Submission

# A1342 - Beta-casein protein preparation from GM Komagataella phaffii

FSANZ Call for Submissions - Eden Brew Pty Ltd | August 2026

Cellular Agriculture Australia

**Cosignatory:** This submission has been formally endorsed and cosigned by

Good Food Institute APAC

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# 1. Introduction

Cellular Agriculture Australia and The Good Food Institute APAC welcome the opportunity to provide this submission to Food Standards Australia New Zealand (FSANZ) Call for Submissions (CFS) on the assessment of **A1342 - Beta-casein protein preparation from GM *Komagataella phaffii*** submitted by Eden Brew Pty Ltd.

Cellular Agriculture Australia led the preparation of this submission with input from members of its Industry Working Group (Regulation), gathering feedback from Australian and international precision fermentation companies.

Cellular Agriculture Australia (CAA) is Australia's leading non-profit charity advocating for emerging food production technologies and ingredient innovation – including cultivated, fermented and plant protein applications - and their integration across the food system. It is building the policy, regulatory, and investment settings required to unlock a new generation of food and ingredient production in Australia.

This submission has been formally endorsed and co-signed by The Good Food Institute APAC (GFI-APAC), Asia's leading alternative protein think tank, accelerating a shift towards a more secure, sustainable, and just food system.

## 2. Response to the consultation questions

**Consultation Question 1: Please provide your overall view on FSANZ's assessment for application A1342 and the draft regulatory measure. Please explain your response.**

CAA welcomes FSANZ's assessment of BCPP1, which found that neither the production strain nor the resulting fermented proteins, when used as intended, raise any public health or safety concerns.

CAA **largely supports** the amendments to the Food Standards Code (the Code) to permit the use of BCPP1 as a wholesale food and as an ingredient in retail & foodservice (consumer) food preparations.

CAA is especially appreciative of the flexibility that the FSANZ assessment provides for future strain improvement (of the genetically modified organism (GMO)). Avoiding unnecessary new applications associated with new strains of *K. phaffii* is in the interest of consumers, regulators and industry and represents best practice.

However, CAA has significant concerns regarding three elements of FSANZ's proposed approach, as outlined in 2.1, 2.2 and 2.3 below.

### 2.1 Variation from the Applicant's proposed ingredient specification

CAA notes that FSANZ has proposed a variation from the ingredient specification that the Applicant originally applied for:

> *(b) Composition: (i) Total Protein (%)– no less than 20; and*
> *(c) Purity: (i) Beta-casein protein (%)–more than 20 (of total protein)*

Whereas, FSANZ has proposed:

> *(b) Composition: (i) Total Protein (%) 20-**24***
> *(c) Purity: (i) Beta-casein protein (%) more than **4***

In the absence of a rationale for this variation being provided by FSANZ, CAA asks FSANZ to share its reasoning for the variation and, subject to CAA's review of supportive evidence, it advocates that the Applicant's original proposal to the *specification* in subsection S26–4(6), namely:

- **Remove the upper limit on total protein in the BCCP1** (currently set at 24%);

instead set a minimum of 20%; and

- **Express the beta-casein specification as "> 20% of total protein"** rather than as an absolute minimum ("more than 4% of the preparation").

be written into the Code (S26-4(6)).

CAA's rationale for its requested changes to FSANZ's proposed approach is:

- **No identified safety rationale:** Setting an upper limit on total protein is unnecessary because FSANZ's risk assessment found no safety concerns related to a higher protein content. Specifically, FSANZ did not set a maximum use level for the BCCP1 preparation, having identified "no risk-based reasons from a health or safety perspective to support such limits." This same logic should be applied to the protein maximum. Further, other compositional limits control the preparation's variability; therefore, an upper protein limit is superfluous.

- **More representative beta-casein specification:** A beta-casein specification of more than 20% would also more closely reflect the composition of bovine milk proteins, as beta-casein typically represents approximately 28–30% of total milk protein.

- **Inconsistent with broader Code practice:** CAA notes that an upper limit on protein also appears inconsistent with the general treatment of other food specifications elsewhere in the Code. To CAA's knowledge, the only foods that have *upper* limits for protein set by the Code are those regulated by Standard 2.9.1 Infant formula products. Since BCPP1 is not permitted for use in most Special Purpose Foods (including Infant nutrition), CAA believes a minimum protein specification of 20% is sufficient.

- **Unnecessary manufacturing constraint:** The Applicant's original proposed specification allows necessary manufacturing flexibility, leading to greater efficiencies and more refined products (without additional risks). FSANZ's proposed 24% upper limit may lead to unnecessary batch rejections and arguably represents an unsustainable regulatory burden.

## 2.2 Front-of-Pack advisory statement

Further, CAA notes FSANZ's intention to require a Front-of-Pack (FOP) advisory statement indicating the product is not suitable for consumption by consumers with (bovine) milk allergy. CAA fully supports milk-allergic consumers being informed of the presence of milk protein in foods formulated with BCPP1. However, it does not support this mandatory FOP allergen labelling and respectfully requests that FSANZ reconsider its approach.

CAA is concerned that the proposed mandatory FOP allergen labelling diverges from the principles of Proposal 1044 Plain English Allergen Labelling (PEAL), which established "one source" of allergen information for allergic consumers, being the ingredients list and summary statement. The Codex Committee for Food Labelling has advised against statements such as "not suitable for people with X allergy" (p 12) because they may cause consumers to miss information about other allergens present in the food. FSANZ's proposed wording is the exact phrasing that Codex rejected.

For example, if BCPP1 is used in a plant-based milk analogue, consumers may focus on the FOP milk-allergy statement and overlook BOP information identifying other relevant allergens, such as soy or oats (gluten).

Additionally, CAA notes that FSANZ's proposed FOP advisory statement for PF proteins does not appear to have a direct international regulatory precedent. Most comparable jurisdictions rely on existing allergen declarations, with additional qualification targeted to potentially misleading claims rather than imposed as a blanket FOP requirement.

CAA suggests that an additional allergen communication device (over and above the current, mandated requirements introduced under PEAL) should not be introduced via an Application, but rather justified by evidence and considered for its cost and benefit under a dedicated FSANZ proposal. Imposing such requirements in the manner suggested appears to also unjustifiably increase regulatory burden. Until such an assessment is made, CAA advocates that the existing allergen labelling arrangements applicable to all food and beverages are a risk-appropriate approach.

### 2.3 GM Food Labelling of BCPP1

CAA notes the following commentary in Supporting Document 2 (SD2) - Labelling:

> *"7.2 Discussion: FSANZ's risk and technical assessment noted that batch analyses of BCPP1 contained low concentrations of residual host DNA from the GM production strain K. phaffii strain EB-ST-537 (see sections 4.2.5 and 4.3 of SD1). If novel DNA or novel protein from the GM production strain is present in food for sale containing BCPP1 as an ingredient, the requirement to label BCPP1 as "genetically modified" would apply."*

CAA understands that the discussion refers *only* to the unintended residual novel DNA and protein arising from any retained GM production strain. Section 7.2 of SD2 does not refer to the fermentation's target protein (i.e. recombinant bovine A2 beta-casein) and secondary yeast proteins, which CAA understands are defined as "novel protein" — defined as protein encoded by novel DNA under the Standard 1.5.2 — and that are intentionally present. CAA therefore understands that the recombinant beta-casein itself would trigger the

requirement to label BCPP1 as "genetically modified" (GM), irrespective of whether residual novel DNA or protein from the production strain remains in the final preparation.

If this interpretation is correct, CAA considers that section 7.2 of SD2 should more clearly explain the basis on which the GM labelling requirement applies. As currently written, its focus on residual material from the production strain may create the impression that GM labelling would apply **only** where such residual material is present. CAA requests that FSANZ clarify this point for other stakeholders and include the resulting labelling obligations for foods formulated with BCPP1.

CAA recognises the importance of compliant and suitable terminology for consumer labelling of the "BCPP1" ingredient. It supports FSANZ's conclusion that no additional measures to Standard 1.2.4 for the labelling of the ingredient are required. Specifically, CAA will seek to collaborate with the Applicant and wider stakeholders to meet this requirement (detailed in SD2):

> *'Ingredients must be listed using either a name by which the ingredient is commonly known, a name or description sufficient to indicate the true nature of the ingredient'*

and promote consistent, future-proof labelling approaches. CAA appreciates that FSANZ has considered (as part of its assessment) its Precision Fermentation Communication Guide, which identifies industry-informed, regionally aligned nomenclature designed to support accurate, clear, and consistent terminology for PF ingredients.

CAA has also identified broader issues regarding the inequitable treatment of PF ingredients in GM labelling requirements. These concerns are not specific to BCCP1, and are therefore detailed in section 2.5 below.

**Consultation Question 2: If there is any other information you would like to provide for the application A1362 consultation, please include this below.**

Beyond the specific concerns raised above, CAA considers that A1342 raises several broader issues relevant to the future regulation of precision-fermented (PF) food ingredients in ANZ, detailed in 2.4-2.8 below.

CAA recognises that some of the broader issues raised below extend beyond the scope of A1342 and does not seek to unnecessarily delay progression of the application while they are considered. As such, CAA would welcome the opportunity to engage directly with FSANZ on these matters at a later date.

## 2.4 Precedent and consequences

Although FSANZ has previously evaluated numerous food processing aids, several human milk oligosaccharides (HMOs), a steviol glycoside and soy leghemoglobin produced via gene technology, BCPP1 represents the first PF bovine milk protein to undergo assessment. It is anticipated that the regulatory approach adopted for this application will have implications for future ingredients produced using precision fermentation and therefore, should be carefully considered for potential precedent and (unintended) consequences.

Accordingly, CAA accepts FSANZ's inclusion of the specification of BCPP1 in Schedule 24 but queries that it is not to be added into Schedule 3, when other specifications for PF ingredients such as HMOs, soy leghemoglobin, and steviol glycosides appear in Schedule 3. It is conceivable that future PF ingredients might also be novel rather than *substantially equivalent* to traditional ingredients; therefore, inclusion in Schedule 3 would seem appropriate.

Further, the Food Regulation Policy guideline on novel foods, which seeks to "protect commercially sensitive information and recognise industry's intellectual property to the maximum extent possible", includes an exclusive-use mechanism that can give applicants a limited first-mover period. However, FSANZ's current approach limits this exclusivity to novel foods and nutritive substances only. As a result, PF nutritive substances such as HMOs and soy leghemoglobin may benefit from exclusivity protections, while BCPP1, despite being produced using the same underlying gene technology, does not. This inconsistent treatment appears inequitable and creates a potential barrier to innovation, risking ANZ becoming a less attractive market for future applications which ultimately denies local consumers access to innovative products.

## 2.5 Inequity in current GM food labelling requirements

CAA accepts that BCPP1 must comply with the GM labelling requirements currently prescribed by the Code. However, A1342 also highlights a broader question about whether the existing GM labelling requirements remain appropriate for the growing range of foods produced through precision fermentation.

The current requirements can result in materially different labelling outcomes for PF ingredients depending on their composition and function in the final food. For example, PF-derived HMOs (being carbohydrates) do not require "genetically modified" labelling where no novel DNA or novel protein remains in the final ingredient, while PF-derived processing aids (e.g. chymosin) are similarly exempted on the basis that they have no technological purpose in the final product. Products containing chymosin (in cheese) have been commercially available for many years and have benefited from widespread consumer acceptance because they do not have to bear a GM label.

By contrast, **novel protein itself triggers the GM labelling requirement for all PF proteins, with no equivalent exemption currently available. CAA considers this differential treatment inequitable.**

CAA is concerned that applying the same "genetically modified" descriptor to a purified recombinant protein *produced by a* gene technology as applied to a food *which is a GMO* may not provide consumers with sufficiently meaningful information about the nature of the food or, how it was produced, to enable informed consumer choice. For example, PF-derived proteins are materially different from foods such as a whole GM fruit, where the GMO itself, including its novel DNA and protein, is consumed. Given that PF technology and the ingredients it can produce are generally unfamiliar and poorly understood within the ANZ consumer population (FSANZ 2025 Consumer Insights Tracker found 50.1% of consumers had never heard of PF), a mandatory GM label risks leading consumers to extrapolate existing perceptions of GM foods to PF ingredients without understanding the material differences between them.

CAA is concerned that applying a GM label to PF proteins could also negatively shape consumer perceptions, particularly given existing hesitancy towards foods labelled as "genetically modified." FSANZ's 2022 nationally representative survey found that 40% of ANZ consumers oppose GM foods entirely, and nearly half expressed some degree of concern. Similarly, nationally representative research by the OGTR in 2024 found that only one-third of Australian consumers were willing to consume GM foods. Acknowledging that consumer acceptance is not itself a primary statutory objective of FSANZ, CAA is concerned that unnecessarily negative impacts on consumer acceptance could have broader consequences for the ANZ market, in particular:

- Lower anticipated demand may make ANZ a less attractive market for product entry, leading companies to deprioritise ANZ launches and limiting local consumer access to innovative and sustainable food products.
- It may also constrain investment and domestic industry growth, creating an additional barrier to commercialisation and increasing the risk that food biomanufacturing companies either fail to scale or move production offshore—with the associated loss of Australian IP, economic value and sovereign capability.

In contrast, selected international jurisdictions provide evidence of alternative, more equitable approaches to GM labelling:

- **European Union:** major PF proteins (such as beta-lactoglobulin) are yet to be approved by the European Food Safety Authority (EFSA). If the current Dec 2025 European Commission Proposal is adopted, CAA understands that they will not be required to be labelled as GM, subject to conditions (e.g. the GMO is removed, there are no viable cells present and host strain DNA is below 10 ng/g). It is expected that a qualifying term (e.g. "microbially derived," "by fermentation," or similar) will be required.
- **Switzerland**: Switzerland retains mandatory GM labelling generally, but expressly exempts qualifying products of fermentation produced using GMOs where the product is isolated from the organism, chemically defined and purified so that neither the GMO nor its DNA is detectable in the final product. While the framework has so far only assessed and exempted PF-derived HMOs, CAA understands the exemption would likely also apply to purified PF proteins meeting these conditions.
- **United States:** The US maintains a mandatory federal "bioengineered" food disclosure standard, but disclosure is triggered by the presence of detectable modified genetic material in the final food. Accordingly, PF ingredients produced using GMOs can fall outside the mandatory bioengineered labelling regime where no modified genetic material is detected in the final product. In-market, PF products also demonstrate a range of voluntary descriptive approaches, including descriptive qualifiers, e.g. Bored Cow (Perfect Day) - *Animal-free whey protein (from fermentation)*; Orgain Better Whey - *Whey protein isolation from fermentation*; Healthier Comfort (EVERY OvoPro) - *Animal-free egg white protein*; Vivitein™ BLG (Vivici) bovine beta-lactoglobulin - *made by precision fermentation;* LF+ (Turtle Tree bovine lactoferrin) - *made using precision fermentation technology*.

Together, these international examples provide relevant precedents for a more nuanced and outcome-based approach to mandatory labelling, focused on the material characteristics of the final food rather than applying a uniform descriptor based on

production method alone. CAA therefore asks that FSANZ consider, through an appropriate future assessment:

- An exemption to the GM labelling requirement for PF proteins that can demonstrate "substantial equivalence" to a conventional counterpart with an established history of consumption
- Whether the use of a qualifying term such as "fermented" protein would be more appropriate.

## 2.6 Further progression of the regulation of novel and gene-technology derived foods

CAA calls upon FSANZ to continue its progression towards best-practice regulation for PF ingredients. Proposal P1055 identified outstanding issues, particularly regarding nutritive substances, that are also relevant to other PF food ingredients that may be used at higher inclusion rates in formulated foods. Proposal P1024, Revision of the Regulation of Nutritive Substances and Novel Foods, provides an appropriate existing mechanism to progress this work, as it was established specifically to improve and clarify the regulatory framework and pre-market pathways for these categories of food. CAA therefore respectfully asks that P1024 be reactivated to include outstanding issues for PF ingredients within its scope and be progressed as a priority.

## 2.7 Use in Special Purpose Foods

CAA notes that FSANZ has determined that BCPP1 cannot be used in selected Special Purpose Foods. It is understood that the Applicant did not apply for permission to use BCPP1 in Special Purpose Foods beyond formulated supplementary food and formulated meal replacements (Standard 2.9.3). However, CAA estimates specialised PF ingredients are highly relevant to and beneficial in other Special Purpose Foods. In the interests of future applications, CAA requests that FSANZ make any incremental data requirements associated with the use of recombinant proteins in Special Purpose Foods clear, proportionate to identified risks, and supported by scientific rationale.

## 2.8 Updated Application Guidance

CAA welcomes the recent publication of A guide to definitions for genetically modified food and novel DNA in the Australia New Zealand Food Standards Code by the ANZ Food Regulation System. More immediately, CAA requests that FSANZ provide detailed guidance to future Applicants on how best to:

- Characterise PF-ingredients and;
- Demonstrate "substantial equivalence" of PF ingredients with their conventionally-produced counterparts.

CAA also notes that the current Application Handbook (October 2025) relating to foods derived from gene technology is largely focused on GM crops and needs urgent updating to provide clearer, more relevant guidance for PF foods. We understand this update is in progress but reiterate our request that the next edition of the Handbook be provided in a timely manner.

## 3. Contact

CAA warmly welcomes the opportunity to engage further on any of the comments made within this submission; please contact:

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