



ADIC SUBMISSION



Australian Dairy Industry Council Inc.

FSANZ Application A1342 - Beta-casein protein preparation (BCPP1) from GM Komagataella phaffii

About us

This submission is informed by the perspectives of the dairy industry's peak and service bodies.

Australian dairy industry Council (ADIC)

The ADIC is the peak national body of the Australian dairy industry, representing the interests of dairy farmers and dairy processors through its two constituent bodies, Australian Dairy Farmers (ADF) and the Australian Dairy Products Federation (ADPF). It aims to create a more prosperous and sustainable future for the local industry and the regional communities that rely on it.

Australian Dairy Farmers

ADF is the national peak industry representative body for dairy farmers across Australia's six dairy-producing states. Its membership includes the State Dairy Farming Organisations from each state, as well as direct farmer members.

Australian Dairy Products Federation

ADPF is the national peak policy and advocacy body representing the post-farmgate members of the Australian dairy supply chain, including processors, traders and marketers. ADPF members process more than 90 per cent of Australian milk volumes and supply dairy products to domestic and export markets.

Dairy Australia

Dairy Australia is the national services body and research and development corporation (RDC) for the dairy industry. It is the industry's investment arm, funding research, development and extension that cannot be undertaken efficiently by individual farmers or companies and helping farmers adapt to a changing operating environment to achieve a profitable, sustainable industry

Signed



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FSANZ Application A1342 - Beta-casein protein preparation (BCPP1) from GM *Komagataella phaffii*

The Australian Dairy Industry Council (ADIC) appreciates the opportunity to comment on FSANZ Application A1342 (A1342). The application seeks to amend the Australia New Zealand Food Standards Code (the Code) to permit a beta-casein protein preparation (BCPP1), produced using a genetically modified strain of *Komagataella phaffii*, as an ingredient in a wide range of foods.

A1342 raises novel regulatory considerations because BCPP1 is produced through precision fermentation using a genetically modified yeast containing the bovine gene encoding A2 beta-casein, rather than being derived from milk.

ADIC recognises that this application forms part of a growing area of food production technology, with FSANZ considering an increasing range of foods and ingredients produced using novel technologies.

Given the likely growth in applications of this nature, ADIC considers it important that, where possible, common regulatory principles are established to support consistent and predictable assessment of future applications, rather than regulatory policy developing incrementally through individual approvals, while protecting public health and safety, supporting informed consumer choice and maintaining confidence in the food regulatory system.

We provide the following principles for consideration, along with associated recommendations.

Principles for A1342 and future applications

1. Science-based safety assessment

Consumer safety must remain paramount. Regulatory decisions must be based on robust scientific evidence appropriate to the nature, composition and intended use of the finished ingredient. Where significant components of an ingredient form part of the food supply, the evidence supporting safety conclusions should adequately characterise those components rather than relying unnecessarily on inference.

2. Truth in labelling and informed consumer choice

Consumers must receive clear and accurate information about the nature, source and method of production of foods and food ingredients. This is particularly important where a novel ingredient has structural or compositional similarities to a component of an established food but differs materially in its source or method of production. Labelling must also communicate relevant allergen risks clearly without creating a misleading impression about the origin or nature of the ingredient.

3. Protection and accurate use of established dairy terminology

Established and clearly defined dairy terminology must be used consistently with its recognised meaning, including relevant definitions and principles established in the Food Standards Code and Codex standards, including the General Standard for the Use of Dairy Terms (CXS 206-1999).

While the Code permits certain dairy terms to be used for non-dairy products where qualifying terminology makes the nature of the food clear, this approach should not be assumed to apply automatically to new categories of foods and ingredients produced using precision fermentation or other novel technologies.

ADIC continues to advocate for alignment with international standards. Accordingly, established dairy terms are reserved for milk, milk products and milk-derived ingredients in accordance with the principles of the Codex General Standard for the Use of Dairy Terms.

Foods and ingredients that are not derived from milk, including those produced through precision fermentation, should not acquire a dairy identity or use established dairy terminology merely because they contain a component that is structurally or functionally similar to one found in milk. The production of a protein with similarities to a component naturally occurring in milk should not, of itself, confer a dairy identity on the ingredient or a food containing it.

4. Evidence-based substantiation of equivalence and similarity

Claims or representations that imply nutritional or compositional equivalence or similarity must be supported by robust evidence and must not extend beyond what that evidence demonstrates. Evidence demonstrating similarity or equivalence between a particular protein and its bovine counterpart should not, by itself, establish nutritional or compositional equivalence between the finished ingredient, or a food containing it, and milk or dairy foods.

Application of these principles to A1342

1. Science-based safety assessment – strengthen the finished-product evidence base

ADIC notes FSANZ's conclusion that there are no public health and safety concerns associated with the proposed use of BCPP1, aside from the identified milk-allergen risk.

ADIC nevertheless considers that the evidence supporting this conclusion should adequately reflect the composition of the finished ingredient.

BCPP1 is described as a beta-casein protein preparation, yet beta-casein comprises approximately 5.5 per cent of the preparation. The protein fraction itself comprises approximately 25 per cent beta-casein and 75 per cent co-purified host cell proteins, while other constituents include a substantial carbohydrate fraction.

ADIC notes that aspects of the assessment infer the identity or nature of some non-beta-casein components from the production organism and manufacturing process rather than direct analysis of the finished preparation. Evidence concerning the history of safe use of the production organism should not, by itself, substitute for appropriate characterisation of material constituents present in the finished ingredient.

While scientifically justified inference can form part of a safety assessment, direct analytical characterisation of substantial components provides a stronger basis for confirming that the safety conclusion applies to the finished ingredient as a whole.

ADIC recommendation:

- **that FSANZ ensure its safety conclusions are supported by appropriate analytical characterisation of the major constituents of the finished BCPP1 preparation, including its material non-beta-casein protein and carbohydrate fractions.**

2. Truth in labelling and informed consumer choice – establish clear naming, origin and allergen requirements

ADIC agrees with FSANZ that ingredient-naming requirements apply to BCPP1 as a whole rather than to the beta-casein component alone. This distinction is important because beta-casein comprises approximately 5.5 per cent of BCPP1 and a name that places disproportionate emphasis on beta-casein may not adequately communicate the nature or composition of the preparation as a whole.

Consumers should also be able to distinguish between a protein or ingredient derived from milk and an ingredient produced through precision fermentation that contains a protein with similarities to a milk protein.

ADIC therefore considers that the ingredient name and associated labelling should communicate both the nature of the preparation and its production origin.

A standardised descriptor, such as 'precision-fermented' or 'fermentation-derived' would assist consumers to understand that the ingredient has not been derived from milk.

This is particularly important in relation to allergen communication.

ADIC supports mandatory communication of the milk-allergen risk associated with BCPP1.

However, the regulatory approach must communicate that risk without creating the inaccurate impression that BCPP1 itself is milk or has been derived from milk. The allergen declaration and ingredient description should therefore operate together to communicate both the allergen risk and the non-milk origin of the ingredient clearly.

ADIC recommendations:

- **Specify an appropriate name for BCPP1 for use in ingredient declarations that accurately reflects the preparation as a whole.**
- **Require clear identification of its fermentation-derived origin using an appropriate standardised descriptor.**
- **Ensure allergen requirements clearly communicate the milk-allergen risk while distinguishing the source and nature of BCPP1 from milk-derived ingredients.**

3. Protection and accurate use of established dairy terminology

A1342 highlights the need for consistency in dairy terminology as novel technologies enable production of components with similarities to those naturally occurring in milk, but which are not sourced from milk.

The Code currently recognises circumstances in which dairy terms may be used for non-dairy products where the context or qualifying terminology makes clear that the product is not a dairy food.

However, the emergence of precision-fermentation-derived and other novel ingredients raises different questions regarding source, composition and consumer understanding.

Existing conventions for plant-based products do not establish a precedent for the regulatory treatment of these new categories. The presence of a protein that is similar or equivalent in some respects to a single milk protein should not, by itself, provide a basis for conferring a dairy identity on either the ingredient or a food containing it.

In addition, ADIC is particularly concerned by the use of terms such as 'dairy analogue' in regulatory and consultation documents. 'Dairy analogue' is not formally defined in the Code and may imply an association or degree of comparability with dairy foods that has not been established.

Where FSANZ is referring specifically to plant-based products or beverages, these products must be described and assessed on the basis of their own nature, composition and nutritional profile, rather than by reference to dairy foods.

ADIC recommendations:

- **Apply established dairy terminology consistently with its recognised regulatory meaning.**
- **Existing conventions permitting qualified dairy terms for some non-dairy products do not establish a precedent for their application to precision-fermentation-derived or other novel foods and ingredients.**
- **Ensure terminology for emerging categories does not confer a dairy identity or use established dairy terms for products or ingredients that are not derived from milk, merely because they contain a component similar or equivalent to that found in milk.**
- **Avoid the terms 'dairy analogue', 'cheese analogue', 'yoghurt analogue' and similar terminology for products that are not dairy foods.**
- **Use terms such as 'plant-based product' or 'plant-based beverage' when referring specifically to plant-derived products and describe and assess them on the basis of their own nature, composition and nutritional profile.**

4. Evidence-based substantiation - prevent unsupported equivalence or similarity

The application compares the A2 beta-casein component of BCPP1 with bovine A2 beta-casein. Such comparison may be relevant to the scientific assessment of that component, but conclusions about an individual protein must not be extrapolated beyond the evidence available. This is particularly important given that the assessment identifies differences in protein quality relative to high-quality reference proteins.

In particular, similarity or equivalence between the 'precision fermentation' beta-casein component and bovine beta-casein does not establish nutritional or compositional equivalence between BCPP1 and milk, dairy protein ingredients or dairy foods.

Similarly, foods containing BCPP1 should not be represented as nutritionally or compositionally equivalent or similar to dairy foods solely because they contain a single protein that is structurally similar to a protein occurring naturally in milk.

Dairy foods provide a broader nutritional matrix comprising highly bioavailable proteins, vitamins, minerals and other constituents that cannot be represented by comparison with beta-casein alone.

ADIC recommendation:

- **that FSANZ ensure claims, descriptions and representations concerning nutritional or compositional equivalence or similarity are appropriately substantiated, are specific to the characteristic demonstrated, and do not imply whole-product equivalence or similarity where this has not been established.**

A consistent framework for future applications

A1342 illustrates how regulatory frameworks will increasingly need to address ingredients that reproduce individual components associated with established foods without being derived from those foods.

ADIC expects applications involving precision fermentation and related technologies to continue to grow. Addressing recurring regulatory questions solely through individual applications risks inconsistent outcomes. ADIC therefore encourages FSANZ to use A1342 and other relevant applications to develop, where appropriate, a consistent principles-based approach for future assessments.

At a minimum, such an approach should address science-based assessment of the finished ingredient; truth in labelling, including clear identification of the nature and production origin of an ingredient; accurate and consistent use of established food terminology, including consideration of how existing terminology and naming conventions should apply to emerging categories of foods and ingredients; clear communication of allergen risk; and evidence-based substantiation of claims of nutritional or compositional equivalence or similarity.

Establishing common principles would provide greater regulatory certainty for consumers, industry and applicants as this area develops, while ensuring that innovation occurs within a framework that protects public health and safety, informed consumer choice and the integrity of established food standards.

Conclusion

A1342 provides an important opportunity to establish sound and enduring regulatory principles for a growing area of food technology.

ADIC considers that science-based safety assessment, truth in labelling and informed consumer choice, protection and accurate use of established dairy terminology, and evidence-based substantiation of equivalence or similarity claims should underpin both A1342 and, where relevant, future applications.

Getting these principles right now will help avoid inconsistent regulatory outcomes and provide greater certainty for consumers, industry and future applicants.

ADIC welcomes the opportunity to work with FSANZ on the issues identified in this submission and on the development of a clear and consistent approach to future precision-fermentation-derived ingredients and foods.