21 July 2026
405-26

Call for submissions – Application A1344

A1344 - Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children

FSANZ has assessed an application made by Arla Foods Ingredients Group P/S to permit bovine milk fat globule membrane-enriched whey protein concentrate for use as an optional nutritive substance in formulated supplementary foods for young children and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub.

All submissions on applications and proposals will be published on the Consultation Hub. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published following consultation and before the next stage in the statutory assessment process.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at Making a submission.

For information on how FSANZ manages personal information when you make a submission, see FSANZ's Privacy Policy.

FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices. There is no need to send an email or hard copy of your submission if you have submitted it through the FSANZ Consultation Hub.

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 13 August 2026

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

For information about making a submission, visit the FSANZ website at current calls for public comment and how to make a submission.

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

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PO Box 5423
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Supporting document

The following document which informed the assessment of this Application are available on the A1344 page on the FSANZ website:

SD1 Risk and technical assessment – Application A1344

Executive summary

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Arla Foods Ingredients P/S to amend the Australia New Zealand Food Standards Code (the Code) to permit bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) to be used as an optional nutritive substance in formulated supplementary foods for young children (FSFYC) i.e. children aged 1–3 years.

The MFGM-WPC that is the subject of this application is the same as the MFGM-WPC previously assessed and approved for use as an optional nutritive substance in infant formula products under Application A1307 (FSANZ 2024). This application seeks to extend its use to FSFYC.

FSANZ's risk and technical assessment concludes that MFGM-WPC is an appropriate source of phospholipids for inclusion in FSFYC. Its use is consistent with its intended purpose to restore and enrich MFGM-derived components and support immune function, and does not raise health or safety concerns for children aged 1–3 years.

For reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit bovine MFGM-WPC for use as a nutritive substance in FSFYC in accordance with the Code.

If approved, the draft variation would amend Standard 2.9.1 and Schedule 29 to:

- permit the use of bovine MFGM-WPC for use as a nutritive substance in FSFYC subject to a maximum limit of 2.3 g per serving
- impose a labelling requirement that the average quantity, including any naturally occurring amount, of bovine MFGM-WPC and any other substance used as a nutritive substance in FSFYC (except lutein) must be declared in the Nutrition Information Panel on the label of the packaged food
- prescribe bovine MFGM-WPC as the permitted form of MFGM-WPC when used as a nutritive substance in FSFYC.

The proposed amendments would also revise and restructure the current provisions relating to nutritive substances (other than vitamins and minerals) permitted for voluntary use in FSCYC. At present, only lutein is permitted as an optional nutritive substance in FSFYC. The proposed amendments in the draft variation would not change the existing voluntary use, composition or labelling requirements for lutein in FSFYC.

MFGM-WPC is derived from bovine milk. Therefore, FSFYC to which MFGM-WPC has been added would be required to declare the presence of MFGM-WPC using the term milk in the statement of ingredients for the food.

An existing specification for bovine MFGM-WPC is set out in section S3—53 of Schedule 3 with which bovine MFGM-WPC would have to comply whenever it is added to FSFYC or sold for such use.

If approved, MFGM-WPC would be permitted to be used as an optional nutritive substance in FSFYC in accordance with the Code.

FSANZ now seeks submissions on the draft variation (Attachment A).

1 Introduction

1.1 The applicant

Arla Foods Ingredients P/S is a Danish food ingredient manufacturer supplying dairy-based ingredients, using standard whey processing techniques, for a variety of food applications and medical nutrition manufacturing formulations for all ages.

1.2 The application

The application seeks to amend the Australian New Zealand Food Standards Code (the Code) to permit bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) for use as an optional nutritive substance in formulated supplementary foods for young children (FSFYC). FSFYC is defined in subsection 1.1.2—3(2) of the Code as meaning a formulated supplementary food for children aged 1–3 years.

The applicant has not requested an exclusive use permission for their specific brand of MFGM-WPC.

MFGM-WPC is a whey protein concentrate sourced from bovine milk containing a higher concentration of MFGM lipid and protein components compared to standard whey protein concentrate.

The MFGM-WPC that is the subject of this application is the same as the MFGM-WPC previously assessed and approved for use as an optional nutritive substance in infant formula products under Application A1307 (FSANZ 2024). This application seeks to extend its use to FSFYC.

1.3 The current standard

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

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(b) requires that, unless expressly permitted, a food for sale must not have as an ingredient or component, a substance that was *used as a nutritive substance*.

Section 1.1.2—12 provides that a substance is *used as a nutritive substance* in relation to a food if it is added to that food to achieve a nutritional purpose and, among other things, is identified in the Code as one that may be used as a nutritive substance.

If the draft variation is approved, the applicant's MFGM-WPC would be *used as a nutritive substance* for the purposes of the Code because its use in FSFYC is intended to achieve specific nutritional purposes and it would be identified in the Code as a permitted nutritive substance.

1.3.2 Identity and purity

Section 1.1.1—15 requires that a substance that is *used as a nutritive substance* must comply with any relevant identity and purity specification set out in Schedule 3 when added to food in accordance with the Code or sold for use in food. There is an existing specification for MFGM-WPC in section S3—53 of Schedule 3.

1.3.3 Formulated supplementary foods for young children

Standard 2.9.3 regulates the composition and labelling requirements for formulated meal replacements and formulated supplementary foods, including FSFYC. Division 4 of this Standard sets out provisions specifically for FSFYC.

1.3.3.1 Composition of formulated supplementary foods for young children

Section 2.9.3—7 sets out composition requirements for FSFYC, including specific requirements for protein, energy, vitamins and minerals. It also provides for the voluntary addition of lutein as a nutritive substance, and separately permits the addition of inulin-type fructans or galacto-oligosaccharides in FSFYC. However, section 2.9.3—7 does not currently permit the use of bovine MFGM-WPC as a nutritive substance in FSFYC.

1.3.3.2 Microbiological limits

Section 1.6.1—2 provides unacceptable microbiological limits for foods listed in Schedule 27. FSFYC is not listed in Schedule 27. Microbiological limits for bovine MFGM-WPC are set out in section S3—53.

1.3.3.3 Labelling of formulated supplementary foods for young children

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

Division 3 of Standard 1.2.3 sets out the requirements for mandatory declarations of certain foods or their derivatives when they are present in a food for sale.

The Code requires food for sale to be labelled with a statement of ingredients in accordance with Standard 1.2.4. Subject to Division 3 of Standard 1.2.3, section 1.2.4—4 requires that ingredients be identified using:

- a name by which they are commonly known
- a name that describes their true nature, or
- a generic ingredient name if one is specified in Schedule 10 in accordance with any conditions specified in that Schedule.

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

Standard 1.2.8 sets out the nutrition information requirements for foods for sale required to be labelled under the Code, which also apply to FSFYC. These requirements include (but are not limited to):

- A nutrition information panel (NIP) setting out certain information, for example, the following information per serving of the food and a unit quantity of the food: the average energy content, and the average quantity of protein, carbohydrate, sugars, fat and sodium. The name and the average quantity of any other nutrients or biologically active substances must also be declared in the NIP in accordance with section 1.2.8—6 if a health or nutrition content claim is made about them (see section 1.2.8—6).[1]
- The NIP must be set out in a format in accordance with the relevant format prescribed in Schedule 12 unless the Code provides otherwise.

[1] 'Nutrition information panel', 'serving', 'average energy content', 'average quantity' and 'health claim' are defined in subsection 1.1.2—2(3) of the Code. 'Nutrition content claim' is defined in section 1.1.2—9 of the Code.

Section 2.9.3—8 sets out the specific labelling requirements for FSFYC. These include (but are not limited to):

- Declaration in a NIP on the label on a packaged FSFYC of the average quantity of any vitamin and mineral that is listed in Column 1 of the table to section S29—15 and used as a nutritive substance (section 2.9.3—8(1)).
- The label on the package of FSFYC must not indicate (by words or otherwise) that the product contains lutein unless the total amount of lutein is no less than 30 µg per serving (subsection 2.9.3—8(6)).

1.4 International regulations

1.4.1 Codex standard

The Codex Standard for Follow-up Formula for Older Infants and Product for Young Children Section B (CXS 156-1987) captures drinks and products for young children aged 12 months to 3 years with or without added nutrients (Codex 2023). CXS 156-1987 prescribes the essential and optional composition requirements, requirements for the labelling of these products, and specific permissions for flavourings. It does not contain specific provisions for MFGM-WPC, however it does contain provisions for 'optional ingredients' which would apply to the addition of substances such as MFGM-WPC.

1.4.2 International regulations

Formulated products for young children that contain or mention added MFGM-WPC or sphingomyelin are available in countries including, but not limited to, Greece, Great Britain, Ireland, Slovakia, Hungary, Poland, Spain, the Netherlands, Portugal, Czech Republic, Sweden, Singapore, Hong Kong, Peoples Republic of China, Thailand, Malaysia, Philippines, Indonesia, Vietnam, South Korea, Japan, Sri Lanka, South Africa, United Arab Emirates, Saudi Arabia, Egypt, Russia, Ukraine, United States of America, Canada, Colombia, Argentina, Peru and Mexico. In many of these countries, MFGM-WPC is listed as whey protein concentrate or whey protein concentrate (containing MFGM).

1.4.2.1 European Union

The use of bovine MFGM-WPC ingredients precedes the implementation date of the European Union (EU) novel food regulation and therefore is exempt from safety assessment required under that regulation. The applicant's MFGM-WPC has been consumed in formulated products for children aged 1–3 years sold in the EU for at least the past 15 years.

1.4.2.2 United Kingdom

On exiting the European Union, the United Kingdom (UK) adopted the majority of the EU food laws, including approved novel foods and those not deemed novel under the EU regulations. As MFGM-WPC falls into this latter category, it may be used in FSFYC in the UK.

1.4.2.3 United States of America

The applicant's MFGM-WPC is self-determined as Generally Recognized as Safe (GRAS) based on scientific procedures for its intended use. It is intended for use in foods other than infant formula, targeting the general population. This includes foods intended for children aged 1–3 years.

1.5 Reasons for accepting Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act)
- it related to a matter that warranted the variation of a food regulatory measure.

1.6 Procedure for assessment

The application is being assessed under the General Procedure in accordance with the FSANZ Act.

2 Summary of the assessment

2.1 Risk assessment

Food Standards Australia New Zealand (FSANZ) undertook a risk and technical assessment for the purposes of this Application (see SD1). The MFGM-WPC assessed in this application is the same as that previously assessed under Application A1307 and, therefore, FSANZ also had regard to its assessment of Application A1307. The outcomes of those assessments are summarised below.

MFGM-WPC is prepared from bovine milk using similar methods to those used to prepare standard whey protein concentrate (WPC). Additional filtration and concentration steps are applied to produce a WPC with concentrations of major milk fat globule membrane (MFGM) lipid and protein components that are 2 to 4 times higher than those in standard WPC. FSANZ determined that an addition level of approximately 4.5-6 g/L MFGM-WPC to FSFYC would result in phospholipid and sphingomyelin levels that are in the range of those reported for bovine milk.

The applicant has provided evidence that their MFGM-WPC could meet existing identity and purity specifications in the Code. FSANZ's risk and technical assessment confirmed that sphingomyelin, as set out in the existing specification, is an appropriate marker to quantify the presence of MFGM-WPC to FSFYC.

Following its assessment of Application A1307, FSANZ previously concluded that MFGM-WPC has an established history of safe use in many countries, with no case reports of adverse effects. No public health and safety concerns were identified in that assessment, except for individuals with milk protein allergies, but MFGM-WPC has no more allergenic potential than other bovine milk-based foods. No new information was identified to indicate a need to revise the conclusions of FSANZ's previous assessment for the purposes of Application A1344.

The nutrition assessment in Application A1344 found that the proposed use of MFGM-WPC in FSFYC does not raise nutrition concerns for children aged 1–3 years.

Estimated phospholipid intakes from MFGM-WPC in FSFYC, based on the maximum proposed use level, do not exceed the regulatory limits for phospholipids established for infant formula products in the Code. These limits provide a relevant benchmark for assessing phospholipid exposure in children aged 1–3 years. FSANZ has also assessed that the potential benefits of adding bovine MFGM-WPC to infant formula products would also apply if MFGM-WPC is added to FSFYC. These include anti-pathogenic effects, immunomodulation and support for the gut microbiome, although the magnitude of these effects may differ in children aged 1–3 years due to their more diverse diets and more established gut

microbiome.

No microbiological concerns associated with MFGM-WPC when added to FSFYC were identified.

Based on the available evidence FSANZ concludes there are no health and safety concerns from the addition of MFGM-WPC to FSFYC under the proposed use conditions.

2.2 Risk management

Formulated supplementary food is food specifically formulated as, and sold on the basis that it is, a supplement to a normal diet to address situations where intakes of energy and nutrients may not be adequate to meet an individual's requirements. FSFYC is a formulated supplementary food suitable for children aged 1–3 years. Changes to the composition of FSFYC must be established as safe and suitable prior to being permitted.

While the applicant notes that the addition of MFGM-WPC is intended to enrich milk-based FSFYC with MFGM-derived lipid and protein components, the proposed permission is not limited to such products and instead applies to all FSFYC. In some instances, milk-based beverages (e.g. young child formula) were used as the basis for assessment across FSFYC due to limited data on other product formats. In addition, powdered infant formula product was used in certain cases as a proxy for FSFYC products presented as beverages.

2.2.1 Risk management options

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation to the Code.

For the reasons set out in this report, FSANZ has decided to prepare a draft variation to the Code to permit MFGM-WPC for use as an optional nutritive substance in FSFYC, in accordance with the Code.

Further details on the proposed permission and associated proposed conditions are provided below. FSANZ has had regard to the requirements of the FSANZ Act (see section 2.4 below) in developing the draft variation.

2.2.2 MFGM-WPC for use as a nutritive substance in FSFYC

This application sought an amendment to the Code to permit MFGM-WPC for use as an optional nutritive substance in FSFYC. As stated above, FSANZ has previously assessed and approved the applicant's MFGM-WPC for use as an optional nutritive substance in infant formula products under Application A1307 (FSANZ 2024). The MFGM-WPC assessed in this application is the same as that previously assessed under Application A1307.

The Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods[2] sets out specific policy principles, including that the composition of special purpose foods should be consistent with the intended purpose. The applicant identified that the intended purpose for the addition of MFGM-WPC is to restore components that are reduced during processing of bovine milk and to enrich products with concentrated MFGM-derived lipid and protein components, as well as to contribute to the support of immune function in children aged 1–3 years.

[2] Policy guideline on intent of Part 2.9 of the Food Standards Code - Special purpose foods

A full substantiated health benefit assessment was carried out as part of Application A1307. The following benefits were identified: (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp. (FSANZ 2024). The assessment in Application A1344 determined that the mechanisms underlying these benefits are expected to be relevant when MFGM-WPC is added to FSFYC. However, the magnitude of any effect may differ due to the more diverse diet and more established gut microbiome in children aged 1–3 years. FSANZ considers that the evidence demonstrates that MFGM-WPC added to FSFYC would meet its intended purpose.

2.2.3 Public health and safety considerations

FSANZ's risk and technical assessment at (see SD1) reported no public health and safety concerns with the use of the applicant's MFGM-WPC in FSFYC at the proposed amount. This is supported by the assessment completed for Application A1307 which assessed the use of MFGM-WPC in infant formula products (FSANZ 2024).

Overall, FSANZ's assessment found that bovine MFGM-WPC is a safe and suitable ingredient in FSFYC and that its proposed use as a nutritive substance in FSFYC would meet its intended purpose.

2.2.4 Proposed maximum amount

The application seeks to permit the addition of MFGM-WPC to FSFYC at a maximum amount of 2.3 g per serving. FSANZ determines that this maximum amount equates to 771 mg phospholipids per litre (see section 2.2.2 of SD1). While this phospholipid level is higher than that present in bovine milk, consistent with the concentrated nature of MFGM-WPC, the dietary intake assessment indicates that estimated intakes from FSFYC remain below those associated with the maximum amount of phospholipid permitted in infant formula products, and is therefore appropriate for children aged 1–3 years.

FSANZ's risk and technical assessment does not identify any health and safety concerns arising from the addition of MFGM-WPC to FSFYC at the proposed maximum amount (see section 2.1 of this report and SD1).

The applicant does not request a minimum amount of MFGM-WPC. As FSFYC is not intended as a sole source of nutrition, a minimum amount was not considered necessary nor assessed by FSANZ in this application. Generally, minimum levels for optional nutritive substances in special purpose foods are set to ensure that, where added, they are present at levels sufficient to achieve their intended purpose.

FSANZ proposes to insert a new provision in Schedule 29 i.e. section S29—15A containing a table that lists optional nutritive substances (other than vitamins or minerals), including MFGM-WPC, that are permitted for addition to FSFYC. The table also sets out associated minimum and maximum levels for those nutritive substances, where applicable.

2.2.5 Sphingomyelin content as a condition in the permission

MFGM-WPC is a mixture of substances, and no analytical methods are currently available to directly quantify its addition. However, in Application A1307, FSANZ's assessment concluded that sphingomyelin, as a major phospholipid present in MFGM-WPC, is a suitable analytical marker to measure the addition of MFGM-WPC to infant formula products. For application A1344, the applicant seeks permission for sphingomyelin at a maximum of 40 mg per serving, on the basis that it is an appropriate marker of MFGM-WPC.

FSANZ considers the sphingomyelin content of the nutritive substance is already sufficiently characterised and constrained by the specification in section S3—53 of the Code (1.3 – 2.3%

sphingomyelin). Not including a condition of use that limits the total amount of sphingomyelin (from both added MFGM-WPC and naturally occurring sources) to 40 mg per serving provides greater flexibility where sphingomyelin is present in other ingredients.

2.2.6 Specification

Section 1.1.1—15 requires that a substance used as a nutritive substance must comply with any relevant identity and purity specification in Schedule 3 when added to food in accordance with the Code or sold for use in food.

A specification for bovine MFGM-WPC is set out in section S3—53 of the Code. This specification was inserted following approval of Application A1307.

Accordingly, MFGM-WPC would have to comply with the specification in section S3—53 when added to FSFYC for use as a nutritive substance in accordance with the Code (or sold for such use) (see section 2.4 of SD1).

2.2.7 Labelling

The applicant did not request any changes to existing labelling requirements in the Code. If the draft variation is approved, the general labelling requirements set out in section 1.3.3.3 of this report would therefore apply to FSFYC to which the applicant's MFGM-WPC has been added. FSANZ is also proposing to include declaration requirements for optional nutritive substances added to FSFYC, which are not vitamins or minerals (see section 2.2.7.2).

2.2.7.1 Mandatory allergen declarations

The applicant's MFGM-WPC is derived from bovine milk. FSANZ considers the potential for allergenicity of FSFYC that includes this nutritive substance to be similar to that of other bovine milk-derived products (see section 3.1.3 of SD1).

Allergen declaration requirements in Division 3 of Standard 1.2.3 would apply to FSFYC to which the applicant's MFGM-WPC has been added. In accordance with these Code requirements, the term 'milk' would be the required name and would need to be declared in conjunction with the applicant's MFGM-WPC in the statement of ingredients and in a summary statement on the label of the FSFYC.

2.2.7.2 Mandatory nutrition information

Under existing requirements for FSFYC (subsection 2.9.3—8(1)), the average quantity of any vitamin or mineral listed in Column 1 of the table to section S29—15 and used as a nutritive substance in the FSFYC would have to be declared in the NIP on the label of a packaged FSFYC.

As outlined in section 2.2.4 above, FSANZ is proposing to insert a new provision in Schedule 29 (section S29—15A) that would contain a table listing optional nutritive substances other than vitamins or minerals, which would be permitted for addition to FSFYC, including MFGM-WPC. FSANZ is also proposing to insert a new subsection in section 2.9.3—8 (subsection 2.9.3—8 (1A)) to require the average quantity of any substance listed in Column 1 of that table, except lutein, to be declared in the NIP on the label of a packaged FSFYC when used as a nutritive substance in the FSFYC (see item [3] of the draft variation). This requirement would apply regardless of whether a claim about the nutritive substance is made elsewhere on the label. This approach would align with existing declaration requirements for permitted nutritive substances in other special purpose foods and support informed consumer choice.

Lutein is expressly excluded from this labelling requirement, reflecting a previous assessment and regulatory decision in Application A0597. As such, existing NIP declaration requirements in the Code for lutein remain unchanged.

2.2.8 Risk management conclusions

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has decided to prepare a draft variation to the Code to permit MFGM-WPC for use as a nutritive substance in FSFYC.

If the draft variation is approved, the applicant's MFGM-WPC would be subject to relevant requirements and conditions in the Code, which include (but are not limited to) the following:

- It would be permitted to be added to FSFYC up to a maximum level of 2.3 g per serving.
- 'Bovine milk fat globule membrane-enriched whey protein concentrate' would be the permitted form.
- If added, the average quantity, including any naturally occurring amount, of the applicant's MFGM-WPC would have to be declared in the NIP. Existing general labelling requirements in the Code would also apply.
- Bovine MFGM-WPC must comply with the specification at section S3—53 of the Code, when added to FSFYC for use as a nutritive substance in accordance with the Code (or sold for such use).

Application A1344 also requested an amendment to Standard 2.9.3—7 to provide permission for sphingomyelin as an analytical marker for MFGM-WPC. While FSANZ's risk and technical assessment for Application A1307 confirmed sphingomyelin as a suitable analytical marker for MFGM-WPC (FSANZ 2024), FSANZ considers it appropriate that the permission should reflect the nutritive substance MFGM-WPC, rather than a single component of the substance (see section 2.2.5 of this report). Sphingomyelin content is instead set out in the specification for MFGM-WPC in section S3—53 of the Code (see section 2.2.6 of this report).

For clear management of optional nutritive substance permissions in FSFYC in the Code (other than permissions related to vitamins and minerals) in the future, FSANZ is proposing to restructure the permissions and associated requirements for the use of optional nutritive substances (other than vitamins and minerals) in FSFYC. In particular, FSANZ is proposing that permissions for all optional nutritive substance (other than vitamins and minerals) in FSFYC would be set out in Standard 2.9.3 and Schedule 29. There would be no substantive changes to the existing permission for lutein in FSFYC, as part of this application e.g. changes to its voluntary use, composition and labelling requirements. Amending Standard 2.9.3 and Schedule 29 as proposed in the draft variation (see below) would be consistent with the approach taken for optional nutritive substances added to other types of special purpose foods e.g. infant formula products.

2.2.9 Proposed regulatory approval

This application requested an amendment to Standard 2.9.3—7 to permit MFGM-WPC for use as an optional nutritive substance in FSFYC at a maximum amount of 2.3 g per serving.

FSANZ is proposing the following amendments to the Code:

Amendments to Standard 2.9.3:

- insert new subsection 2.9.3–7(2A) setting out when a substance may be used as a nutritive substance in FSFYC
- repeal existing subsection 2.9.3—7(4) that prescribes when lutein may be used as a nutritive substance in FSFYC (these requirements would be covered by proposed

new subsection 2.9.3–7(2A) (see above) and the proposed amendments to Schedule 29 (see below))
- insert new subsection 2.9.3–8(1A) requiring that the NIP on the label on a package of FSFYC must include a declaration of the average quantity (including any naturally occurring amount) of any substance used as a nutritive substance in FYSYC (except lutein) that is listed in Column 1 of the table to section S29—15A (see below).

Amendments to Schedule 29:

- insert new section S29—15A containing a table listing permitted optional nutritive substances in FSFYC and their associated minimum and maximum amounts per serve – this table would list MFGM-WPC up to 2.3 g per serving and lutein up to 100 µg per serving (no minimum amounts are prescribed for these substances)
- insert a new section S29—15B containing a table listing permitted forms of nutritive substances in FSFYC – this table lists 'bovine milk fat globule membrane-enriched whey protein concentrate' as the permitted form of MFGM-WPC and 'Lutein from *Tagetes erecta L*.' as the permitted form of lutein.

Amending the existing permission and its requirements for the use of lutein as an optional nutritive substance in FSFYC as proposed would be consistent with how permissions and associated requirements for the use of lutein as an optional nutritive substance in infant formula products are structured in the Code. The proposed amendments in the draft variation would not alter the existing voluntary use, composition or labelling requirements for lutein in FSFYC.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process.

FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the FSANZ Notification Circular, media release, FSANZ's digital channels and Food Standards News. Interested parties are also notified about the availability of reports for public comment.

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties of the draft variation.

The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received through this call for submissions.

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards and amending the Code to permit the voluntary use of bovine MFGM-WPC as a nutritive substance in FSFYC is unlikely to have a significant effect on international trade as the substance is already permitted in similar products overseas. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

FSANZ has assessed that a Regulation Impact Statement is not required for this application. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor in impact or deregulatory in nature as their use will be voluntary if the draft variation concerned is approved.

FSANZ had regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (as per paragraph 29(2)(a) of the FSANZ Act).

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the applicant's MFGM-WPC as an optional nutritive substance in FSFYC.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

Community
There is limited evidence on consumer awareness, understanding and potential behavioural response to the addition of MFGM-WPC to FSFYC. As a recent newly permitted ingredient in infant formula products in the Australian market, awareness is likely to be low but may increase over time as more consumers are exposed to the ingredient and related nutrition information labelling. International survey evidence presented by the applicant suggests that some consumers may have knowledge of MFGM-WPC and would prefer to purchase a FSFYC with this ingredient. While no Australian and New Zealand data is available, some consumers may benefit from increased product choice. There is no evidence to suggest that any subpopulations (e.g., particular cultural groups) will experience differential impacts from the addition of MFGM-WPC to FSFYC.

It is possible that industry may achieve some price premium for this product in the short-term, which may affect purchasers of FSFYC containing the applicant's MFGM-WPC. However, historically price premiums typically exist for a short period before useful innovations become a standard feature across the market meaning better quality products for consumers at a similar or sometimes lower price.

Industry
If the draft variation is approved, the proposed permissions provided by that draft variation would apply to FSFYC products manufactured and/or sold in Australia and New Zealand.

Domestic manufacturers and importers of FSFYC products that contain the applicant's MFGM-WPC would be permitted to sell their products in Australia and New Zealand (where the products fully comply with the Code).

Given the applicant's MFGM-WPC is already being widely used in some overseas countries (see section 1.4.2 of this report) the proposed permission may favour trade and growth of overseas markets for exporters of FSFYC in Australia and New Zealand. On the other hand, producers of FSFYC products in Australia and New Zealand may also face greater competition from overseas-based producers of FSFYC.

Government
If the draft variation is approved, the draft variation might result in a small but likely inconsequential cost to Australian and New Zealand governments in terms of monitoring for compliance.

Conclusion of costs and benefits
FSANZ's assessment is that the direct and indirect benefits that would arise from permitting use of the applicant's MFGM-WPC as proposed are likely to outweigh the associated costs.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than this food regulatory measures proposed as a result of the application.

2.4.1.3 Any relevant New Zealand standards

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

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

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

2.4.2.1 Protection of public health and safety

FSANZ completed a risk and technical assessment (SD1) which is summarised in section 2.1 of this report. In doing so, FSANZ considered the evidence of any public health and safety risk associated with the intake of the applicant's MFGM-WPC, as well as the intended purpose of addition in FSFYC. FSANZ's assessment concludes that at the proposed amount, this MFGM-WPC is an appropriate source of phospholipids for inclusion in FSFYC. Its use is consistent with its intended purpose to restore and enrich MFGM-derived components and support immune function, and does not raise health or safety concerns for children aged 1–3 years.

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

Current labelling requirements outlined in section 1.3.3.3 of this report would apply to FSFYC containing the applicant's MFGM-WPC and would provide information to enable consumers to make an informed choice.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements of this report that aim to prevent misleading or deceptive conduct, would apply to FSFYC containing the applicant's MFGM-WPC.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

Using the risk analysis framework[3], FSANZ has considered the best available scientific evidence to reach its conclusions on the safety, technical outcomes and intended purpose of MFGM-WPC in FSFYC.

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

FSANZ considered the promotion of consistency between domestic and international food standards and the desirability of an efficient and internationally competitive food industry. The applicant's MFGM-WPC is permitted for addition to FSFYC equivalent products in many overseas jurisdictions. The proposed permission would promote consistency between domestic and several international food standards.

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

The proposed permission would support an internationally competitive food industry (see section 2.4.1.1 of this report).

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

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

As part of assessing Application A1344, FSANZ has had regard to both high order and specific policy principles in the Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods.

Noting the risk and technical assessment set out in SD1 and section 2.1 of this report; as well as the assessment above of the FSANZ Act requirements, FSANZ considers this policy guideline would be met by the proposed permission, if approved.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

[3] Risk analysis and assessment | Food Standards Australia New Zealand

4 References

Codex Alimentarius Commission (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. Codex CXS 156-1987. Codex Alimentarius Commission, Rome. Available online at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B156-1987%252FCXS_156e.pdf

FSANZ (2024) A1307 - Milk fat globule membrane as a nutritive substance in infant formula products. Supporting Document 1 – Risk and technical assessment at approval. Food Standards Australia New Zealand, Canberra Accessed from https://www.foodstandards.gov.au/sites/default/files/2025-05/A1307%20SD1%20at%20approval_1.pdf

Attachments

A. Draft variation to the Australia New Zealand Food Standards Code
B. Draft Explanatory Statement

Attachment A – Draft variation to the Australia New Zealand Food Standards Code

Food Standards (Application A1344 – Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children) Variation

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The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position title]
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC XX on XX Month 20XX. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1344 – Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children) Variation*.

2 Variation to Standards in the *Australia New Zealand Food Standards Code*

The Schedule varies Standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

Standard 2.9.3—Formulated meal replacements and formulated supplementary foods

[1] After subsection 2.9.3—7(2)

Insert:

(2A) A substance may be *used as a nutritive substance in a formulated supplementary food for young children if:

(a) the substance is listed in Column 1 of the table to section S29—15A; and

(b) the total of the naturally occurring and added amount of the substance in a serving is not less than the amount, if any, set out in relation to that substance in Column 2 of the table; and

(c) the total of the naturally occurring and added amount of the substance in a serving is not more than the amount, if any, set out in relation to that substance in Column 3 of the table; and

(d) the substance is in a permitted form specified in the table to section S29—15B.

[2] Subsection 2.9.3—7(4)

Repeal the subsection.

[3] After subsection 2.9.3—8(1)

Insert:

(1A) The nutrition information panel on the label on a package of formulated supplementary foods for young children must include a declaration of the *average quantity (including any naturally occurring amount) of any substance, except lutein, that:

(a) is listed in Column 1 of the table to section S29—15A; and

(b) is *used as a nutritive substance in the food.

Schedule 29—Special purpose foods

[4] After section S29—15

Insert:

S29—15A Optional nutritive substances in formulated supplementary food for young children

For subsections 2.9.3—7(2A) and 2.9.3—8(1A), the table is set out below:

Optional nutritive substances in formulated supplementary food for young children

Column 1	***Column 2***	***Column 3***
Substance	*Minimum amount per serve*	*Maximum amount per serve*
Lutein		100 µg

Milk fat globule membrane-enriched whey protein concentrate	2.3 g

S29—15B Permitted forms of nutritive substances in formulated supplementary food for young children

For subsection 2.9.3—7(2A), the table is set out below:

Permitted forms for nutritive substances used in formulated supplementary food for young children

Column 1 *Substance*	***Column 2*** *Permitted forms*
Lutein	Lutein from *Tagetes erecta L*.
Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate

Attachment B – Draft Explanatory Statement

DRAFT EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1344 – Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children) Variation

1. Authority

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

The Authority accepted Application A1344 which sought to amend the Code to permit milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) for use as an optional nutritive substance in formulated supplementary foods for young children (FSFYC).

The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1344 – Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children) Variation* (the draft variation).

2. Variation will be a legislative instrument

If approved, the draft variation would be a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and be publicly available on the Federal Register of Legislation (www.legislation.gov.au).

If approved, this instrument would not be subject to the disallowance or sunsetting provisions of the *Legislation Act 2003.* Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunsetting if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunsetting legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the Food Ministers Meeting (FMM). The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards on gazettal and registration are incorporated into and become part

of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

3. Purpose

The Authority has prepared a draft variation to permit bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) for use as an optional nutritive substance in FSFYC.

4. Documents incorporated by reference

The draft variation prepared by the Authority does not incorporate any documents by reference.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1344 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for a 4-week period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

A regulation impact statement (RIS) has not been prepared. FSANZ's assessment is that a RIS is not required for this application. This is on the basis that the application is minor and deregulatory in nature. Also, the application seeks to permit the use of nutritive substance found to be safe and, if the draft variation concerned is approved, that use will be voluntary.

6. Statement of compatibility with human rights

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

7. Variation

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1344 – Milk fat globule membrane-enriched whey protein concentrate for use as a nutritive substance in formulated supplementary foods for young children) Variation*.

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

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

Items [1] and **[2]** of the Schedule to the variation would amend section 2.9.3—7 of Standard 2.9.3 of the Code.

Standard 2.9.3 contains compositional and labelling requirements for formulated meal replacements and formulated supplementary foods. The Standard also includes provisions setting out when vitamins and minerals (and for FSFYC – lutein) may be permitted to be used as nutritive substances in those foods.

FSFYC means a formulated supplementary food for children aged 1 to 3 years (see subsection 1.1.2—3(2) of the Code).

Section 1.1.2—12 of the Code provides that a substance is used as a nutritive substance in relation to a food if it is added to that food to achieve a nutritional purpose and, among other things, is identified in the Code as one that may be used as a nutritive substance.

Division 4 of this Standard contains compositional and labelling requirements for; and sets out when other substances may be added to, FSFYC.

Section 2.9.3—7 prescribes compositional requirements for FSFYC.

Item [1] would insert a new subsection 2.9.3—7(2A) after existing subsection 2.9.3—7(2).

New subsection 2.9.3—7(2A) prescribes when a substance may be used as a nutritive substance in an FSFYC. According to this proposed new provision, a substance may be used as a nutritive substance in an FSFYC if all of the following conditions are satisfied:

- the substance is listed in Column 1 of the table to section S29—15A (see **item [4]** below); and
- the total of the naturally occurring and added amount of the substance in a serving is not less than the amount, if any, set out in relation to that substance in Column 2 of the table; and
- the total of the naturally occurring and added amount of the substance in a serving is not more than the amount, if any, set out in relation to that substance in Column 3 of the table; and
- the substance is in a permitted form specified in the table to section S29—15B (see **item [4]** below).

Nutritive substances to which this provision applies are *optional nutritive substances* because their addition to FSFYC would not be mandatory – it would be permitted.

'Serving' means an amount of the food which constitutes one normal serving when prepared according to manufacturer's directions or when the food requires no further preparation before consumption, and in the case of a formulated meal replacement is equivalent to one meal (see subsection 1.1.2—2(3) of the Code).

Item [2] repeals existing subsection 2.9.3—7(4).

Subsection 2.9.3—7(4) is a provision setting out when lutein may be used as a nutritive substance in FSFYC.

This proposed amendment is consequential to the amendments proposed in **items [1]** (above) and **[4]** (below). This is because if the draft variation is approved, the proposed amendments in **items [1]** and **[4]** would capture the existing requirements for using lutein as a nutritive substance in FSFYC and, as a consequence, subsection 2.9.3—7(4) would no longer be necessary.

The proposed amendments would not make any substantive changes to the existing voluntary use, composition or labelling requirements for lutein in FSFYC.

Item [3] of the Schedule to the variation would amend section 2.9.3—8 of Standard 2.9.3.

Section 2.9.3—8 prescribes labelling requirements for FSFYC.

Item [3] would insert a new subsection 2.9.3—8(1A) after existing subsection 2.9.3—8(1).

New subsection 2.9.3—8(1A) requires that the nutrition information panel on the label on a package of FSFYC must include a declaration of the average quantity (including any naturally occurring amount) of any substance, except lutein, that is:

- listed in Column 1 of the table to section S29—15A; and
- used as a nutritive substance in the food.

'Nutrition information panel' means a nutrition information panel that is required to be included on a label on a package of food in accordance with Standard 1.2.8 (see subsection 1.1.2—2(3) of the Code).

'Average quantity' of a substance in a food means the average, for such foods from that producer or manufacturer, of:

- where a serving or reference amount is specified—the amount of the substance that such a serving or reference amount contains; or

- otherwise—the proportion of that substance in the food, expressed as a percentage (see subsection 1.1.2—2(3) of the Code).

The term 'package' is also defined in subsection 1.1.2—2(3) of the Code. According to that definition, 'package' means any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged. If food is carried or sold or intended to be carried and sold in more than one package—the term includes each package. The definition of 'package' specifically excludes certain things including (but not limited to): a crate and packages which do not obscure labels on the food, a vending machine, a hamper or a transportation vehicle.

The aim of this proposed amendment is to create a requirement for the average quantity of an optional nutritive substance, other than lutein, that may be added to FSFYC to be included on the nutrition information panel. This approach would align with existing declaration requirements for permitted nutritive substances in other special purpose foods and support informed consumer choice. Lutein is explicitly excluded from this labelling requirement, reflecting a previous assessment and regulatory decision in Application A0597.

Item [4] of the Schedule to the variation would amend Schedule 29 by inserting new sections S29—15A and S29—15B into the Schedule, each containing a table. These new provisions would be inserted after section S29—15.

New section S29—15A contains a table listing the nutritive substances which FSFYC may contain for the purposes of subsections 2.9.3—7(2A) and 2.9.3—8(1A) (see **items [1]** and **[3]** above). The table to this section also sets out the corresponding limits for each substance.

The table to new section S29—15A lists the following substances in Column 1 of the table and their associated maximum limits in Column 3 of the table:

Lutein	100 µg
Milk fat globule membrane-enriched whey protein concentrate	2.3 g

No minimum limits are prescribed for those substances.

New section S29—15B contains a table listing the permitted form for each nutritive substance that may be used in FSFYC for the purposes of subsection 2.9.3—7(2A) (see **item [1]** above).

The table to new section S29—15B lists the following substances in Column 1 of the table and their associated permitted forms in Column 2 of the table:

Substance	*Permitted forms*
Lutein	Lutein from *Tagetes erecta L*.
Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate

If the draft variation is approved, the effects of the proposed amendments would be:

- bovine milk fat globule membrane-enriched whey protein concentrate would be permitted to be used as a nutritive substance in FSFYC in accordance with the Code and subject to the following conditions:
  - the amount of MFGM-WPC in FSFYC must not be greater than 2.3 g per serving; and
  - the permitted form of MFGM-WPC is bovine MFGM-WPC; and
- lutein would continue to be permitted to be used as a nutritive substance in FSFYC in accordance with the Code, but under the proposed new provisions in Standard 2.9.3 and Schedule 29 - there would be no substantive changes to the existing permission for lutein.