

24 June 2026
400–26

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

Submissions on this application need to be made through the [Consultation Hub](#).

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

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [How to make a submission](#).

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

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

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 22 July 2026

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

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

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Table of contents

EXECUTIVE SUMMARY.....	2
1 INTRODUCTION	3
1.1 THE APPLICANT.....	3
1.2 THE APPLICATION	3
1.3 THE CURRENT STANDARD	3
1.3.1 <i>Permitted use of cell-cultured food</i>	3
1.3.2 <i>Identity and purity requirements</i>	4
1.3.3 <i>Labelling requirements</i>	4
1.3.4 <i>Prohibition on addition to special purpose foods</i>	6
1.3.5 <i>Code definitions</i>	6
1.3.6 <i>Microbiological limits for cell-cultured food</i>	6
1.4 INTERNATIONAL SITUATION	6
1.5 REASONS FOR ACCEPTING THE APPLICATION.....	7
1.6 PROCEDURE FOR ASSESSMENT	7
2 SUMMARY OF THE ASSESSMENT	7
2.1 RISK ASSESSMENT	7
2.2 RISK MANAGEMENT	8
2.2.1 <i>Regulatory approval</i>	8
2.2.2 <i>Sale of cell-cultured duck</i>	8
2.2.3 <i>Labelling</i>	8
2.2.4 <i>Nutrition</i>	8
2.2.5 <i>Special purpose foods</i>	9
2.2.6 <i>Specification</i>	9
2.2.7 <i>Application of Standard 3.4.1</i>	9
2.3 RISK COMMUNICATION.....	9
2.3.1 <i>Consultation</i>	9
2.3.2 <i>World Trade Organization</i>	9
2.4 FSANZ ACT ASSESSMENT REQUIREMENTS	10
2.4.1 <i>Section 29</i>	10
2.4.2 <i>Subsection 18(1)</i>	11
2.4.3 <i>Subsection 18(2) considerations</i>	12
3 DRAFT VARIATION.....	13
4 REFERENCES	13
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE	14
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	17

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

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 cell-cultured duck biomass would be mixed with other ingredients to be used in products such as 'cell-cultured foie gras' and 'cell-cultured duck pâté'.

FSANZ has conducted a comprehensive safety assessment of cell-cultured duck biomass, including the cell line utilised in its production, drawing on the most current scientific evidence. The assessment identified no public health or safety concerns associated with either the production cell line or the resulting biomass.

Following assessment, for the reasons summarised in this report, FSANZ has prepared a draft variation to the Code.

FSANZ propose:

- An amendment to Schedule 3 to include a specification for the applicant's cell-cultured duck biomass.
- An amendment to section S25A—2 to include a definition of 'cell-cultured duck biomass' for the purposes of Schedule 25A.
- An amendment to the table to section S25A—3 to list the applicant's cell-cultured duck biomass as a permitted cell-cultured food.
- A new division in Schedule 25A, Division 2A, to set specific conditions for the sale and labelling of cell-cultured duck biomass.
- An amendment to the table to section S25A—6 to add an 'assessed cell line' for the applicant's cell-cultured duck biomass into that table for the purposes of Standard 3.4.1. These are cell lines permitted to be used in the production of cell-cultured foods in Australia only.

If approved, the effect of the draft variation would amend Schedules 3 and 25A of the Code would be to permit the cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*, to be wholesale food (i.e. not food for retail sale) and to be used as an ingredient in food for sale in accordance with the Code.

FSANZ seeks submissions on the draft variation to the Code.

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 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 (respectively).

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 interchangeable 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.

The permission for cell-cultured quail referred to in item 1 of the table to section S25A—3 (see above) is subject to corresponding sale and labelling conditions. Conditions on sale are that cell-cultured quail must not be a food for retail sale, but a food for retail sale may have cell-cultured quail as an ingredient (see section S25A—4).

Standard 3.4.1 sets food safety requirements for processing and production of cell-cultured foods in Australia. These requirements apply from the point of collection of cells from a donor animal through to the production of the final biomass used as an ingredient in a food for sale. This Standard does not apply in New Zealand.²

1.3.2 Identity and purity requirements

Section 1.1.1—15 of the Code requires that, when added to food in accordance with 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 in Schedule 3 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 or have other information provided with it; and sets out 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 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)).

² For further information, see section 2.5.1.3 of this report.

- 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 (see below).

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 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 (see above).

- 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, which FSANZ proposes to apply to cell-cultured duck

(see section 2.3.2 below). 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 (see above);
 - a statement required by section 1.5.4—6 (see above).
- 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 (see above).

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 3 cell-cultured foods for human consumption: GOOD Meat’s cultivated chicken, approved in December 2020; Vow Group’s cultivated quail, approved in early 2024; and PARIMA’s cultivated chicken, approved in October 2025. The latter marked the first time a European company received regulatory clearance to sell cultivated meat for human consumption.

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. FDA has completed 5 premarket consultations of foods made with cultured chicken cell material.³

³ Human Food Made with Cultured Animal Cells Inventory – <https://www.cfsanappsexternal.fda.gov/scripts/fdcc/?set=AnimalCellCultureFoods>

WHO analysis of global developments in the regulation and risk assessment indicated that, in most countries, cell-based foods are likely to be assessed within existing novel food regulations (WHO 2023). The objectives of section 3⁴ of the FSANZ Act 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 the 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 is being assessed under the General procedure in accordance with the FSANZ Act.

2 Summary of the assessment

2.1 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, meets established acceptance standards and employs proven pathogen-reduction measures 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 is proposed to be combined with other components to create a final mixed food product. FSANZ's assessment did not consider additional processing of the harvested cells. Food businesses are responsible for ensuring that all constituents present in the final mixed food product, meet all requirements of Australian and New Zealand food laws, including the Code.

⁴ [Section 3 of the FSANZ Act](#)

2.2 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation to the Code.

For the reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*, to be a wholesale food (i.e. not food for retail sale) or an ingredient in a food for sale in accordance with the Code.

2.2.1 Regulatory approval

Cell-cultured duck would be a cell-cultured food for Code purposes. FSANZ proposes to amend section S25A—2 to include a definition for cell-cultured duck as duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus* (see item [3] of the draft variation at Attachment A). This definition would apply for the purposes of Schedule 25A.

FSANZ also proposes to list the applicant's cell-cultured duck in the table to section S25A—3 (see item [4] of the draft variation at Attachment A) with corresponding sale and labelling conditions with which the applicant's cell-cultured duck would have to comply (see below). Those conditions would be set out in a new Division 2A and apply to cell-cultured duck (as defined in section S25A—2) that is permitted by the Code to be food for sale.

2.2.2 Sale of cell-cultured duck

FSANZ proposes to set the same conditions on the sale of cell-cultured duck as currently apply for cell-cultured quail in Division 2 of Schedule 25A.

The proposed conditions on the sale of cell-cultured duck are:

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

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

2.2.3 Labelling

Division 2 of Standard 1.5.4 of the Code sets out labelling requirements for permitted cell-cultured food and would apply to food for sale containing cell-cultured duck as an ingredient and food for non-retail sale that is cell-cultured duck (refer to section 1.3.2 of this report). The applicant did not request any changes to existing labelling requirements and therefore FSANZ is proposing that cell-cultured duck would be subject to the same labelling conditions that apply to cell-cultured quail (section S25A—5 of the Code) (see section 1.3.2 of this report).

2.2.4 Nutrition

FSANZ's nutrition risk assessment concluded there are no issues with the consumption of the applicant's cell-cultured duck (see section 2.1 of this report and SD1). FSANZ does not consider any specific risk management measures to be warranted based on the nutritional assessment undertaken.

2.2.5 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 of this report).

2.2.6 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, FSANZ has proposed a new specification within Schedule 3 for cell cultured duck biomass based on analytical data submitted by the applicant (see Table 3 of SD1).

2.2.7 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. Consequently, if the draft variation is approved, Standard 3.4.1 would only apply to the processing and production of the applicant's cell-cultured duck biomass in Australia only. 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. That definition provides that an *assessed cell line* is a cell line listed in section S25A—6 (see section 3.4.1—2). Section 3.4.1—7 provides that a cell culturing food business must only use an *assessed cell line* for cell proliferation.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ has developed a standard communication strategy for this application. This call for submissions will be notified via the FSANZ Notification Circular, media release, 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. The draft variation will be considered for approval by the FSANZ Board, having regard to all submissions received from this call for submissions.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. All comments are valued and contribute to the rigour of FSANZ's assessment.

2.3.2 World Trade Organization

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

At present, no relevant international standards for cell-cultured foods exist. If permitted, the sale of cell-cultured duck in this region is unlikely to impact international trade since global volumes of cell-cultured foods remain minimal. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 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.

2.4.1 Section 29

2.4.1.1 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 if the draft variation concerned is approved.

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. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

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

If the draft variation is approved, 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.

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.

If the draft variation is approved, 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.

The approval of 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.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

The draft variation proposes to amend Schedules 3 and 25A, both of which apply in Australia and New Zealand.

However, if the draft variation is approved, Standards 1.5.4 and 3.4.1 and Chapter 3 of the Code would also apply to the applicant's cell-cultured duck biomass.

Standard 1.5.4 applies in both Australia and New Zealand.

However, 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*.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ has completed a risk assessment (SD1) which is summarised in section 2.1 of this report. The assessment concluded there are no public health and safety concerns associated with permitting cell cultured duck biomass as a food ingredient.

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

Current labelling requirements outlined in section 2.3.3 of this report would apply to food for sale that is, or contains as an ingredient, cell-cultured duck and would provide adequate information to enable consumers to make an informed choice.

2.4.2.3 *The prevention of misleading or deceptive conduct*

The proposed labelling requirements outlined in section 2.3.3 of this report would provide information to identify the applicant's cell-cultured duck ingredient..

2.4.3 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 pertinent 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.

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

Whilst there are other cell-cultured foods provided permission overseas, the applicant's cell-cultured duck has only been assessed by FSANZ. At the time of submission of this application to FSANZ, the applicant has also sent applications to the US FDA, Singapore Food Agency, the Federal Food Safety and Veterinary Office in Switzerland, the UK FSA, the European Commission and European Food Safety Authority. All applications are currently under review by the respective authorities. Providing permission for 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 were identified for this application relevant to this objective.

- **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 Guidelines specifically applied to this application:

- Regulation of 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 considers these policy guidelines would be met by the proposed permission and associated requirements, if approved.

3 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.

4 References

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>

Attachments

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

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

2. Variation will be a legislative instrument

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

If approved, this instrument would not be subject to the disallowance or 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 Authority has prepared a draft variation amending Schedules 3 and 25A to permit cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*, to be wholesale food (i.e. not food for retail sale) or 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a six-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 will be available in an approval report published on the Authority's website at www.foodstandards.gov.au

FSANZ's assessment is that a regulatory impact statement 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 if the draft variation concerned is approved.

6. Statement of compatibility with human rights

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

7. Variation

References to 'variation' in this section are references to the 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 would amend 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) (see paragraph S3—2(1)(a)).

Item [1] would amend 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] would insert new section S3—61 into Schedule 3, which provides a specification for cell-cultured duck.

Subsection S3—61(1) provides that cell-cultured duck, for the purposes of the specification, means and therefore applies to ‘duck cell biomass obtained from culturing embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*’.

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.

If the draft variation is approved, the effect of the amendments in **items [1]** and **[2]** would be that cell-cultured duck biomass obtained from culturing embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus* would have to comply with the specification in section S3—61 when it is added to food for sale or sold for such use.

Items [3] to **[6]** of the Schedule to the variation would amend Schedule 25A of the Code.

Schedule 25A sets out permitted cell-cultured food, their corresponding conditions and ‘assessed cell lines’. The existing Standard only contains provisions relating to cell-cultured quail (cell line 221523-Fib-Quail).

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

According to that proposed new definition, cell-cultured duck means ‘duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*’.

Unless otherwise stated, references below to ‘cell-cultured duck’ for the purposes of Schedule 25A are references to duck cells obtained from culturing embryonic stem cells from *Anas platyrhynchos domesticus*’.

Item [4] would amend 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 would add 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 would be item ‘2’ and added as the last entry of the table.

Item [5] would amend 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 (sections S25A—5A and S25A—5B) for the purposes of the table to section S25A—3 (see **item [4]** above).

New section S25A—5A contains the following conditions on the sale of cell-cultured duck:

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

Consequently, if the sale is other than a retail sale (see sections 1.2.1—4, 1.2.1—10 and 1.2.1—18 of the Code) - cell-cultured duck may be a food for sale and/or an ingredient in a food for sale.

However, if the sale is a retail sale - 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.

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

Subsection S25A—5B(1) provides the requirements set by section S25A—5A apply only to a food for retail sale that has 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 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 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 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] would amend 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, if the draft variation is approved, Chapter 3 standards, including Standard 3.4.1, would apply to the processing and production of the applicant’s cell-cultured duck biomass in Australia only.

The definition in section 3.4.1—2 provides that an *assessed cell line* is a cell line listed in section S25A—6 (see section 3.4.1—2). Section 3.4.1—7 provides that a cell culturing food business must only use an *assessed cell line* for cell proliferation.

The new entry would be added as the second and last entry of the table and consists of:

‘2. The cell line **8516-Duck-DP**.’

If the draft variation is approved, the effect of the amendments in **items [3] to [6]** would be that cell-cultured duck biomass, made from embryonic stem cells (cell line 8516-Duck-DP) sourced from *Anas platyrhynchos domesticus*, would be permitted to be a wholesale food (i.e. not food for retail sale) or be used as an ingredient in a food for sale in accordance with the Code.