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Supporting document 2

Labelling – Application A1342

Beta-casein protein preparation from GM *Komagataella phaffii*

Executive summary

The applicant has sought permission for the use of their fermentation-derived beta-casein protein preparation (referred to as BCPP1) as an ingredient in a wide range of foods. The applicant described the beta-casein component of BCPP1 as providing an animal-free, lactose-free option compared to bovine beta-casein protein. If permitted, it would be sold to food manufacturers and caterers for use as a food ingredient in a range of foods for retail sale such as dairy analogues, protein beverages, baked goods and shelf stable formulations.

FSANZ considered whether the existing labelling requirements in the Australia New Zealand Food Standards Code (the Code) remain appropriate for food containing BCPP1 or whether any additional measures are warranted. FSANZ concluded existing Code requirements remain appropriate for ingredient names, directions for use and storage, nutrition information, nutrition content and health claims, and labelling of genetically modified (GM) food. FSANZ also considers that no change to the Code is required in relation to voluntary 'allergen-reduced' representations because such representations would not align with the Code's allergen declaration framework.

FSANZ considers that BCPP1 should be required to be declared as 'milk' when present in a food for sale because it poses a risk to individuals with milk allergy. FSANZ also considers that food names for dairy analogue products containing BCPP1, such as 'oat milk' or 'cashew cheese', could lead consumers with milk allergy to perceive the product is safe and overlook mandatory allergen information elsewhere on the label. Voluntary front-of-pack representations such as 'animal-free' and 'vegan' may similarly give rise to these perceptions.

FSANZ therefore proposes the following labelling amendments to the Code:

1. A requirement to declare 'milk' when BCPP1 is present in a food for sale or is sold to a caterer or manufacturer (a wholesale food).
2. A requirement for an advisory statement indicating the product is not suitable for people with milk allergy. The advisory statement would apply to dairy analogue products containing BCPP1, and to products containing BCPP1 that are represented in a form which expressly or by implication suggests the food does not contain milk.

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1 Introduction

1.1 Background

1.1.1 Food Standards Code requirements

General labelling requirements in Part 1.2 (Labelling and other information requirements) of the Australia New Zealand Food Standards Code (the Code) apply to the food for sale that contains a genetically modified (GM) food ingredient. These include requirements for name of the food and ingredient, statement of ingredients, mandatory advisory statements and declarations for certain foods (allergens), date marking, directions for use and storage, nutrition information, nutrition content and health claims and characterising ingredients.

General provisions in Division 3 (Sales of food to caterers) in Standard 1.2.1 apply to GM food and food ingredients. Section 1.2.1—17 states the caterer must be provided with any information (a) requested by the caterer or (b) required by the relevant authority to be provided, that is necessary to enable the caterer to comply with any compositional, labelling or declaration requirement of the Code in the sale of the food or of another food using it as an ingredient.

Similarly, the general provision in Division 4 Other sales in Standard 1.2.1 would apply. This Division regulates other food sales, such as the sale of an ingredient by an ingredient supplier to a manufacturer of a food. Section 1.2.1—21 is consistent with section 1.2.1—17 mentioned above, except that it requires the information is provided in writing if requested by the purchaser or required by the relevant authority.

Standard 1.5.2 sets out the labelling requirements for GM food. Subsection 1.5.2—4(3) states that the information relating to GM food is the statement ‘genetically modified’ used in conjunction with the name of the GM food. Subsection 1.5.2—4(3) states that if the GM food is an ingredient (including an ingredient of a compound ingredient), the information may appear in the label other than in the statement of ingredients.

Chapter 2 of the Code establishes standards for the composition, identity and labelling of specified named foods to promote uniformity, uphold product integrity and support fair trade practices. For example, products such as ‘milk’, ‘cheese’ and ‘yoghurt’ are named foods that must adhere to specific definitional, compositional and labelling standards before they can be offered for sale.

FSANZ refers to specific Code requirements in the relevant sections below.

1.1.2 International regulations

The Food and Agriculture Organization (FAO) of the United Nations published the paper ‘Precision fermentation with a focus on food safety’ in April 2025 (Sturme et al 2025). The scope of the paper included nomenclature issues in relation to how fermentation is defined and/or referred to by different sectors. It also included discussion on identifying and explaining the generic model of fermentation processes, and the potential associated food safety hazards and possible consumer outcomes. Of particular interest to FSANZ was the chapter on the current status of regulations and regulatory activities that apply to fermentation-derived foods in different countries, including marketing and labelling.

The FAO paper indicated that (as of April 2025) none of the jurisdictions¹ consulted reported having labelling provisions specifically for fermentation. Many indicated having existing labelling regulations which apply to certain product categories, such as additives and ingredients. The authors of the FAO paper noted that while dairy products derived from fermentation may partially align with established legal names (e.g., 'milk' or 'milk product'), numerous jurisdictions still have uncertainty about the naming of milk-identical or similar components. Comparable challenges exist for other fermentation-derived compounds, for example ovalbumin (egg protein).

FSANZ undertook a scan of international regulatory approvals for fermentation-derived allergenic foods.

1.1.2.1 United States

FSANZ observed that at least seven dairy and egg proteins produced via microbial fermentation have Generally Recognized As Safe (GRAS) status in the United States: five Beta-lactoglobulin whey proteins (GRAS notices 863, 1145, 1200, 1241, 1247); one ovalbumin egg white protein (GRAS notice 1249); and one recombinant bovine lactoferrin glycoprotein (GRAS notice 1219). The US Food and Drug Administration (US FDA) noted in their 'No Questions' letters that these ingredients require allergen labelling in accordance with general provisions in the Federal Food, Drug and Cosmetic Act because they contain protein derived from milk (or, in the case of ovalbumin, egg) (US FDA 2025).

In industry guidance, the US FDA explained that it considers fermentation-derived proteins to be essentially equivalent to major food allergens because they are produced in a manner than uses the major food allergen's DNA sequence. The Guidance also notes additional information may be helpful in some cases to make the relationship to the source ingredient clear, such as 'Contains milk-derived protein'. The Guidance is legally nonbinding.

In the United States, milk, cheese, and yoghurt are standardised foods which must meet specific definitions and compositional requirements. Non-dairy foods may still use these terms descriptively if they are clearly qualified and not represented as the standardised product.

1.1.2.2 Canada

In Canada, a fermentation-derived beta-lactoglobulin whey protein was approved as a novel food in 2024 for use in dairy alternative products (Health Canada 2024). The novel food would be labelled in accordance with general allergen declaration requirements for 'milk' in either a 'contains' statement or in the ingredient list. Health Canada noted that food products containing beta-lactoglobulin would be subject to the general prohibitions against information and claims (including images) that are false or misleading, or likely to create an erroneous impression. An example was provided that claims must be truthful and should not give the impression that food products containing the beta-lactoglobulin are free from dairy without qualifying that there may be a risk to consumers allergic to milk.

The 'Letter of No Objection' also stated that the fermentation-derived beta-lactoglobulin would not meet the definition of 'milk', 'milk product' or 'milk solid', which are defined as standardised dairy products. A food containing this novel ingredient would also not be permitted to use dairy ingredient common names or the collective class names 'milk ingredients' or 'modified milk ingredients'. The Food and Drug Regulations specify the common name of any protein isolate (including this novel food) is the name of the source of

¹ Represented a global snapshot of thirty-five countries and jurisdictions in relation to regulatory frameworks for precision fermentation.

the protein plus 'protein' (e.g. 'yeast-derived whey protein') or the common name of the protein isolate (e.g. 'yeast-derived r- β -lactoglobulin').

1.1.2.3 European Union

No fermentation-derived allergenic proteins (e.g., milk or egg proteins) have completed approval under the EU Novel Foods Regulation. Applications must include an allergenicity assessment, and some (e.g. for casein) are under review. If fermentation-derived products contain known allergens, then general labelling requirements under EU Regulation 1169/2011 would apply (i.e. in the ingredient list).

Dairy designations such as 'milk', 'cheese' and 'yoghurt' are reserved exclusively for products derived from milk, which is defined as 'exclusively the normal mammary secretion obtained from one or more milkings without either addition thereto or extraction therefrom' (EU 2013, EU 2017). Plant-based products are prohibited from using these terms even with qualifiers (e.g. 'vegan', 'plant-based', 'soy')(EU 2017), and dairy analogues containing microbially produced dairy proteins would be similarly prohibited.

1.1.2.4 United Kingdom

FSANZ understands that fermentation-derived proteins like whey, casein, or egg white are being evaluated by the Food Standards Agency (FSA), but none have received market authorisation yet. The FSA has identified allergenicity and novel allergen exposure as key safety concerns in fermentation-derived products. A recent review report stated that 'if a PF product is a milk protein, and marketed as a dairy alternative, applicants need to demonstrate that products will be labelled with the appropriate allergens' (FSA 2025).

1.1.2.5 China

China provided regulatory approval for the use of a fermentation-derived bovine lactoferrin in the infant formula market. FSANZ notes allergen declaration requirements (GB7718 –2025, which requires allergens to be declared either in the ingredient list or in a separate statement directly adjacent to it), would apply to this ingredient.

1.1.3 Industry perspectives

The Allergen Bureau is the peak industry body serving Australia and New Zealand food industry that focusses on best practice risk management of food allergens.

In January 2025, the Allergen Bureau issued technical guidance that clearly defines fermentation processes, as well as fermented materials. This guidance presents a systematic approach for evaluating the allergen status of ingredients derived from fermentation with respect to labelling requirements. While its primary focus is on feedstocks and substrates containing allergens—such as the use of soy derivatives in fermentation media—it also illustrates cases involving GM organisms that produce specific proteins. For instance, proteins produced through fermentation, like animal-free milk proteins, may be classified as allergens (Allergen Bureau 2025).

The Food Industry Guide to Allergen Management and Food Labelling (Allergen Bureau and AFGC, 2024) is jointly overseen by the Allergen Bureau and the Australian Food & Grocery Council (the peak industry body for Australian food and grocery suppliers). This guide addresses voluntary vegan representations primarily in relation to the unintended presence of animal-derived substances (e.g. milk protein) from cross-contact. It highlights that:

- products described as vegan representations may not be appropriate for individuals with allergies to milk or other listed food allergens.

- consumers with food allergies might incorrectly interpret vegan as synonymous with ‘allergen-free’ for animal-origin allergens.
- combining vegan representations with allergen-free claims may inadvertently support the misconception that ‘vegan’ denotes a food safety standard.

The technical guide recommends that voluntary ‘dairy-free’ representations be reserved for products where manufacturers have substantiated that neither milk nor milk derivatives are present as ingredients or cross-contact allergens. The technical guide does not address the use of fermentation-derived dairy or egg ingredients engineered to emulate conventional animal proteins, nor does it offer recommendations regarding ‘animal-free’ product representations.

The Good Food Institute Asia-Pacific Region (GFI APAC) together with Cellular Agriculture Australia (CAA) collaborated in 2024 to develop and publish a ‘Precision Fermentation Communication Guide’ (the Guide) (GFI APAC & CAA 2024a) and a four-page Cheat Sheet of the guide (GFI APAC & CAA 2024b) as resources for the fermentation industry. The GFI APAC is an alternative protein think tank in Asia, advocating for ‘a more secure, sustainable, and just food system through open-access food science R&D, corporate engagement, and public policy’. The CAA is a registered not-for-profit dedicated to advancing Australia’s cellular agriculture sector.

These resources outline agreed industry views relating to:

- nomenclature (i.e. preferred terms ‘precision-fermented’ or ‘fermentation-derived’ but also referring to ‘animal-free’) to describe ingredients and products.
- descriptions (i.e. common and high-level ways of describing the technology and the typical processes it involves)
- key messages.

Key considerations for use of ‘animal-free’ in the Guide included that it may be conflated with plant-based products which could result in misinterpretation of allergenicity risks, and it is unlikely to be suitable for expected regulatory labelling requirements in APAC (GFI APAC & CAA 2024(a)).

FSANZ understands these industry views are based on preliminary findings of consumer research study on fermentation nomenclature and messaging (undertaken in France, Germany, Spain, the United Kingdom and the United States) that was published in January 2025 (GFI 2025).

This report noted that process-focused terms ‘precision-fermented’ and ‘fermentation-derived’ were deemed the most accurate descriptors of the process. However, they were not well understood by consumers, who held low baseline awareness of fermentation and preferred simple, non-technical terminology. Furthermore, the terms did not directly communicate the product benefit or outcome. However, the authors noted they may still play a role in supporting secondary information i.e. a description of the production process. In contrast, ‘animal-free’ was found to be highly effective for consumer communication, providing clarity, appeal and differentiation, and outperforming technical production descriptors. The report did not evaluate how terms like ‘animal-free’ interact with allergen expectations (GFI 2025).

FSANZ notes there is a United States-based company producing dairy protein ingredients produced via microbial fermentation for sale to food manufacturers or licensing those ingredients to other food manufacturers. Perfect Day acknowledges their ‘animal-free dairy protein’ ingredients are not allergen-free and outline on their website the three steps they require of their partners when selling consumer retail brands containing their ingredients:

1. Clearly indicate “Contains Milk Allergen” or “Contains: Milk Protein” on the front of product packaging.
2. Include “non-animal whey protein” in the ingredients list on the product packaging, in compliance with US allergen labelling requirements.
3. Include “Contains: Milk Allergen” or “Contains: Milk Protein” in bold type following the ingredients list on the back of product packaging, in compliance with US allergen labelling requirements (Perfect Day, 2021).

2 Labelling of ingredients

2.1 Existing labelling requirements

General labelling provisions in Standard 1.2.4 (Information requirements – statement of ingredients) require food for sale to be labelled with a statement of ingredients unless exempt. 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, or, if permitted, a generic name specified in Schedule 10 (Generic names of ingredients and conditions for their use).

Section S10—2 of Schedule 10 in the Code includes the generic ingredient names ‘milk protein’ and ‘milk solids’. ‘Milk protein’ has no conditions of use, whereas ‘milk solids’ may be used to describe milk powder, skim milk powder or dried milk products, or any two or more of the following ingredients: whey, whey powder, whey proteins, lactose, caseinates, milk protein or milk fat. Generic ingredient names may be used in place of a more specific name or names (for example, to allow for ingredient substitutions or several types of that food to be used together without the need for declaration).

The Code defines ‘milk’ in subsection 1.1.2—3(2) as the mammary secretion of milking animals, obtained from one or more milkings for consumption as liquid milk or for further processing, excluding colostrums, and including such a product with phytosterols, phytostanols and their esters added.

2.2 Discussion

FSANZ considers that existing ingredient naming requirements remain appropriate for BCPP1 because they provide flexibility for industry while ensuring consumers are given sufficient information and are not misled. The Code generally does not prescribe ingredient names, but any name used must reflect the true nature of the ingredient.

The existing generic ingredient names ‘milk protein’ and ‘milk solids’ would not apply to BCPP1 because their use depends on the definition of ‘milk’ in the Code. FSANZ therefore considers these generic names should not be used on their own for BCPP1, as the beta-casein is produced from yeast rather than obtained from milk.

Section S10—2 also permits ‘cheese’ as a generic ingredient name without conditions of use. However, ‘cheese’ is defined in part as a ‘ripened or unripened solid or semi-solid milk product’ (section 1.1.2—3 of the Code), and therefore also depends on the definition of ‘milk’. In contrast, cheese analogues are typically made from oils, starches, proteins and additives. Accordingly, ‘cheese’ as a generic ingredient name would not apply to a cheese analogue made with BCPP1 when that cheese analogue is used as an ingredient in a food for sale.

However, in these circumstances, a qualifier or other description could be provided alongside the generic ingredient name to indicate the true nature of the ingredient.

FSANZ also notes that ingredient name requirements apply to BCPP1 as the ingredient, rather than to the beta-casein component alone. Describing the ingredient as 'beta-casein' would not reflect its true nature, because BCPP1 is a preparation comprising approximately 5.5% beta-casein (see section 2.2 in SD1).

2.3 Proposed approach

FSANZ considers the existing ingredient naming requirements in the Code are appropriate for BCPP1 and that no change to the Code is required. The ingredient would need to be declared using a commonly known name, a name or description sufficient to indicate its true nature, or a generic name if permitted under Schedule 10. In this case, generic dairy ingredient names that depend on the definition of 'milk' would not be appropriate.

3 Allergen risk management

The applicant describes the beta-casein component of BCPP1 as an animal-free, lactose-free option compared to bovine beta-casein protein. FSANZ's risk assessment found that, as beta-casein is a known milk allergen, foods containing BCPP1 would present an allergenicity risk for individuals allergic to milk proteins (see SD1).

3.1 Mandatory allergen declaration requirements

3.1.1 Existing labelling requirements

General allergen declaration requirements are that if milk or a derivative of milk is present in a packaged food for retail sale, the term 'milk' would be the required name and would need to be declared in accordance with the provisions in Division 3 of Standard 1.2.3 of the Code.

These provisions state (amongst other things) that 'milk' must be declared separately for each ingredient in the statement of ingredients and appear in bold font and in a type size at least as large as the surrounding text. 'Milk' must also appear in the summary statement, using the same typeface and type size as the required name in the statement of ingredients, and in bold font that clearly contrasts with other text (section 1.2.3—7 of the Code).

The term 'required name', of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (subsection 1.1.2—2(3) of the Code).

If the food for retail sale is not required to bear a label, allergen information must be displayed in connection with the display of the food or provided to the purchaser on request (subsection 1.2.1—9(6) and paragraph 1.2.1—9(7)(b) of the Code).

If the food is sold to a caterer, allergen information must be provided on the label of a packaged food (subsection 1.2.1—12(1) and (2) and paragraph 1.2.1—15(c) of the Code). If the food is not required to bear a label, labelling containing the allergen information must be provided to the caterer with the food (section 1.2.1—13 and paragraph 1.2.1—15(c)) of the Code).

For other sales of food (such as a sale between an ingredient supplier and a food manufacturer), the allergen information must be provided to the purchaser if that information is requested in writing by the purchaser or required by the relevant authority, and necessary to enable the purchaser to comply with any compositional, labelling or declaration requirement of this Code in a sale of the food or of another food using it as an ingredient (section 1.2.1—21 of the Code) .

3.1.2 Consumer evidence

FSANZ conducted a rapid literature review to assess evidence on consumer understanding of fermentation-derived beta-casein, focusing on potential confusion between voluntary front-of-pack representations (e.g. 'animal-free' or 'vegan') and mandatory milk allergen declarations, and whether consumers could identify beta-casein as a milk allergen when paired with these representations and declarations (see Appendix 1 Consumer literature review for animal-free and vegan labelling and allergen understanding to this Supporting Document).

A specific question was whether consumers can accurately identify beta-casein as a milk allergen when terms like 'animal-free' or 'vegan' are used alongside the ingredient name and mandatory 'milk' declaration. However, no evidence was found on consumers' ability to accurately identify allergens in this context. The available evidence on ingredient naming focusses on consumer appeal rather than allergen understanding or safety.

3.1.3 Discussion

3.1.3.1 *Application of allergen declaration requirements including the required name 'milk'*

The allergenic properties of beta-casein extracted from bovine milk and the allergenic potential of beta-casein in BCPP1 are discussed in sections 5.1.3 and 5.2 of SD1. Individuals who are allergic to the protein found in bovine milk are expected to experience allergic reactions to beta-casein in BCPP1. Therefore, FSANZ considers the use of BCPP1 as a food ingredient in food products should require an allergen declaration, to ensure the safety and informed choice of consumers with known milk protein allergies. This proposed approach is consistent with international approaches and aligns with industry expectations and guidance (see section 1.1.4 of this report).

The beta-casein in BCPP1 is derived from yeast and technically would not meet the definition of 'milk' in the Code (see section 2.1 of this report). This means a 'milk' declaration could be viewed as misleading. However, individuals with milk allergy and the people who purchase food on their behalf are instructed to look for 'milk' in the statement of ingredients and the summary statement. Establishing a different required name for BCPP1 would require considerable consumer education and may cause confusion in labelling associated with acute food safety risks. FSANZ considers the potential for a milk declaration about BCPP1 to be misleading is outweighed by these safety concerns, and therefore its presence in food should be declared with the required name 'milk' next to the name of the ingredient and in the summary statement. For clarity, this would be achieved by amending the table to section S9—3 of the Code to include BCPP1 as a food for which the required name 'milk' must be declared. The proposed approach is consistent with FSANZ's priority order objectives, noting that the protection of public health and safety has a higher priority over the prevention of misleading or deceptive conduct. FSANZ notes that misleading or deceptive conduct would also be managed by the ingredient itself having a name that accurately reflects its true nature (see section 2 of this report).

The allergen declaration requirement would apply to BCPP1 if present in the food for sale as an ingredient or an ingredient of a compound ingredient. In regard to the latter, the declaration requirement applies irrespective of the amount of the compound ingredient in the food for sale (subsection 1.2.4—5(6) of the Code).

Existing allergen declaration requirements described in section 4.1.1 above would apply when BCPP1 is present in food for retail sale, or in a mixed food sold to a caterer or manufacturer, and when BCPP1 itself is a food sold to a caterer or manufacturer (that is, a

wholesale food).

3.1.3.2 Use of voluntary representations as part of the ingredient name

Existing ingredient name requirements require a name or description sufficient to indicate the true nature of the ingredient, where no common name or generic ingredient name applies (see section 2.1 of this report). Including voluntary representations in the ingredient name may make the name longer and more difficult for consumers to interpret. FSANZ therefore considered whether representations such as 'animal-free' or 'vegan', when included in the ingredient name, could reduce consumers' ability to identify the ingredient as an allergen.

Standard 1.2.3 of the Code specifies the format and location of allergen declarations to ensure visibility for consumers. The required allergen name must be adjacent to the ingredient and in bold type in the statement of ingredients. It must also be declared in the summary statement.

For example:

Statement of ingredients: ingredient, ingredient, 'animal-free beta-casein preparation' (**milk**), ingredient.
Contains: milk.

There was no evidence available that examined consumers' ability to accurately identify the presence of allergens when qualifiers such as 'animal-free' or 'vegan' in conjunction with the name 'beta-casein' and the mandatory declaration for 'milk'.

In the absence of evidence demonstrating reduced consumer understanding and given the existing requirements for prominent and repeated allergen declaration, FSANZ considers that the current framework is sufficient to support the identification of allergens in this context.

3.1.4 Conclusion

Taken together, FSANZ considers that the required name 'milk' should be declared when BCPP1 is present in a food for sale or is a food sold to a caterer or manufacturer, because this would best support the safety and informed choice of consumers with milk allergy. FSANZ also considers that existing allergen declaration requirements remain appropriate where voluntary representations form part of the ingredient name.

3.1.5 Proposed approach

FSANZ proposes 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).

The allergen declaration requirement for BCPP1 is proposed in item [2] of the draft variation (see Attachment A to the Call for Submissions (CFS)).

3.2 Allergen risk associated with food names and front-of-pack voluntary representations

The BCPP1 ingredient is intended for inclusion in various dairy analogues, including milk alternatives, yoghurt-style products, and cheese substitutes. These products typically refer to the alternative protein source in the name of the food to reflect its true nature (e.g. 'oat milk', 'cashew cheese').

Additionally, the applicant cited current industry practices for using voluntary representations

such as 'animal-free', 'animal-free dairy', 'vegan' and 'plant-based' on product labels.

FSANZ has considered allergen identification issues associated with these front-of-pack voluntary representations made about products that contain BCPP1 as an ingredient.

3.2.1 Existing labelling requirements

3.2.1.1 Food name requirements for dairy analogue products

Dairy analogue products are subject to general labelling requirements in the Code, including food name requirements.

Subsection 1.2.2—2(1) in Standard 1.2.2 (Information requirements – food identification) of the Code requires a prescribed name to be used (if one is required), or a name or description sufficient to indicate the true nature of the food and any additional words that the Code requires to be included in the name of the food.

'Milk', 'fermented milk', 'cheese' and 'yoghurt' are not prescribed names. However, these dairy products are named foods that are subject to definitional and composition requirements and/or labelling conditions of sale.

Dairy analogues are not permitted to be sold using the terms 'milk', 'fermented milk', 'cheese' or 'yoghurt' unless the sale context is qualified in accordance with subsection 1.1.1—13(4) in Standard 1.1.1 (Structure of the Code and general provisions) of the Code. For dairy analogue products, that context is typically provided by qualifiers or descriptors in the food name, such as 'soy', 'oat', 'almond', which indicate the product is not a conventional dairy food, but an analogue intended to resemble it. The context of the sale helps distinguish products such as 'oat milk' or 'cashew cheese' from the named dairy foods 'milk' and 'cheese' under the Code.

3.2.1.2 Voluntary representations

The Code does not regulate 'animal-free', 'vegan' or 'plant-based' representations. These types of voluntary representations are regulated under domestic consumer protection legislation, which prohibits misleading or deceptive conduct and false or misleading representations about goods and services. Australian States and Territories and New Zealand are responsible for enforcing food legislation under their respective Food Acts, including compliance with the Code, as well as food-specific misleading or deceptive conduct provisions. General consumer protection laws prohibiting false and misleading conduct are enforced under the Australian Consumer Law and the *Fair Trading Act 1986* (NZ) by the Australian Competition and Consumer Commission (ACCC) and New Zealand Commerce Commission (NZCC), respectively.

3.2.2 Consumer evidence

FSANZ assessed the available evidence on whether voluntary front-of-pack representations such as 'animal-free' or 'vegan' could confuse or mislead consumers when the ingredient list includes a 'milk' allergen declaration for the beta-casein ingredient (that is, whether these claims might discourage consumers from checking allergen declarations).

Consumer evidence indicates that when voluntary front-of-pack 'vegan' representations are used on foods containing animal-derived allergens, some consumers may incorrectly assume those products are safe for people with food hypersensitivities, even when allergens are correctly declared on the back of the pack. Some consumers use 'vegan' claims on the front of pack as a proxy for allergen safety, which may lead them to overlook mandatory

allergen declarations and increase the risk of safety issues. There was no direct evidence that consumers would interpret 'animal-free' representations in the same way.

More broadly, available consumer evidence indicates that understanding of dairy analogues with microbially produced milk proteins is low and marked by uncertainty about how these products are produced, how they should be categorised, and whether they are conventional dairy, plant-based, vegan, or a distinct product type. Consumers frequently expressed confusion about animal involvement and the presence of milk proteins, and this uncertainty often persisted even after explanatory information was provided. The term 'animal-free' was interpreted inconsistently and was often associated with plant-based products before the technology was explained. Although providing information improved the appeal of, and perceived differentiation associated with, 'animal-free' terminology, it did not reliably resolve confusion or support consistent understanding of ingredient composition (see Appendix 1 to this Supporting Document).

FSANZ's consumer evidence assessment did not examine whether dairy analogue food names affect consumer behaviour when seeking allergen information.

3.2.3 Discussion

3.2.3.1 Allergen risks associated with dairy analogue food names

FSANZ does not propose changing existing food name requirements for dairy analogue products. Where the context of sale makes clear that a product is not a conventional dairy food, names that reflect the predominant protein source or sources (such as 'oat and almond milk', 'cashew cheese' or 'coconut yoghurt') are sufficient to indicate the true nature of the food. The addition of BCPP1 would be minimal and would not contribute protein in amounts that would warrant a different product name.

However, despite the adequacy of these food names for general food identification purposes, FSANZ considers that names indicating a plant-based protein source (for example, 'oat milk') may lead consumers with milk allergy to assume the product is suitable for them, even where it contains BCPP1. The presence of beta-casein from BCPP1 introduces a milk-allergen risk and therefore a public health and safety concern. Plant-based product names, combined with consumers' familiarity with plant-based dairy analogues, may reduce the likelihood that they check mandatory allergen declarations for the presence of milk.

For this reason, FSANZ considers that additional front-of-pack labelling is warranted to prompt consumers to check allergen information.

3.2.3.2 Allergen risks associated with voluntary representations

The use of voluntary front-of-pack representations for products containing BCPP1 raises potential public health and safety concerns where such representations may be interpreted by consumers as indicating the absence of milk allergens. This is particularly relevant for representations that align with consumer expectations about plant-based or non-animal products, such as 'animal-free', 'vegan', 'plant-based', or 'dairy-free'. These terms do not have a regulatory definition in the Code, and while FSANZ is not assessing whether these terms would accurately represent products containing BCPP1, it notes that their use presents a risk of misleading consumers about the presence of milk allergens in such products.

As outlined in section 1.1.4 of this report, industry has identified 'animal-free' as a preferred term, and the applicant has described the beta-casein component of BCPP1 as an 'animal-free option' compared to bovine beta-casein protein. The Guide describes this term as consumer-friendly, informative for vegetarians and vegans, and useful for branding and marketing purposes (GFI APAC & CAA 2024a).

However, the Guide also acknowledges that products with 'animal-free' representations may be confused with plant-based products, which could contribute to misunderstanding of allergen risks. For example, consumers with milk allergy may incorrectly assume that fermented dairy analogue products with an 'animal-free' representation are as safe as plant-based alternatives made from cereals, nuts or seeds even if they contain microbially produced milk proteins similar to those in cow's milk, and may therefore trigger allergic reactions. The Guide therefore concludes that 'animal-free' is unlikely to be appropriate for regulatory labelling purposes. FSANZ notes that while Perfect Day refer to their ingredients as 'animal-free dairy protein', they specify an allergen statement on the front of pack to protect consumers.

The Guide also discusses 'vegan' representations and notes that, as with 'animal-free', consumers with egg or milk allergy may assume these products are safe. Although 'vegan' is not identified as a preferred term, the Guide recommends that industry and regulators ensure labels are accurate and that consumers are appropriately informed of the associated allergen risks.

Consumer evidence supports these concerns. As discussed in section 3.2.2 of this report, 'vegan' labelling may be used by some consumers with animal-derived food allergies as a proxy indicator of suitability, which may reduce the likelihood that they check allergen information elsewhere on the package. Although there was no direct evidence on how 'animal-free' representations affect milk-allergic consumers' understanding of allergen risks, the available evidence indicates that some consumers associate this term with plant-based products. Taken together, these findings indicate that such representations may function as implicit safety cues and contribute to misinterpretation of allergen risk.

The Guide does not identify 'plant-based' as a preferred term, likely reflecting that fermentation-derived proteins such as whey and casein are typically produced using microorganisms rather than plants. However, manufacturers of products that already use 'plant-based' representations on the front of pack may continue to do so for products comprising predominantly of plant-derived ingredients but contain BCPP1 as a minor ingredient. In these circumstances, there is a similar risk that consumers may interpret 'plant-based' representations as indicating the absence of milk allergens, despite the presence of BCPP1.

A related issue is the use of 'dairy-free'. An allergy advocacy group raised concerns with FSANZ in October 2023 that use of the term 'dairy-free' could mislead consumers with milk allergy if used on dairy analogues with microbially produced milk proteins. FSANZ also considers that use of this term would present a clear risk of misunderstanding, because products containing BCPP1 may still provoke reactions in people with milk allergy. While neither the Guide nor the applicant proposes the use of 'dairy-free' labelling for these products, FSANZ considers that the potential for such representations to be used in the broader market remains relevant to this risk assessment.

These concerns are broadly consistent with developments in the international context. The FAO paper highlights the importance of considering allergens in product and ingredient labelling and notes uncertainty about whether current labelling approaches adequately protect consumers. As outlined in section 1.1.3 of this report, most regulators rely on existing allergen labelling requirements, with declarations typically appearing in or near the ingredient

list on the back of pack. Canada is the main exception, having specifically addressed the risk of misleading voluntary claims. In the United States, guidance refers to 'contains milk-derived protein' but does not specify front-of-pack placement. FSANZ also notes that some companies have adopted front-of-pack allergen disclosures to complement mandatory declarations.

Based on these factors, FSANZ considers that front-of-pack voluntary representations that might imply an absence of milk proteins, such as 'animal-free', 'vegan', 'plant-based' (in some contexts) and 'dairy-free', pose a safety risk to consumers with milk allergy if used on products containing BCPP1. These representations may lead consumers with milk allergy to infer that a product does not contain milk allergens and therefore reduce the likelihood that they check the mandatory allergen declaration. While this issue is particularly relevant for dairy analogue products, due to strong consumer expectations that these products are milk-free, it is not confined to that category and may arise wherever such representations are used.

3.2.4 Regulatory options

FSANZ has considered four options to manage the allergen risks identified in sections 3.2.3.1 and 3.2.3.2. These were:

1. No additional labelling
2. Require an advisory statement
3. Require a summary statement
4. Prohibit certain voluntary representations

Option 1: No additional labelling

Option 1 would maintain the current regulatory approach, with no additional front-of-pack labelling requirements. Allergen information would continue to be provided in the statement of ingredients and summary statement, typically located on the back of pack. This option would support innovation by allowing continued use of voluntary representations and existing dairy analogue food names.

FSANZ considers that this option would leave a significant risk that consumers with milk allergy may overlook back-of-pack allergen information and is therefore not consistent with FSANZ's priority objectives. While it would align with intended regulatory approaches in jurisdictions such as the United Kingdom and the European Union, which rely on general allergen labelling requirements, FSANZ considers these approaches do not adequately address the identified risk. This conclusion is supported by industry perspectives, which have identified that 'animal-free' and 'vegan' representations could introduce consumer confusion and would likely not be suitable for regulatory purposes (see section 1.1.4 of this report).

Option 2: Require an advisory statement

Option 2 would require a front-of-pack advisory statement indicating that the product is not suitable for people with milk allergy. The wording of the advisory statement would not be prescribed. The statement would be located on the front of the package and apply to dairy analogue products and to any other food that has voluntary front-of-pack representations that imply the absence of milk proteins, such as 'animal-free', 'vegan' and 'dairy-free'.

This option would support industry innovation by allowing product names and voluntary representations that highlight that a salient attribute of the product, while providing a front-of-pack safety cue for consumers. It would complement existing labelling requirements by prompting milk-allergic consumers to check mandatory allergen declarations elsewhere on

the label. Unlike allergen declarations in the statement of ingredients or summary statement, the required name 'milk' would not need to appear in bold type.

Although this option could result in wording and format differences between the front-of-pack advisory statement and back-of-pack allergen declarations, it would better alert consumers with milk allergy to unsuitable products. Existing allergen declaration requirements would still apply. FSANZ considers this option would satisfy the three priority objectives in the FSANZ Act and is the most consistent with the Canadian regulatory approach.

The proposed requirement for the advisory statement to appear on the front of the package would not apply to other sale scenarios listed below. However, existing Code requirements would ensure the advisory statement is supplied in these cases:

- for food for retail sale not required to bear a label — the advisory statement must be displayed with the food or provided to the purchaser on request.
- for food sold to a caterer — the advisory statement must be on the label or provided with the food.
- for other sales — the advisory statement must be provided in writing if requested by the purchaser.

Option 3: Require a summary statement

Option 3 would require the allergen summary statement in paragraph 1.2.3—6(2)(b) of the Code to appear on the front-of-pack in addition to the existing requirement for it to appear directly next to the statement of ingredients. Similar to Option 2, the requirement would apply to dairy analogue products and to any other food that has voluntary front-of-pack representations that imply the absence of milk proteins, such as 'animal-free', 'vegan' and 'dairy-free'. Unlike Option 2, the wording would be prescribed rather than flexible.

The presence of a front-of-pack summary statement could lead consumers to assume that it identifies all allergens present in the food. It could therefore be misleading, and pose a safety risk, if only 'milk' were declared on the front-of-pack when other allergens were also present. Accordingly, if any other listed allergen is present in the food for sale containing BCPP1, the required name for that allergen would also need to be declared on the front of pack in the same manner as for milk (for example, 'Contains: milk, almond'). The same principle of using only the required name, without other terms or additional words, would apply.

Similar to Option 2, this option would provide a clear and consistent front-of-pack safety cue. However, it would duplicate information provided elsewhere on packaging, would provide less flexibility to industry than Option 2 and is not consistent with any overseas regulations.

FSANZ nevertheless considers that this option would satisfy the three priority objectives in the FSANZ Act.

For other sale scenarios, the same existing allergen declaration requirements described under Option 2 would apply.

Option 4: Prohibit voluntary representations

Option 4 would prohibit voluntary front-of-pack representations that imply an absence of milk proteins, such as 'animal-free', 'vegan', and 'dairy-free', on products containing BCPP1. This option would eliminate the risk that consumers with milk allergy are misled by these representations when the product contains a milk allergen. However, it would not address the allergenicity risk associated with dairy analogue food names that solely refer to plant-based protein sources (e.g. 'oat milk').

This option would only partially support the priority objectives relating to public health and safety and the prevention of misleading or deceptive conduct. It would also provide consumers with less information than Option 2, inhibit industry innovation by preventing representation of a salient attribute of the product, and is inconsistent with international regulations and regulatory guidance. FSANZ therefore does not prefer this option.

3.2.5 Conclusion

FSANZ considers that Option 2 provides the best balance between protection of public health and safety and flexibility for industry. It would provide a clear front-of-pack safety cue for consumers with milk allergy while allowing continued use of voluntary representations and existing dairy analogue food names.

3.2.6 Proposed approach

FSANZ proposes to amend the Code to require a front-of-pack mandatory advisory statement indicating that the product is not suitable for people with milk allergy. The advisory statement would apply to dairy analogue products containing BCPP1, and to products containing BCPP1 that are represented in a form which expressly or by implication suggests that the food does not contain milk.

The requirements for the mandatory advisory statement are proposed in items [1] and [3] of the draft variation (see Attachment A to the CFS).

3.3 Voluntary ‘Allergen-reduced’ representations

3.3.1 Existing labelling requirements

There are no requirements in the Code for voluntary ‘allergen-reduced’ representations. This type of representation would be subject to consumer protection legislation.

3.3.2 Discussion

The applicant observed that products containing beta-casein produced via fermentation are typically positioned as ‘allergen-reduced’ alternatives to conventional dairy products. The applicant stated that, for this reason, the allergenicity risk associated with BCPP1 is low. However, they also acknowledged that BCPP1 may still elicit reactions in individuals with casein-specific IgE sensitisation and that allergen labelling in accordance with existing Code requirements would apply.

FSANZ considers that voluntary use of the term ‘allergen-reduced’ could mislead consumers and may present a safety concern. Because food containing BCPP1 would still require a mandatory ‘milk’ allergen declaration, use of ‘allergen-reduced’ could confuse consumers who are sensitive to milk and lead some to assume the product is safer than it is. In Australia and New Zealand, food allergy diagnosis and management are generally based on the listed allergen ‘milk’, rather than on specific milk proteins such as beta-casein or beta-lactoglobulin (ASCIA 2025; Allergy New Zealand 2025).

This risk may be heightened if the representation appears prominently on the front of the package, as consumers may rely on it and overlook allergen information provided elsewhere on the label. FSANZ also notes that allergen declaration requirements under the Code are based on the presence of the listed allergen, not on the presence or concentration of individual milk proteins. For this reason, voluntary ‘allergen-reduced’ representations would not align with the Code’s allergen declaration framework.

3.3.3 Proposed approach

FSANZ considers that no change to the Code is required.

4 Directions for use and storage

4.1 Existing labelling requirements

Standard 1.2.6 (Information requirements – directions for use and storage) requires directions for use and storage to be provided on the label of a packaged food under certain circumstances. These include where:

- specific storage conditions are required to ensure that the food will keep until the use-by date or the best-before date, a statement of those conditions (paragraph 1.2.6—2(a)), and
- the food must be used or stored in accordance with certain directions for health and safety reasons, those directions (paragraph 1.2.6—2(b)).

If the food for sale is not in a package, the directions relating to use and storage in paragraph 1.2.6—2(b), if relevant, would apply and must be stated in labelling that accompanies the food for sale (paragraph 1.2.1—9(4)(a)).

4.2 Discussion

Section 2.2 of the CFS stated there are no public health and safety concerns associated with the addition of BCPP1 to food.

The microbiological safety of food containing BCPP1 will depend on the characteristics of the final food product, including formulation, shelf life, packaging, storage conditions and consumer preparation.

In this context, the need for any directions for use or storage would need to be assessed at the level of the food for sale. The supplier of the food would remain responsible for providing any directions for use and storage, and any storage conditions, necessary for that product.

FSANZ considers these labelling provisions are appropriate for food products containing the applicant's BCPP1 ingredient.

4.3 Proposed approach

FSANZ considers that the existing labelling requirements for directions for use and storage remain appropriate for food products containing BCPP1 as an ingredient. FSANZ therefore considers that no change to the Code is required.

5 Nutrition information

5.1 Existing labelling requirements

Standard 1.2.8 (Nutrition information requirements) mandates a nutrition information panel (NIP) on the label of a packaged food unless exempt. The NIP must include (among other things) the average energy content and average quantity of protein, carbohydrate, sugars, fat and sodium in a serving of the food and a unit quantity of the food.

5.2 Discussion

These requirements would apply to packaged food for sale containing BCPP1 as an ingredient. The nutrition information panel would reflect the nutrient composition of the final food, to which BCPP1 may contribute.

5.3 Proposed approach

FSANZ considers that the existing nutrition information requirements remain appropriate for packaged food for sale containing BCPP1 as an ingredient. FSANZ therefore considers that no change to the Code is required.

6 Nutrition content and health claims

6.1 Existing labelling requirements

Standard 1.2.7 (Nutrition, health and related claims) in conjunction with Schedule 4 sets out the requirements for the use of voluntary nutrition content and health claims on foods, including the criteria that must be met before claims can be made.

6.2 Discussion

Existing requirements for voluntary nutrition content and health claims would apply to food containing BCPP1 as an ingredient. Claims are based on the nutrient profile of the food for sale, meaning that more than one ingredient may contribute to the total amount of a particular nutrient. For example, the applicant states that BCPP1 provides a lactose-free protein. FSANZ notes that a 'lactose free' nutrition content claim is permitted under Schedule S4—3 of the Code provided the food for sale contains no detectable lactose.

6.3 Proposed approach

FSANZ considers that the existing requirements for nutrition content and health claims remain appropriate for food for sale containing BCPP1 as an ingredient. FSANZ therefore considers that no change to the Code is required.

7 Labelling as 'genetically modified'

7.1 Existing labelling requirements

Standard 1.5.2 (Genetically modified food) of the Code establishes the labelling requirements for GM food. Under section 1.5.2—4, a food for sale must be labelled as 'genetically modified' in conjunction with the name of the GM food:

- where the food contains, or consists of, a GM food listed in Schedule 26 and that GM food contains novel DNA or novel protein, or
- is otherwise specified in section S26—3 as being subject to mandatory GM labelling because of an altered characteristic, such as a changed composition or nutritional profile, compared with its conventional counterpart.

The Code requires GM labelling unless a specific exemption applies. These exemptions include where the GM food is unintentionally present at no more than 10 grams per kilogram of each ingredient, or where the food is intended for immediate consumption and is prepared and sold from food premises such as restaurants, takeaway outlets, caterers, self-catering

institutions or vending vehicles.

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 in accordance existing requirements for GM labelling.

7.3 Proposed approach

FSANZ considers that the existing GM food labelling requirements remain appropriate for BCPP1 as a GM food ingredient, where used in a food for sale. FSANZ therefore considers that no change to the Code is required.

8 Summary of the proposed approach

FSANZ proposes to amend the Code 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).
- require a front-of-pack mandatory advisory statement indicating the product is not suitable for people with milk allergy. The advisory statement would apply to dairy analogue products containing BCPP1, and to products containing BCPP1 that are represented in a form which expressly or by implication suggests that the food does not contain milk.
- retain the existing requirements for ingredient names, directions for use and storage, nutrition information, nutrition content and health claims, and labelling of GM food.

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Appendix 1: Consumer literature review for animal-free and vegan labelling and allergen understanding

Executive summary

Food Standards Australia New Zealand (FSANZ) conducted a rapid literature review to inform Application A1342 – Beta-casein protein preparation (BCPP1) from GM *Komagataella phaffii*. The review assessed evidence on consumer understanding of fermentation-derived beta-casein, focusing on potential confusion between voluntary front-of-pack representations (e.g. 'animal-free' or 'vegan') and mandatory milk allergen declarations, and whether consumers could identify beta-casein as a milk allergen when paired with these representations and declarations.

The review included three primary research papers and two reports. No studies were conducted in Australia or New Zealand. Some studies included countries where fermentation-derived dairy protein was not available at the time of assessment (similar to the situation in Australia and New Zealand) such as the United Kingdom (UK), Spain and Germany.

There was evidence that consumers are uncertain with how to classify fermentation-derived dairy protein products. Twenty six percent of consumers associated the term 'animal-free' with plant-based products when they did not understand the production process of the food ingredients. Once participants were aware of the process, 'animal-free' was considered to effectively differentiate these products from plant-based or conventional dairy by the highest number of participants (61% positive responses for differentiating from plant-based products). However, there were narrow margins between different terms tested. The impact of 'animal-free' terminology on milk-allergic consumers' understanding of allergen risks was not explored.

Only 50% of UK consumers with food hypersensitivities to allergens of animal origin were aware that vegan products might not be suitable for their consumption and only 57% were aware they should check precautionary allergen labelling. Over 50% of UK consumers with these food hypersensitivities reported relying on front-of-pack 'vegan' representations as a proxy for allergen information and of these only 56% reported subsequently checking the back-of-pack ingredients list.

There was limited evidence on whether consumers could accurately identify beta-casein as a milk allergen when 'animal-free' or 'vegan' qualifiers and a mandatory milk declaration were used. General consumers favoured shorter ingredient names like 'animal-free whey protein', but it is unclear from the available research whether this adequately conveys allergen information to consumers. Overall, the evidence suggests a potential risk of misinterpretation of 'animal-free' or 'vegan' representations, highlighting the need for clear communication about fermentation-derived food ingredients in the context of allergens of animal origin.

Social science assessment

Background

In general, Australian and New Zealand consumers have low awareness of and confidence in the safety of foods produced using precision fermentation. A nationally representative sample of 1,231 Australians and 884 New Zealanders were surveyed in April 2024 as part of the FSANZ annual Consumer Insights Tracker (FSANZ 2025). When asked about their awareness of precision fermentation, 47% of consumers had never heard of it, 30% had heard of it but knew very little, 18% knew what it was but could not explain it to others, and only 5% knew enough to explain it to others. In addition, 45% reported not feeling confident in the safety of precision fermentation technology, 26% felt neutral and 29% felt confident. No studies were identified that explored Australian and New Zealand consumers' willingness to try fermentation-derived dairy protein or whether consumers would incorporate or replace conventional dairy or plant-based alternatives with fermentation-derived dairy protein.

International evidence synthesised by the United Kingdom Food Standards Agency (FSA) in their rapid review of consumer responses to fermentation-derived dairy and egg suggested that consumers were more likely to be willing to try fermentation-derived dairy protein than to regularly purchase or incorporate fermentation-derived dairy protein into their diet (FSA 2025). There was no evidence identified to suggest that the introduction of fermentation-derived dairy protein would negatively impact any population groups.

Approach

FSANZ has reviewed the available evidence on consumer understanding of fermentation-derived dairy protein with regard to the following risk assessment questions:

1. Would consumers be confused or misled by voluntary front-of-pack representations such as 'animal-free' or 'vegan' when the ingredient list includes a 'milk' allergen declaration for the beta-casein ingredient? (e.g. would these kinds of front-of-pack claims deter people from checking the allergen declarations?)
2. Can consumers accurately identify that beta-casein is a milk allergen if the ingredient list uses qualifiers such as 'animal-free' or 'vegan' in conjunction with the name 'beta-casein' and the mandatory declaration for 'milk'?

To address the risk assessment questions, FSANZ considered the available consumer evidence. During an initial scoping literature search in Google Scholar on 3 November 2025², FSANZ identified two relevant reports published by the FSA and one primary research study (Dominguez et al. 2023; FSA 2024, 2025).

The FSA's 'Rapid Evidence Review on Consumer Responses to Precision Fermentation' was published in May 2025 (FSA 2025). The review included 19 studies³ published between 2015 and 2025 from peer reviewed journals (n = 14) and grey literature (n = 5) with a focus on fermentation-derived dairy and egg. Studies were restricted to English with no restriction on country. The report had a strong focus on research relevant to the UK but also reported international evidence.

Through citation screening of this report, two additional primary research papers and one report were included (Broad et al. 2022; Powell et al. 2023; GFI 2025). The methodology and

² Screened the first 100 results on Google Scholar; search terms included 'understanding', 'non-animal', 'animal-free', 'precision fermentation', 'allergy'.

³ 17 documents were included with one document reporting three separate studies

findings of these studies are reported in the results section of this assessment. The FSA report authors specifically noted there was no evidence related to naming and allergen understanding and it was therefore unclear whether the terms 'animal-free' or 'non-animal' conveyed sufficient allergen information to consumers or created confusion.

FSANZ undertook an additional literature search on 1 December 2025 using the EBSCO Discovery Service⁴ to identify any relevant studies on whether consumers are confused about 'animal-free' product labels and allergen information. This search was restricted to peer-reviewed literature in English with no restriction on date and used the terms:

(animal-free OR non-animal OR "milk protein" OR "egg protein" OR "animal-free dairy" OR "non-animal dairy" OR "animal-free milk" OR "non-dairy milk" OR dairy-free OR "dairy free" OR "animal free" OR "non animal" OR "precision-fermented dairy" OR "precision fermented dairy" OR "precision ferment*" OR milk-allergic OR "milk allergy" OR egg-allergic OR "egg allergy" OR vegan OR beta-casein OR "beta casein") AND AB⁵ (consumer* OR perception* OR understand* OR confus* OR misunderstand* OR aware* OR attitude* OR misled OR mislead* OR conception*) AND (allergy OR "allergic reaction" OR allergen* OR anaphyla* OR allergic) NOT "infant formula"

This search returned 866 results but did not identify any additional relevant studies.

Due to the low number of relevant studies identified, an additional literature search was conducted without the terms related to allergens on 1 December 2025 (restricted to peer-reviewed literature in English with no date restriction) using the terms:

(animal-free OR non-animal OR "milk protein" OR "egg protein" OR "animal-free dairy" OR "non-animal dairy" OR "animal-free milk" OR "non-dairy milk" OR dairy-free OR "dairy free" OR "animal free" OR "non animal" OR "precision-fermented dairy" OR "precision fermented dairy" OR "precision ferment*" OR milk-allergic OR "milk allergy" OR egg-allergic OR "egg allergy") AND TI⁶ (consumer* OR perception* OR understand* OR confus* OR misunderstand* OR aware* OR attitude* OR misled OR mislead* OR conception*) NOT "infant formula"

This returned 378 studies (16 reviewed at full text) and did not identify any additional papers relevant to animal-free dairy labelling and allergen information.

In total, five papers or reports were considered in this assessment (Broad et al. 2022; Dominguez et al. 2023; Powell et al. 2023; FSA 2024; GFI 2025).

Results

1. Would consumers be confused or misled by voluntary front-of-pack representations such as 'animal-free' or 'vegan' when the ingredient list includes a 'milk' allergen declaration for the beta-casein ingredient? (e.g. would these kinds of front-of-pack claims deter people from checking the allergen declarations?)

No studies directly explored the interaction between front-of-pack representations of 'animal-free' and allergen declarations in the ingredients list. However, five studies contributed indirect evidence towards this research question, including two multi-country studies (United

⁴ EBSCO Discover Service searches Science Direct, Food Science Source, FSTA, MEDLINE, SocINDEX and EconLit databases.

⁵ AB indicates that the terms in brackets after this marker must appear in the abstract of the publication.

⁶ TI indicates that the terms in brackets after this marker must appear in the title of the publication.

Kingdom [UK], United States [US], Germany and Singapore in Broad et al. 2022 and UK, US, France, Germany, Spain in GFI 2025), two studies from Canada (Dominguez et al. 2023; Powell et al. 2023) and one from the UK (FSA 2024). No studies were undertaken in Australia or New Zealand.

Three studies explored how general consumers (including vegan consumers) characterise animal-free dairy products including whether animal-free dairy was considered plant-based or vegan (Broad et al. 2022; Powell et al. 2023; GFI 2025). One study explored consumers' naming preferences for fermentation-derived food ingredients (GFI 2025). Two studies explored how consumers with allergies or intolerances to egg and/or milk interact with products labelled as 'vegan', including how they use back-of-pack labelling information in the context of cross-contamination (Dominguez et al. 2023; FSA 2024).

1.1 How do consumers characterise fermentation-derived dairy protein products?

Broad et al. (2022) reported results from a focus group study with 34 participants across 8 groups in 2021 from the UK, US, Germany and Singapore (two groups each) to examine participants' views on animal-free dairy (Broad et al. 2022). Participants were selected based on holding generally favourable views of new foods and the role of technology (classified as 'early adopters') and therefore were not representative of the general population. Two additional focus groups from the UK where participants held less favourable views of new foods and technology were not included in this paper as the scope was focused on 'early adopters'. Results were not reported separately by country.

Participants were provided with a basic description of the concept and technological principles of fermentation-derived dairy protein, omitting the term 'animal-free dairy' from the description and from the focus group discussions more broadly. Through the focus group discussions, participants were asked for their general thoughts on the description of the fermentation process and if they had any key questions around clarity of the technology.

The study used 'mood boards' mixed with text and images framing key arguments in favour and opposition of the technology. Positive frames included the value of animal-free dairy in terms of animal welfare, climate change and environment, overall power of technology, individual health benefits and reduction of public health risks. Negative frames included messing with nature, creating health risks, hurting farmers and increasing corporate power. For each frame, participants were asked the extent to which they believed these were strong or weak arguments in favour or opposition of this new way of making dairy.

After receiving the initial description of the fermentation process, participants were asked if they had any further questions. Some participants asked questions related to the process, safety and regulation of the products and how animal-free dairy may compare to existing dairy alternatives. The authors reported that there was uncertainty by participants for how to classify animal-free dairy, whether it should be considered vegan or plant-based at all, and whether it should be considered real dairy. While there was no direct consideration of fermentation-derived dairy protein from an allergen perspective in this study, this finding may indicate that some participants were unsure of what characterises these products. Participants also discussed where animal-free dairy products may fit within the broader context of foods and whether they were healthy, processed, or vegan animal product alternatives.

One author of this study was employed by a novel food technology company. No participant characteristics were reported in the paper beyond their views of new foods and technology.

Powell et al. (2023) conducted a pilot mixed methods survey with a non-representative sample of 115 participants from British Columbia, Canada in 2019 to explore consumer

perception and acceptance of yeast-derived dairy⁷ (Powell et al. 2023). The study used convenience sampling through electronic mailing lists, social media and direct outreach to recruit consumers with a general interest in food and vegan or other dairy-avoidant diets. The study included an explainer sheet defining cellular agriculture (that the milk production process involved inserting genes for key milk proteins (casein and whey) from cows into yeast cells, which reproduce these proteins through fermentation).

Participants were predominantly female (78.3%), aged 35 years and older (61.7%) with at least some undergraduate coursework or degree (81.8%). 38.3% of consumers were vegan, with 51.3% self-reporting very good or excellent knowledge of the food system. Approximately 56.0% of respondents reported having previously heard of cellular agriculture and 34.8% reported that they had heard of it and understood what it was. 43.5% and 38.3% of all respondents were at least likely to try yeast-derived milk/cream or ice cream, respectively. There was lower likelihood to purchase (31.3 and 27.8%), incorporate (25.2 and 20.0%) or replace other dairy products with (15.7 and 17.4%) yeast-derived dairy milk/cream or ice cream. Vegan respondents were less likely to try, purchase, incorporate and replace with yeast-derived milk/cream or ice cream compared to non-vegan respondents.

When asked to respond to a set of statements about yeast-derived agriculture, 42.6% of all respondents agreed that products made with yeast-derived technologies were ‘animal-free’ (34.8% neutral, 22.6% disagree) and 27.0% agreed they were ‘vegan’ (42.6% neutral, 30.4% disagree). However, when comparing responses based on dietary preference, those who self-identified as vegan were less likely to consider yeast-derived products as ‘animal-free’ or ‘vegan’ compared to non-vegans (29.5% compared to 50.7% for ‘animal-free’ and 20.5% compared to 31.0% for ‘vegan’, respectively). These results suggest there was a high level of uncertainty around the classification of these products both in vegan and general populations.

In response to the open-ended question “I would be more likely to consume yeast-derived dairy if it...”, one participant stated “...*If I didn’t have an allergy, I would definitely be more interested in eating yeast-derived dairy than animal-derived [sic] dairy, mainly for environmental reasons...*” (Powell et al. 2023, pg7). This suggests that some consumers with an allergy may understand that these products are not safe for consumption. However, a single quote is not generalisable to the broader population of those with allergies. The type or severity of the allergy was not specified, and it was unclear whether their interpretation was because of ‘animal free’ or ‘vegan’ descriptions, or other information provided about the fermentation process in the study.

Good Food Institute (GFI) conducted a mixed methods consumer research project in France, Germany, Spain, UK and US on the naming and messaging of fermentation-derived dairy and egg (GFI 2025). This included one-on-one interviews with 31 participants (aged between 20 and 62 years, even gender split), two rounds of consumer co-creation groups with 60 participants (aged between 18 and 65 years, even gender split) to develop communication archetypes (product stimuli including images, text and messaging)⁸ and a quantitative survey with a nationally representative sample (by age and gender for each country) of 5,128 respondents (aged between 18 and 75 years, even gender split). Across both qualitative study components, participants represented a range of political beliefs, had equal representation from urban and rural areas, and had at least partial purchasing responsibility for their household. The qualitative studies specifically excluded participants with dairy or egg allergies. This assessment focuses on results specific to fermentation-derived dairy or the fermentation-derived protein products in general (e.g. where questions were not separated

⁷ Yeast-derived dairy is another term used to describe fermentation-derived protein products.

⁸ It was not clear whether quotes throughout the report were from one-on-one interviews or co-creation group discussions.

for fermentation-derived dairy and egg).

Each study component was designed to gradually introduce more information about the microbial fermentation process to replicate real-world learning. One-on-one interviews began by exploring ways to describe fermentation-derived products without explaining the process. Participants in the co-creation groups were provided with a detailed explanation of the production process of fermentation-derived ingredients at the end of the second round. During the quantitative survey, respondents were gradually introduced to more information about the production process.

During one-on-one interviews, participants expressed feeling at a loss to understand what fermentation-derived dairy was, including not knowing which questions to ask to address confusion. Questions from participants were associated with a need to understand the manufacturing process, ingredients used and potential health impacts. Participants also had different views depending on whether they considered fermentation-derived dairy as plant- or animal-based, with concerns including whether they needed to worry about casein (for vegans). One vegan participant stated: *“The whole ‘real dairy that’s animal-free’ confuses me... Is it artificial? With ‘real dairy’, I’d assume it came from an animal, so I’m really confused. If it’s real dairy, how is it made –because if animals were involved, do I really want to put that into my body?”* (GFI 2025, pg. 40).

Consumers from the US wanted specificity in ingredients, with one participant stating *“Telling me this is not from an animal isn’t enough. I need to know what kind of milk it is, like almond, oat milk? Adding ‘precision fermentation’ doesn’t change my [understanding].”* (GFI 2025, pg. 42). Consumers also noted that increased technical and scientific details did not add to understanding or confidence. One participant stated *“I can eat it if I don’t know what’s in it, but then [if] you give me this scientific stuff, then [I think] ‘I actually don’t want to eat this anymore.’ ... More information is probably going to make me want to eat it less.”* (GFI 2025, pg. 47).

1.2 What terms for fermentation-derived dairy protein are most appealing and effective for product characterisation?

GFI (2025) conducted a quantitative survey (5,128 respondents, aged between 18 and 75 years, even gender split) that tested naming options across five countries (France, Germany, Spain, UK and US), with seven terms tested across all countries and translated to local languages, as appropriate (GFI 2025). These included ‘animal-free’, ‘non-animal’, ‘made from microflora’, ‘made from precision fermentation’, ‘made from fermentation’, ‘made from precision brewing’ and ‘cultivated’. The terms ‘precision-fermented’, ‘microflora-made’, ‘fermentation-made’ and ‘precision-brewed’ were tested in the UK and US only due to small differences when translated to other languages. Two additional terms were tested in German only and one additional term was tested in Spanish only.

Before being presented with information on the production process, consumers considered ‘animal-free’ as the term most associated with plant-based products (26% of respondents associated ‘animal-free’ with plant-based products). However, after receiving a definition of the production process⁹ including how the products differ from conventional dairy or plant-based products, consumers considered the term ‘animal-free’ as the most appealing in all

⁹ GFI 2025 described the fermentation-derived protein production process as “The process uses an innovative form of fermentation in some ways similar to brewing beer. The process encodes microorganisms with milk or egg DNA to produce the same proteins you’d find in cow’s milk or chicken eggs, without using animals. These proteins are used in dairy and egg products made in a new way.” (GFI 2025, pg. 54).

countries¹⁰ except France, where the preferred term was ‘non-animal’¹¹. The next best performing terms for appeal after receiving information on the production process were ‘non-animal’ in Germany, UK and US, ‘made from precision brewing’ in France and a Spanish translation of ‘carefully crafted’ in Spain. Technical names related to processes and microflora (e.g. ‘microflora-made’, ‘made from microflora’ or ‘fermentation-made’) were considered less appealing by consumers.

‘Animal-free’ was also considered the most effective at differentiating fermentation-derived protein products from conventional dairy or egg (50% net effectiveness¹²; individual results for all terms were not reported in GFI 2025¹³) and plant-based products (42% net effectiveness) across all markets (Table 1).

Table 1. Effectiveness of terms for differentiating fermentation-derived dairy or egg protein from plant-based dairy or eggs across France, Germany, Spain, UK and US (adapted from GFI 2025).

Term	Negative responses	Not sure/no opinion	Positive responses	Net effectiveness
Animal-free	19%	21%	61%	42%
Non-animal	20%	22%	58%	38%
<i>Cuidadosamente elaborado (Spain only)</i>	19%	26%	55%	35%
Precision-brewed (UK and US only)	25%	23%	51%	26%
Made from precision brewing (all countries except Spain)	24%	28%	49%	25%
Made from fermentation	23%	29%	48%	25%
Made from precision fermentation	23%	29%	47%	23%
Cultivated	24%	28%	47%	22%
Precision-fermented (UK and US only)	26%	25%	48%	22%
Fermentation-made (UK and US only)	27%	25%	48%	21%
Made from microflora	26%	29%	45%	19%
Microflora-made (UK and US only)	29%	25%	46%	16%
<i>Mikrobengebraut (Germany only)</i>	30%	32%	37%	7%
<i>Microbe-brewed (Germany only)</i>	33%	35%	32%	-1%

Notes: a negative response combined the two lowest options on a 5-point scale, ‘not sure’ or no opinion was the middle option and a positive response combined the two highest options. Net effectiveness was calculated as the difference between positive responses and negative responses. Terms in italics were not tested in English. Due to

¹⁰ ‘Animal-free’ was ranked the highest in Germany with a score of 3.7, Spain with 3.3, the UK with 3.9 and the US with 4.3. The lower the score within each country, the higher the ranking. A different number of terms were tested in each country, so the results are not comparable between countries.

¹¹ ‘Non-animal’ had a score of 3.6 while ‘animal-free’ scored 4.2 and was the 5th most appealing term in France.

¹² Net effectiveness was calculated as the difference between positive responses (e.g. ‘somewhat appealing’ and ‘very appealing’) and negative responses (e.g. ‘somewhat unappealing’ and ‘very unappealing’).

¹³ Selected terms were reported for net effectiveness for differentiating fermentation-derived dairy or eggs from conventional dairy or eggs in-text only: animal-free 50%, non-animal 45%, made from precision brewing 24%, made from fermentation 23%, cultivated 19%.

rounding, percentages may not add up to 100%.

During qualitative research, some participants provided quotes indicating uncertainty in how to view fermentation-derived protein products even with the clarifying terminology¹⁴, including one participant stating *“It’s still contradictory. If we just walked into a supermarket and we saw that and you go well, is it made with milk or not? Is it animal-free or not? It seems to contradict itself.”* (GFI 2025, pg. 54) and another stating *“I need to know whether this is plant-based or animal-based, so that I can watch out for what unhealthy ingredients or processes to look out for.”* (GFI 2025, pg. 54).

The authors noted that when using ‘animal-free’ as a name for fermentation-derived products, it was essential to also provide consumers with information on the process to avoid confusion around allergen information and to differentiate from plant-based products. However, it was unclear how the authors came to this conclusion as individuals with allergies were excluded from the qualitative studies and no questions were asked about consumer allergen understanding during the quantitative survey. There were some inconsistencies between the classification of terms tested in different countries between the methods and appendices of the report and limited information was provided on analysis methods.

Australian and New Zealand consumers were not included in any component of the study and therefore results may not be applicable to these consumers based on different population characteristics. However, at the time of the survey and this assessment, the UK, Spain, France and Germany did not have any fermentation-derived dairy products approved and therefore some sentiments on familiarity with the new technology may be similar to those held by Australian and New Zealand consumers.

1.3 How do milk-allergic consumers use and interact with vegan front-of-pack representations and back-of-pack allergen information?

The FSA (2024) conducted an online survey in December 2023 of consumers who have or buy food for individuals with food hypersensitivities¹⁵ (FHS) to allergens of animal origin (e.g. milk, eggs, fish, crustaceans or molluscs) (FSA 2024). The survey explored consumer use and understanding of vegan labelling. The nationally representative sample included 4,085 participants living in England, Wales or Northern Ireland aged between 16 and 75 years, weighted by age, gender and working status. Respondents were screened based on whether they and/or people they regularly shop for experienced bad reactions to allergens of animal origin. This resulted in a sample of 821 respondents (563 who experienced bad reactions themselves and 330 who regularly purchased food for someone that experienced bad reactions; there was an overlap with some responding yes to both). The allergen safety risks for vegan products in the context of this study came from cross-contamination rather than from ingredients that include animal-identical proteins (i.e. not fermentation-derived protein products).

The survey found that only 50% of respondents knew that vegan products might not be suitable for those with FHS to allergens of animal origin. Further, only 57% of respondents were aware they should check precautionary allergen labelling (e.g. ‘may contain’ statements) to determine whether a product was safe. Sixty two percent of consumers were either quite or very confident that vegan terminology meant a product was safe for those with a FHS to allergens of animal origin. Fifty seven percent of those with severe reactions (or who shop for someone with a severe reaction) were confident the term vegan meant the product was safe.

¹⁴ The placement of quotes in the report suggests they were given after participants received a definition of the fermentation process however this was not explicit.

¹⁵ Food hypersensitivity includes consumers with allergies and intolerances to allergens of animal origin.

There was evidence of misunderstanding what different labelling terms meant regarding safety for those with FHS, including 'free from [animal ingredient]' (a safe descriptor), 'vegan' and 'plant based'. Of all respondents, 68% were confident in the safety of products labelled 'free from [animal ingredient]', 63% were confident in those labelled 'plant based' and, as reported above, 62% were confident in those labelled 'vegan'. Additionally, when asked for the suitability of 'vegan' compared to 'free from [animal ingredient]' for FHS safety, 20% stated that vegan was most suitable, 30% said 'free from [animal ingredient]' and 40% stated they were equally suitable¹⁶.

Some respondents reported using vegan labelling as a proxy for allergen labelling for packaged food. 54%¹⁷ of people who have and 53%¹⁸ of people who shop for someone with a FHS reported at least sometimes doing this practice. Of those who reported at least sometimes using vegan labelling as a proxy for allergen labelling, 56% reported checking the ingredients list¹⁹, and 47% checked for cross-contamination risks (e.g. through 'may contain' statements) as additional actions to ensure the food is safe. Sixteen percent responded that they don't take any additional action.

The study authors noted that results should be interpreted with care due to potential sources of error not easily identified or corrected including sample imbalances and incorrect interpretations of survey questions by respondents. The authors also noted that online survey panels may not be representative of the population. Data was self-reported which may result in inaccurate recollection or socially desirable answers. There were also some differences in values reported between the text and figures of the report.

Dominguez et al. (2023) presented the results of one survey question related to vegan claims from a broader online survey of 1,080 Canadian adults with, or parents of a child with, a food allergy conducted in 2021. The other findings of the survey along with the study methods were reported elsewhere (Graham et al. 2025). Participants were selected from a Food Allergy Canada database or by targeting allergic consumers from a representative third-party panel of the general population. All food allergy diagnoses were confirmed by a medical professional. Limited demographic characteristics were reported for participants in both papers.

Respondents who stated that they or their child had an allergy to egg or milk (n = 211, 20% for egg and n = 211, 20% for milk) answered "when buying food products you will consume (or that will be consumed by your child with an allergy to egg or milk), how often, if ever, do you purchase products containing a vegan claim?". 337 respondents²⁰ answered the question with 14% responding 'never', 72% responding 'sometimes/depends on the situation' and 14% responding 'always'.

As in the FSA (2024) study, the allergen risk for plant-based vegan products that was investigated in Dominguez et al. (2023) was from cross-contamination, as conventional egg- and milk-based products are not generally included as ingredients. The survey did not explore any further reasons behind choosing products with a vegan claim (i.e. whether respondents considered vegan claims as proxies for allergen information) and it did not ask whether respondents looked at ingredients lists or allergen statements when purchasing

¹⁶ The remaining 10% is assumed to include responses for 'neither' or 'don't know' based on the questionnaire.

¹⁷ 54% reported in the text of the report but 53% reported in the associated figure.

¹⁸ 53% reported in the text of the report but 65% reported in the associated figure.

¹⁹ The preceding question included separate response options for packaged and non-packaged foods, with the question for checking the ingredients list or checking for cross-contamination risks asked to respondents who provided answers for either packaging option. The options included an example of asking service staff, which would not apply to packaged foods.

²⁰ The number of respondents with both an egg and milk allergy were not reported, but it is assumed there were some respondents with multiple food hypersensitivities.

these products. The study did not report any limitations for the online survey and did not provide any characteristics of the sample population, making it difficult to determine how applicable the findings are to the general Canadian population.

2. Can consumers accurately identify that beta-casein is a milk allergen if the ingredient list uses qualifiers such as 'animal-free' or 'vegan' in conjunction with the name 'beta-casein' and the mandatory declaration for 'milk'?

No studies directly examined the identification of beta-casein as a milk allergen in conjunction with ingredient qualifiers such as 'animal-free' or 'vegan'. One study indirectly explored general consumers' preferences for fermentation-derived food ingredient names (GFI 2025).

GFI (2025) tested the most appealing options for describing key fermentation-derived food ingredients (using the example of whey protein) in their quantitative survey (GFI 2025). Study sample and methods for the quantitative survey were described in sections 1.1 and 1.2 above. The study tested 18 ingredient name variations (two were only tested in Germany) where participants could select their preferred option from the list, including 'none of the above' (Table 2).

Table 2. Ingredient naming options for key fermentation-derived food ingredients (adapted from GFI 2025).

Ingredient name option	All-market average	France	Germany	Spain	UK	US
Animal-free whey protein	19%	11%	21%	15%	28%	20%
None of the above	10%	15%	11%	6%	10%	9%
Non-animal whey protein	10%	11%	13%	6%	12%	10%
Cultivated whey protein	7%	6%	6%	5%	7%	12%
Animal-free whey protein made from precision fermentation	6%	6%	4%	9%	5%	7%
Animal-free whey protein made from fermentation	6%	6%	7%	8%	5%	4%
Animal-free whey protein made from precision brewing	5%	4%	5%	6%	5%	6%
Whey protein made from precision brewing	5%	4%	4%	7%	5%	4%
Non-animal whey protein made from precision fermentation	5%	6%	5%	6%	3%	3%
Whey protein made from fermentation	4%	6%	3%	5%	3%	4%
Non-animal whey protein made from precision brewing	4%	5%	4%	5%	2%	4%
Whey protein made from precision fermentation	4%	4%	2%	4%	4%	5%
Non-animal whey protein made from fermentation	4%	6%	5%	3%	2%	2%
Cultivated whey protein made from precision fermentation	4%	4%	2%	6%	3%	4%
Cultivated whey protein made from fermentation	3%	3%	3%	5%	2%	3%
Cultivated whey protein made from precision brewing	3%	2%	2%	4%	2%	4%
Mikrobengebrautes Molkenprotein	2%	-	2%	-	-	-
Microbe-brewed Mikrogenprotein	0%	-	0%	-	-	-

The preferred naming approach across all countries was ‘animal-free whey protein’ at 19% (and for each individual country except France). ‘Non-animal whey protein’ (10%) was the next most preferred option, however ‘none of the above’ was equally ranked second at 10%. While ‘animal-free whey protein’ had a low overall percentage, it ranked much higher compared to options that included longer ingredient names (e.g. ‘animal-free whey protein made from precision fermentation’, 6%).

Participants were also asked to choose the most appealing individual components of the definition provided for the fermentation-derived protein production process during the

quantitative survey²¹. Across all countries, ‘without using animals’ (36%) and ‘produces the same proteins you’d find in cow’s milk or chicken eggs’ (29%) were the most appealing components of the descriptor.

The naming conventions presented in the report were not specifically tested with allergic consumers in mind, and there was no testing of whether these terms provided enough information to identify the protein product as a milk allergen.

Discussion

FSANZ considered three primary research papers and two reports to address the risk assessment questions (Broad et al. 2022; Dominguez et al. 2023; Powell et al. 2023; FSA 2024; GFI 2025). No studies directly explored consumer understanding of front-of-pack representations of ‘animal-free’ and allergic consumers’ interactions with allergen declarations for fermentation-derived beta-casein on the back-of-pack ingredients list.

1. Would consumers be confused or misled by voluntary front-of-pack representations such as ‘animal-free’ or ‘vegan’ when the ingredient list includes a ‘milk’ allergen declaration for the beta-casein ingredient? (e.g. would these kinds of front-of-pack claims deter people from checking the allergen declarations?)

From the available literature, there was evidence that general consumers were uncertain how to categorise fermentation-derived dairy products and may consider them as vegan, plant-based, or closer to conventional dairy products (Broad et al. 2022; Powell et al. 2023; GFI 2025). In one study, vegan consumers were less likely than non-vegan consumers to view the products as ‘animal-free’ (29.5% versus 50.7%) or ‘vegan’ (20.5% versus 31.0%), however it is not clear if other populations (e.g. milk-allergic consumers) would hold similar views to vegan consumers (Powell et al. 2023). Participants in one study expressed wanting to know more about the ingredients and the production process (GFI 2025). However, after reading a definition of the production process, they remained unsure of how to classify fermentation-derived dairy and whether the products were or were not made with milk or animals.

One study tested general consumers’ preferences for fermentation-derived dairy product names (GFI 2025). Before reading a definition of the production process, 26% of consumers across multiple markets considered the term ‘animal-free’ as most associated with plant-based products. However, after reading a definition of the production process, consumers considered ‘animal-free’ as the most appealing and effective at differentiating fermentation-derived protein products from conventional dairy and plant-based products. The margins between the preferred naming options were narrow, especially in the case of ‘non-animal’ which showed only slight differences in consumer appeal and ability to differentiate from plant-based or conventional dairy compared to ‘animal-free’.

People with food hypersensitivities to allergens of animal origin including milk, or who shop for people with these hypersensitivities may at least sometimes purchase products with a vegan claim (86% of Canadian consumers surveyed) or use voluntary front-of-pack ‘vegan’ labelling as a proxy for allergen information (over 50% of UK consumers surveyed) (Dominguez et al. 2023; FSA 2024). Of the UK consumers reporting this behaviour, only 56% checked the back-of-pack ingredients list and only 47% checked for cross-contamination

²¹ GFI 2025 described the fermentation-derived protein production process as “The process uses an innovative form of fermentation in some ways similar to brewing beer. The process encodes microorganisms with milk or egg DNA to produce the same proteins you’d find in cow’s milk or chicken eggs, without using animals. These proteins are used in dairy and egg products made in a new way.” (GFI 2025, pg. 54).

risks to help determine if a food was safe for consumption (FSA 2024).

Both GFI (2025) and the FSA (2025) noted that it was unclear whether the naming of fermentation-derived dairy products as 'animal-free' appropriately conveyed allergen information or created confusion for allergic consumers (FSA 2025; GFI 2025).

While the allergen risk in the FSA (2024) study was in the context of cross-contamination risk for allergens of animal origin, the general findings indicated that understanding of this terminology and associated safety behaviours for those with food hypersensitivities was of potential concern (FSA 2024). It was not clear how applicable these findings were to the context of fermentation-derived dairy products and the presence of ingredients with milk allergens (compared to cross-contamination).

2. Can consumers accurately identify that beta-casein is a milk allergen if the ingredient list uses qualifiers such as 'animal-free' or 'vegan' in conjunction with the name 'beta-casein' and the mandatory declaration for 'milk'?

There was no direct consumer evidence testing allergic consumers' abilities to identify beta-casein as a milk allergen in conjunction with 'animal-free' or 'vegan' representations and the mandatory milk declaration. GFI (2025) tested general consumer preferences for fermentation-derived food ingredient names across different markets (GFI 2025). They found that consumers found the term 'animal-free whey protein' the most appealing. It was unclear whether this naming convention conveyed enough information for allergic consumers.

There was no evidence available for either risk assessment question for Australian or New Zealand consumers. The results may not be generalisable to Australian or New Zealand consumers due to differences in population characteristics (e.g. food literacy, openness to new food technology or other diet and demographic differences). However, some countries explored in the available studies (e.g. UK and European Union countries) similarly have not regulated fermentation-derived dairy at the time of writing and therefore general awareness and knowledge of fermentation-derived dairy may be similar to Australian and New Zealand consumers.

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