



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL



AFGC Response Public consultation: **1269 Cultured Quail as a Novel Food**

10 January 2025

CONSULTATION QUESTIONS

ABOUT YOU

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Submitter name

Organisation - please write your organisation name in the box below.

Enter initials if you are an individual, or enter your organisation name:

Australian Food & Grocery Council

Where are you or your organisation located?

Australia

Which group do you most identify with?

Food industry

If you wish to provide general background information about yourself or your organisation (if any), include this in the box below.

The Australian Food and Grocery Council (AFGC) is the leading national organisation representing Australia's food, beverage and grocery manufacturing sector. With an annual turnover in the 2022-23 financial year of \$162 billion, Australia's food and grocery manufacturing sector makes a substantial contribution to the Australian economy and is vital to the nation's future prosperity. Each business in the sector has contributed towards an industry-wide \$4.2 billion capital investment in 2022-23. Food, beverage and grocery manufacturing together forms Australia's largest manufacturing sector, representing over 32 per cent of total manufacturing turnover in Australia. The industry makes a large contribution to rural and regional Australia economies, with almost 40 per cent of its 281,000 employees being in rural and regional Australia. It is essential to the economic and social development of Australia, and particularly rural and regional Australia, that the magnitude, significance and contribution of this industry is recognised and factored into the Government's economic, industrial and trade policies. The industry has a clear view, outlined in Sustaining Australia: Food and Grocery Manufacturing 2030, of its role in the expansion of domestic manufacturing, jobs growth, higher exports and enhancing the sovereign capability of the entire sector. This submission has been prepared by the AFGC and reflects the collective views of the

YOUR SUBMISSION

Have you read the A1269 consultation documents?

Yes

Regulation of cell-cultured foods: FSANZ proposes two draft standards and one draft schedule to regulate the production and sale of cell-cultured foods in Australia and New Zealand. This differs from FSANZ's proposed approach at the 1st CFS, which suggested regulating the sale of these foods as novel foods. FSANZ considers this approach will deliver enhanced regulatory clarity, ensuring protection of public health and safety whilst supporting innovation in producing cell-cultured food.

Question 1: Do you agree with FSANZ's approach to regulating cell-cultured foods, which involves developing two draft standards and one draft schedule, as outlined in section 2.4 of the second call for submissions?

Yes, I agree.

The AFGC considers FSANZ's proposed approach to regulating cell-cultured foods provides a solid regulatory framework for the emerging category of cell-cultured foods. The AFGC makes the following key points:

Regulatory certainty: The AFGC supports FSANZ's proposed approach of developing two new draft standards and one draft schedule as these provide clear guidelines for industry, regulators and consumers, reducing uncertainty and enabling innovation.

Food safety: The proposed food safety requirements provide outcome-based measures to manage risks associated with the production and consumption of cell-cultured foods.

Consumer information and transparency: Mandating the use of terms "cell-cultured" or "cell-cultivated" on labels ensures transparency and informed consumer choice.

Balanced approach to innovation: The regulatory approach supports innovation while protecting public health and safety.

Safe food handling and production requirements (refer to Supporting Document 4): FSANZ proposes to establish microbiological criteria for food safety and as indicators of process hygiene and handling. These are based on established criteria for other foods and production process monitoring as well as the applicant's proposed criteria which included specifications for *Salmonella* spp. and hygiene indicator organisms: SPC, Enterobacteriaceae and *E. coli*. FSANZ proposes (i) criteria for *L. monocytogenes* and *Salmonella* spp. in Schedule 27 (i.e. food safety criteria for cell-cultured food); and (ii) cell culturing process hygiene indicators (SPC, Enterobacteriaceae, *E. coli*, yeasts and moulds and coagulase-positive staphylococci) in the Compendium of Microbiological Criteria for Foods.

Question 2: Do you agree the approach outlined above effectively supports the assessment of safe food products and provides clear guidance on maintaining adequate process control?

No, I do not agree.

While the AFGC agrees with the general approach for providing guidance on process hygiene criteria to support the safe manufacture of cell-cultured food, the rationale for including

microbiological criteria in Schedule 27 does not align with the outcomes of the risk assessment. As the application is specific to the assessment of harvested cells, the AFGC considers the inclusion of *L. monocytogenes* and *Salmonella* spp. in specifications within Schedule 3 (as proposed at the first Call for Submission) more appropriate. This would align with approaches in other international markets where these foods have been approved for sale.

AFGC agrees with the developments additional guidance on maintaining adequate process control through inclusion processing hygiene indicators in the FSANZ Compendium of Microbiological Criteria for Foods.

Further explanation:

The risk assessment for Application A1269 (Supporting Document 4) clearly states it considered 'up the harvested cells stage only' of production, and that further processing steps were not considered as these are addressed through existing provisions of the Code.

The proposed microbiological criteria in Schedule 27 apply to a lot* of 'cell-cultured food' (as defined in proposed subsection 1.1.2-2(3)). Section 1.1.1-11 of the Code provides that a food for sale must not have an unacceptable level of microorganisms as determined by Standard 1.6.1. It is not clear whether the proposed microbiological criteria apply to the harvested cells or the final finished product.

In the case of the Applicant's cell-cultured quail, the practical application of the proposed microbiological criteria in Schedule 27 is unclear as the product would normally be sold* as a finished product (containing other ingredients and requiring further cooking).

The AFGC does not agree with the rationale for the proposed microbiological criteria for *L. monocytogenes* in 'cell-cultured food', considering it is not a ready-to-eat food (i.e. will undergo cooking that will mitigate the risk). This would be out of step with existing microbiological criteria in Schedule 27 that apply to ready-to-eat foods only.

The AFGC considers these hazards are more appropriately controlled through the application of the process and hygiene controls provided the newly proposed Standard 1.5.4 amendments to Chapter 3.

Assessed cell line: The proposed processing standard for cell-cultured food restricts processing to only those cell lines assessed by FSANZ.

Question 3a: Do you agree with this approach?

Yes, I agree.

The AFGC agrees with this approach, to be considered on a case-by-case basis for future applications.

Question 3b: Do the requirements in Standard 3.4.1, when considered alongside Standard 1.5.4 and Schedule 25A, effectively achieve the intended outcome where cell lines for use in producing food are subject to pre-market assessment?

Yes, they achieve the intent.

The AFGC considers the proposed approach clearly requires pre-market assessment of cells lines used in producing cell-cultured food.

Although not relevant to this current application, consideration should be given as to a future scenario of a cell-cultured food produced using a GM cell line, and which regulatory pathway would apply (i.e. the proposed 'cell-cultured food' standards, or GM/novel food standards) – both subject to

pre-market assessment.

FSANZ proposes the following definition for 'cell-cultured food': Cell-cultured food means 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.

Question 4: Does the proposed new definition for 'cell-cultured food' provide regulatory certainty and clarity for industry, enforcement agencies and other stakeholders?

Unsure.

It is unclear whether the definition for 'cell-cultured food' applies to the harvested cells only, or a 'finished product' containing cultured cells (this also relates to our response to Q2 regarding the application of microbiological criteria and the scope of the application).

Clarification is also sought on the inclusion of particular sources of cells in the definition to ensure they are consistent with the other parts of the Food Standards Code (e.g. 'seafood', 'livestock'). This also applies to the proposed definition of 'animal' in the Section 3.4.1-2.

Labelling: FSANZ proposes a revised labelling approach for cell-cultured food in relation to food identification and food sold to a caterer (see section 2.3.3 of the second call for submissions document and supporting document 2 to that document).

Question 5a: Do you have any comments or additional evidence to inform the proposed labelling approach?

No.

Question 5b: Do you agree with this approach?

Yes, I agree

Please explain your answer below.:

The AFGC supports the FSANZ proposed labelling approach. It is based on results from consumer research while providing flexibility for industry.

Question 6: Costs and barriers. Would proposed Standards 1.5.4 and 3.4.1 restrict or impose significant costs or barriers to the production of cell-cultured foods? Can you please provide specifically, the potential costs to your business?

I have no feedback for this question

Question 7: Please provide any additional information or insights in relation to Application A1269 in the box below.

The AFGC has the following specific comments.

In describing the production and processing requirements for cell-cultured foods, Part 4.2.1 of Supporting Document 4 provides expansion on definition of 'cells line suppliers' as those entities creating a cell line 'that will be used to produced cell-cultured food'.

To avoid capture of businesses supplying cell lines or proliferating cells for purposes other than producing 'cell-cultured food', the AFGC recommend the following the definitions in the new Standard 3.4.1 be limited in scope to those associated with producing 'cell-cultured food'.

[Definitions as drafted]

cell culturing food business means a business, enterprise or activity that undertakes cell proliferation.

cell line supplier means a business, enterprise or activity that involves both of the following:

- (a) sourcing cells for use in creating a cell line;
- (b) creating a cell line.

The AFGC welcomes the opportunity to discuss with FSANZ any points raised in this submission should further clarification be required.

Confidential information

Do you wish to provide confidential information as part of your submission?

No.