

20 August 2026

Project Manager
Food Standards Australia New Zealand
PO Box 5423
Kingston ACT 2604, Australia

Email: submissions@foodstandards.gov.au

Dear FSANZ

Attached are the comments that the Australian Food and Grocery Council wishes to submit on the *Call for submissions – Application A1342 Beta-casein protein preparation from GM Komagataella phaffii*.

If you have any queries, please contact Anne-Marie Mackintosh anne-marie.mackintosh@afgc.org.au

Yours faithfully



Dr Duncan Craig
Director - Health, Trade and Regulatory Affairs
Australian Food and Grocery Council

**FSANZ Call for submissions –
Application A1342 Beta-casein protein
preparation from GM *Komagataella phaffii***

20 August 2026



AUSTRALIAN
**FOOD &
GROCERY**
COUNCIL

PREFACE

The Australian Food and Grocery Council (AFGC) is the leading national organisation bringing Australia's fast-moving consumer goods (FMCG) sector together to champion growth.

With an annual turnover in the 2024-25 financial year of \$182.6 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 \$4.5 billion capital investment in 2024-25, underpinning the sector's continued growth.

Food, beverage and grocery manufacturing together forms Australia's largest manufacturing sector, representing over 33% of total manufacturing turnover in Australia. The industry makes a large contribution to rural and regional Australia economies, with over 30 per cent of its 301,000 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's growth ambition to 2030 is set out in *Sustaining Australia: Food and Grocery Manufacturing 2030*, which outlines a path to expand domestic manufacturing, create jobs, increase exports and strengthen the sovereign capability of the entire sector.

This submission has been prepared by the AFGC and reflects the collective views of the membership.

.

EXECUTIVE SUMMARY

AFGC supports FSANZ's assessment that BCPP1 may be permitted as a genetically modified food, subject to appropriate conditions of use and specifications.

We also support FSANZ's proposal to require declaration of "milk" when BCPP1 is present in food, given the conclusion that the beta-casein component presents the same allergenicity risk as bovine milk proteins for consumers with milk allergy. The existing allergen labelling framework, including mandatory declaration of milk and the Plain English Allergen Labelling requirements, provides a clear and effective mechanism for communicating this risk to consumers.

AFGC supports maintaining the existing ingredient-naming requirements in the Code, which already provide an appropriate framework for describing the true nature of BCPP1, including its fermentation-derived or non-animal origin. We consider that the existing labelling framework is largely fit for purpose and that any regulatory response should be limited to addressing clearly identified allergen-related risks.

AFGC does not support in principle the proposed mandatory front-of-pack advisory statement that a product is "not suitable for persons with milk allergy". While we recognise that consumer understanding of fermentation-derived allergenic proteins is an emerging issue, an allergen-specific front-of-pack statement may create unintended consequences by directing attention to a single allergen and reducing the likelihood that consumers check the full ingredient list, allergen declaration and precautionary allergen labelling.

AFGC supports consumers to refer to the established allergen information without prioritising one allergen over another providing a more consistent approach for future precision fermentation applications.

SUMMARY OF AFGC RECOMMENDATIONS

1. AFGC supports permitting BCPP1 as a genetically modified food, subject to appropriate conditions of use and specifications.
2. AFGC recommends that FSANZ clarify the basis for excluding infant formula products, infant foods and other special purpose foods from the proposed permissions for BCPP1, and whether these exclusions reflect the scope of the application or a broader regulatory policy position.
3. AFGC recommends that FSANZ amend the proposed BCPP1 specification so that total protein and beta-casein are expressed as minimum values, without an upper limit, i.e. 'more than 20%' of total protein, and 'more than 4%' beta-casein (purity).
4. AFGC supports mandatory declaration of "milk" when BCPP1 is present in food for sale or supplied to caterers or manufacturers.
5. AFGC supports maintaining the existing Plain English Allergen Labelling framework, including the summary statement "Contains: milk".
6. AFGC supports maintaining the existing ingredient-naming requirements in the Code, which already provide a suitable framework for describing the true nature of BCPP1, including its fermentation-derived or non-animal provenance.
7. AFGC does not support any proposed allergen-specific front-of-pack advisory statement.
8. AFGC recommends that FSANZ rely on existing food and consumer protection laws to address potentially misleading voluntary representations, rather than introducing additional allergen-specific labelling requirements.

GENERAL COMMENTS

The AFGC and its members appreciate the opportunity to respond to the Food Standards Australia New Zealand (FSANZ) *Application A1342 Beta-casein protein preparation from GM Komagataella phaffii*, submitted by Eden Brew.

In response to the consultation, the AFGC has had the opportunity to review the submissions by the Allergen Bureau and the New Zealand Food and Grocery Council. (NZFGC). The AFGC strongly supports the positions as stated in their submissions and shares the concerns that they raise.

This application presents a unique regulatory challenge. While the primary public health and safety concern relates to allergenicity, the nature and source of the protein may also create the potential for consumer misunderstanding regarding the true nature of the food. The AFGC considers that addressing this issue requires careful consideration of how best to provide consumers with clear and meaningful information without undermining established allergen labelling principles or creating unintended regulatory precedents.

SPECIFIC COMMENTS

Genetically modified food, novel food, protein source

AFGC notes FSANZ's assessment that BCPP1 is produced by fermentation using a genetically modified strain of *Komagataella phaffii* containing the bovine gene encoding the beta-casein A2 protein. FSANZ concluded that the production organism is well characterised, non-pathogenic and non-toxicogenic, and that no public health and safety concerns were identified for the general population, other than the allergenicity risk for individuals allergic to milk proteins.

AFGC supports a science-based assessment that focuses on the identity, composition, safety and allergenicity of the final ingredient. This is particularly important for precision fermentation and other new production technologies, where the source organism and production process may differ from conventional foods, but the expressed protein may be identical or highly similar to a known allergenic food protein.

Additionally, we note that while the applicant sought approval for BCPP1 as a novel food, FSANZ has determined that the ingredient is more appropriately regulated as a genetically modified food because it is derived from an organism containing novel DNA. We understand FSANZ's view that the Code does not require GM foods to also be assessed and permitted as novel foods, and that a food assessed and approved under the GM food framework would not meet the definition of a novel food because it would no longer require a separate public health and safety assessment before permission is granted.

AFGC seeks further clarity on how FSANZ has considered the regulatory pathway for GM-derived foods that may also have novel characteristics, particularly where the ingredient is intended to be used as a source of protein. This is important because the way BCPP1 is regulated may have broader implications for future precision fermentation applications, including innovation, investment certainty and potential

exclusivity considerations. AFGC encourages FSANZ to consider how the regulatory pathway can support innovation while keeping the assessment focused on the relevant safety and regulatory issues and avoiding unintended consequences for future applications.

Recommendation

1. AFGC supports permitting BCPP1 as a genetically modified food, subject to appropriate conditions of use and specifications.

Exclusions in foods

AFGC notes FSANZ's conclusion that BCPP1 is not proposed to be added to infant formula products, food for infants, food for special medical purposes, formulated supplementary sports foods or formulated supplementary foods for young children. While these uses were not assessed as part of this application, the AFGC seeks clarification on the rationale for excluding these food categories. Given FSANZ's conclusion that BCPP1 does not raise public health and safety concerns for the general population, other than the identified allergenicity risk for individuals allergic to milk proteins, it is unclear why these categories should be excluded. AFGC is concerned that such exclusions may create uncertainty regarding the future regulatory pathway for novel foods and precision fermentation-derived proteins in infant and special purpose foods.

Recommendation

2. AFGC recommends that FSANZ clarify the basis for excluding infant formula products, infant foods and other special purpose foods from the proposed permissions for BCPP1, and whether these exclusions reflect the scope of the application or a broader regulatory policy position.

BCPP1 specifications

AFGC notes FSANZ's proposed specification for BCPP1, including total protein content, beta-casein protein content, compositional limits, heavy metal limits and microbiological limits.

We support the inclusion of appropriate specifications to ensure the approved ingredient is consistent with the material assessed by FSANZ and that microbiological controls are maintained for this low-moisture powdered ingredient.

However, AFGC recommends that FSANZ reconsider the proposed specification so that the relevant protein requirements are expressed without an upper limit where appropriate. In particular, if total protein is specified as 'more than 20%', the beta-casein specification should also be expressed as a minimum proportion of total protein, rather than only as an absolute percentage of the preparation. Under the current proposed specification, BCPP1 is required to contain 20–24% total protein and 'more than 4%' beta-casein (purity). This creates uncertainty about how the beta-casein content tracks with the total protein content, despite beta-casein being the key functional component of the ingredient.

AFGC supports an approach where both the total protein and beta-casein specifications are expressed as minimum values, without an upper limit, where this reflects the composition of the assessed ingredient. A beta-casein specification of 'more than 20%' of total protein may better maintain alignment

with the intended composition of BCPP1, support product integrity and reduce the risk of compositional drift over time. This approach would also more closely reflect the composition of bovine milk proteins, where beta-casein typically represents approximately 28–30% of total milk protein.

Recommendation

3. AFGC recommends that FSANZ amend the proposed BCPP1 specification so that total protein and beta-casein are expressed as minimum values, without an upper limit, ie 'more than 20%' of total protein, and 'more than 4%' beta-casein (purity).

Labelling requirements

AFGC notes and supports FSANZ's conclusion that the existing labelling framework in the Code is generally fit for purpose for foods containing BCPP1. For this reason, AFGC does not support the proposed mandatory front-of-pack advisory statement that a product is "not suitable for persons with milk allergy".

In particular, the current requirements relating to ingredient naming, directions for use and storage, nutrition information, nutrition content and health claims, and the labelling of genetically modified food provide an appropriate regulatory framework for this ingredient. The AFGC agrees with FSANZ that these existing provisions should continue to apply and that any regulatory response should be limited to addressing clearly identified allergen-related risks.

Ingredient declaration and naming

AFGC supports FSANZ's proposal to require declaration of "milk" when BCPP1 is present in food for sale or supplied to caterers or manufacturers. FSANZ has concluded that the beta-casein component of BCPP1 presents the same allergenicity risk as milk proteins for consumers with milk allergy. Requiring declaration of "milk" is therefore consistent with established allergen risk management principles and with the way consumers with milk allergy, and those purchasing food on their behalf, are currently advised to identify and manage allergen risks.

AFGC also supports maintaining the existing Plain English Allergen Labelling approach, including the summary statement "Contains: milk". This approach is familiar to consumers with food allergies and helps ensure allergen information remains clear, consistent and easy to identify. The AFGC does not support introducing alternative allergen terminology for fermentation-derived proteins where the protein remains clinically relevant to consumers with milk allergy.

It is important that the ingredient name accurately reflects the true nature of the ingredient. AFGC considers that the existing provisions of Standard 1.2.4 - *Information requirements – statement of ingredients* (specifically clause 1.2.4-4) already provide a suitable framework for this purpose. Ingredient names can appropriately identify both the allergen identity and the fermentation-derived or non-animal origin of the protein, while continuing to support mandatory declaration of "milk" as required under the allergen labelling provisions. Accordingly, the AFGC does not consider that additional ingredient-naming requirements are necessary, as the current provisions of the Code already enable accurate and meaningful description of the ingredient to consumers.

Recommendation

4. AFGC supports mandatory declaration of “milk” when BCPP1 is present in food for sale or supplied to caterers or manufacturers.
5. AFGC supports maintaining the existing Plain English Allergen Labelling framework, including the summary statement “Contains: milk”.
6. AFGC supports maintaining the existing ingredient-naming requirements in the Code, which already provide a suitable framework for describing the true nature of BCPP1, including its fermentation-derived or non-animal provenance.

Front-of-pack advisory statement

AFGC notes FSANZ’s assessment that certain front-of-pack representations, including dairy analogue food names and claims such as “animal-free”, may result in some consumers interpreting a product containing BCPP1 as being suitable for consumers with milk allergy. FSANZ considers that this could reduce the likelihood that consumers consult the ingredient list and allergen declaration and therefore warrants additional regulatory measures.

AFGC also notes FSANZ’s proposal to introduce a mandatory front-of-pack advisory statement for foods containing BCPP1. FSANZ considers that a statement indicating the product is “not suitable for persons with milk allergy”, in addition to the mandatory declaration of “milk”, would assist consumers with milk allergy by drawing attention to the allergen information and encouraging them to check the ingredient list and allergen declaration.

AFGC does not support in principle any proposed mandatory front-of-pack advisory statement. While we recognise FSANZ’s concern that some consumers may misinterpret terms such as “animal-free”, “vegan”, “plant-based” or “dairy-free”, we do not consider that an allergen-specific front-of-pack statement is the most appropriate or effective way to address this risk.

Codex¹ explicitly advises against “not suitable for people with X allergy” statements because they can cause consumers to miss information about other allergens present in the food. The *Food Industry Guide to Allergen Management and Labelling* (FIGAML)² reinforces this approach. The guide makes it clear that claims such as “vegan” should not be interpreted as meaning a product is free from allergens.

Instead, consumers with food allergies are advised to rely on the ingredient list, allergen summary statement and precautionary allergen labelling when assessing whether a food is suitable for them. This supports the AFGC’s view that allergen-specific front-of-pack statements are neither necessary nor the most effective way to communicate allergen risk.

¹ FAO/WHO, 47th Session of the Codex Committee on Food Labelling, 15–19 May 2023, para 68

² *Food Industry Guide to Allergen Management and Labelling (FIGAML)*, joint industry guide developed by the Australian Food & Grocery Council (AFGC) and the Allergen Bureau, p.45

Consumers with food allergies are consistently advised by Australian patient advocacy organisations³ to check the full ingredient list, summary allergen statement and any precautionary allergen labelling every time they purchase or consume a food. A front-of-pack statement that highlights milk only may unintentionally signal that milk is the primary or only allergen concern, even where other allergens are present as ingredients or through cross-contact.

This concern is particularly important where a product contains BCPP1 and also contains, or may contain, other allergens such as soy, egg, tree nuts, peanut or gluten-containing cereals. A milk-specific front-of-pack warning could draw attention away from the full allergen declaration and precautionary allergen labelling, potentially increasing risk for consumers with other food allergies.

AFGC is also concerned that this approach may set a broader precedent for future applications involving fermentation-derived allergenic proteins, such as egg, soy, fish or other prescribed allergens. If each allergenic protein generated through fermentation were to trigger a front-of-pack allergen-specific advisory statement, labels could become increasingly cluttered and inconsistent, while consumers may be trained to look for front-of-pack allergen warnings instead of the established mandatory allergen information.

Recommendation

7. AFGC does not support any proposed allergen-specific front-of-pack advisory statement.

Vegan, animal-free and other voluntary representations

The AFGC agrees with FSANZ that voluntary representations such as “vegan”, “animal-free”, “plant-based” and “dairy-free” may be misunderstood by some consumers when used on foods containing milk-identical proteins produced through fermentation. However, these terms are not defined in the Food Standards Code and are generally regulated through consumer law and fair-trading frameworks, rather than through food safety standards.

Manufacturers that choose to make voluntary claims are responsible for ensuring those claims are accurate, not misleading and appropriately qualified. Compliance and enforcement of misleading or deceptive claims are matters for food enforcement agencies, the Australian Competition and Consumer Commission (ACCC), and the New Zealand Commerce Commission (NZCC) under existing food and consumer protection laws⁴.

³ National Allergy Council; Allergy & Anaphylaxis Australia

⁴ Australian Consumer Law and the Fair Trading Act 1986 (NZ) by the Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC)

The AFGC considers that FSANZ should avoid addressing marketing and consumer law issues through an allergen-specific front-of-pack advisory statement where the same objective can be achieved through clear ingredient naming and mandatory allergen declaration.

Recommendation

8. AFGC recommends that FSANZ rely on existing food and consumer protection laws to address potentially misleading voluntary representations, rather than introducing additional allergen-specific labelling requirements.

CONCLUSION

The AFGC supports proportionate, science-based regulation that enables innovation while protecting consumers, particularly consumers with food allergy.

We support the proposed mandatory declaration of milk for foods containing BCPP1, as this aligns with established allergen labelling practice and consumer education.

However, we urge FSANZ to reconsider the proposed front-of-pack allergen-specific advisory statement, as it may create unintended risks for consumers with other allergies and set an inconsistent precedent for future fermentation-derived allergenic proteins.

The AFGC would welcome the opportunity to discuss these comments further with FSANZ and to support development of a clear, consistent and future-focused regulatory approach for fermentation-derived allergenic proteins.

State of the Industry

2024-25



The figures on this page exclude the fresh food sector and are based on 2024-25 ABS data.

1: This is total number of employees, head count basis and does not include seasonal employees.

2: Gross fixed capital formation for food, beverage and tobacco manufacturing subsector is taken as indicator of capital investment.