9 July 2026
402-26

Call for submissions – Application A1342

Beta-casein protein preparation from GM *Komagataella phaffii*

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Eden Brew Pty Ltd to amend the Australia New Zealand Food Standards Code to permit the use of a beta-casein protein preparation (BCPP1) from a genetically modified strain of *Komagataella phaffii* as an ingredient in a wide range of foods 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 Making 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) 20 August 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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Supporting documents

The following documents, which informed the assessment of this application, are available on the A1342 page on the FSANZ website:

SD1 Risk and technical assessment
SD2 Labelling

Executive summary

Eden Brew Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit a preparation (referred to as BCPP1) to be sold as a food and to be present in a food for sale.

BCCP1 contains beta-casein and is intended to provide a source of protein in food. It is produced by fermentation from a genetically modified strain of a yeast, *Komagataella phaffii,* containing the bovine (*Bos taurus*) *CNS2* gene encoding the beta-casein A2 protein.

FSANZ's safety assessment concluded there are no public health and safety concerns associated with the addition of BCPP1 to food. However, as beta-casein is a known milk allergen, foods containing BCPP1 would present an allergenicity risk for individuals allergic to milk proteins.

Following assessment, FSANZ has prepared a draft variation to the Code to permit the use of BCPP1 as a genetically modified food.

If approved, the draft variation would:

- define BCPP1 as a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant
- list the preparation in Schedule 26 as a permitted GM food
- prohibit the sale of the preparation itself as a food for retail sale
- permit its presence in food, excluding infant formula products, food for infants, food for special medical purposes, formulated supplementary sports foods and formulated supplementary foods for young children
- set specifications in proposed subsection S26—4(6) with which BCPP1 would have to comply with when sold for use in food or when added to food
- require 'milk' to be declared when BCPP1 is present in a food for sale or is sold to a caterer or manufacturer (a wholesale food)
- require an advisory statement indicating the product is not suitable for people with milk allergy where the preparation is used in dairy analogue products or in products represented as not containing milk.

FSANZ seeks submissions on the draft variation to the Code.

1 Introduction

1.1 The applicant

The applicant, Eden Brew Pty Ltd, is an Australian-based company specialising in the development of precision-fermented proteins.

1.2 The application

Eden Brew Pty Ltd submitted an application to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the sale and use of a preparation referred to as BCPP1 - as a novel food produced using gene technology. The applicant stated the preparation provides an animal-free, lactose-free alternative to bovine beta-casein. The intended use of the preparation is a functional and nutritional ingredient in a wide range of foods. During assessment of the application, the applicant clarified that their request did not include permission to add BCPP1 to infant formula products, food for infants, food for special medical purposes, formulated supplementary sports foods and formulated supplementary foods for young children.

BCPP1 is produced by microbial fermentation using a genetically modified (GM) strain of the yeast *Komagataella phaffii* (EB-ST-537) containing the bovine (*Bos taurus*) *CNS2* gene encoding the beta-casein A2 protein.

Approval for BCPP1 as an ingredient in food was sought under Standard 1.5.2 – Genetically modified food and Standard 1.5.1 – Novel foods. The applicant also sought exclusive permission for the sale of BCPP1 as a novel food ingredient.

1.3 The current standard

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

1.3.1 Genetically modified food and novel food

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a genetically modified food[1]. Standard 1.1.2 defines what constitutes a 'genetically modified food' (referred to generally as a 'GM food" in this report)[2].

The above in effect requires pre-market approval of a GM food before it can enter the Australian and New Zealand food supply. GM foods are only approved after a comprehensive pre-market safety assessment by FSANZ.

Standard 1.5.2 sets out the permissions and conditions for foods for sale that are or contain GM foods. Section 1.5.2—3 provides a food for sale may contain, or consist of, a GM food if that GM food is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule.

Standard 1.1.1 of the Code provides that, unless expressly permitted by the Code, a food for sale cannot be, or have as an ingredient or component, a novel food. Standard 1.1.2 defines a novel food to mean, among other things, a non-traditional food that requires an assessment of the public health and safety considerations.

[1] See paragraphs 1.1.1—10(5)(c) and 1.1.1—10(6)(g)
[2] See definition in section 1.1.2—16

1.3.2 Formulated supplementary foods and formulated meal replacements

Standard 2.9.3 includes compositional and labelling requirements for formulated supplementary foods and formulated meal replacements and includes minimum protein requirements.

Paragraph 2.9.3—3(1)(b) requires that a *formulated meal replacement* must contain no less than 12 g of protein in a serving. Paragraph 2.9.3—5(1)(b) requires that a *formulated supplementary food* must contain no less than 8 g of protein in a serving.

1.3.3 Labelling

Subsection 1.1.1—10(8) requires that food for sale must comply with all relevant labelling requirements in the Code for that food.

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

Division 2 of Standard 1.2.3 requires that food for sale is subject to a mandatory advisory statement if it contains a food listed in the table to Column 1 in the table to section S9—2.

Division 3 of Standard 1.2.3 sets out the requirements for mandatory declarations about certain foods listed in Column 1 of the table to section S9—3 and their derivatives when they are present in a food for sale.

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.

Standard 1.2.7 sets out the restrictions, requirements and conditions for making voluntary nutrition, health and related claims about food.

Standard 1.2.8 generally requires food products to be labelled with nutrition information.

Section 1.5.2—4 sets out the labelling requirements for GM food. Section 1.5.2—4 requires a food for sale to be labelled ‘genetically modified’ in conjunction with the name of the GM food, where the food for sale:

- contains, or consists of, a GM food that is listed in Schedule 26, and
- the GM food:
  - contains novel DNA or novel protein, or
  - is listed in section S26—3 as being subject to a condition that its labelling must comply with section 1.5.2—4 (these foods are considered to have an altered characteristic, such as an altered composition or nutritional profile, when compared to the existing counterpart food that is not a GM food), and
- is not a food for sale that contains a GM food that is:
  - unintentionally present in the food for sale, and
  - present in the food for sale in an amount of no more than 10 g in a kilogram of each ingredient, and
- is not a food for sale that is:
  - intended for immediate consumption, and
  - prepared and sold from food premises (including restaurants, take away outlets, caterers, self-catering institutions and vending vehicles).

1.4 International standards

There are no relevant international standards.

1.5 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act)
- 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 Technical assessment

BCPP1 is a preparation produced via fermentation using a genetically modified strain of the yeast *Komagataella phaffii* (EB-ST-537). It is a white to off-white powder consisting of approximately 22% protein, about 25% of which is beta-casein (i.e., 5.5% of BCPP1). The remaining protein fraction comprises host cell proteins. Carbohydrate, consisting primarily of common dietary polysaccharides, makes up approximately 68%. During its production, the product is subject to heat treatment prior to ultrafiltration, diafiltration and spray drying. Stability studies confirm that BCPP1 can be added to a range of food matrices and remain stable under the relevant storage conditions for those foods.

Although the preparation exhibits functions such as emulsification, foaming, gelation and water-binding, FSANZ considers these functions are secondary to the primary purpose of its addition to food as a protein source. The intended use of BCPP1 is therefore not as a food additive as defined in the Code.

There is no single method of detection for the preparation itself, due to its mixed composition. The identity and concentration of beta-casein in BCPP1 can be confirmed using standard analytical methods for beta-casein.

2.2 Risk assessment

The production organism *K. phaffii* is a well characterised, non-pathogenic and non-toxigenic yeast with a long history of safe use. No public health or safety concerns were identified with its use as the production organism. Molecular analyses confirmed the introduced genetic elements are present as intended, do not include antibiotic resistance marker genes and are stably maintained.

The beta-casein A2 protein in BCPP1 was shown to be equivalent to that naturally present in bovine milk and is therefore expected to have the same allergenic potential as beta-casein present in conventional milk. Bioinformatic analyses of the host cell proteins in BCPP1 did not identify any proteins with homology to known toxins or allergens.

Except for the allergenicity risk for individuals with milk allergy, BCPP1 does not raise safety concerns under its intended condition of use. The preparation is susceptible to pepsin

digestion. The carbohydrate fraction in BCPP1 is expected to consist predominantly of common dietary polysaccharides, which are not of toxicological concern. Supporting studies on related *K. phaffii* protein preparations showed no genotoxicity and no adverse effects in 28-day and 90-day oral toxicity studies in rats.

The nutrition assessment found that using BCPP1 as a substitutional protein ingredient does not raise nutritional concerns for Australian or New Zealand consumers. Mean and high-percentile intakes were estimated to contribute only small amounts of additional protein (approximately 2.9–3.9 g/day), mainly from bakery products and soy beverages, and are unlikely to pose a risk.

FSANZ concludes there are no public health and safety concerns for the general population associated with the addition of BCPP1 to food. However, as beta-casein is a known milk allergen, foods containing BCPP1 would present an allergenicity risk for individuals allergic to milk proteins.

2.2.1 Consumer evidence on allergen labelling

Given the allergenicity risk of BCPP1 to individuals with milk protein allergies, FSANZ conducted a social science risk assessment (see Appendix 1 of SD2) which examined whether consumers would be confused by voluntary front-of-pack representations (e.g. 'animal-free' or 'vegan', terms that may be used to describe products containing BCPP1) and mandatory milk allergen declarations. It also assessed whether consumers could identify beta-casein as a milk allergen when these representations and declarations were used together.

The available evidence indicated some consumers associated 'animal-free' representations with plant-based products when they did not understand the production process of the food ingredients. However, there was no evidence available on how animal-free terminology affected milk-allergic consumers' understanding of allergen risks.

A UK survey of consumers with hypersensitivities to animal-derived allergens found that only half were aware products labelled as 'vegan' may be unsuitable for them (due to cross-contamination risks). More than half of consumers reported relying on front-of-pack 'vegan' claims as a proxy for allergen information, and only approximately half went on to check the back-of-pack ingredients list.

Although consumers in a multi-country study generally preferred shorter ingredient terms such as 'animal-free whey protein', there was no available evidence on whether this terminology adequately identified milk allergens.

No studies were conducted in Australia or New Zealand.

Overall, the findings indicated a potential risk of misinterpretation associated with 'animal-free' or 'vegan' representations for products containing a milk allergen.

2.3 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 outlined in this report, FSANZ has prepared a draft variation to the Code to permit BCPP1 - as a GM food – to be sold as a food (other than by retail sale) and to be present in certain types of food for sale, subject to specific conditions.

Further details on the proposed permission and associated conditions are provided below.

2.3.1 Regulatory approval

BCPP1 is a GM food for the purposes of the Code as it is derived from 'an organism that contains novel DNA'.

FSANZ is proposing to add a new section to Schedule 26 – Genetically modified food, setting out the permissions and associated conditions for BCPP1.

For this purpose, the proposed new section would define and refer to the BCPP1 preparation as 'a preparation containing beta casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant'.

The subject of the application was BCPP1 produced from a GM strain of *K. phaffii.* The draft variation proposed by FSANZ would instead provide a permission for BCPP1 produced from GM *K. phaffii* without specifying the strain of *K. phaffii*. FSANZ has not identified any safety concerns that would justify limiting the approval to the strain level. This approach would provide greater flexibility in terms of strain improvement and avoid the need for new applications to be lodged for permissions for new strains of GM *K. phaffii* to produce the preparation containing beta-casein.

The new section would list BCPP1 as 'a permitted genetically modified food' (see item 3 of the draft variation at Attachment A). This reflects the approach and text of subsection S26—3(1). That subsection states for the purposes of Standard 1.5.2 that the tables to subsection S26—3(4) and (7) list 'permitted genetically modified food'.

The effect of the above is to permit BCPP1 to be a food for sale and for a food for sale to contain BCPP1 in accordance with the Code.

The new section would state BCPP1 must not be a food for retail sale i.e. the preparation itself must not be sold to consumers. This aligns with the request from the applicant which was not seeking to permit the sale of BCCP as a food for retail sale.

The new section would also provide that BCPP1 must not be added to any of the following foods:

(a) infant formula products
(b) food for infants
(c) food for special medical purposes
(d) formulated supplementary sports foods
(e) formulated supplementary foods for young children.

This is consistent with the scope of the application, as the applicant did not seek permission for the use of BCPP1 in these special purpose foods. Accordingly, the use of BCPP1 in these food categories was not assessed.

FSANZ is not proposing to prohibit use of BCPP1 in foods other than those listed above, as it would be unlikely to be used if it was found to be not technologically feasible or was not appropriate for use in a certain food. This additional regulation is therefore not justified.

The applicant also requested approval of BCPP1 as a novel food. This is not an option given

BCPP1's status as GM food. The Code does not require GM foods to also be assessed and permitted as novel foods. A food that is assessed and approved as a GM food would not meet the definition of a novel food. That is, it would not be a food 'that requires an assessment of the public health and safety considerations …'.

Businesses manufacturing products like BCPP1 need to comply with good manufacturing practices, good hygienic practices and apply a HACCP based approach to the manufacturing (such as those requirements in Chapter 3 of the Code). This aims to ensure that only safe and suitable food is sold in Australia and New Zealand.

2.3.2 Conditions of use

FSANZ is not proposing to set limits on the amount of BCPP1 that can be added to foods. No risk-based reasons from a health or safety perspective have been identified to support such limits. FSANZ considers its use in food would be limited by its technological function in the food and impact on the organoleptic properties of the food.

The applicant proposed a specification with which BCPP1 must comply for inclusion in Schedule 3. FSANZ is proposing BCPP1 must comply with a set of conditions or 'specifications' when added to food or sold for use in food (see Table 1 below). These would be set out in proposed new section S26—4 rather than in Schedule 3. This reflects the fact that Schedule 3 does not apply to foods approved only as GM foods (see section 1.1.1—15 of the Code).

The proposed specifications reflect the request by the applicant, with the exceptions described below. Additional information is provided in SD1.

FSANZ has proposed a narrower range for total protein than that requested by the applicant (20-24% rather than no less than 20%), to more accurately reflect the composition of the product assessed. Specifying both minimum and maximum values limits variability in the composition of the preparation, noting other compositional parameters are expressed as maximum limits.

FSANZ has proposed modified and additional microbiological specifications for BCPP1 as indicators that process-related microbiological safety of BCPP1 has been maintained (aerobic mesophilic bacteria total count, *Enterobacteriaceae*, yeasts and moulds). These proposed limits are broadly consistent with existing microbiological criteria for low moisture, powdered ingredients and with specifications in Schedule 3.

FSANZ proposes including the limits requested by the applicant in the proposed specification for lead, arsenic, mercury and cadmium. It is noted the maximum permissible levels (MPLs) for these metals as listed in section S3—4 of the Code, which are higher than the levels proposed by the applicant, do not apply to foods approved only as GM foods.

Table 1: Proposed specifications for BCPP1

Parameter	Proposed specification
(a) Appearance	White to off-white powder
(b) Composition:	
(i) Total Protein (%)	20-24
(ii) Carbohydrates (%)	no more than 70
(iii) Fat (%)	no more than 3
(iv) Ash (%)	no more than 3
(v) Moisture (%)	no more than 6
(vi) Total Sugars (%)	no more than 1
(c) Purity:	

(i) Beta-casein protein (%)	more than 4
(d) Metals	
(i) Lead (mg/Kg)	no more than 0.05
(ii) Arsenic (mg/Kg)	no more than 0.05
(iii) Mercury (mg/Kg)	no more than 0.05
(iv) Cadmium (mg/Kg)	no more than 0.05
(e) Microbiological	
(i) *Escherichia coli*	absent in 10 g
(ii) *Salmonella* species.	absent in 25 g
(iii) *Listeria* species	absent in 25 g
(iv) Aerobic mesophilic bacteria total count	not more than 500 CFU/g
(v) *Enterobacteriaceae*	not more than 10 CFU/g
(vi) Yeasts and moulds	not more than 100 CFU/g

2.3.3 Exclusive use

An applicant may request exclusive permission to use and sell a food for a certain period of time to recognise the investment made in developing that food, and the need to achieve return on this investment, thereby supporting innovation[3].

The applicant requested an exclusive use permission for BCPP1 as a novel food. The applicant identified the significant research, development and investment undertaken to develop the proprietary *K. phaffii* strain (EB-ST-537) and the associated process used to produce BCPP1 as reasons for this request.

FSANZ is not proposing to grant exclusive use permission for BCPP1. Existing policy limits exclusive use permissions in the Code to novel foods and nutritive substances[3]. As outlined in Section 2.4.1 above, FSANZ is proposing to permit BCPP1 as a GM food, not a novel food.

2.3.4 Labelling requirements

FSANZ considered whether the existing labelling requirements in the Code remain appropriate for food containing BCPP1 or whether any additional measures are warranted (see SD2 Labelling). FSANZ has concluded current requirements for ingredient names, directions for use and storage, nutrition information, nutrition content and health claims, and the labelling of GM food remain fit for purpose. However, FSANZ has identified 2 specific allergen-related risks that warrant targeted amendments to the Code.

First, recognising the beta-casein component of BCPP1 would present an allergenicity risk for individuals allergic to milk proteins (see section 2.2 in this report), FSANZ is proposing to require declaration of 'milk' when BCPP1 is present in a food for sale or is sold to a caterer or manufacturer (a wholesale food). Further detail is provided in section 3.1 of SD2.

Second, FSANZ has identified a risk associated with dairy analogue food names (e.g. 'oat milk') and products using certain voluntary representations (e.g. 'animal-free') where they contain BCPP1 (see section 3.2 of SD2). These front-of-pack representations may lead consumers to assume the product is suitable for people with milk allergy, even when it contains BCPP1. This may reduce the likelihood that allergen declarations on the back of pack are checked and therefore poses a public health and safety risk.

To address this risk, FSANZ is proposing to introduce a mandatory advisory statement for foods containing BCPP1. This statement would be required on the front of the package of food for retail sale required to bear a label and would clearly indicate the product is not

[3] See Exclusivity of use for novel foods and nutritive substances | Food Standards Australia New Zealand

suitable for people with milk allergy. The advisory statement would be in addition to the mandatory declaration of 'milk' and would prompt consumers to check the statement of ingredients and allergen summary statement. Further detail is provided in section 3.2 of SD2.

2.3.5 Nutrition

The nutrition assessment (section 2.2) concluded there are no nutritional concerns associated with the use of BCPP1 as a protein source in general foods, formulated meal replacements or formulated supplementary foods. The applicant did not request permission for BCPP1 in any other special purpose food categories.

The assessment identified BCPP1 has a lower protein quality than high-quality reference proteins, with a protein quality comparable to purified bovine beta-casein, an isolated protein fraction. The requested food categories are intended to form part of a varied diet, rather than to serve as sole sources of nutrition. Population dietary data indicate protein intakes among Australian and New Zealand consumers are generally adequate.

The proposed use levels are not intended to position BCPP1 as the sole protein source. In addition, formulated meal replacements and formulated supplementary foods must comply with the compositional requirements in the Code, including minimum protein content (Section 1.3.3).

Based on this assessment, FSANZ considers that no specific nutrition-related risk management measures are required.

2.4 Risk communication

2.4.1 Consultation

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, digital channels and Food Standards News. Subscribers and interested parties are also notified about the availability of reports for public comment.

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 taking into account all public comments received through this call for submissions.

The applicant, individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

2.4.2 World Trade Organization (WTO)

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.

There are no relevant international standards. Amending the Code to permit the sale of BCPP1 as a GM food, subject to certain conditions, is unlikely to have a significant effect on international trade as its use would be voluntary. 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.

2.5 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:

2.5.1 Section 29

2.5.1.1 Consideration of costs and benefits

2.5.1.1.1 Costs and benefits of permitting the proposed use of BCPP1

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because applications relating to permitting GM 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 (as per 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 sale of BCPP1 as a GM food.

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.

Due to the voluntary nature of the permission, manufacturers would only use BCPP1 where they believe a net benefit exists for them either in terms of creating a product that is valued by consumers or to reduce their costs. If any cost savings are experienced by the food industry some of these might be passed onto consumers over time.

If the sale and use of foods containing BCPP1 is permitted under the Code, this may give consumers access to a wider range of food choices that they value. For those food products containing BCPP1, existing GM labelling requirements would apply to assist consumers to make informed choices to purchase.

If the draft variation is approved, there might be small and likely inconsequential costs of monitoring an additional GM food for regulators to ensure compliance with requirements.

2.5.1.1.2 Conclusion of costs and benefits

FSANZ's assessment is the direct and indirect benefits that would arise from permitting BCPP1 to be a food for sale other than retail and for certain foods for sale to contain BCCP1 as proposed are likely to outweigh the associated costs.

2.5.1.2 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.

2.5.1.3 Any relevant New Zealand standards

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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 the addition of BCPP1 to food, except that beta-casein in BCPP1 would present an allergenicity risk for individuals allergic to milk proteins. Labelling measures have been proposed to address this risk (see section 2.3.4).

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

Existing general labelling requirements described in section 1.3.3 would apply to BCPP1 as a food for sale or as an ingredient in a food for sale. Additional BCPP1-specific labelling requirements proposed in section 2.3.4 would apply where BCPP1 is present in a food for sale. Together, these requirements would provide adequate information to enable consumers to make informed choices.

2.5.2.3 The prevention of misleading or deceptive conduct

The proposed labelling requirements outlined in section 2.3.4 of this report would provide consumers with information relating to the presence of BCPP1 as a milk allergen to reduce the likelihood that consumers are misled by product names or voluntary representations.

2.5.3 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 used the best available scientific evidence to conduct the risk assessment (SD1 and SD2) which formed the basis of the risk analysis. The applicant provided a dossier containing information and scientific literature in support of their application. This dossier together with other relevant technical and scientific data was used in assessing the application.

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

As noted above, there are no international food standards directly relevant to this application.

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

Permission for BCPP1 as a food for sale would provide an alternative source to protein sourced from animals for manufacturers and allow for more innovation in the area of protein-enriched foods and increased market opportunities generally.

As outlined in section 2.3.1, approval of BCPP1 from GM *K. phaffii* without specifying a specific strain supports innovation and competitiveness by avoiding the need for a new application should the production organism undergo strain improvement

- **the promotion of fair trading in food**

No issues relevant to fair trading in food have been identified.

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

FSANZ must have regard to any written policy guidelines formulated by the Food Ministers' Meeting (formerly the Ministerial Forum on Food Regulation) when developing or reviewing food standards. There is one policy guideline relevant to FSANZ's consideration of this application – the Policy Guideline on the intent of Part 2.9 – Special Purpose Foods. Noting the safety, nutrition and labelling assessments detailed in this report, FSANZ considers this policy guideline has been met.

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.

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 A1342–Beta-casein protein preparation from GM *Komagataella phaffii*) Variation

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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 clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1342–Beta-casein protein preparation from GM* Komagataella phaffii*) 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 9—Mandatory advisory statements and declarations

[1] Section S9—2 (at the end of the table)

Add:

12	(a) A food that is an analogue of a dairy product and that contains a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant. (b) A food that contains a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant and that is represented in a form which expressly or by implication suggests that the food does not contain milk. **Example**: A food containing the preparation and represented as 'animal-free', 'dairy-free' or 'vegan'.	the product is not suitable for persons with milk allergy

[2] Section S9—3 (at the end of the table)

Add:

14	A preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant	milk	milk

Schedule 26—Genetically modified food

[3] After section S26—3

Add:

S26—4 Preparations containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant

(1) In this section:

the preparation means a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant.

(2) The preparation is a permitted genetically modified food.

(3) The preparation must not be a food for retail sale.

(4) The preparation must not be added to any of the following foods:

(a) infant formula products;
(b) food for infants;
(c) food for special medical purposes;
(d) formulated supplementary sports foods;
(e) formulated supplementary foods for young children.

(5) The preparation must comply with each specification set out in subsection (6) when

added to food in accordance with this Code or sold for use in food.

(6) The specifications for the preparation are the following:

(a) appearance—white to off-white powder;

(b) composition:

(i) total protein (%)—20 to 24;

(ii) carbohydrates (%)—no more than 70;

(iii) fat (%)—no more than 3;

(iv) ash (%)—no more than 3;

(v) moisture (%)—no more than 6;

(vi) total sugars (%)—no more than 1;

(c) purity:

(i) beta-casein protein (%)—more than 4;

(d) metals:

(i) lead (mg/kg)—no more than 0.05;

(ii) arsenic (mg/kg)—no more than 0.05;

(iii) mercury (mg/kg)—no more than 0.05;

(iv) cadmium (mg/kg)—no more than 0.05;

(e) microbial limits:

(i) *Escherichia coli*—absent in 10 g;

(ii) *Salmonella* spp.—absent in 25 g;

(iii) *Listeria* spp.—absent in 25 g;

(iv) aerobic mesophilic bacteria total count—not more than 500 cfu/g;

(v) *Enterobacteriaceae*—not more than 10 cfu/g;

(vi) moulds—not more than 100 cfu/g;

(vii) yeasts—not more than 100 cfu/g.

(7) This subsection applies to a food for sale that:

(a) contains the preparation; and

(b) is one of the following:

(i) an analogue of a dairy product;

(ii) is represented in a form which expressly or by implication suggests that the food does not contain milk; and

(c) is required to bear a label because of section 1.2.1—6.

(8) The mandatory advisory statement required by subsection 1.2.3—2(1) for a food to which subsection (7) applies must appear on the front of the package.

Note: An advisory statement to the effect that the product is not suitable for persons with milk allergy is required for such a food. See subsection 1.2.3—2(1) and the table to section S9—2.

(9) Subsection (8) does not prevent the statement from appearing more than once on the label.

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1342 – Beta-casein protein preparation from GM* Komagataella phaffii*) 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 A1342 which seeks to amend the Australia New Zealand Food Standards Code to permit the use of a beta-casein protein preparation (BCPP1) from a genetically modified strain of *Komagataella phaffii* in a wide range of foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation – the *Food Standards (Application A1342 – Beta-casein protein preparation from GM* Komagataella phaffii*) 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 sunsetting 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 sunsetting 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 sunsetting 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 9 and 26 to permit a genetically modified preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant, to be a food for non-retail sale and to be present in certain foods for sale.

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 A1342 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 6-week period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A Regulation Impact Statement (RIS) has not been prepared for this application. This is because applications relating to permitting the use of GM food that have been determined to be safe are considered to be minor in impact and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Therefore, the Authority's assessment is that a RIS is not required for this application.

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 is a non-disallowable instrument under section 44 of the *Legislation Act 2003.*

7. Variation

In this section, references to 'the variation' are references to the draft variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1342 – Beta-casein protein preparation from GM* Komagataella phaffii*) Variation.*

Clause 2 of the variation provides that the Code is amended by the Schedule 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 9 of the Code.

Item [1] would insert a new entry, in numerical order, into the table to section S9—2. The table lists the foods subject to the mandatory advisory statement requirements in Division 2 of Standard 1.2.3 and the mandatory advisory statement required for each listed food.

The new entry would be 'item 12' of the table.

The new entry consists of the following foods listed in column 1 of the table:

(a) A food that is an analogue of a dairy product and that contains a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant.

(b) A food that contains a preparation containing beta-casein derived from *Komagataella phaffi* containing the gene for bovine beta-casein A2 variant and that is represented in a form which expressly or by implication suggests that the food does not contain milk.

The new entry includes an example in relation to the second above-mentioned food. The example provides 'animal-free', 'dairy-free' and 'vegan' as examples of representations that imply the food does not contain milk.

The mandatory advisory statement required for the above-mentioned foods would be prescribed by column 2 of the table as an advisory statement indicating that the product is not suitable for persons with milk allergy.

A reference to 'milk' in the new entry would be a reference to *milk* as defined in section 1.1.2—3(2).

Item [2] would insert, in numerical order, a new entry to the table to section S9—3. The table lists the foods subject to the mandatory declaration requirements in Division 3 of Standard 1.2.3 and the mandatory declarations required for each listed food.

The new entry would be 'item 14' of the table.

The new entry consists of the following food listed in column 1 of the table: a preparation containing beta-casein derived from *Komagataella phaffii* containing the gene for bovine beta-casein A2 variant.

The new entry would list the word 'milk' in column 3 of the table as the required name for declarations in a statement of ingredients.

The new entry would list the word 'milk' in column 4 of the table as the required name for any other declarations. Other declarations are those declarations made in relation to:

- food for sale that is not required to have a statement of ingredients on its label; and
- food that is not required to bear a label; and
- food that is sold to caterers; and
- food sold in individual portion packs.

The above declarations would be required for foods for sale that contain, as an ingredient or an ingredient of a compound ingredient, a preparation containing beta-casein derived from *Komagataella phaffii* for bovine beta-casein A2 variant.

Item [3] would add a new section S26—4 to Schedule 26.

The new section would permit, for the purposes of paragraphs 1.1.1—10(5)(c) and (6) 1.1.1—10(6)(g) of the Code, a preparation containing beta casein derived from *Komagataella phaffi* containing the gene for bovine beta-casein A2 variant to be a food for sale and to be present in a food for sale. The new section would also prohibit the preparation's use in certain foods, set specifications for its use and apply certain labelling requirements.

Subsection S26—4(1) defines ‘the preparation’ to which the section applies to mean ‘a preparation containing beta-casein derived from *Komagataella phaffi* containing the gene for bovine beta-casein A2 variant’.

Subsection S26—4(2) states the preparation is a permitted genetically modified food.

Subsection S26—4(3) states the preparation must not be a food for retail sale.

Subsection S26—4(4) prohibits the addition of the preparation to any of the foods listed in that subsection. The listed foods are infant formula products; food for infants; food for special medical purposes; formulated supplementary sports foods; and formulated supplementary foods for young children.

Subsection S26—4(5) requires the preparation when it is added to food for sale or sold for such use to comply with each specification set out in subsection S26—4(6).

Subsection S26—4(6) sets specifications for the preparation in relation to appearance, composition, purity, metals and microbial limits.

New subsections S26—4(7), S26—4(8) and S26—4(9) would set labelling conditions for certain foods for sale that contain the preparation.

Subsection S26—4(7) applies to a food for retail sale that:

(a) contains the preparation, and
(b) is one of the following:
    (i) an analogue of a dairy product;
    (ii) is represented in a form which expressly or by implication suggests that the food does not contain milk; and
(c) is required to bear a label because of section 1.2.1—6.

Subsection S26—4(8) requires the mandatory advisory statement required by subsection 1.2.3—2(1) (see Item [1] above) for a food to which subsection (7) applies to appear on the front of the package. The specific location of the mandatory advisory statement on the front of the package is not prescribed.

A Note would be inserted after subsection S26—4(8). The note would explain that the advisory statement referred to in subsection S26—4(8) is an advisory statement to the effect that the product is not suitable for persons with milk allergy. The Note would refer the reader to subsection 1.2.3—2(1) where the requirement for the advisory statement is located and the table to section S9—2, which would contain the listed foods and specific advisory statement.

Subsection S26—4(9) provides the statement in subsection S26—4(8) may appear more than once on the label.