

- An amendment to section S25A—2 to include a definition of cell-cultured duck obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*.
- An amendment to the table to section S25A—3 listing cell-cultured duck derived from the cell line 8516-Duck-DP as detailed in application A1341.
- A new division in Schedule 25A, Division 2A, setting conditions for the sale and labelling of cell-cultured duck.
- An amendment to the table to section S25A—6 adding the assessed cell line 8516-Duck-DP for the purposes of Standard 3.4.1.

The approved draft measures ensure the use of cell-cultured duck biomass from embryonic stem cells sourced from *Anas platyrhynchos domesticus* as an ingredient in food for sale is safe for consumers.

1 Introduction

1.1 The applicant

Suprême SAS (Gourmey) is a Paris-based company specialising in the development of cell-cultured food products derived from animal cells.

1.2 The application

Gourmey submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of cell-cultured duck biomass¹ as a food ingredient. The cell-cultured duck biomass is made from embryonic stem cells sourced from *Anas platyrhynchos domesticus* (Pekin duck).

Approval would permit the use of cell-cultured duck biomass, in combination with other permitted ingredients, in the manufacture of food for sale in food service settings or as mixed food for retail sale, and would also permit the non-retail sale of the cell-cultured duck biomass as a wholesale ingredient to caterers or food manufacturers.

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

1.3.1 Permitted use of cell-cultured food

Paragraphs 1.1.1—10(5)(ba) and 1.1.1—10(6)(fa) of the Code provide that, unless expressly permitted by the Code, food for sale cannot be, or contain as an ingredient or component, a cell-cultured food.

For the purposes of the Code, ‘cell-cultured food’ is defined as meaning a food obtained by culturing cells isolated from any of the following sources: livestock; poultry; game; seafood (including fish); an egg or an embryo of any of the former’ (subsection 1.1.2—2(3)).

The applicant’s cell-cultured duck biomass would fall within the definition of ‘cell-cultured food’ because the food would be made from embryonic stem cells sourced from Pekin duck and, consequently, would be regulated by the Code as a cell-cultured food.

The sale and use of cell-cultured foods are primarily regulated by Standard 1.5.4, Standard 3.4.1 (when produced or processed in Australia) and Schedule 25A of the Code.

Section 1.5.4—3 provides that a food for sale may be, or have as an ingredient, a cell-cultured food if:

- the cell-cultured food is listed in Schedule 25A; and
- any corresponding conditions listed in that schedule are complied with.

Schedule 25A sets out food that is permitted cell-cultured food, sale and labelling conditions associated with each permission, and the cell lines that are permitted to be used in the production of cell-cultured foods in Australia.

¹ In this application, the term ‘cell-cultured duck biomass’ is used interchangeably with terms ‘cell-cultured duck’ or ‘harvested cells’ as short forms or due to context.

- The table to section S25A—3 lists permitted cell-cultured food. The only permitted cell-cultured food currently listed in that table is cell-cultured quail.
- The table to section S25A—6 lists assessed cell lines for the purposes of the definition of ‘assessed cell line’ in section 3.4.1—2 of the Code. The definition provides that an assessed cell line is a cell line listed in section S25A—6. Section 3.4.1—7 provides that a cell-culturing food business must only use an assessed cell line for cell proliferation. The table to section S25A—6 does not list the applicant’s cell line.

Permitted cell-cultured foods listed in section S25A—3 are subject to corresponding sale and labelling conditions set by Schedule 25A’s other provisions. For example, conditions on the sale of cell-cultured quail set out in section S25A—4 are that it must not be a food for retail sale, but a food for retail sale may have cell-cultured quail as an ingredient.

Although not specifically relevant to the decision to approve this application, the biomass will be imported into Australia in accordance with imported food requirements, and further processing and production of cell-cultured foods will be subject to the requirements of Standard 3.4.1 and other Chapter 3 standards in the Food Standards Code, as appropriate to the food business. These Standards do not apply in New Zealand.

1.3.2 Identity and purity requirements

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

Schedule 3 sets specifications by listing them or by applying a specification in an international publication listed in sections S3—2 and S3—3 of that schedule. There is currently no relevant specification for cell-cultured duck biomass 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. Labelling requirements relevant to cell-cultured food are summarised below.

Standard 1.2.1 sets out when food for sale must bear a label or have other information provided with it, along with the information that must be provided.

- Food sold for retail sale or sold as suitable for retail sale without any further processing, packaging or labelling:
 - Packaged food that is required to bear a label - the information must be provided on the label (section 1.2.1—6 and paragraph 1.2.1—8(1)(la)).
 - Food not required to bear a label - the information must be stated in labelling that accompanies the food or is displayed in connection with the display of the food (subsection 9(1) and (2); and paragraph 1.2.1—9(3)(baa)).
- Food sold to a caterer:
 - If the food is in a package and is required to bear a label – the information must be provided on the label of the food (see subsection 1.2.1—12(1) and (2) and paragraph 1.2.1—15(h)).
 - If food is not required to bear a label - labelling containing the information must be provided to the caterer with the food (section 1.2.1—13 and paragraph 1.2.1—15(h)).

- Other sales of food (such as a sale between an ingredient supplier and a food manufacturer) - the information must be provided to the purchaser if that information is:
 - requested in writing by the purchaser or required by the relevant authority, and
 - necessary to enable the purchaser to comply with any compositional, labelling or declaration requirement of this Code in a sale of the food or of another food using it as an ingredient (section 1.2.1—21).

Standard 1.2.1 requires the labelling for certain foods for sale to include ‘information relating to cell-cultured food’. Subsections 1.5.4—5(2), 1.5.4—6(3) and 1.5.4—7(2) specify what that information is.

Standard 1.2.2 sets out information requirements for food identification, including requirements for the name of a food. If the food does not have a prescribed name, the name or description of the food must be sufficient to indicate the true nature of the food and include any additional words required by the Code to be included in the name of food (paragraph 1.2.2—2(1)(b)).

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

Division 2 of Standard 1.5.4 sets out the following general labelling requirements for cell-cultured foods:

- Section 1.5.4—5 applies to food for sale that has a cell-cultured food as an ingredient and requires that, for the labelling provisions in Standard 1.2.1, ‘information relating to cell-cultured food’ requires the use of either ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the name of the ingredient that is a cell-cultured food.
- Section 1.5.4—6 applies to a food for sale that:
 - (a) is for retail sale or suitable for retail sale without any further processing, packaging or labelling; and
 - (b) is packaged; and
 - (c) has a cell-cultured food as an ingredient; and
 - (d) is represented in words, images or both as being from the animal from which the cell-cultured food was sourced.

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

Subsection 1.5.4—6(3) provides that, for the labelling provisions, the information relating to cell-cultured food is the use in the name of the food for sale of the same statement that is used in conjunction with the name of the ingredient in accordance with section 1.5.4—5.

- Section 1.5.4—7 sets out the labelling requirements for a cell-cultured food that is either sold to a caterer, or sold other than by retail sale, sales to caterers or intra-company transfers (as defined in subsection 1.2.1—18 (2)). Subsection 1.5.4—7(2) provides that for the labelling provisions in Standard 1.2.1, the information relating to cell-cultured food is the use of the statement ‘cell-cultured’ or ‘cell-cultivated’ in conjunction with the name of the cell-cultured food.

Division 2 of Schedule S25A sets out specific labelling conditions for food for sale that has

cell-cultured quail as an ingredient. These conditions are:

- The label on the package of food must not contain the phrase ‘poultry meat’ (subsection S25A—5(2)).
- The labelling of the food must not contain the word ‘meat’ other than in conjunction with the following statements (subsection S25A—5(3)):
 - the statement required by section 1.5.4—5;
 - a statement required by section 1.5.4—6.
- Subparagraph 1.2.4—4(b)(iii), which permits the use of generic ingredient names specified in Schedule 10 to identify certain ingredients in a statement of ingredients, including ‘meat’ and ‘poultry meat’, does not apply to the food (subsection S25A—5(4)).

1.3.4 Prohibition on addition to special purpose foods

Subsection 1.5.4—4 prohibits the addition of cell-cultured food to special purpose food standardised by Part 2.9 of the Code. Foods under Part 2.9 of the Code include infant formula products, food for infants, formulated meal replacements and formulated supplementary foods, formulated supplementary sports foods and food for special medical purposes.

1.3.5 Code definitions

Standard 1.1.2 contains definitions applying across the Code. It includes a definition for cell-cultured food.

1.3.6 Microbiological limits for cell-cultured food

Section 1.1.1—11 of the Code requires that a ‘lot’ of a food must not have an unacceptable level of microorganisms as determined in accordance with Standard 1.6.1. A ‘lot’ is defined in subsection 1.1.2—2(3) as meaning an amount of a food that the manufacturer or producer identifies as having been prepared, or from which foods have been packaged or otherwise separated for sale, under essentially the same conditions. Standard 1.6.1 sets out how to determine whether a specific lot of food has an unacceptable level of microorganisms.

1.4 International situation

Regulatory frameworks for cell-based foods are still being developed in many countries (World Health Organization (WHO) 2023).

As of May 2026, the Singapore Food Agency has approved 5 cell-cultured foods for human consumption: GOOD Meat’s cultivated chicken, approved in December 2020 and their second cultivated chicken produced using serum-free media in January 2023; Vow Group’s cultivated quail, approved in March 2024; PARIMA’s (the parent company of Gourmey) cultivated chicken, approved in October 2025 and their cultivated duck (the subject of this application), approved in April 2026 (SFA 2026, PARIMA 2026).

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 oversee cell collection, growth and differentiation of cells, then transfer oversight at the cell harvest stage to FSIS. FSIS then oversees the cell harvest, processing, packaging and labelling of products. As of May 2026, the FSIS and FDA had completed 5 pre-market consultations for human food made with cultured cells material. Of the 5 approved products, 3 are cultured chicken cell material, one is cultured pork fat cells, and the other cultured salmon cell

material (U.S. FDA 2026).

Israel's Food Risk Management Department of the Ministry of Health (MoH) National Food Service approved a cultivated beef product on 17 January 2024 (MoH 2024).

WHO analysis of global developments in regulation and risk assessment indicated that, in most countries, cell-based foods are likely to be assessed within existing novel food regulations (WHO 2023). The objectives of Section 3 of the FSANZ Act² include 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), and;
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application was assessed under the General Procedure.

1.7 Decision

For the reasons outlined in this report, FSANZ approved the draft variation proposed at the call for submissions without amendment.

The approved draft variation will take effect on gazettal and is at Attachment A.

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

2 Summary of submissions

2.1 Summary of issues raised in submissions

FSANZ released the call for submissions on 24 June 2026 for a 4-week consultation period, closing on 22 July 2026. In total, 17 submissions were received (see Table 1). The submissions, excluding the confidential submission are available on the [A1341 Consultation Hub](#) page of the FSANZ website.

The submissions reflect a variety of views and highlight a range of issues, some of which were previously addressed by FSANZ during assessment of application [A1269 Cultured quail as a novel food](#). Some submitters were supportive of the application, FSANZ's assessment and conclusions and the draft variation. Other submitters raised concerns about the safety of the cell line and production inputs, including media components and growth factors. They also raised issues about microbiological safety of the harvested cells and final food, including expectations for production scale-up.

Table 1: Number of submissions received by submitter groups

² [Section 3 of the FSANZ Act](#)

Submitter group	Total
Food industry groups	6
Food manufacturers (Cell-cultured Food)	2
Government	5
Consumer advocacy group	1
Individuals	3
TOTAL	17

2.2 Submissions related to risk assessment

FSANZ conducted a risk assessment of the applicant's cell-cultured duck biomass, the full details of which are available in the supporting document (SD1).

With some exceptions, submitters generally agreed with FSANZ's risk assessment and draft variation, including the conclusion that the applicant's cell-cultured duck biomass raises no public health and safety concerns. There was support for the proposed Schedule 3 specification, sale conditions, labelling approach, continued prohibition on use in special purpose foods and consistency with the existing cell-cultured food framework. Several submitters also noted that the permission could support innovation, consumer choice and development of the cellular agriculture sector. Submitters raised several issues around the assessment and proposed draft variation. Two submitters opposed the approval of the cell-cultured duck and aspects of other submissions were out of scope.

A detailed summary of submissions and FSANZ's responses is provided at Appendix 1, Table A3, with specific issues also addressed in sections 2.2 and 2.3 of this report. The summary of submissions and FSANZ responses are provided in Appendix 1, Table A3.

3. Assessment summary

The application was assessed under FSANZ's recently developed regulatory framework for cell-cultured foods (described in Section 1.3 above) in accordance with established risk analysis principles and international best practice. In applying these principles, FSANZ adopted a cautious approach that recognises cell-cultured foods are an emerging and innovative food, and regulatory experience assessing these foods is still developing. This ensures a strong focus on safety is maintained as regulatory experience is gained, while also providing a clear and predictable pathway to market for cell-cultured foods assessed as safe.

3.1 Risk assessment

FSANZ's risk assessment considered the cell line, the production process, relevant inputs used to grow and propagate the duck cells in culture and the harvested cell-cultured duck biomass.

In summary, the assessment concluded the following:

- Embryonic stem cell line 8516-Duck-DP was confirmed to be of duck origin and the cells remained genetically and phenotypically stable during the production process.
- There are no safety concerns from exposure to the substances used in the production process at the estimated consumption levels.
- There were no microbiological concerns in relation to the cell line or production process. The production process is adequately controlled and meets established acceptance standards for manufacture of the cell biomass.

- There are no nutritional concerns associated with the consumption of cell-cultured duck biomass, particularly given its expected infrequent consumption.

The cell-cultured duck biomass will be combined with other components to create a final mixed food product. FSANZ's assessment did not consider additional incorporation of the harvested cell biomass into final mixed foods. Food businesses are responsible for ensuring all constituents present in the final mixed food product meet all relevant requirements of Australian and New Zealand food laws, including the Code.

3.2 Risk management

Following assessment, FSANZ prepared a draft variation and called for submissions from 24 June to 22 July 2026. The options available to FSANZ after the submission period were to:

- approve the draft variation proposed following assessment
- approve that draft variation subject to such amendments as FSANZ considers necessary
- reject the draft variation.

Having regard to the submissions received and for the reasons set out in this report, FSANZ approved the draft variation proposed following assessment (Attachment A).

Further details on the approval for cell-cultured duck and associated conditions are provided below.

3.2.1 Regulatory approval

The approved draft variation will amend the Code as follows.

The approved draft variation will amend section S25A—2 to define 'cell-cultured duck' as duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus* (see item [3] of the Schedule to the approved draft variation at Attachment A). This definition will apply to references in Schedule 25A to 'cell cultured duck'. That is, in the new cell cultured food permission to be added to section S25A—3 and in sections S25A—5A and S25A—5B, which impose sale and labelling conditions on the cell cultured duck that will be permitted by section S25A—3.

The approved draft variation will amend the table to section S25A—3 to list cell cultured duck derived from the applicant's assessed cell line as a permitted cell cultured food (see item [4] of the Schedule to the approved draft variation at Attachment A). The permission does not apply to any cell cultured duck. The permission is expressly limited to cell cultured duck that is derived from the cell line 8516-Duck-DP and detailed in Application A1341.

As explained below, the approved draft variation will also insert new Division 2A into Schedule 25A of the Code to set conditions on the sale and labelling of cell-cultured duck that is listed as a permitted cell-cultured food. Those conditions will be the same as those set out in the current Division 2 of Schedule 25A and which apply to cell-cultured quail.

The effect of these amendments will be to permit cell-cultured duck (as defined) to be a food for sale and an ingredient in a food for sale in accordance with the Code, including applicable conditions and restrictions set by the Code.

3.2.2 Sale of cell-cultured duck

The approved draft variation will amend Schedule 25A of the Code to set the same conditions for cell-cultured duck listed as a permitted cell-cultured food as are set by Division 2 of that Schedule for cell-cultured quail listed as a permitted cell-cultured food. That is:

- the cell-cultured duck must not be a food for retail sale, and
- food for retail sale may have the cell-cultured duck as an ingredient.

This will mean food that is not for retail sale e.g. food sold to a manufacturer or caterer, may be the cell-cultured duck.

3.2.3 Labelling

Division 2 of Standard 1.5.4 sets out general labelling requirements for permitted cell-cultured foods which apply to foods for sale containing cell-cultured food as an ingredient or when the cell-cultured food is sold to a caterer or a manufacturer (see section 1.3.3). The applicant did not request any changes to these requirements. FSANZ considered these requirements are appropriate and they will apply to cell-cultured duck.

The approved draft variation will also set specific labelling conditions for foods for sale containing cell-cultured duck permitted as a cell-cultured food as an ingredient. These will be identical to those set by section S25A—5 of the Code for foods for sale containing cell-cultured quail listed as a permitted cell-cultured food as an ingredient. That is, the label on the package of the food must not contain the phrase 'poultry meat'. The use of the word 'meat' on the labelling of the food will also be restricted (see section 1.3.3 and item 5 of the approved draft variation).

3.2.4 Nutrition

FSANZ's nutrition risk assessment concluded there are no issues with the consumption of the applicant's cell-cultured duck (see section 3.1 and the SD). FSANZ does not consider any specific risk management measures to be warranted based on the nutritional assessment undertaken.

3.2.5 Special purpose foods

The applicant did not seek any change to the current prohibition of the use of cell-cultured food in special purpose food standardised by Part 2.9 of the Code. Current restrictions on use in special purpose foods will therefore apply to the applicant's cell-cultured duck (see section 1.3.4).

3.2.6 Specification

Section 1.1.1—15 of the Code requires that cell-cultured foods meet relevant identity and purity specifications in Schedule 3 of the Code.

In the absence of international specifications for cell-cultured food, the approved draft variation will amend Schedule 3 of the Code to set a new specification for the cell-cultured duck biomass permitted as a cell-cultured food. The proposed specification is based on analytical data assessed by FSANZ (see Table 3 of the SD).

3.2.7 Application of Standard 3.4.1

Standards in Chapter 3 of the Code, including Standard 3.4.1, set food safety requirements for the processing and production of food, including cell-cultured food, in Australia only. For cell-cultured food, these requirements apply from the point of collection of cells from a donor animal through to the production of the end product used as an ingredient in a food for sale. Standard 3.4.1 will apply to the processing and production of the applicant's cell-cultured duck biomass in Australia only.

Section 3.4.1—7 of the Code provides that a cell culturing food business must only use an *assessed cell line* for cell proliferation. An *assessed cell line* is a cell line listed in the table to section S25A—6 of the Code (see section 3.4.1—2). The approved draft variation will amend table to section S25A—6 to list the applicant's cell line as an assessed cell line.

3.3 Risk communication

3.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ has developed a standard communication strategy for this application. All calls for submissions are notified via the FSANZ Notification Circular, FSANZ's digital channels and Food Standards News.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the call for submissions period.

3.3.2 World Trade Organization (WTO)

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

At present, there are no harmonised international standards for cell-cultured foods. Existing regional laws and regulatory mechanisms are considered sufficient, and trade in cell-cultured food and food ingredients remains limited or non-existent (van der Heijden 2026). The sale of cell-cultured duck in Australia and New Zealand would therefore be unlikely to affect international trade. Accordingly, notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade Agreement or the Agreement on the Application of Sanitary and Phytosanitary Measures was not considered necessary.

3.4 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.

3.4.1 Section 29

3.4.1.1 *Consideration of costs and benefits*

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because applications related to permitting cell-cultured foods determined to be safe are considered to be minor in impact or deregulatory in nature as their use will be voluntary.

FSANZ had 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) of the FSANZ Act).

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 applicant's cell-cultured duck biomass as a food ingredient.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

3.4.1.2 *Costs and benefits of permitting cell-cultured duck as a food ingredient*

Industry would only use cell-cultured duck biomass as a food ingredient where they consider a net benefit exists, given the voluntary nature of the permission.

While cell-cultured foods might displace some future demand for substitute products, including traditional proteins, such impacts remain uncertain due to the current unpredictability of future growth and consumption patterns of cell-cultured foods.

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

Consumers might have increased choice of foods. Some consumers might view a range of potential benefits from an ethical and environmental point of view, subject to an individuals' dietary, nutritional and other considerations.

Granting a permission to the applicant for their unique cell-culturing process, linked to the assessed cell-line, might create a short-term barrier to competition between suppliers and might negatively impact the prices paid by consumers for the final mixed food products containing the food ingredient.

Permitting the cell-cultured duck biomass as a food ingredient might result in a small but likely inconsequential cost to government in terms of an addition to the potential range of

cell-cultured foods monitored for compliance.

Conclusions of costs and benefits consideration

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the applicant's cell-cultured duck biomass as a wholesale food (i.e. not food for retail sale) or an ingredient in a food for sale as proposed in the draft variation are likely to outweigh the associated costs.

3.4.1.3 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.

3.4.1.4 Any relevant New Zealand standards

The variation amends Schedules 3 and 25A, both of which apply in Australia and New Zealand.

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

3.4.1.5 Any other relevant matters

Other relevant matters are considered below.

3.4.2. Subsection 18(1)

FSANZ has also considered the 3 objectives in subsection 18(1) of the FSANZ Act during the assessment.

3.4.2.1 Protection of public health and safety

FSANZ has completed a risk assessment (see the SD) which is summarised in section 3.1. The assessment concluded there are no public health and safety concerns associated with permitting cell-cultured duck biomass as a food ingredient.

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

The labelling requirements outlined in sections 1.3.3 and 3.2.3 will apply to food for sale that is, or contains as an ingredient, cell-cultured duck. These will ensure appropriate information is provided to enable consumers to make an informed choice.

3.4.2.3 The prevention of misleading or deceptive conduct

The labelling requirements outlined in section 3.2.3 of this report will provide information to identify the applicant's cell-cultured duck ingredient.

3.4.3 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 conducted the risk analysis utilising the best available scientific evidence. The applicant provided a comprehensive dossier containing information and scientific literature in support of their application. FSANZ evaluated this dossier alongside other relevant technical and scientific data during its assessment of the application.

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

As the cultivation of cells for food purposes represents an emerging global technology, international food standards for these products have not yet been established. FSANZ is, however, monitoring and will be involved in Codex work relating to cell-cultured foods, which will progress in the coming years, including:

- Meeting 55 of the Codex Committee on Food Hygiene (CCFH55), which discussed a proposal for new work on a code of hygienic practice for the manufacturing of cell-based foods. It was agreed at CCFH55, that the proposal would remain in the Forward Workplan and that it could be reconsidered at a future session of CCFH.
- Meeting 56 of the Codex Committee on Food Additives (CCFA56), which discussed the development of a guideline for the conduct of food safety assessment of cell culture media components used in the production of cell-based foods. CCFA56 agreed to further work on guidance for assessing cell-culture media components, including scope, scientific advice needs and regulatory approaches.

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

The applicant's cell-cultured duck has been assessed and approved by the Singapore Food Agency. The applicant also lodged applications with the Federal Food Safety and Veterinary Office in Switzerland, the Food Standards Agency in England, Wales and Northern Ireland, and the European Commission, and is also undertaking pre-market consultation with the US FDA. Permitting the applicant's cell-cultured duck in Australia and New Zealand 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 relevant to this objective were identified for this application.

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

FSANZ has had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines³ specifically applied to this application:

- Policy Guideline on Novel Foods
- Labelling of foods produced or processed using new technologies.

Noting the assessment in the SD and the assessment of FSANZ Act requirements, FSANZ

³ [Ministerial policy guidelines](#)

considers the proposed permission and labelling requirements are consistent with these policy guidelines.

4 Draft variation

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

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

5 References

MoH 2024. Food Risk Management Department of the Ministry of Health National Food Service. [First in the World: the Ministry of Health Has Approved Cattle-Based Cultivated Meat Ministry of Health. https://www.gov.il/en/pages/17012024-02](https://www.gov.il/en/pages/17012024-02)

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>

SFA 2026. Singapore Food Agency List of Approved Novel Foods (As at 17 March 2026). Singapore Food Agency. <https://www.sfa.gov.sg/docs/default-source/regulatory-standards-frameworks-and-guidelines/2026-03-sfa-list-of-approved-novel-foods.pdf>

PARIMA 2026. PARIMA Becomes the First Company to Obtain Cultivated Food Approval Across Two Species. <https://parima.bio/blog/parima-becomes-the-first-european-company-to-obtain-cultivated-food-approval-across-two-species#:~:text=PARIMA%20Becomes%20the%20First%20Company%20to%20Obtain%20Cultivated%20Food%20Approval%20Across%20Two%20Species>

USFDA 2026. Human Food Made with Cultured Animal Cells Inventory. <https://hfpappexternal.fda.gov/scripts/fdcc/index.cfm?set=AnimalCellCultureFoods>

van der Heijden 2026. Regulatory frameworks for cell-based food and precision fermentation-derived food products – An overview of legal issues and solutions. FAO Legal Papers, No. 114. Rome, FAO. <https://doi.org/10.4060/cd8165en>

Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1341 – Cell-cultured duck (*Anas platyrhynchos domesticus*) biomass) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name of Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1341 – Cell-cultured duck (Anas platyrhynchos domesticus) biomass) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

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

Insert:

cell-cultured duck

section S3—61

[2] After section S3—60

Insert:

S3—61 Specification for cell-cultured duck

- (1) For the purposes of this specification, **cell-cultured duck** means duck cell biomass obtained from culturing embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*.
- (2) For cell-cultured duck, the specifications are the following:
 - (a) protein—not less than 10% (70% on a dry basis);
 - (b) moisture—not less than 80%;
 - (c) ash—not more than 1.7%;
 - (d) fat—not more than 1.8%;
 - (e) carbohydrates—not more than 0.1%;
 - (f) lead—not more than 0.01 mg/kg;
 - (g) arsenic—not more than 0.01 mg/kg;
 - (h) cadmium—not more than 0.005 mg/kg;
 - (i) mercury—not more than 0.005 mg/kg;
 - (j) microbiological:
 - (i) total aerobic mesophilic plate count—not more than 3,000 cfu/g;
 - (ii) *Listeria monocytogenes*—absent in 25 g;
 - (iii) *Salmonella* spp.—absent in 25 g;
 - (iv) Enterobacteriaceae—not more than 100 cfu/g;
 - (v) yeasts—not more than 100 cfu/g;
 - (vi) moulds—not more than 100 cfu/g.

Schedule 25A—Permitted cell-cultured foods

[3] Section S25A—2

Insert:

cell-cultured duck means duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*.

[4] Section S25A—3 (table)

Add:

2. Cell-cultured duck that is: See Division 2A of this Standard
 (a) derived from the cell line 8516-Duck-DP; and
 (b) detailed in application A1341.

[5] After Division 2

Insert:

Division 2A Cell-cultured duck

S25A—5A Conditions on sale

- (1) Cell-cultured duck must not be a food for retail sale.
- (2) A food for retail sale may have cell-cultured duck as an ingredient.

S25A—5B Labelling conditions

- (1) This section applies to a food for retail sale that has cell-cultured duck as an ingredient.
- (2) The label on the package of the food must not contain the phrase 'poultry meat'.
- (3) The labelling of the food must not contain the word 'meat' other than in conjunction with the following:
 - (a) the statement required by section 1.5.4—5;
 - (b) a statement required by section 1.5.4—6.
- (4) Subparagraph 1.2.4—4(b)(iii) does not apply to the food.

Note Subparagraph 1.2.4—4(b)(iii) permits the use of generic names specified in Schedule 10 to identify certain ingredients in a statement of ingredients, including the generic names 'meat' and 'poultry meat'.

[6] Section S25A—6 (table)

Add:

2. The cell line **8516-Duck-DP**.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1341 – Cell-cultured duck (*Anas platyrhynchos domesticus*) biomass) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1341 which seeks to permit the use of cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*, (***the cell-cultured duck biomass***) as a food ingredient.

The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - *Food Standards (Application A1341 – Cell-cultured duck (*Anas platyrhynchos domesticus*) biomass) Variation* (the approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

2. Variation will be a legislative instrument

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

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the

FMM, the food standards on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The approved draft variation will permit the cell-cultured duck biomass to sold as a food for non-retail sale and to be (used as an ingredient in a food for sale in accordance with the Code.

4. Documents incorporated by reference

The draft variation does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1341 included one round of public consultation following assessment and the preparation of a draft variation and associated summary report. Submissions were called for on 24 June 2026 for a 4-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in this report (see section 2 and Appendix 1).

A regulatory impact statement (RIS) was not prepared. FSANZ's assessment is that a RIS is not required for this application. This is because applications relating to permitting the use of cell-cultured foods that have been determined to be safe are minor and deregulatory in nature, as their use will be voluntary.

6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

References to 'variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1341 – Cell-cultured duck (Anas platyrhynchos domesticus) biomass) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedules to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Schedule to the variation

Items [1] and [2] of the Schedule to the variation amends Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code.

Section 1.1.1—15 requires certain substances, such as cell-cultured food, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) of Schedule 3 (see paragraph S3—2(1)(a) of the Code).

Item [1] amends the table to subsection S3—2(2) by inserting, after the table item dealing with 'carboxymethyl cellulose ion exchange resin', 'cell-cultured duck' and a corresponding reference to new section S3—61.

Item [2] inserts a new section S3—61 into Schedule 3 to set a specification for the cell-cultured duck listed in the table to section S25A—3 as a permitted cell-cultured food.

Subsection S3—61(1) defines 'cell-cultured duck' for the purposes of the specifications set by subsection S3—61(2). The term 'cell cultured duck' is defined for these purposes to mean - and the specifications therefore apply to - 'duck cell biomass obtained from culturing embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*'. This is the cell-cultured duck that will be listed in the table to section S25A—3 as a permitted cell-cultured food. See item [4] below.

Subsection S3—61(2) sets specifications for cell-cultured duck in relation to protein, moisture, ash, fat, carbohydrates, arsenic and heavy metals, and microbiological parameters.

The effect of the amendments in **items [1] and [2]** is the cell-cultured duck biomass must comply with the specifications in section S3—61 when added to food for sale or when sold for such use.

Items [3] to [6] of the Schedule to the variation amends Schedule 25A of the Code.

Schedule 25A sets out permitted cell-cultured food, their corresponding conditions and 'assessed cell lines'.

Item [3] amends section S25A—2 by inserting a new definition for cell-cultured duck for the purposes of Schedule 25A.

The term 'cell-cultured duck' is defined to mean 'duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*'.

Item [4] amends the table to section S25A—3, which lists permitted cell-cultured foods and their conditions of use for the purposes of section 1.5.4—3 of the Code. Permitted cell-cultured foods are listed in Column 1 of the table. The conditions of use, if any, for each permitted cell-cultured food is listed in the corresponding row in Column 2 of the table.

This item adds a new entry into that table as follows:

- (in Column 1 of the table):

'Cell-cultured duck that is:

- (a) derived from the cell line 8516-Duck-DP; and
- (b) detailed in application A1341.'

- (in Column 2 of the table):

'See Division 2A of this Standard.'

The new entry becomes item '2' and added as the last entry of the table.

The amendment's effect is to permit the following as a cell cultured food for the purposes of the Code: cell-cultured duck (ie, duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*) that is derived from the cell line 8516-Duck-DP and detailed in Application A1341. As a result, the latter may be a food for sale or be present in a food for sale in accordance with the Code and the conditions and restrictions set by the Code – including the conditions and restrictions mentioned below.

Item [5] amends Schedule 25A by inserting (after Division 2 of the Schedule) a new Division – Division 2A.

New Division 2A comprises of two new sections setting out sale and labelling conditions for cell-cultured duck permitted as a cell-cultured food (sections S25A—5A and S25A—5B).

The new section S25A—5A contains the following conditions on the sale of cell-cultured duck (as defined by section S25A—2) permitted as a cell-cultured food:

- the cell-cultured duck must not be a food for retail sale (subsection S25A—5A(1))
- a food for retail sale may have the cell-cultured duck as an ingredient (subsection S25A—5A(2)).

Consequently, cell-cultured duck that is listed in the table to section S25A—3 as a permitted cell cultured food may be sold as a food or be present in a food for sale if the sale is other than a retail sale. However, if the sale is a retail sale – the cell-cultured duck may only be used as an ingredient in food for retail sale. Cell-cultured duck must not itself be a food for retail sale.

The new section S25A—5B sets labelling conditions for a food for retail sale that has cell-cultured duck permitted as a cell-cultured food as an ingredient.

Subsection S25A—5B(1) provides the requirements set by section S25A—5B apply only to a food for retail sale that has the cell-cultured duck as an ingredient.

Subsection S25A—5B(2) provides that the label on the package of a food for retail sale that has the cell-cultured duck as an ingredient must not contain the phrase 'poultry meat'.

Subsection S25A—5B(3) provides that the labelling for a food for retail sale that has the cell-cultured duck as an ingredient must not contain the word 'meat' except when used in conjunction with the statement required by section 1.5.4—5 or a statement required by section 1.5.4—6. Section 1.5.4—5 requires the use - in accordance with the Code's labelling provisions - of the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the name of the ingredient that is a cell-cultured food. If section 1.5.4—6 applies to the food for sale, that section would require the same statement (i.e. either 'cell-cultured' or 'cell-cultivated') that is used to comply with section 1.5.4—5 to be used in conjunction with the name of the food for sale.

Subsection S25A—5B(4) provides that subparagraph 1.2.4—4(b)(iii) of the Code does not apply to a food for retail sale that has the cell-cultured duck as an ingredient. The Note to this subsection explains that subparagraph 1.2.4—4(b)(iii) permits the use of generic names specified in Schedule 10 to identify certain ingredients in a statement of ingredients, including the generic names 'meat' and 'poultry meat'.

Item [6] amends the table to section S25A—6 by adding a new entry into that table.

The table to section S25A—6 lists assessed cell lines for the purposes of the definition of *assessed cell line* in section 3.4.1—2 of the Code.

Standard 3.4.1 is part of Chapter 3 of the Code. Standards in Chapter 3 of the Code, including Standard 3.4.1, set out food safety requirements for the processing and production of food, including cell-cultured food, in Australia only. These standards apply to all food businesses in Australia. Consequently, Chapter 3 standards, including Standard 3.4.1, apply to the processing and production of the applicant's cell-cultured duck biomass in Australia only.

Section 3.4.1—7 of Standard 3.4.1 provides that a cell culturing food business must only use an *assessed cell line* for cell proliferation.

Section 3.4.1—2 defines an *assessed cell line* for this purpose to mean a cell line listed in section S25A—6 (see section 3.4.1—2).

Item [6] amends the table to section S25A—6 by adding a new entry as the second and last entry of the table. The new entry consists of:

'2. The cell line **8516-Duck-DP**.'

The effect of this amendment is that cell line 8516-Duck-DP will be an assessed cell line for the Code purposes. In turn, it will mean a cell culturing food business in Australia can only use that assessed cell line for cell proliferation of cell cultured duck.

The approved draft variation's effect will be to permit cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus* to be a food for non-retail sale and to be used as an ingredient in a food for sale in accordance with the Code.

Appendix 1 – Summary of submissions

Table 1 provides a list of submitters to the consultation, including private individuals whose identity will remain undisclosed, together with the abbreviation used in the summary of submissions provided in Table 2.⁴

Table 1: List of Submitters

Submitter	Abbreviation
Industry groups	
Asia Pacific Society for Cellular Agriculture	APAC-SCA
Australian Meat Industry Council	AMIC
Australian Pork Limited	APL
Cattle Australia	CA
Cellular Agriculture Australia	CAA
New Zealand Food and Grocery Council	NZFGC
Industry	
Luv – a – Duck Pty Ltd	
Cellular Agriculture Limited	CAL
Government	
Department of Agriculture, Forestry and Fisheries	DAFF
New South Wales Food Authority	NSW FA

⁴ Artificial intelligence (AI; Co-Pilot) was used to support the preparation of the response-to-submitter table. All AI-assisted submission summaries and responses were checked, reviewed and quality assured by FSANZ.

Submitter	Abbreviation
New Zealand Food Safety – Ministry for Primary Industries	NZFS MPI
South Australia Health	SA Health
Department of Energy, Environment and Climate Action - Agriculture Victoria	DEEC Vic
Consumer / advocacy groups	
Gene Ethics	GE
Individual - BL	BL
Individual - BM	BM
Individual - CM	CM

Table 2: Summary of submissions and FSANZ response

2.1 Risk assessment comments

Submission viewpoint	Raised by	FSANZ response
General		
This submitter opposes the approval, arguing that key information requirements have not been met and that concerns from A1269 remain unresolved (not regulating media inputs as processing aids, not future proofing the definition of cell-cultured food, prohibition on the word “meat”, public disclosure of confidential information). They seek independent, peer-reviewed and publicly available evidence, including independent review of safety-critical confidential information. Claim that key confidential safety data should be publicly	GE	FSANZ has undertaken a comprehensive and independent safety assessment of cell-cultured duck in accordance with the FSANZ Act using risk analysis and the best available scientific evidence. This safety assessment underwent extensive internal peer review by scientific experts and was reviewed by submitters, with this approval report addressing the issues raised. No new evidence was identified that would change FSANZ’s conclusions. FSANZ consider the issues raised by GE during A1269 have been adequately addressed and the current regulation for cell-cultured foods effectively manages food safety risks and provides consumers with adequate information.

Submission viewpoint	Raised by	FSANZ response
scrutinised, as without access to this information independent experts cannot assess whether FSANZ's conclusions are justified.		The information in question is confidential commercial information (CCI) for the purposes of the FSANZ Act. FSANZ's ability to disclose that information is restricted by that Act and other Australian laws.
Submitters considered that further evidence is needed to confirm the safety and consistency of commercial-scale production, including harvesting, washing, thawing and finished-food manufacture. They questioned whether five batches at one production scale adequately address variability, extended cell propagation, contamination risks, microbiological performance, and potential residues or metabolites. They requested additional commercial-scale batch data, defined passage limits, routine genomic and phenotypic testing, post-market reporting, and reassessment where changes to media, cell banks, equipment, facilities or production scale could affect safety. They also raised concerns about information gaps in pathogen controls and reliance on end-product testing rather than preventive controls.	GE, Luv – a – Duck Pty Ltd,	FSANZ requires data from a minimum of three production batches to support its safety assessment, consistent with international practice; in this case, data from five batches were provided. Manufacturers are responsible for ensuring that final foods containing cell-cultured duck biomass are safe and suitable in accordance with Australian and New Zealand food laws and comply with the Code as applied as part of these laws. This includes any applicable microbiological limits, specifications, nutrition and labelling Code requirements applied by those laws. Cell culturing food businesses are required to comply with Standard 3.4.1 of the Code. This requires development and continued compliance with a food safety plan and relevant preventive controls in Standards 3.2.2 and 3.2.3. As with other manufactured foods, these products are subject to audit and compliance oversight by the relevant jurisdictions rather than assessment of each finished product by FSANZ. Assessing at the biomass stage enables the approved biomass to be used in a range of final foods. FSANZ's assessment confirms the safety of that biomass with the onus on the food manufacturer to produce safe and suitable food using that biomass, consistent with other manufactured foods.
Notes that there is no long-term consumption data for cell-cultured foods, because it is a brand-new food production method and do not know the long-term effects of consuming cell-cultured products.	CM	Although there is no long-term history of animal cell-culture for food development in Australia and New Zealand, FSANZ is satisfied the safety of the cell-cultured duck has been established and appropriate risk management measures put in place for the new production method.
Requested post-market monitoring of cell-cultured duck products following approval. As part of this monitoring, submitters would like:	GE, SA Health	Regarding A1269, FSANZ undertook a comprehensive assessment of the cell-cultured quail including the cell line and all media inputs. The assessment did not identify any hazards that would indicate an ongoing need to monitor for long-term adverse health outcomes. Similarly, with cell-cultured

Submission viewpoint	Raised by	FSANZ response
- Adverse event, incident and allergenicity surveillance; independent testing; microbiological monitoring; batch tracking and retained samples; public reporting, registers and periodic review mechanisms. - Monitoring of labelling compliance. - Consideration of the product's classification under the Imported Food Inspection Scheme. SA Health considers a post-market monitoring programme would be consistent with the approach recommended for cell-cultured quail.		duck, our assessment did not identify any hazards, therefore it would be an unnecessary use of resources to coordinate a national post-market monitoring programme for cell-cultured duck products, particularly as the volumes consumed are likely to be minimal in terms of the entire food supply. As stated during A1269 however, FSANZ will continue to monitor the scientific literature and consult with regulatory agencies for any emerging risks associated with these types of foods. Poultry, including duck protein, are not considered to be allergens of public health significance for Australian and New Zealand consumers and are therefore not listed in the Code as foods requiring a mandatory allergen declaration. The Code provides adequate provisions to ensure labelling compliance, targeted microbiological testing against the Schedule 3 specification, negating the need for FSANZ involvement. This is the case with any other manufactured food. FSANZ has engaged with DAFF on matters relating to the importation of cell-cultured foods into Australia and NZFS MPI on those imported to New Zealand FSANZ is working with DAFF on the importation of cell-cultured foods and is providing science-based advice to support their border activities. This work is ongoing.
Cell line identity and stability		
Raised concerns regarding the applicant's claim that the production cell line is not genetically modified, including that: - applicant-provided data should not be relied upon to verify the non-GM status of the cell line; independent verification of the claim should be required - the designated name of the cell line (8516 Duck-DP) indicates a link to duck plague virus propagation and implies that genetic modification was used for immortalisation and functional enhancement.	GE, CM	Consistent with international practice, FSANZ's assessments are based on information submitted by applicants in support of their application. As set out in the FSANZ Application Handbook, studies submitted in support of an application must be clearly documented, generated using appropriate and validated methods and be accompanied by evidence of quality control or independent auditing. FSANZ critically evaluates the quality of the submitted evidence as part of its safety assessments. FSANZ assessed the data provided on the source and identity of the cell line and is satisfied that the cell line assessed in this application is not genetically modified.

Submission viewpoint	Raised by	FSANZ response
		For clarity, 'DP' in the cell line name does not stand for 'duck plague' virus. As outlined in subsection 2.5.2 of SD1, the embryonic stem cell line assessed in this application is inherently pluripotent and did not require the introduction of novel DNA or other genome modifications to induce immortalisation.
Argued that although the cell line is not genetically modified, the establishment of the cell line and the biomass production process rely on a range of inputs including serum, feeder cells and recombinant proteins. Concerned consumers will not understand the origin of these inputs due to the end product not being labelled as GM. Requested disclosure where the inputs remain in the food or may affect consumers' ethical, religious or allergen-related choices.	GE	FSANZ's safety assessment considered all substances used during cell line establishment and production of cultured duck biomass, including recombinant proteins (see section 3.2.3 of SD1). As outlined in section 2.3 of SD1, serum and feeder cells are used only to establish the cell line, with cells being transferred to media free of these substances before production. FSANZ is satisfied the substances, including recombinant proteins, do not raise allergenicity or other health and safety concerns. Under Standard 1.5.2 (Genetically modified food), substances used to support the growth and viability of cells as part of the production of cell-cultured food do not meet the definition for <i>genetically modified food</i>. Accordingly, the use of these substances does not trigger GM labelling requirements. However, cell-cultured duck will be required to comply with the applicable labelling provisions for cell-cultured food, enabling consumers to identify the nature of the food and make informed choices. Consumers seeking additional information for ethical or religious reasons may contact the manufacturer.
Stated the cell-cultured duck biomass is not the biological equivalent of duck meat. Considers it a synthetic product, maintained in an undifferentiated state and propagated indefinitely under artificial, contained, culture conditions. A third party originally developed the cell line as a platform for producing vaccines and therapeutic proteins, not food.	GE	FSANZ has not suggested the cell-cultured duck biomass is equivalent to duck meat. FSANZ assessed the safety of the harvested cell-cultured duck biomass with respect to biological, toxicological, microbiological and nutritional considerations. Based on the available data, FSANZ is satisfied that cell-cultured duck does not raise food safety or nutrition concerns when consumed at expected levels. FSANZ notes the original purpose for which a cell line was developed does not itself determine its suitability for food production.
Raised concerns about genetic variation during cell culture, specifically that: monitoring the cells for changes in growth characteristics,	CM	Genetic variation occurs in all organisms used for food and does not necessarily result in phenotypic variation, including variation that would raise food safety concerns. FSANZ assessed both genetic and phenotypic stability of the production cell line (see section 3.3 of SD1) and found that cells

Submission viewpoint	Raised by	FSANZ response
morphology and pluripotency is an inadequate method for detecting mutations, relative to the immune system of a live duck - the 'seed train' process used for production creates ideal conditions for genetic drift and accumulation of mutations - independent auditing of cell line stability testing should be required, with results published publicly.		maintained the expected karyotype for diploid duck cells, as well as consistent phenotypic characteristics. Phenotypic characteristics such as growth, cell morphology and pluripotency provide information on whether any genetic variation is affecting the behaviour, identity or performance of the production cell line and are therefore relevant indicators of cell stability and non-conformity during production. FSANZ also notes that cell identity and stability were evaluated throughout the production process, including assessment of cells at multiple stages of the 'seed train' from cell bank to harvest (see section 3.1 of SD1). Based on the information provided, FSANZ concluded the cell line was sufficiently stable for its intended use and did not identify any food safety concerns associated with genetic variation during production. Concerns regarding independent auditing of applicant-supplied data are addressed in the response above relating to verification of the non-genetically modified status of the cell line.
Noted there is currently a lack of capability to verify the identity of approved cell lines and suggested this may represent a future regulatory gap. Recommended FSANZ develop guidance and criteria for assessing cell line conformity and stability, including appropriate parameters and acceptable ranges for these parameters. Noted that a business's food safety program must identify when cell proliferation is non-conforming but that regulators and industry would benefit from a compilation of common metrics to assess these aspects.	DAFF	These matters are unlikely to represent a future regulatory gap. Responsibility for ensuring cell line identity and conformity rests with the cell-culturing food business, which as part of a food safety programme must maintain appropriate records to support traceability and demonstrate that cell line identity and growth parameters are consistent with the approved cell line. Verification would involve checking these records. Given the diversity of cell types, production processes and available analytical approaches, it is impractical to compile a set of parameters or acceptable ranges that would be broadly applicable to all cell lines. FSANZ is reviewing the Application Handbook and is developing a supporting user guide for cell-cultured food which will contain information on the types of evidence and parameters needed for assessment of cell line identity and stability. These parameters can also support a business's food safety program in identifying when cell proliferation is non-conforming. The nature of these cell line specific parameters can be found in the application dossier and in FSANZ's safety assessment for this application.

Submission viewpoint	Raised by	FSANZ response
Raised concerns that the use of genome editing to produce future cell-cultured foods will not be disclosed to consumers; expressed the view that mandatory labelling of these foods as genome edited should be required.	CM	Any future application for a cell-cultured food would be subject to a pre-market safety assessment by FSANZ before approval, regardless of how the cell line was immortalised. Immortalisation of a cell line can be achieved through spontaneous genome changes or deliberate genome modifications. Many genome modifications introduced using genome editing will be equivalent to those that occur naturally or spontaneously, and the resulting cell lines will be indistinguishable. If a cell line contains <i>novel DNA</i>, as defined in section 1.1.2—17 of the Code, the cell-cultured food derived from that cell line would also be a genetically modified food for Code purposes, and GM labelling requirements would apply. The cell line used in this application does not contain novel DNA as defined in the Code.
Microbiological		
Notes that food safety systems generally prioritise validated preventive process controls over reliance on finished-product testing alone. Suggest that consideration be given to identifying harvest and washing as critical control or preventative points in the production system as well as their validation for managing contamination. Similar expectations for environmental monitoring of <i>L. monocytogenes</i>. The assessment identifies <i>L. monocytogenes</i> as the primary microbiological hazard in post-bioreactor steps. Given the intended use of the ingredient in ready-to-eat products that may receive limited thermal processing, including pâté and foie gras-type products, effective management of environmental <i>L. monocytogenes</i> is particularly important.	DEEC Vic	Where CCF biomass is manufactured in Australia, the business is required to develop and operate according to a food safety system in compliance with Standard 3.4.1. This requires the business to consider all hazards and develop appropriate control measures to ensure the food is safe and suitable. For imported CCF biomass, DAFF will determine the relevant requirements to have assurance of safety. FSANZ is working with DAFF and is providing science-based advice to support their border activities. This work is ongoing. Further information regarding the use of the cell biomass has confirmed that the intended food products are expected to be thermally heated to achieve a 6D <i>Listeria</i> reduction as recommended in the Safe Food Australia guidance.
NZFS MPI noted the proposed permission and specification are	NZFS MPI, GE,	Any production changes, such as scale-up, would be discussed with the

Submission viewpoint	Raised by	FSANZ response
based on the assessed harvested duck cells and 200 L production process, while the applicant intends to scale up to 2,500 L. NZFS MPI considered that HACCP plans and food safety programmes should be reviewed and verified during scale-up to ensure larger production volumes do not introduce new risks and that the biomass continues to meet the Schedule 3 specifications. Submitters considered that any significant production change that could affect the safety assessment conclusions should require further assessment.	Luv – a – Duck Pty Ltd	relevant authority in the first instance, which in this case is DAFF. FSANZ has worked with DAFF, and the applicant has also engaged with DAFF, on these matters. Import oversight is outside FSANZ's remit; however, FSANZ continues to assist DAFF and provide relevant information as required. If the cell culturing food business is in Australia, Standard 3.4.1 of the Code requires the business to consider all hazards and appropriate controls, which includes during any scale up activities. The relevant state or territory government regulator would be involved in this activity and may require the business to make a new application to FSANZ. If scale-up results in changes to the cell-cultured food such that it no longer meets the specification in S3 or the conditions in S25A, the manufacturer is responsible for submitting a further application. This approach is consistent with the oversight of other manufactured foods.
Requested demonstration that microbiological safety remains effective when production is scaled from 200 L to 2,500 L, particularly during harvesting and washing.	SA Health	Please see response above. For imported cell biomass, DAFF will determine if the product meets the production and quality requirements for importation.
Request for clarification on whether further information sought for the harvesting, washing and harvested biomass steps was provided and assessed. The submitter also asked that the outcome of any assessment be published, or that FSANZ explain how the assessment was completed if the information was not provided. The submitter noted that Table A3.1 in Supporting Document Appendix 3 still records "further information requested" for bacterial hazards during harvesting and washing, and for indicator organisms/pathogens in harvested biomass, including packaging. The submitter requested that FSANZ update the table at approval.	Luv – a – Duck Pty Ltd; NSW FA	FSANZ received additional information and has updated the SD document as appropriate. The extent to which harvesting and washing procedures may affect the risk of microbiological contamination of the cell biomass was not able to be assessed; FSANZ noted that no specific pathogen reduction steps are applied at this stage of biomass production. Accordingly, the harvested biomass is considered a potentially hazardous food (PHF) requiring temperature controls sufficient to achieve a 6D reduction in <i>Listeria</i> in the final foods as per Chapter 3 in the FSC. This does not change the outcome of the microbiological risk assessment, and the requirement to apply appropriate pathogen controls during manufacture of the final food products. It requires temperature controls including thorough cooking (i.e. a heat treatment sufficient to meet FSC requirements)
Noted an apparent inconsistency between different sections of	Luv – a – Duck	FSANZ notes the cell expansion phase is a tightly controlled process, and

Submission viewpoint	Raised by	FSANZ response
the assessment documents regarding the role of pathogen-reduction steps in the production process. Requested clarification of whether a validated pathogen-reduction step was relied upon in the microbiological risk assessment and, if so, where that step occurs and how it was validated.	Pty Ltd	that the cells contained within the bioreactor are considered to be sterile. Any microbial growth that occurs within the bioreactor would be detected during routine monitoring (which will also be required if approved, by Standard 3.4.1 and as a critical control point in the food safety plan) of the fermentation and the process halted. As noted above, no specific pathogen-reduction steps are applied during the biomass production. Microbiological testing data of multiple batches of the cell biomass were assessed as supporting evidence in determining risks, with the noted constraints and uncertainty on the microbiological assessment. The final determination was that microbiological hazards associated with the harvested cell biomass are low, and therefore the cell biomass should be treated as a PHF. The food manufacturer is responsible for ensuring the food is produced in accordance with the requirements listed in the Food Standards Code (Standard 3.4.1) and food safety plan.
Noted that identification of harvested cell-cultured duck biomass as a PHF in the risk assessment should be reflected in the Code through a specific condition of sale or handling requirement. Suggested explicit regulatory recognition of the PHF status to support temperature control and risk management throughout importation, storage, distribution and manufacture of foods containing the biomass.	Luv – a – Duck Pty Ltd	Businesses producing foods containing the cell biomass are required to meet the requirements in section 3.4.1—8 of the Code for temperature control. In addition to meeting specific requirements listed in the Code for production of foods containing cell cultured biomass, businesses must also produce food in accordance with the requirements of Chapter 3 which are designed to ensure the food produced is safe and suitable. This will be verified by the jurisdictions.
Raised concerns that the intended end uses for cell-cultured duck biomass include products such as pâté and foie gras that may receive minimal heat treatment and be sold as ready-to-eat foods. The submitter considered that given there is no critical control point beyond harvesting to manage the risk, the proposed permission should include measures to ensure foods containing the biomass are subject to appropriate pathogen control, validation and verification of microbiological safety prior to sale.	Luv – a – Duck Pty Ltd	FSANZ has classified the cell cultured duck biomass as a PHF. Australian and New Zealand food laws require businesses producing foods containing the biomass to supply safe and suitable food and be able to demonstrate it is safe in accordance with the Code requirements in Standard 1.6.1, Schedule's 3 and 27.
Agreement that harvested cell-cultured duck biomass should be treated as a PHF and noted that foods containing the biomass	NSW FA	Noted.

Submission viewpoint	Raised by	FSANZ response
may also require consideration as potentially hazardous and ready-to-eat foods, particularly where final products receive minimal cooking. The submitter noted that Australian food businesses handling these foods would be subject to relevant requirements under Standards 3.2.2 and 3.2.2A.		
Queries whether this meets the same level of food safety criteria and production monitoring required for red meat and meat products.	CA	From a food safety perspective, meat production from animals is a completely different process compared to the production of a cell-cultured biomass from isolated animal cells. The microbiological hazards identified in the risk assessment align with those that can be found in food processing environments, namely <i>Listeria</i> and <i>Salmonella</i> . For animal production, most of the foodborne pathogens are associated with faecal contamination such as STEC, <i>Campylobacter</i> and <i>E. coli</i> and are not relevant for this type of product.
Toxicology		
A request that the applicant's proposed limits for poloxamer 188, insulin and ethanolamine be included in the Schedule 3 specification. The submitter considered that including these monitored media residue limits would provide enforceable identity and purity parameters for the biomass, particularly for imported product	Luv – a – Duck Pty Ltd	As stated in the supporting document (section 4.1), these inputs do not pose a risk to consumers. The applicant's food safety program also includes and monitors a range of other inputs to ensure production consistency. This information will be available for the manufacturer's internal audit processes, as part of its responsibility to produce safe and suitable food under Australian and New Zealand food laws. It will also be available to jurisdictions with oversight of the production process, regardless of where the product is produced.
Reliance on theoretical dilution factors questioned to exclude certain Category C substances from further assessment, particularly beta-mercaptoethanol, penicillin, streptomycin and recombinant growth factors. The submitter requested analytical verification, at stated limits of detection, to confirm their absence in harvested biomass.	Luv – a – Duck Pty Ltd	Beta-mercaptoethanol, penicillin and streptomycin are all used in the early stages of cell isolation, prior to the creation of the cell banks. The application specifies a dilution factor of 1.76E+77 at the master cell bank and 1.26E+94 at the time of harvesting. FSANZ is satisfied they are so heavily diluted during the subsequent process of biomass production that there is negligible likelihood of their presence in the final product.
Apparent unit, margin of exposure and reference attribution errors were identified in the ethanolamine assessment and	Luv – a – Duck	The arithmetic and referencing errors have been corrected.

Submission viewpoint	Raised by	FSANZ response
requested these be corrected. The submitter also requested clarification of the margin of exposure that would apply if an alternative developmental toxicity study were relied upon.	Pty Ltd	The only alternative developmental study for ethanolamine available is that of Mankes (1986). That study, which was not conducted according to any guideline, had several interpretative errors on the part of the author. The author asserted that some adverse findings including prenatal deaths, resorptions and malformations were treatment-related, but the effects did not show a dose-response relationship which is critical to concluding that the finding is treatment-related. In addition, a few findings were recorded by Mankes as deformities which are now recognized by international consensus to be developmental delays and not adverse, such as wavy ribs and differences in vertebral ossification. Recalculation of the statistics from the study after subtracting all these findings is complicated by the absence of individual data and the use of a disproportionately large control group.
Question on whether the safety assessment adequately addressed the complexity of cell-cultured biomass, including potential unknown metabolites, altered protein expression and chronic effects. The submitter requested independent evidence, including repeated-dose feeding studies using commercial-scale biomass and finished products.	GE	FSANZ's safety assessment comprehensively evaluated the cell-cultured biomass, including the cell line, production process and inputs, cell stability, toxicological, microbiological and nutritional considerations, and dietary exposure. The assessment approach was scientifically rigorous, proportionate to the potential hazards identified and considered adequate to address the complexity of the biomass. FSANZ critically evaluates the quality and relevance of all submitted data and information, together with the broader scientific evidence base, when reaching its conclusions. Based on the available evidence, FSANZ did not identify any food safety concerns or a scientific basis for requiring animal feeding studies or long-term monitoring.
Considered data insufficient to identify uncommon allergic reactions, long-term effects, contamination trends or process drift. The submitter requested conditional and time-limited approval, active surveillance, and prior FSANZ approval for material changes to the cell line, cell banks, passage limits, media, recombinant inputs, facility, production scale, harvesting or intended food uses.	GE	Uncommon allergic reactions cannot be predicted for any food. FSANZ does not time-limit approvals, or mandate active surveillance. The Code permits cell-cultured duck only where it is produced using the process described in Application A1341 and assessed and approved by FSANZ. Should any changes to the production process or inputs result in changes to the cell-cultured food such that it no longer meets the specification in S3 or the conditions in S25A, the manufacturer is responsible for submitting a further application. This approach is consistent with the oversight of other manufactured foods.

Submission viewpoint	Raised by	FSANZ response
Concerns were raised that the allergenicity assessment may not adequately address differences between conventional duck meat and biomass derived from fertilised duck eggs, including altered protein expression, cross-reactivity or matrix effects. The submitter requested prominent labelling for duck embryonic-cell origin, advice for people with poultry or egg allergies to avoid the product, and post-market monitoring of allergic and immune reactions.	GE	FSANZ's evidence-based risk assessment concluded that cell-cultured duck does not pose an allergenic or other public health risk. Duck and other poultry proteins are not recognised as allergens of public health significance in Australia and New Zealand and do not require mandatory allergen declarations under the Code; given no risk was identified, no additional post-market consideration is warranted.
Request for clearer regulatory visibility of media components and other production inputs assessed for cell-cultured duck, including whether relevant substances and any assessed levels should be identified in the Code. The submitter also sought clarification on how changes to inputs would be managed and when they may require a further application.	DAFF	FSANZ assessed all media inputs used to support duck cell growth during culture and concluded they do not raise public safety concerns. The regulatory approach for media components, production inputs and production requirements generally, was established by FSANZ and supported by all jurisdictions via the FMM when it agreed to amend Standards 1.1.1, 1.1.2, 1.2.1, 3.1.1, create Standard 3.4.1 and Schedule 25A and amend Schedules 3 and 27 for A1269. Any change to the development or production of the cell-cultured duck biomass may require further consideration by FSANZ. As with any significant change to biomass production, the first step would be to discuss the change with the relevant jurisdiction(s).
Nutrition		
Considers manufactured biomass is an ultra-processed food and that assessing biomass alone does not adequately capture the potential nutritional and health effects of foods containing manufactured biomass.	GE	FSANZ assessed the cell-cultured duck biomass as a food ingredient, including its safety, nutritional impacts and intended uses, in accordance with the requirements of the FSANZ Application Handbook. Any other ingredients used in final products must be permitted under the Code and be safe and suitable for human consumption. The broader issue of ultra-processed foods and their role in the food supply is beyond the scope of this application.
Identified an apparent transcription error in SD1, noting that the selenium concentration was reported as <0.02 µg/100 g in Table	Luv – a – Duck Pty Ltd	FSANZ agrees the selenium concentration reported in SD1 was incorrect. The correct value is <20 µg/100 g (<0.2 mg/kg). Section 4.3.4.7 and Table

Submission viewpoint	Raised by	FSANZ response
A1.3 but <0.2 mg/100 g in Section 4.3.4.7.		A1.3 of SD1 have been amended accordingly.
Questioned whether the assessment used inconsistent consumption assumptions, noting that conclusions regarding nutrient composition differences referred to expected infrequent consumption, while the dietary intake assessment modelled cell-cultured duck consumption using chicken consumption data and an 80% inclusion scenario.	Luv – a – Duck Pty Ltd	Different consumption assumptions were used for different purposes in the nutrition and dietary intake assessments. The 40% inclusion scenario was used as a realistic midpoint formulation to support comparisons of nutrient contribution and adequacy, while the 80% inclusion scenario represented a conservative high-inclusion scenario for assessing potential excessive intakes, including comparisons with relevant Upper level of Intake (UL) values. Chicken consumption data were used as a proxy for long-term consumption because consumption of conventional duck was too low in the national nutrition survey data to give reliable estimates, and chicken provides a more frequently consumed comparator. The use of conservative assumptions in the dietary intake assessment was intended to avoid underestimating potential dietary intake and is not intended to represent likely consumption patterns for cell-cultured duck.
The chemical forms and bioavailability of iron and folate in cell-cultured duck were not characterised in the assessment. Noted that the form of iron may affect the interpretation of dietary exposure and nutrient intake assessments, particularly for young children.	Luv – a – Duck Pty Ltd	For folate, FSANZ adopted the conservative assumption that all folate was present as folic acid when assessing dietary intakes against the UL. For iron, the nutrition assessment was based on the measured iron concentrations in the cell-cultured duck biomass and estimated dietary intakes were assessed against the relevant nutrient reference values (NRVs), which are expressed in terms of total iron intake rather than specific iron forms. While iron bioavailability may vary according to chemical form, neither the predominantly non-haem nature of the iron nor the anticipated levels of consumption of cell-cultured duck are likely to materially affect iron intake or nutritional status. There was no evidence to indicate a nutritional concern associated with iron bioavailability or consumption of the food.
Queried whether FSANZ should establish criteria or limits for nutrients that may be transferred from the growth medium into cell-cultured duck biomass. Concerns were raised regarding nutrients that are not present in conventional duck or are present at higher concentrations than in conventional duck or chicken, including iron and folate, and whether additional criteria or limits are required to ensure nutritional and microbial safety.	NZFGC; Luv – a – Duck Pty Ltd	FSANZ considered the concentrations of nutrients present in cell-cultured duck as part of the assessment, including nutrients present at higher concentrations than comparator foods. FSANZ did not identify any nutritional or food safety concerns associated with these nutrients therefore additional compositional requirements were not considered necessary. Specifications are proposed where they are needed to manage identified food safety or nutritional risks, with no such risks being identified for these nutrients.

Submission viewpoint	Raised by	FSANZ response
		FSANZ also considered whether nutrients transferred from the growth medium could affect microbial safety. While cells in the biomass are a rich source of nutrients that could potentially support microbial growth, any nutrients derived from the media per se that remain after washing are unlikely to further increase the potential of microbial growth, should a contamination event occur.
Considered the nutrition assessment may underestimate future consumption of cell-cultured duck by relying on assumptions that intake would be infrequent. Noted the potential for wider use of cell-cultured duck in a range of food products and that consumption may increase over time as cell-cultured foods become more widely available, affordable and accepted by consumers. Recommended that dietary modelling assess habitual and high-consumption scenarios across all proposed food uses and that restrictions on serving sizes or permitted uses be considered.	GE; NZFS MPI	FSANZ considered potential consumption in both the nutrition and dietary intake assessments. As part of its risk analysis framework, FSANZ considers anticipated consumption patterns and levels of intake when assessing potential nutrition and public health impacts. The nutrition assessment evaluated nutrient intakes assuming the applicant's maximum proposed inclusion rate of 80% cell-cultured duck biomass, representing a conservative high consumption scenario, and compared estimated nutrient intakes with relevant NRVs where established. The dietary intake assessment used chicken consumption as a proxy for cell-cultured duck consumption, reflecting a higher-consumption scenario than would be estimated using conventional duck consumption patterns. Based on these conservative assumptions, FSANZ did not identify nutritional concerns associated with the proposed uses of cell-cultured duck. Accordingly, FSANZ did not consider restrictions on serving sizes or permitted uses necessary.
Considered the nutrition assessment should include a more comprehensive evaluation of the nutritional composition of cell-cultured duck, including protein quality, fat quality and the bioavailability of key nutrients from animal source foods such as iron, zinc and vitamin B12, noting that the iron present is expected to be non-haem iron with poorer bioavailability.	NZFS MPI	The nutrition assessment considered the nutritional composition of cell-cultured duck, including protein, amino acids, total fat, saturated fat, trans fat, vitamins and minerals, and compared these with conventional duck and chicken breast. FSANZ also considered whether antinutritional factors were present that could affect nutrient utilisation and did not identify any concerns. The assessment did not include a detailed evaluation of the relative bioavailability of individual nutrients in cell-cultured duck compared with conventional duck. However, no evidence was identified to suggest that cell-cultured duck would adversely affect nutrient absorption or utilisation, and the applicant advised that no antinutrients are used in the cell culture media. Cell-cultured duck contains a low level of total fat and has a similar total fat content per portion to conventional duck and chicken breast. FSANZ also

Submission viewpoint	Raised by	FSANZ response
		assessed information provided by the applicant on saturated, unsaturated and trans-fat levels and did not identify nutritional concerns associated with the fat composition of cell-cultured duck. The nutrition assessment also considered the protein and amino acid composition of cell-cultured duck. While protein and essential amino acid levels were lower than conventional duck and chicken breast, these differences were not considered a nutritional concern. The available information indicates that neither the predominantly non-haem nature of the iron nor the anticipated levels of consumption of cell-cultured duck are likely to materially affect iron intake or nutritional status.
Questioned whether duck and chicken breast were appropriate comparator foods given the proposed use of cell-cultured duck in foie gras and pâté products and requested consideration of alternative comparators such as chicken liver.	NZFS MPI	The nutrition assessment considered that cell-cultured duck may be used in products including foie gras and pâté analogues. However, the assessment was designed to evaluate the nutritional composition of the cell-cultured duck biomass itself. Conventional duck breast was used as a generic comparator food because cell-cultured duck is intended for use across a range of duck-based products. Given the low consumption of duck in Australia and New Zealand, chicken breast was also included as a comparator to reflect a higher potential consumption scenario. Breast meat was selected because it is the primary muscle tissue consumed from poultry and is widely used as a reference food in dietary surveys, food composition databases and dietary exposure assessments. FSANZ did not identify nutritional concerns associated with the composition of cell-cultured duck.
Requested review of comparator nutrient values for lean duck, including vitamin A, vitamin D, folate and calcium noting there are differences within the Australian and New Zealand food composition databases.	NZFS MPI	FSANZ has reviewed the nutrient values for conventional duck in the New Zealand Food Composition Database in response to the submitter comments. Vitamin A, folate and calcium values for lean duck are higher than those reported in the Australian Food Composition Database. However, these nutrients are present at relatively low levels in lean duck, each contributing less than 10% of the EAR per 100 g. FSANZ therefore considers that the differences between the databases do not affect the conclusions of the nutrition assessment. FSANZ also reviewed the vitamin D value for conventional duck. Following publication of updated data in the Australian Food Composition Database,

Submission viewpoint	Raised by	FSANZ response
		the vitamin D value used in the assessment has been revised (see Table A1.2). The revised value is lower than the value originally used in the assessment and is closer to the value reported in the New Zealand Food Composition Database. This revision does not affect the conclusions of the nutrition assessment.
Considered that cell-cultured duck differs substantially from conventional duck in its nutrient composition, including lower levels of some proteins, vitamins and essential amino acids and higher levels of some minerals. Questioned whether sufficient information had been provided to demonstrate that these differences would not be nutritionally disadvantageous to consumers and requested: • additional information on key nutritional parameters relevant to the assessment of nutritional safety; • consideration of how nutrition information should be made available to consumers to support informed choice, given the compositional differences between cell-cultured and conventional foods, consistent with section 18(1)(b) of the FSANZ Act and the Ministerial Policy Guideline for Novel Foods.	NZFS MPI; Luv – a – Duck Pty Ltd; DEEC Vic	FSANZ acknowledges the composition of cell-cultured duck differs from conventional duck in the concentration of some nutrients. The purpose of the nutrition assessment was not to establish nutritional equivalence with conventional duck, but to determine whether these compositional differences raise nutritional safety concerns. FSANZ considered both the compositional data and anticipated consumption patterns, noting that cell-cultured duck is expected to be used as an ingredient in mixed food products and is not intended to substantially replace conventional duck products. The nutrition assessment concluded that the observed compositional differences do not raise nutritional concerns and FSANZ therefore did not consider any specific risk management measures to be warranted.
Dietary Exposure		
The submitter questioned the reliance on adult consumer intention data from the 2023 FSANZ Consumer Insight Tracker to dismiss modelled iron upper level exceedances in young children. The submitter requested that FSANZ either base its conclusion on the chronic intake rationale in the assessment or rerun the exposure assessment using a consistent consumption assumption. The submitter acknowledged that section 4.6 of SD1 provides a different and stronger justification, namely that upper levels are intended to protect against chronic sustained intakes, and that single-portion modelled exceedances do not	Luv – a – Duck Pty Ltd	The overall conclusions of the risk assessment have been provided in section 4.6 of the SD1 including the strong justification about the iron upper level exceedance that the submitter acknowledged. Several pieces of evidence have been included in the SD1 to support the nutrition and dietary exposure assessments. These include data from the 2023 FSANZ Consumer Insights Tracker and information on the basis and use of the Upper level of Intake (UL) and its applicability to chronic dietary intakes. Together, these have all been used to inform the overall risk assessment conclusions.

Submission viewpoint	Raised by	FSANZ response
indicate a safety concern.		
The submitter questioned the reliability of the serving size used in the toxicological and nutritional exposure assessments, noting that it was based on limited and older duck consumption data. The submitter requested disclosure of the number of survey respondents underlying the serving size and sensitivity testing using plausible alternative serving sizes.	Luv – a – Duck Pty Ltd	FSANZ acknowledges the age limitation in the food consumption data used in the dietary intake assessment and the small proportion of consumers. Estimated serving sizes of chicken meat were provided as a comparator food due to more frequent consumption. However, the mean serving size (181 g) used for duck is consistent with serving sizes available in the market in Australia and New Zealand and is therefore appropriate for the risk assessment. These examples include: • 1 serving fresh duck breast = 190 g (Luv-A-Duck Fresh Duck Breast Fillets 380g Woolworths) • 1 serving of Peking Duck Breast = 190 g (Buy Luv A Duck Cooked Duck Breasts Peking Flavoured 380g Coles) • 1 serving Peking spiced duck breast = 230 g (Pams Finest Peking Spiced Duck Breast 460g Pams) • 1 serving confit duck leg = 186 g edible portion (Luv-A-Duck Confit Duck Legs Slow Cooked 450g Woolworths) • 1 serving confit duck leg = 120 g (Buy Riverside Farm Duck Leg Confit Style online at Woolworths NZ) • 1 serving of boneless roasted duck = 175 g (Royal Duck Boneless Roasted Half Duck 350g Woolworths)

2.2 Risk management, regulatory framework and other comments

Submission viewpoint	Raised by	FSANZ response
Labelling		
Food identification requirements		
Considered the absence of an applicant request for labelling	Luv – a – Duck	FSANZ considers the applicability of existing labelling requirements in every

Submission viewpoint	Raised by	FSANZ response
changes should not preclude FSANZ from considering whether changes are needed. Also considered cell-cultured quail and cell-cultured duck were not equivalent, because quail is a minor species with a small conventional market and low consumer familiarity, while duck is an established agricultural commodity with a domestic industry, defined retail and foodservice categories and a recognised provenance value. The consequences of imprecise naming are materially greater.	Pty Ltd	assessment. Existing general food identification requirements require the name of the ingredient or food to reflect the true nature of the food for sale. Existing labelling requirements for cell-cultured food apply the required statement 'cell-cultured' or 'cell-cultivated' to the ingredient name and the name of the food if the food is represented as being from the source animal. Together, these requirements ensure consumers have sufficient information to distinguish between cell-cultured duck and its conventional counterpart and make informed choices (see section 1.3.3 of the CFS). FSANZ disagrees that existing food identification requirements would result in imprecise naming of cell-cultured duck when used as an ingredient in food for sale. FSANZ has previously noted that it expects food businesses will likely want to feature the name of the species (see Table 2 to Appendix 1 in the A1269 2nd CFS), to assist consumer understanding of the nature and source of the food and to facilitate comparison with other foods.
Raised concerns that cell-cultured food products would not be subject to mandatory, clear and prominent labelling, including on the front-of-pack. Considered that stronger labelling is needed to allow consumers to avoid cell-cultured foods for ethical, religious, environmental, health or personal reasons.	GE; CM	The labelling approach for cell-cultured food was established through an evidence-based assessment undertaken for A1269 Cell-cultured quail as a novel food, and subsequently agreed by the FMM. No evidence was presented to warrant a change to this approach for cell-cultured duck. As noted above, existing labelling requirements for cell-cultured food apply the required statement 'cell-cultured' or 'cell-cultivated' to the ingredient name and the name of the food if the food is represented as being from the source animal. Consumer evidence indicates that either statement 'cell-cultured' or 'cell-cultivated' will assist consumers to distinguish between the cell-cultured food and its conventional counterpart (see the 2nd CFS of A1269 Cell-cultured quail as a novel food). Further, general legibility requirements in section 1.2.1—24 of the Code, which provides for required statements to be legible and prominent so as to contrast distinctly with the background of the label, will apply.
Supported the proposed labelling approach for cultivated duck but questioned FSANZ's preference for the qualifier "cell-" in cultivated food names. They submitted that alternative	CAA	The FSANZ literature review conducted for A1269 found that in addition to enabling consumers to understand the nature of the food, the terms 'cell-cultured' and 'cell-cultivated' were also the best performing terms in relation

Submission viewpoint	Raised by	FSANZ response
terminology may better support consumer acceptance and trust and raised concerns about the adequacy and currency of the evidence informing FSANZ's terminology approach.		to consumer understanding of allergenicity and their ability to correctly identify that the product was not safe to consume for those with an allergy to the traditional counterpart food. FSANZ considers the evidence supporting terminology that assists consumers to accurately identify cell-cultured food from conventional food, thus enabling informed choice and ensuring they are not being misled. Consumer acceptance is not a primary issue for setting labelling regulations.
<i>Terminology</i>		
Sought clarification on the use of 'cell-cultured' and 'cell cultured' in the consultation materials, noting both forms appear to be used interchangeably in the CFS. The submitter welcomed flexibility for industry to use either form, provided the intended meaning is retained.	APAC-SCA	FSANZ acknowledges the term 'cell-cultured' was incorrectly presented without a hyphen in parts of section 1.3.3 of the CFS, including the summaries of sections 1.5.4—5 and 1.5.4—6 of the Code, and in some other parts of the CFS. The term was correctly presented with a hyphen in the summary of section 1.5.4—7. The Code requires the statement 'cell-cultured' to include the hyphen when that statement is used to meet the general labelling requirements for cell-cultured food.
<i>Legibility and location of statement</i>		
Recommended a requirement for the qualifying statement to appear immediately adjacent to the name of the food and to the name of the ingredient, in the same font style, in a size no smaller than the name it qualifies, and where the food bears a front-of-pack presentation of the animal name, on the front of pack. These proposed requirements would ensure consumers are given the information they need at the point of sale.	Luv – a – Duck Pty Ltd	As noted in the response above to GE and CM regarding food identification requirements, the labelling approach for cell-cultured foods was established through A1269 and agreed by FMM. No evidence was presented that would warrant a change to this approach. FSANZ considers the requirement for the statement to be used in conjunction with the name of the cell-cultured ingredient and/or in the name of the food (if other representations warrant it) is sufficient to inform consumers. Further, general legibility requirements in section 1.2.1—24 of the Code, which provides for required statements to be legible and prominent so as to contrast distinctly with the background of the label, will apply.

Submission viewpoint	Raised by	FSANZ response
<i>Use of ‘meat’ and ‘poultry meat’ terms</i>		
Noted the proposed added wording about labelling requirements in Division 2A S25A—5B (2) states that the label on the package of the food not for retail sale must not contain the phrase “poultry meat” or the word “meat”. This submitter questioned whether there will be specific requirements for consumer descriptions of cell-cultured foods used in food service settings (such as in menus).	NZFGC	Existing requirements permit the use of the term ‘meat’ with the required statement in food service settings. Restrictions on the term ‘poultry meat’ apply only to packaged foods. Paragraph S25A—5B(3)(a) of the draft variation limits the term ‘meat’ to its voluntary use in conjunction with the statement required by section 1.5.4—5. That section applies to the name of the ingredient in a food for sale irrespective of whether it is packaged or unpackaged (i.e. a food that is not required to bear a label such as food offered for sale in food service settings). Paragraph S25A—5B(3)(b) and subsection S25A—5B(4) are not relevant because they refer to packaged food provisions. By contrast, subsection S25A—5B(2) and paragraph S25A—5B(4) refer to the term ‘poultry meat’ in relation to packaged food only. In developing the standard, FSANZ considered that caterers would be unlikely to describe a cell-cultured ingredient in a menu item as ‘poultry meat’, given the term’s lack of specificity. These labelling information requirements are consistent with those for cell-cultured quail and FSANZ considers they are sufficient to enable consumers to make informed choices. FSANZ has no plans to set further requirements for unpackaged food.
<i>Food for sale not required to bear a label</i>		
Two submitters sought clarity on the information requirement for food containing cell-cultured duck that is sold in a food service setting. They considered it was unclear whether Division 2 of Standard 1.5.4 ensured adequate information is provided to consumers to enable informed choices in accordance with FSANZ Act requirements. One submitter stated the provision of information to caterers does not necessarily ensure disclosure of required information to the final consumer in restaurants, cafés and other food-service	Luv – a – Duck Pty Ltd; APL; AMIC	The Code requires food businesses, including caterers, to provide any required information for unpackaged food sold at retail. Under section 1.2.1—9 of the Code, information relating to cell-cultured food must accompany the food or be displayed in connection with it, but businesses may choose how to present it (for example, on a shelf label or menu alongside the relevant food). Caterers may rely on information supplied through the supply chain but remain responsible for ensuring the required information is available to consumers at the point of sale.

Submission viewpoint	Raised by	FSANZ response
settings. They stated that disclosure should not depend on a consumer specifically requesting this information.		
<i>Nutrition information</i>		
Noted differences in the concentrations of several nutrients between cell-cultured duck and conventional duck. While acknowledging FSANZ's conclusion that these differences are not a nutritional concern, the submitter considered that the overall nutrient profile differs from conventional duck and that this should be reflected in consumer information at the point of sale.	Luv – a – Duck Pty Ltd	Existing nutrition information requirements would apply. These requirements would enable consumers to compare the amount of sodium, protein and other nutrients mandated for declaration in packaged products containing cell-cultured duck with other packaged foods (including those containing conventional duck as an ingredient). The nutrition information of the food for retail sale would reflect the overall nutritional profile of that food. Previously, FSANZ noted the Code exempts poultry that comprises a single ingredient or a category of ingredients from the requirement for a nutrition information panel. This exemption would not apply to the applicants' cultured duck cells because it is intended be used as an ingredient in a mixed food (i.e. not a single ingredient), and it is not poultry meat in accordance with the definition of 'meat' (see section 4.4 in SD4 to the A1269 1st CFS).
<i>Nutrition content and health claims</i>		
Noted compositional differences between the duck cell biomass and conventional duck (e.g. the protein content of 12.1 g per 100 g against 21.2 g per 100 g, respectively). This submitter recommended FSANZ considers whether nutrition content claims and health claims under Standard 1.2.7 should be restricted in respect of foods containing cell-cultured duck, and in particular whether a claim relating to protein, iron or folate should be permitted where the food is also presented as duck.	Luv – a – Duck Pty Ltd	Consistent with its assessment of A1269, FSANZ considers that foods containing cell-cultured duck biomass may make nutrition content and health claims where the applicable requirements in Standard 1.2.7 and Schedule 4 of the Code are met. Such claims relate to the nutrient content of the food for sale as a whole, rather than the cell-cultured ingredient in isolation. The contribution of other ingredients and the proportion of cell-cultured duck biomass used will determine the food's overall nutrient profile and whether it meets the relevant qualifying criteria, including any applicable nutrient profiling requirements. FSANZ therefore does not consider that claims relating to protein, iron, folate or other nutrients should be prohibited solely because the food contains a cell-cultured ingredient or is presented as duck.

Submission viewpoint	Raised by	FSANZ response
Seeks restrictions on nutrition content claims.	GE	See the previous response for the regulatory approach for nutrition content claims made about food for sale containing the cell-cultured duck biomass. The submitter provided no justification or evidence to support their request.
Other labelling issues		
<u>Claims of equivalence or substitution</u> Considered that nutrition content and health claims must accurately reflect the composition and nutritional content of the relevant product. Raised concerns that product descriptions, marketing or other representations could expressly or implicitly misrepresent or appropriate the health benefits, nutritional value or other attributes of conventional foods, including by suggesting that cell-cultured foods are nutritionally equivalent to, or suitable substitutes for, conventionally produced animal products despite potential compositional differences.	DEEC Vic; CA	Any comparative nutrition content claim must comply with section 1.2.7—16 of the Code, including by using an appropriate and clearly identified reference food, comparing the foods in the same form and satisfying the prescribed conditions. Comparative claims about vitamins or minerals are not permitted. Claims or other representations that a cell-cultured food is nutritionally equivalent to, or a suitable substitute for, a conventional animal food must accurately reflect the composition of the food for sale and must not be false, misleading or deceptive. The Code does not prohibit words, images or other marketing representations referring to the source animal (in this case, duck). However, where a label includes words, images or both that indicate the source animal, either statement 'cell-cultured' or 'cell-cultivated' in conjunction with the ingredient name would also be required in the name of the food. This requirement would help consumers to distinguish the food from its conventionally produced counterpart. All other marketing representations would remain subject to broader consumer protection legislation including prohibitions on false, misleading or deceptive conduct.
<u>Use of conventional animal-product terminology</u> Noted concerns about using established animal-product and meat descriptors for cell-cultured foods, including terms such as 'duck', 'duckling', 'Pekin', 'foie gras', 'confit', 'rillettes', 'pâté', 'liver', and livestock species names. Views ranged from requiring these terms to be accompanied by a qualifying statement to prohibiting their use altogether. These submitters considered that such terminology could misrepresent the product's identity	DEEC Vic; Luv-a-Duck Pty Ltd; AMIC; GE; CA; APL	FSANZ considers the words 'duck', 'duckling' or 'Pekin' (a breed of duck) would identify the animal source of the cell-cultured ingredient and trigger the requirement for the statement 'cell-cultured' or 'cell-cultivated' in conjunction with the ingredient name to be included in the name of the food. The Code also requires the use of either statement in conjunction with the ingredient name in the statement of ingredients. However, FSANZ considers the requirement need not apply separately to every additional term describing an anatomical part, product style or culinary

Submission viewpoint	Raised by	FSANZ response
or composition and allow cell-cultured products to benefit from the reputation of conventionally produced animal products.		process, such as “liver”, “confit”, “pâté” or “foie gras”, provided the ingredient name (and name of the food, if represented as such) clearly identifies its cell-cultured nature. Requiring the statement to accompany each such descriptor may result in repetitive labelling without materially improving consumer understanding. FSANZ considers consumers are adequately informed by the existing provisions. The overall presentation must also comply with applicable requirements concerning false, misleading or deceptive representations.
<u>Use of animal imagery and associated representations</u> Considered that images of ducks, poultry, livestock or other animals, and related marketing representations, should be restricted or prohibited on cell-cultured foods for the following reasons: such imagery could imply that a product was derived from conventionally raised or harvested animals, confuse consumers about its nature or production method, and weaken the distinct identity and reputation of livestock-derived products.	AMIC; GE; CA; APL	As noted in previous responses, the labelling approach for cell-cultured foods was established through A1269 and agreed by FMM. No evidence was presented that would warrant a change to this approach. FSANZ considers a specific prohibition or restriction on animal imagery is unnecessary. The existing labelling framework is intended to assist consumers to distinguish cell-cultured foods from their conventional counterparts. If a packaged food for retail sale is represented in words, images or both as being from the animal from which the cell-cultured food was sourced, the Code requires the statement ‘cell-cultured’ or ‘cell-cultivated’ to be included in the name of the food. Submitters provided no evidence that animal imagery would undermine these requirements or that existing consumer protection legislation is inadequate. FSANZ considers a separate restriction on imagery is therefore not justified.
Highlighted evidence relating to consumer confusion associated with the labelling and presentation of alternative protein products (Pollinate survey). They requested that consumer understanding of product descriptors, animal imagery and other labelling attributes be considered when developing labelling requirements for cultivated foods.	CA	FSANZ notes the information provided regarding consumer understanding of alternative protein product labelling. DAFF commissioned FSANZ to undertake consumer and market research on consumer understanding of plant-based labelling alternative labelling. The cited report was captured in the literature review, alongside the other relevant research on the topic. The commissioned reports are available on DAFFs website Plant-based alternative product labelling - DAFF. The Australian Government’s April 2026 response to the Senate Inquiry report on the definitions of meat and other animal products announced that it will work with the Alternative Proteins Council to develop a voluntary Industry Code of Practice for the labelling of plant-based protein products.

Submission viewpoint	Raised by	FSANZ response
		Please see prior response regarding the use of these attributes and animal imagery for cell-cultured/cultivated foods.
<u><i>Additional disclosure of production method</i></u> Considered the proposed qualifying terms 'cell-cultured' and 'cell-cultivated' and specific labelling conditions would not adequately explain how cell-cultured food is produced. Requested the statement 'No duck meat. Biomass derived from duck stem cells' be required to appear prominently on the front-of-pack. It would distinguish the product from conventional meat and identify its cellular origin to consumers. The submitter recommended that equivalent disclosures appear on packaging, ingredient lists, online sales pages, menus, catering information and information displayed with unpackaged food.	GE	The regulatory approach regarding the statements 'cell-cultured' and 'cell-cultivated' was established through A1269 for the reasons described in the approval report and agreed by the FMM. No new evidence was provided by the submitter to indicate that the proposed statement would have greater understanding that the information already required. FSANZ considers the proposed statement would largely duplicate information already required in the statement of ingredients, where 'cell-cultured' or 'cell-cultivated' must be used in conjunction with the name of the relevant ingredient. Consumers of packaged foods can therefore determine from the statement of ingredients whether a food contains a cell-cultured ingredient. In FSANZ's view, the required statement provides sufficient information for informed choice. Where a food is not required to bear a label, the Code requires this information to accompany the food, be displayed in connection with its display or, as applicable, be provided to the purchaser on request at the point of sale. FSANZ therefore considers that an additional statement would provide limited further information to consumers while imposing unnecessary duplication and regulatory burden.
Consumer evidence		
Expressed concerns about the scope, quality and limitations of the consumer research used to inform cultivated food labelling decisions. Additional contemporary and Australia and New Zealand-specific evidence was considered necessary to support regulatory decision-making	CAA; APL	The limitations associated with the consumer research both in the University of Adelaide systematic review and the FSANZ literature review used to inform requirements for cell-cultured/cultivated foods were acknowledged by the authors in their reviews (SD3 in CFS2 and SD2 in CFS1, in A1269). FSANZ based its decisions on the best available evidence at the time. FSANZ continues to monitor consumer awareness and understanding of cell-cultured/cultivated food, as well as their consumption intentions in the annual consumer survey (Consumer Insights Tracker). The Consumer

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		Insights Tracker uses a representative sample from both Australia and New Zealand. Detailed findings are available on the FSANZ website Consumer Insights Tracker Food Standards Australia New Zealand .
Cost benefit analysis		
The consideration of costs and benefits under section 29 of the FSANZ Act contains no assessment of any cost to the existing Australian and New Zealand duck industry, its growers or its supply chain, or to the integrity of the conventional duck category into which the applicant proposes to sell. The word "industry" appears in the analysis only in relation to the applicant and to prospective users of the ingredient. Voluntariness of use by the party seeking the permission is not the test. A measure can be voluntary for its beneficiary and involuntary in its effects on third parties. If a product carrying the word "duck" enters the market with weaker provenance disclosure than the conventional product it sits beside, and if a food safety incident occurs in that product, the conventional category bears reputational damage it cannot control and did not cause. That is an indirect cost of the measure. It should be identified and weighed, or its exclusion should be explained. Undertake and publish a consideration under section 29(2)(a) that expressly addresses the direct and indirect costs to existing Australian and New Zealand duck producers, growers and supply chains, or state the basis on which those costs were excluded from consideration.	Luv – a – Duck Pty Ltd	FSANZ's consideration of costs and benefits has been updated and now has regard to potential costs to traditionally farmed duck meat providers. The impacts of cell-cultured foods remain uncertain however due to unpredictability of future growth and consumption patterns of cell-cultured foods.
It should be acknowledged there are no consumer data specific to indigenous peoples, specifically Māori and Pasifika consumers' expectations around cell-cultured foods, and this should be rectified.	NZFGC	FSANZ acknowledges the limited consumer data specific to indigenous populations and notes no new evidence specific to these populations have been provided. FSANZ bases its decision on the best available evidence on consumers' understanding, preference and acceptance at the time.

Submission viewpoint	Raised by	FSANZ response
		FSANZ's annual consumer survey (the Consumer Insights Tracker) has proportionate representation of indigenous populations (Aboriginal and/or Torres Strait Islanders in Australia, and Māori in New Zealand). FSANZ continues to monitor consumer awareness and understanding of these foods through the CIT.
Regulatory framework and drafting		
Suggestion that the Code definition of cell-cultured food may not reflect the broader range of cellular agriculture products now in development, including plant-derived products such as cultivated coffee or cocoa. The submitter requested that FSANZ consider broadening the definition to include animal- and plant-derived cell-cultured foods or alternatively use the term "cell-cultured meat" if the framework is intended to apply only to meat products.	CAA	This submission relates to matters that are out of scope of application A1341.FSANZ notes the regulatory approach was approved by the FMM as part of approving cell-cultured quail under A1269.
The definition is broader than the permission Proposed item [3] inserts into section S25A-2 a definition of cell-cultured duck meaning "duck cells obtained from culturing embryonic stem cells from <i>Anas platyrhynchos domesticus</i>". That definition is not restricted to any cell line. By contrast, the permission at item [4] is restricted to cell-cultured duck derived from cell line 8516-Duck-DP and detailed in application A1341, and the specification at section S3-61(1) is likewise restricted to that cell line. The conditions on sale and labelling in Division 2A operate by reference to the broad definition in section S25A-2, not the narrow permission. The result is an instrument in which the defined term, the permitted food and the specified food do not share the same scope. That is capable of creating uncertainty for enforcement agencies and for later applicants, and it is easily fixed.	Luv – a – Duck Pty Ltd, SA Health	FSANZ does not agree the provisions will create uncertainty for enforcement agencies or future applicants. Standard 1.1.1 of the Code prohibits anything that is a 'cell-cultured food' (as defined) from being a food for sale or being an ingredient or component in a food for sale, unless expressly permitted by the Code. See paragraphs 1.1.1—10(5)(baa) and (6)(fa) of the Code. This prohibition extends to 'duck cells obtained from culturing embryonic stem cells from <i>Anas platyrhynchos domesticus</i>'. Section S25A—3 lists what is a permitted cell-cultured food for the purposes of this prohibition. See section 1.5.4—3. The approved draft variation will list cell-cultured duck derived from cell line 8516-Duck-DP and detailed in application A1341 as a permitted cell-cultured food in that section. Only that one subset of 'cell-cultured duck' will be permitted. Any other 'cell-cultured duck' remains prohibited by Standard 1.1.1 unless and until

Submission viewpoint	Raised by	FSANZ response
Align the definition of cell-cultured duck in section S25A-2 with the permission at item [4] and the specification at section S3-61 by restricting it to biomass derived from cell line 8516-Duck-DP. Noted that the proposed definition of 'cell-cultured duck' in section S25A-2 – 'duck cells obtained from culturing embryonic stem cells from <i>Anas platyrhynchos domesticus</i>' – is broader than the definition used in the Schedule 3 specification (section S3-61(1)), which specifies the cell line as 8516-Duck-DP. SA Health recommends that FSANZ confirm that the permission under Schedule 25A is only applicable to cell-cultured duck derived from cell line 8516-Duck-DP (as set out in item 2 of the table to section S25A-3) and not to any cell-cultured duck product derived from other cell lines, which would require separate assessment and approval.		expressly permitted. Division 2A lists conditions which must be complied with in order for a food for sale to be, or contain as an ingredient, cell-cultured duck that is listed in section S25A—3. See section 1.5.4—3. Division 2A itself also list conditions which apply to foods for sale. As explained above, only cell-cultured duck derived from cell line 8516-Duck-DP and detailed in application A1341 will be permitted to be a food for sale. The above mirrors the regulatory approach and provisions for cell-cultured quail (A1269) agreed by Australian and New Zealand Food Ministers, including South Australia, in June 2025. See the current references, provisions and permissions in Schedule 25A in relation to 'cell-cultured quail'. No enforcement agency or jurisdiction – other than SA Health in responding to this application (see below) - has queried this approach and this decision or provided evidence of a compliance problem. Nor has any applicant. Applicants will also have the guidance available via the Application Handbook. The approach outlined above avoids the need to amend the definition of cell-cultured duck in section S25A—2 every time a new cell-cultured duck product or biomass is approved as a permitted cell cultured food. The cell-cultured food permission provided by the approved draft variation will only apply to 'cell-cultured duck derived from cell line 8516-Duck-DP and detailed in application A1341'. A Schedule 3 specification is not a permission. See section 1.1.1—15 of the Code. The section states a cell-cultured food must comply with the specification when that cell-cultured food is added to food in accordance with the Code or sold for use in food. As stated above, the only 'cell-cultured duck' to be permitted to be added to food or sold for use in food will be 'cell-cultured duck derived from cell line 8516-Duck-DP and detailed in application A1341'. For that reason, the proposed Schedule 3 specification applies only to that one subset of cell

Submission viewpoint	Raised by	FSANZ response
		cultured duck.
Comparing the A1341 definition with that established for cell-cultured quail in A1269 reveals two drafting differences of note. First, the cell type specified differs: the quail definition (section S25A–2 as enacted by A1269) refers to 'embryonic fibroblast cells sourced from <i>Coturnix japonica</i>', while the duck definition refers to 'embryonic stem cells from <i>Anas platyrhynchos domesticus</i>'. This distinction is biologically significant – fibroblast cells and embryonic stem cells (ESCs) have different pluripotency characteristics and production profiles – and its reflection in the definitional drafting is appropriate. However, neither definition explains the biological distinction, which may be a source of confusion for non-specialist readers of the Code. SA Health recommends that the Explanatory Statement for A1341 clearly articulate why ESCs rather than fibroblast cells are used in the duck production process.	SA Health	The permission is linked to a specific cell line and all aspects detailed in application A1341 including the cell type. FSANZ does not consider this would cause confusion. Regarding the request for the Explanatory Statement for A1341 to clearly articulate why ESCs rather than fibroblast cells are used in the duck production process, this is explained in the application. According to the applicant, ESCs exhibit many intrinsic properties that enable them to proliferate extensively in culture compared to somatic cells such as fibroblasts. This is not required in the Explanatory Statement.
Supportive for the microbiological specifications as per SD. Queried differences between the microbiological limits for cell cultured foods in the compendium and those in the SD. Queried the proposed location of the microbiological parameters in the Food Standards Code.	SA Health; NZFS NZFS MPI; APAC-SCA, NSW FA; DAFF	Mandatory microbiological criteria for permitted cell-cultured duck biomass will be specified in Schedule 3, while microbiological criteria for final foods containing cell-cultured duck biomass will be set out in Schedule 27. The microbiological criteria specified in Chapter 7 of the Compendium refer to in-process monitoring, rather than a specification for the final cell biomass product. FSANZ has determined that the microbiological specifications provided in S3-61 will appropriately manage food safety risks.
Supported the proposed Schedule 3 specification for cell-cultured duck biomass, including compositional, heavy metal and microbiological parameters. The submitter recommended considering post-market monitoring of production inputs as scale increases and reviewing the exclusion of <i>Campylobacter</i> if future surveillance or epidemiological data indicate a need.	SA Health	Noted. As stated in the supporting document, these inputs do not pose a risk to consumers, and <i>Campylobacter</i> was not identified as a risk. The applicant's food safety program includes monitoring of relevant inputs to support production consistency. If changes in scale mean the specification can no longer be met, a new application may be required. Food manufacturers would liaise with the relevant jurisdiction in the first instance before any FSANZ involvement.

Submission viewpoint	Raised by	FSANZ response
Supported the proposed sale conditions, noting they are consistent with those applying to cell-cultured quail. It considered that limiting cell-cultured duck to use as a wholesale ingredient, rather than as a standalone retail food, provides a prudent and consistent oversight framework for permitted cell-cultured poultry products.	SA Health	Noted.
Noted that production of cell-cultured food in New Zealand would be regulated through independently evaluated risk management programmes and/or food control plans. NZFS MPI also noted that imports of cell-cultured food products or cell lines would need to meet relevant biosecurity import health standards, with biosecurity controls also applying at manufacturing production sites.	NZFS MPI	Noted.
Requested clarification whether the permission is attached to the company, the cell line, or both, and whether permission would extend to successors, assignees and licensees.	Luv – a – Duck Pty Ltd	The permission relates to the assessed cell line, 8516-Duck-DP, assessed in Application A1341. Any change to the development or production of the cell-cultured duck biomass may require further consideration by FSANZ. As with any significant change to biomass production, the first step would be to discuss the change with the relevant jurisdiction(s).
The submitter requested that FSANZ develop a broader framework for cell-cultured animal-derived foods via a proposal, rather than addressing naming, presentation, disclosure and imported product issues application by application. The submitter also requested a published post-market review within 24 months covering batch conformance, microbiological non-conformances, labelling compliance and consumer understanding.	Luv – a – Duck Pty Ltd	A regulatory framework for cell-cultured food was established as part of FSANZ's consideration of Application A1269 – Cultured quail as a novel food. Regarding a post-market review, matters relating to labelling compliance, batch conformances and microbiological non-conformances are standard compliance matters for jurisdictional food regulators and do not require post-market review by FSANZ. FSANZ will continue to monitor consumer understanding through the Consumer Insights Tracker.
Legislation administered by other agencies		
Support for the existing framework for Australian-produced cell-cultured foods but recommended comparable import controls for	NSW FA	Noted. FSANZ has liaised with DAFF on matters relating to the importation of cell-cultured foods into Australia and NZFS MPI on importation to New

Submission viewpoint	Raised by	FSANZ response
imported products, including liaison with DAFF given Standard 3.4.1 applies to Australian-made product.		Zealand.
Submitters sought clarification on the regulatory oversight and import controls for cell-cultured duck biomass produced overseas and imported into Australia. They asked how compliance with food safety requirements would be verified, particularly where Australian production requirements do not directly apply, and whether overseas production would be subject to HACCP-based systems and oversight equivalent to domestic arrangements, including during future scale-up.	Luv – a – Duck Pty Ltd, NSW FA	Approval of a cell-cultured food does not mean it can be imported. Import requirements are managed separately in Australia and New Zealand. In Australia, import requirements for approved cell-cultured foods are managed by DAFF. Information regarding importation is available from the FSANZ website: Cell-cultured foods Food Standards Australia New Zealand and on the DAFF website: BICON - Case Overview .
Requested clarification on how cell-cultured duck biomass would be regulated under the Imported Food Inspection Scheme, including its classification and the inspection and testing arrangements that would apply at the border. The submitter also sought information on whether compliance with the proposed Schedule 3 specification would be verified through import controls.	Luv – a – Duck Pty Ltd	Noted. This is a matter between the food manufacturer and DAFF.
Requested further information regarding the Biosecurity classification and import requirements for the duck cell cultured biomass	Luv – a – Duck Pty Ltd	Noted. This is a matter between the food manufacturer and DAFF.
DAFF advised that cell-cultured food imports, including imported cell lines, cell biomass or foods containing biomass would require risk assessment and import permit before entering Australia and noted that the product cannot be imported or used until both biosecurity and imported food requirements are met.	DAFF	Noted. This is a matter between the food manufacturer and DAFF.
Agrees with the approach FSANZ has taken. Requested clarification on the regulatory and legislative requirements that would apply to the production of cell-cultured foods in New Zealand, noting that Australia-only Standard 3.4.1 does not	NZFGC	Noted. This is a matter between the food manufacturer and the New Zealand government.

Submission viewpoint	Raised by	FSANZ response
apply in New Zealand and that no specific New Zealand regulations for cell-cultured food production currently exist. Queried whether additional or transitional regulatory arrangements would be required before commercial production of cell-cultured duck could occur in New Zealand.		
Concerns were raised that Australian production requirements may not provide direct oversight of overseas facilities producing cell-cultured duck biomass. A request was made for enforceable import controls, including access to production records, independent inspections, batch certification, traceability, notification of manufacturing changes and disclosure of contamination or recall events.	GE	Noted. This is a matter between the food manufacturer and DAFF.
Trade		
FSANZ's conclusion that WTO notification was unnecessary was questioned, noting the proposed permissions include mandatory naming and labelling requirements for a novel food category where no international standard exists. The submitter requested that FSANZ reconsider whether notification under the WTO Technical Barriers to Trade Agreement is required.	Luv – a – Duck Pty Ltd	FSANZ made a WTO notification for A1269 where the new regulatory framework for cell-cultured foods, including mandatory labelling requirements, was proposed. No submissions were received in response to that notification. FSANZ did not consider it necessary to re-notify this application as no changes to the regulatory framework were being proposed.
Guidance		
Recommended the development and provision of clear regulatory guidance for food businesses and enforcement agencies on cell cultured duck and food safety management requirements. Further recommended engagement with overseas regulators reviewing parallel applications and development of dedicated guidance for future cell-cultured food applicants.	SA Health	FSANZ is involved in developing two non-regulatory guidance documents, a user guide to assist applicants in understanding what data FSANZ requires to assess an application; and another document being developed by FSANZ and jurisdictions that provides general information on cell-culturing food and supporting material for Standard 3.4.1 to assist enforcement agencies and food businesses. FSANZ is engaging proactively with overseas counterparts to facilitate greater harmonisation in relation to data requirements and assessment approaches for cell-cultured foods.

Submission viewpoint	Raised by	FSANZ response
Welcomed the development of FSANZ guidance for cell-cultured foods and requested that it be published promptly and kept updated as the sector evolves. The submitter also requested guidance on “reusable scientific evidence” across applications, expectations for key safety information, regulatory predictability, and the pathway for non-meat cultivated foods.	CAA	FSANZ will seek comment on the user guide for cell-cultured food applications as part of the application handbook review. Once this process has been completed, the user guide will be published and sit alongside the updated legislative instrument, which will set out mandatory information requirements for applications. In relation to “reusable scientific evidence” FSANZ understands this refers to the ability to rely on previous assessments and evidence when considering future cell-cultured food applications. It is standard practice for applicants to bridge from, or read across, from previous published FSANZ assessments, and other publicly available information, to support their own application. FSANZ is open to this approach and encourages applicants to discuss this with FSANZ prior to submitting an application. Such an approach however is not a matter that FSANZ would consider suitable for guidance. The appropriateness of such an approach would need to be considered on a case-by-case basis. In relation to cell-cultured foods specifically, FSANZ notes only two applications have been assessed to date; therefore, the body of evidence may not yet be sufficient for such an approach to be applied to these products. In relation to the other matters referred to such as “expectations for key safety information, regulatory predictability, and the pathway for non-meat cultivated foods”, these are also not matters FSANZ would consider suitable for guidance.
Requested clearer guidance on the management of post-approval changes to cell-cultured foods. Suggestions from submitters included: • Clarifying when process changes would trigger a new application. • Providing guidance on changes to media formulations, manufacturing processes and production scale-up. • Implementing a risk-based, tiered change-management system.	APAC-SCA; NSW FA	Only general guidance can be provided as each change would be on a case-by-case basis and difficult to predict. Any changes to production should be discussed with the relevant jurisdiction in the first instance. It would be the food manufacturer and that jurisdiction that would determine whether a new application is required due to a change in the production process or inputs used in that process. FSANZ, under the FSANZ Act, is unable to advise on whether applications are required. This approach is consistent with the oversight of any other manufactured

Submission viewpoint	Raised by	FSANZ response
- Allowing lower-risk changes to be managed through existing food safety systems. - Ensuring consistent regulatory treatment of post-approval changes across cell-cultured food permissions.		food.
The submitter requested clear communication to industry and enforcement agencies about the scope and obligations of Standard 3.4.1.	SA Health	The scope and obligations of Standard 3.4.1 as applied by the SA Food Act is a matter for SA and ISFR. As mentioned above, a document being developed by FSANZ and jurisdictions that provides general information on cell-culturing food and supporting material for Standard 3.4.1 will assist enforcement agencies and food businesses.
Support the listing of the assessed cell line for the purposes of Standard 3.4.1, noting this would require Australian producers of cell-cultured duck biomass to comply with relevant food safety requirements from cell collection through to biomass harvest.	SA Health	Noted.
Other		
<u>Senate Inquiry on the definitions of meat and other animal products</u> Referred to the Senate Inquiry on the definitions of meat and other animal products and drew attention to the recommendations made to the 'Australian Government in the Senate Inquiry report, Don't mince words: definitions of meat and other animal products'. Noted the Senate Committee strongly opposed the appropriation of animal protein descriptors and animal imagery by the plant-based protein sector.	CA	FSANZ notes the Australian Government's April 2026 response to the Senate Inquiry report announced that it will work with the Alternative Proteins Council to develop a voluntary Industry Code of Practice for the labelling of plant-based protein products. The Code of Practice is intended to strengthen existing arrangements through clearer labelling standards, discouraging animal imagery, improved qualifier placement and a transparent complaints mechanism, while complementing existing consumer law protections against false, misleading or deceptive representations. FSANZ notes the focus of the Senate Inquiry Report was on plant-based products but also referred to cell-cultured foods.
<u>Country of origin</u> Noted the cell biomass is produced in France and would be imported frozen for use in a mixed food for sale in Australia. The submitter suggested consumers should be made aware that duck products with an Australian country of origin labelling (CoOL) claim (based on where the food underwent its last	Luv – a – Duck Pty Ltd	As noted by the submitter, country of origin labelling is governed by Commonwealth legislation in Australia (and is regulated separately in New Zealand via the Consumer's Right to Know (Country of Origin of Food) Act 2018). It would be inappropriate to introduce application-specific country of origin requirements into the Code, which is given effect through state and territory food legislation and the New Zealand Food Act (2014). Doing so could duplicate or conflict with the Commonwealth and New Zealand

Submission viewpoint	Raised by	FSANZ response
substantial transformation) would not realise the cell-biomass was produced in France. Suggested that CoOL regulation under Australian Consumer Law does not preclude FSANZ's ability under sections 18(1)(b) and (c) of the FSANZ Act to impose a condition in Division 2A of Schedule 25A preventing a representation of Australian or New Zealand origin in relation to the cell-cultured duck component of a food.		regimes and create uncertainty about regulatory and enforcement responsibilities. Any changes to country of origin labelling requirements should instead be considered through the relevant Commonwealth (and New Zealand) policy and legislative processes.
<u><i>'Healthy', 'natural' and 'clean' representations</i></u> Stated that FSANZ must assess finished products, restrict fake "healthy", "natural" or "clean" claims and prevent high Health Star Ratings from hiding processing. Approval of a novel ingredient must not be taken as official endorsement of the resulting formulations.	GE	FSANZ's remit is to undertake a pre-market safety assessment of the cell-cultured food and consider whether existing labelling requirements in the Code are appropriate or if new labelling measures are warranted. The Code does not regulate the use of representations such as 'healthy', 'natural' or 'clean'. These types of representations are subject to relevant consumer protection laws in Australia and New Zealand, which prohibit false or misleading representations about a food offered for sale. FSANZ is currently considering whether to amend the Code to require foods for sale to display a Health Star Rating symbol. This work is being undertaken via Proposal P1067.
<u><i>Sustainability and animal-welfare representations</i></u> Considered that sustainability and animal-welfare representations should not be treated as benefits unless supported by independent, commercial-scale evidence covering the full supply chain and requested that such representations not influence FSANZ's food-safety assessment.	GE	Representations relating to environmental, food-security or animal-welfare benefits are not in the scope of the food safety assessment undertaken by FSANZ.