**11 November 2026**
**420-26**

# Approval report – Application A1344

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

Food Standards Australia New Zealand (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.

On 9 July 2026, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 15 submissions.

FSANZ approved the draft variation on 28 October 2026. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 11 November 2026.

This report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991*.

[1] Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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## Supporting document

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

SD1 Risk and technical assessment – Application A1344 (at Approval)

The published submissions from the call for submissions can be found on the A1344 Consultation Hub page.

# Executive summary

Food Standards Australia New Zealand (FSANZ) assessed an application made by Arla Foods Ingredients Group 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 sought to extend its use to FSFYC.

FSANZ's risk and technical assessment concluded 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.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 9 July to 13 August 2026. Fifteen submissions were received and each was considered as part of our assessment.

For reasons set out in the report, FSANZ has approved the draft variation proposed at the call for submissions with one amendment. The approved draft variation will permit bovine MFGM-WPC for use as a nutritive substance in FSFYC in accordance with the Code.

The approved draft variation will amend Standard 2.9.3 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 as specified 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 approved draft variation will also revise and restructure the provisions relating to nutritive substances (other than vitamins and minerals) permitted for voluntary use in FSFYC. At present, lutein is the only optional nutritive substance permitted in FSFYC. The approved draft variation will 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 will 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 will have to comply whenever it is added to FSFYC or sold for such use.

The effect of the approved draft variation is that MFGM-WPC will be permitted to be used as an optional nutritive substance in FSFYC in accordance with the Code.

# 1 Introduction

## 1.1 The applicant

Arla Foods Ingredients Group 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 sought to amend the Australia 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 did not request an exclusive use permission for their specific brand of MFGM-WPC.

MFGM-WPC is a whey protein concentrate 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 sought 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.

The applicant's MFGM-WPC will 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 will 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.

#### *1.3.3.2 Microbiological specification*

Microbiological specifications 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 (among other things) per serving and unit quantity information of the food, e.g. 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).[2]
- The NIP must be set out in accordance with the relevant format prescribed in Schedule 12 unless the Code provides otherwise.

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)).

[2] '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.

- 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 standards

### 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 will 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 was assessed under the General Procedure in accordance with the FSANZ Act.

## 1.7 Decision

The draft variation as proposed following assessment was approved with an amendment. An amendment was made to item [3] of the draft variation, to require that the declaration of the average quantity in the NIP for permitted optional nutritive substances in FSFYC be expressed in grams, milligrams or micrograms per serving. This requirement will provide clarity and be consistent with other similar nutrition declaration requirements in the Code.

The approved draft variation (as amended) will take effect on the date of gazettal of the variation. The approved draft variation is at Attachment A.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

# 2 Summary of the findings

## 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 9 July to 13 August 2026. FSANZ received 15 submissions to the call for submissions (CFS) (see Table A1 in Appendix 1). Submissions were received from 5 industry stakeholders, 4 government agencies, 2 public health stakeholders and 4 individuals. Seven submitters supported FSANZ's assessment and draft regulatory measure, 6 did not support, and 2 indicated they both supported and did not support parts of the draft regulatory measure. While the majority supported the use of MFGM-WPC as an optional nutritive substance in FSFYC, some submitters raised concerns, particularly about the level of available evidence demonstrating nutritional purpose and the interaction with Proposal P1066 – Review of young child formula.

A summary of submissions and FSANZ's responses is provided at Appendix 1, table A1.

The submissions are publicly available on the FSANZ website A1344 Consultation Hub page.

## 2.2 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 those based on the regulatory limit 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 an anti-pathogenic effect, immunomodulation and development of the gut microbiome through supporting growth of *Bifidobacteria* spp, 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.

## 2.3 Risk management

### 2.3.1 Risk management options

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 9 July to 13 August 2026. The risk management options available to FSANZ after the submission period were to either:

- approve the draft variation proposed following assessment
- approve the draft variation subject to such amendments as FSANZ considers necessary
- reject the draft variation.

For the reasons outlined in this report, FSANZ has decided to approve the draft variation proposed at the CFS with an amendment to clarify the units for declaration of average quantity in the NIP. The approved draft variation will permit bovine MFGM-WPC for use as a nutritive substance in FSFYC in accordance with the Code.

The risk management considerations for the approved draft variation are provided below. FSANZ has had regard to the requirements of the FSANZ Act in developing and approving the draft variation (see section 2.5 of this report).

### 2.3.2 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[3] 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.

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 will meet its intended purpose.

### 2.3.3 Public health and safety considerations

FSANZ's risk and technical assessment (see SD1) reported no public health and safety concerns with the use of the applicant's MFGM-WPC in FSFYC at the permitted 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 use as a nutritive substance in FSFYC will meet its intended purpose.

### 2.3.4 Proposed maximum amount

This application sought to permit the addition of MFGM-WPC to FSFYC at a maximum amount of 2.3 g per serving. FSANZ determined 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 indicated that estimated intakes from FSFYC remain below those associated with the maximum amount of phospholipid permitted in infant formula products, and are therefore appropriate for children aged 1–3 years.

FSANZ's risk and technical assessment did not identify any health and safety concerns arising from the addition of MFGM-WPC to FSFYC at the approved maximum amount (see section 2.2 of this report and SD1).

The applicant did 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.

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

The approved draft variation will 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.

### 2.3.5 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 sought permission for sphingomyelin at a maximum of 40 mg per serving, on the basis that it is an appropriate marker of MFGM-WPC.

FSANZ considered 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.

### 2.3.6 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 will 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).

### 2.3.7 Labelling

The applicant did not request any changes to existing labelling requirements in the Code. The general labelling requirements for allergen declarations, ingredients, nutrition content and health claims and the NIP set out in section 1.3.3.3 of this report will apply to FSFYC to which the applicant's MFGM-WPC has been added. The approved draft variation also includes declaration requirements for MFGM-WPC as an optional nutritive substance when added to FSFYC (see section 2.3.7.2).

#### *2.3.7.1 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 3.1.4 of SD1).

Allergen declaration requirements in Division 3 of Standard 1.2.3 will apply to FSFYC to which the applicant's MFGM-WPC has been added. In accordance with these Code requirements, the term 'milk' will be the required name and will 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.

#### *2.3.7.2 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 must be declared in the NIP on the label of a packaged FSFYC.

As outlined in section 2.3.4 above, the approved draft variation will insert a new provision in Schedule 29 (section S29—15A) that contains a table listing optional nutritive substances other than vitamins or minerals, which are permitted for addition to FSFYC, including MFGM-WPC.

The approved draft variation will also 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 approved draft variation).

In addition, a submission was received in response to the CFS, which suggested specifying the units in which the average quantity is to be expressed in the NIP. FSANZ agreed with that submission, noting the amendment would provide clarity to stakeholders and would be consistent with recently updated provisions in Standard 2.9.1. FSANZ has amended item [3] of the draft variation proposed at the call for submissions. Consequently, new subsection 2.9.3—8 (1A) will now also require that the average quantity required by this new subsection be expressed in grams, milligrams or micrograms per serving (see item [3] of the draft variation).

At the time of approval, these labelling requirements will only apply to MFGM-WPC. These requirements will apply regardless of whether a claim about MFGM-WPC is made elsewhere on the label and will align with other nutrition declaration requirements in the Code.

Lutein will be 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.

These requirements will provide information in the NIP about MFGM-WPC when used as a nutritive substance in FSFYC, so that its presence and quantity will be readily identifiable for consumers and health professionals. These requirements will support transparency, informed use and accurate representation of the product's nutritional composition. The approach is consistent with the Ministerial Policy Guideline for Special Purpose Foods, which states that labelling of special purpose foods should provide adequate information to assist consumers to understand their specific nature. It is also consistent with the mandatory declaration of nutritive substances used in other special purpose foods, such as infant formula and follow-on formula.

### 2.3.8 Risk management conclusions

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

The applicant's MFGM-WPC will be subject to relevant requirements and conditions in the Code, which include (but are not limited to) the following:

- It will 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' will be the permitted form.

- If added, the average quantity, including any naturally occurring amount, of the applicant's MFGM-WPC will have to be declared in the NIP. The average quantity must be expressed in grams, milligrams or micrograms per serving. Existing general labelling requirements in the Code will 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 considered it appropriate that the permission should reflect the nutritive substance MFGM-WPC, rather than a single component of the substance (see section 2.3.5 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 clearer management of permissions for optional nutritive substances other than vitamins and minerals in FSFYC, FSANZ has decided to restructure the Code so that these permissions and associated requirements will be set out in Standard 2.9.3 and Schedule 29. This will result in no substantive change to the existing permission for lutein in FSFYC, as assessed in A0597, including its voluntary use and associated composition and labelling requirements. The approved draft variation (see section 2.3.9) is consistent with the approach taken for optional nutritive substances in other special purpose foods.

### 2.3.9 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.

The approved draft variation will make 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 will be covered by new subsection 2.9.3–7(2A) (see above) and the 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. The average quantity must be expressed in grams, milligrams or micrograms per serving. (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 will 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 will list '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.

The amendments to the existing permission and its requirements for the use of lutein as an

optional nutritive substance in FSFYC are 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 amendments in the approved draft variation will not alter the existing voluntary use, composition or labelling requirements for lutein in FSFYC.

## 2.4 Risk communication

### 2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. The CFS was notified via the FSANZ Notification Circular, media release, FSANZ's digital channels and Food Standards News. Interested parties were also notified about the availability of reports for public comment.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties of the draft variation. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to all submissions made during the CFS period.

## 2.5 FSANZ Act assessment requirements

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

### 2.5.1 Section 29

#### *2.5.1.1 Consideration of costs and benefits*

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.

*Community*

There is limited evidence on consumer awareness, understanding and potential behavioural response to the addition of MFGM-WPC to FSFYC. As a recently 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 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*

The permissions that will be provided by the approved draft variation will 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 will 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 approved 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*

The approved 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 will arise from permitting use of the applicant's MFGM-WPC are likely to outweigh the associated costs.

#### *2.5.1.2 Other measures*

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

#### *2.5.1.3 Any relevant New Zealand standards*

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

#### *2.5.1.4 Any other relevant matters*

Other relevant matters are considered below.

### 2.5.2. Subsection 18(1)

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

#### *2.5.2.1 Protection of public health and safety*

FSANZ completed a risk and technical assessment (SD1) which is summarised in section 2.2 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 concluded that MFGM-WPC added at a level of 2.3 g per serving 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.

#### *2.5.2.2 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 and section 2.3.7 of this report will apply to FSFYC containing the applicant's MFGM-WPC and will provide information to enable consumers to make an informed choice.

#### *2.5.2.3 The prevention of misleading or deceptive conduct*

Current labelling requirements in the Code that aim to prevent misleading or deceptive conduct will apply to FSFYC containing the applicant's MFGM-WPC.

### 2.5.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

Using the risk analysis framework[4], 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. This permission will promote consistency between domestic and several international food standards.

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

The approved draft variation will 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 Food Ministers' Meeting**

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

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 has been met.

# 3 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) Application 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. Approved draft variation to the Australia New Zealand Food Standards Code
B. Explanatory Statement
C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

# Attachment A – Approved 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**

---

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, expressed in grams, milligrams or micrograms per serving, 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 – Explanatory Statement

## 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 a 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 approved 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 approved draft variation).

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

### 2. Variation is a legislative instrument

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

This instrument is not 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 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 approved a draft variation amending Standard 2.9.3 and Schedule 29 of the Code 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 approved 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 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 9 July 2026 to 13 August 2026. 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 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

## 6. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

## 7. Variation

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

### *Schedule to the variation*

**Items [1]** and **[2]** of the Schedule to the variation amends 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 Standard 2.9.3 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]** inserts 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 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) prescribes 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 the amendments in **items [1]** and **[4]** capture the existing requirements for using lutein as a nutritive substance in FSFYC and, as a consequence, subsection 2.9.3—7(4) is no longer necessary.

The amendments do 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 amends section 2.9.3—8 of Standard 2.9.3.

Section 2.9.3—8 prescribes labelling requirements for FSFYC.

**Item [3]** inserts 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, expressed in grams, milligrams or micrograms per serving, 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 aims of the amendment in **item [3]** are to require that:

- the average quantity of an optional nutritive substance, other than lutein, that may be added to FSFYC be included on the nutrition information panel, and
- that average quantity be expressed in grams, milligrams or micrograms per serving.

This approach aligns with existing declaration requirements for permitted nutritive substances in other special purpose foods and supports 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 amends Schedule 29 by inserting new sections S29—15A and S29—15B into the Schedule, each containing a table. These new provisions are inserted after section S29—15.

New section S29—15A contains a table listing the nutritive substances which FSFYC may contain for the purposes of new 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 new 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 |

The effects of the amendments in **items [1]**, **[2]** and **[4]** of the variation are:

- bovine milk fat globule membrane-enriched whey protein concentrate is 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 and under the new provisions in Standard 2.9.3 and Schedule 29 - there would be no substantive changes to the existing permission for lutein.

FSFYC containing MFGM-WPC is subject to all relevant labelling requirements in the Code, including the requirements in **item [3]** of the variation.

# Attachment C – Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

**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 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 |

# Appendix 1 – Summary of issues raised in submissions

**Table A1: Summary of issues**

| Issue | Raised by[5] | FSANZ response |
|---|---|---|
| *MFGM-WPC for use as a nutritive substance in FSFYC* | | |
| Stated the draft variation is consistent with the intended purpose of MFGM-WPC to restore and enrich MFGM-derived components and support immune function in young children. | a2MC | FSANZ notes the submitter's comment. |
| Noted the assessment did not identify a deficiency of MFGM-WPC derived components, phospholipids or related nutrients in young children aged 1–3 years and did not demonstrate that adding MFGM-WPC is consistent with the Ministerial Policy Guideline or the intended purpose of FSFYC.<br>Noted the draft variation may set a precedence leading to other nutritive substances being permitted in special purpose foods without adequate justification. | FHA, HFSA, Individual (NB), Individual (SM), NSW FA, QLDH | FSANZ is satisfied that the proposed measure is consistent with the Ministerial Policy Guideline on the Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods.<br>The Policy Guideline states that the composition of special purpose food should be consistent with its intended purpose. FSFYC is intended to supplement the normal diet of children aged 1–3 years where intakes of energy and nutrients may not be adequate to meet an individual's requirements. Accordingly, FSFYC is formulated to provide nutritional benefit when consumed as part of a balanced diet and is not intended to be a sole source of nutrition.<br>The compositional requirements for FSFYC are therefore based on suitability for the product's intended purpose, rather than on demonstrating a nutrient deficiency within the target population. The Policy Guideline does not specify that ingredients may only be added where a specific population deficiency has been identified.<br>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 in FSFYC. The applicant also demonstrated that these components may contribute to supporting immune function, including the development of the gut microbiome through supporting growth of *Bifidobacteria* |

[5] Abbreviations: a2MC = The a2 Milk Company Limited; Danone = Danone; FHA = Food for Health Alliance; Fonterra = Fonterra Cooperative Group; HFSA = Healthy Food Systems Australia; INC = Infant Nutrition Council, Individual (BL) = Individual 1; Individual (NB) = Individual 2; Individual (SM) = Individual 3; Individual (XW) = Individual 4; NSW FA = New South Wales Food Authority; NZFGC = The New Zealand Food and Grocery Council; NZFS = New Zealand Food Safety; QLDH = Queensland Health; VHEECC = Victorian Department of Health and Department of Energy, Environment and Climate Change.

| Issue | Raised by[5] | FSANZ response |
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| | | spp, in children aged 1–3 years. Further information is provided in section 2.2.2 of this report. |
| Recommended assessment of the nutritional or energy-related need for MFGM-WPC in young children aged 1–3 years, whether normal diets provide inadequate amounts, and whether restoring milk components lost during processing or providing potential health benefits constitutes supplementation. | NSW FA, QLDH | FSANZ did not assess the nutritional or energy-related need for MFGM-WPC nor whether normal diets provide inadequate amounts of MFGM-WPC components for children aged 1–3 years.<br>As noted above, FSFYC is intended to supplement the normal diet of children aged 1–3 years where intakes of energy and nutrients may not be adequate to meet an individual's requirements. FSFYC is consumed as part of a balanced diet and is not intended to be a sole source of nutrition.<br>Consistent with the Ministerial Policy Guideline for Special Purpose Foods, the addition of MFGM-WPC to FSFYC is based on whether the ingredient is appropriate for use in FSFYC and consistent with the product's intended purpose as a supplementary food. The applicant stated that MFGM-WPC is intended to restore milk membrane components reduced during processing and provide concentrated MFGM-derived lipid and protein components associated with immune and gastrointestinal function in young children. These proposed functions are consistent with the role of FSFYC as a supplementary food.<br>The Ministerial Policy Guideline does not specify that ingredients may only be added to FSFYC where a population-level nutritional deficiency or dietary inadequacy exists. |
| Noted that permissions for optional nutritive substance in FSFYC may expand. Requested clarification on whether FSANZ has considered overarching policy principles or framework to guide consideration of the cumulative effect of optional nutritive substance permissions within FSFYC.<br>Raised that maintaining clarity on the intended role of FSFYC and transparency regarding the purpose of optional nutritive substance permissions would support consumer understanding and confidence in the regulatory framework. | VHEECC | FSANZ's assessment of Application A1344 considered the use of a single optional nutritive substance (MFGM-WPC) in FSFYC, as requested by the applicant. The assessment concluded that the use of MFGM-WPC is not expected to result in new or disproportionate dietary intake concerns for children aged 1–3 years.<br>FSFYC is a prescriptive category of food and any request for a new optional nutritive substance is assessed on a case-by-case basis, considering its intended purpose, safety, dietary exposure and consistency with the compositional framework for FSFYC. Where appropriate, compositional limits may be established to ensure FSFYC remains consistent with its intended role as a supplementary food for young children. |
| Noted a typographical error in the Executive Summary which referred to Standard 2.9.1 instead of Standard 2.9.3. | VHEECC | FSANZ thanks the submitter for identifying this typographical error, which has been corrected. |

| Issue | Raised by[5] | FSANZ response |
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| *Risk and technical assessment – general comments* | | |
| Recommended that the potential benefits to young children from the addition of MFGM-WPC to FSFYC should be referred to consistently as:<br>(1) an anti-pathogenic effect;<br>(2) immunomodulation and<br>(3) development of the gut microbiome through increased Bifidobacterium expression. | INC | FSANZ thanks the submitter for this comment and has amended section 2.2 of this report. |
| Stated the assessment relied on outcomes from Application A1307 without sufficiently addressing the specific requirements for FSFYC. | HFSA, NSW FA, QLDH | While A1344 considered relevant findings from Application A1307, FSANZ also assessed the proposed use of MFGM-WPC in FSFYC for children aged 1–3 years. Given the limited FSFYC-specific evidence available, the assessment drew on evidence from infant formula products where appropriate. Although FSFYC is a broad food category, the intended use of MFGM-WPC is primarily in milk-based FSFYC products that share similar composition and manufacturing characteristics with infant formula. FSANZ therefore considered infant formula to be an appropriate comparator to inform the assessment. |
| *Risk and technical assessment – food technology* | | |
| Stated the chemical and physical properties assessment assumes the FSFYC is in a liquid form and the applicant refers to FSFYC formula made using whole milk.<br>Considered the proposed permission broader than the supporting assessment. Noted that evidence and stability assessment was limited to formula-type, beverage-based FSFYC products and did not cover all permitted formats or concentrations, particularly the oxidative stability in toddler formula. Noted that FSANZ's stability assessment considers infant formula products as a suitable proxy for formula-type FSFYC.<br>Noted the applicant mentioned new MFGM containing product concepts. However, the applicant is unclear about their intention to use MFGM-WPC in non-formula FSFYC.<br>Sought clarification on whether the assessment is applicable to all FSFYC, regardless of form. | Individual (XW), NSW FA | The chemical and physical properties assessment relates primarily to the MFGM-WPC ingredient itself rather than the final form of the FSFYC to which it will be added.<br>FSANZ's conclusion on the stability of MFGM-WPC in finished products is limited to its stability in formula-type FSFYC only, in line with the available information and data (see section 2.3.1.1 of SD1). Stability evaluations are conducted by manufacturers of finished products as part of new product development.<br>Formula-type FSFYC and infant formula products share several important compositional and manufacturing similarities. Both product types are typically manufactured using similar base powders and are usually produced within the same manufacturing facilities and production lines. As commercially produced powdered or ready-to-consume formulations, they also share many technological properties, including similar ingredient matrices, processing conditions and use of food additives.<br>MFGM-WPC is manufactured as a free-flowing spray-dried powder of homogeneous composition and has similar properties to other whey protein concentrates, including its incorporation and stability as a bulk ingredient in a range of food matrices. Whey protein concentrates are common food ingredients that can be incorporated into both liquid and powdered products. |

| Issue | Raised by[5] | FSANZ response |
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| | | Therefore, the conclusions of the chemical and physical properties assessment are applicable to FSFYC available in liquid or powdered form. |
| The supporting document includes limited data on the stability of MFGM-WPC at higher levels, namely, levels approaching the proposed maximum use level of 11.5 g/L in formula-type FSFYC. The applicant states that addition of levels higher than those assessed in the stability trials are not expected to introduce new stability risks.<br>Sought clarification from FSANZ that it is satisfied that the addition of MFGM-WPC in formula-type FSFYC at the proposed maximum use level poses no stability concerns. | NSW FA | As part of the assessment, FSANZ considered evidence that MFGM-WPC is stable during storage and that finished products containing MFGM-WPC also remained stable under the conditions assessed. Of note, the addition of MFGM-WPC did not impact on the stability of macronutrients, fatty acids, and vitamins studied, sphingomyelin concentration, nor oxidative stability.<br>FSANZ also considered information indicating that addition of MFGM-WPC does not cause stability-relevant interactions of concern, nor introduce inherently unstable components.<br>Ultimately, the stability of finished products will depend on the final formulation, processing and packaging. Product-specific stability testing, conducted as part of normal product development and validation, remains the responsibility of manufacturers.<br>Based on the available evidence, FSANZ did not identify any stability concerns associated with the proposed use of MFGM-WPC in formula-type FSFYC. |
| Requested that the permission be restricted to beverage or reconstituted beverage formats and include a maximum concentration in the prepared food, expressed per litre or 100 mL, rather than relying solely on a manufacturer-defined serving size. | NSW FA | The approved draft variation permits the addition of MFGM-WPC to FSFYC at a maximum amount of 2.3 g per serving. FSANZ determined that this maximum amount equates to 771 mg phospholipids per litre (see section 2.2.2 of SD1). FSANZ has expressed the maximum level on a per serving basis to maintain consistency with existing permissions for other optional nutritive substances in FSFYC. This approach aligns the permission with the manner in which FSFYC compositional requirements are typically expressed and applied.<br>FSANZ has not restricted the permission to beverage or reconstituted beverage formats. FSFYC is a broad category of food, and the assessment did not identify a safety or technical basis for limiting the use of MFGM-WPC to liquid products only. The established maximum amount applies regardless of product format and was considered sufficient to manage anticipated dietary exposure in children aged 1–3 years. |
| Stated the chemical and physical properties assessment assumes the FSFYC is in a liquid form and the applicant refers to FSFYC formula made using whole milk. Sought clarification from FSANZ that the chemical and physical properties | NSW FA | The chemical and physical properties assessment relates primarily to the MFGM-WPC ingredient itself rather than the final form of the FSFYC to which it will be added.<br>MFGM-WPC is manufactured as a free-flowing spray-dried powder of homogeneous composition and has similar properties to other whey protein concentrates, including its incorporation and stability as a bulk ingredient in a |

| Issue | Raised by[5] | FSANZ response |
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| assessment is applicable to all FSFYC, regardless of form. | | range of food matrices. Whey protein concentrates are common food ingredients that can be incorporated into both liquid and powdered products. FSANZ's assessment did not identify a safety or technical basis for limiting the use of MFGM-WPC to liquid products only. Therefore, the conclusions of the chemical and physical properties assessment are applicable to FSFYC available in liquid or powdered form. |
| *Risk and technical assessment – dietary intake* | | |
| Stated that the dietary intake assessment considered infant formula and follow on formula as a proxy and used the regulatory limit for phospholipids as a comparison. Requested clarification whether the dietary intake assessment is applicable to all FSFYC, regardless of form. | NSW FA | The dietary intake assessment was undertaken to estimate potential exposure to phospholipids arising from the proposed use of MFGM-WPC in FSFYC. A conservative approach was used to help ensure that estimated dietary intake was not underestimated.<br>In the absence of comprehensive consumption data for FSFYC containing MFGM-WPC, FSANZ used relevant information from infant formula and follow-on formula products as a comparator, noting their similarities in composition, preparation and consumption patterns.<br>There is no regulatory limit in the Code for phospholipids in FSFYC. For this assessment, FSFYC were considered proxy foods for infant formula and follow-on formula, for which the Code specifies a regulatory limit for phospholipids of 72 mg/100 kJ. Therefore, this same regulatory limit was used for comparison purposes only when assessing phospholipid intake from FSFYC.<br>In the dietary intake assessment, for infants aged 12 months who consume food as well as FSFYC, it was conservatively assumed that 35% of energy intake was derived from FSFYC. For children aged 2–3 years who consume food as well as FSFYC, the estimated consumption of FSFYC also included consumers of infant formula as explained further in the SD. Mean FSFYC consumption on day one of the 2011–12 NNPAS was used as the estimate of longer-term daily consumption, rather than a two-day average. This presents a worst-case scenario of daily consumption amounts ensuring the assessment is conservative and protective of public health and safety.<br>While FSFYC is a broad food category, the intended use of MFGM-WPC is primarily in milk-based FSFYC products and the FSFYC products captured in the 2011–12 NNPAS were formula-type products, such as toddler milks. Infant formula and follow-on formula products were therefore considered an appropriate proxy for estimating dietary exposure, and the assessment did not identify dietary intake concerns at the proposed maximum use level. |

| Issue | Raised by[5] | FSANZ response |
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| *Composition* | | |
| Supported the proposed permission for the voluntary use of MFGM-WPC in FSFYC and the draft variations to Standard 2.9.3 and Schedule 29, as the permission promotes consistency between domestic and international standards and supports innovation. | NZFS | FSANZ notes this support. |
| Supported the proposed per serving permission as it recognises the supplementary nature of FSFYC and provides a practical basis for formulation, labelling and compliance. | a2MC, Danone, INC | FSANZ notes this support. |
| Supported not prescribing a minimum MFGM-WPC level. | a2MC, INC | FSANZ notes this support. |
| Supported prescribing bovine as the permitted form. | a2MC, INC | FSANZ notes this support. |
| Stated the proposed maximum permission would allow fortification of FSFYC with phospholipids and sphingomyelin beyond the naturally occurring levels in bovine milk. Noted this proposed maximum limit is higher than the existing maximum limit of MFGM-WPC in infant formula products.<br>Considered that the proposed maximum level of MFGM-WPC in FSFYC should not be justified by comparison with phospholipid limits in infant formula, as FSFYC is not a sole source of nutrition and should not replicate infant formula composition.<br>Recommended the maximum level should be assessed against the intended supplementary purpose of FSFYC and the relevant Ministerial Policy Guideline for special purpose foods. | NSW FA | The applicant identified that the intended purpose for the addition of MFGM-WPC to FSFYC is to restore components that are reduced during processing of bovine milk and to enrich products with concentrated MFGM-derived lipid and protein components, including components associated with immune and gastrointestinal function in young children. The proposed maximum level was not intended to replicate naturally occurring levels of phospholipids in bovine milk.<br>Consistent with the Ministerial Policy Guideline for Special Purpose Foods, FSANZ assessed whether the proposed use of MFGM-WPC was appropriate for FSFYC and aligned with the product's intended role as a supplementary food for young children, rather than as a sole source of nutrition. While information from infant formula products was considered where relevant, the proposed permission was assessed in the context of FSFYC.<br>The risk and technical assessment concluded that use of MFGM-WPC at the proposed maximum level would not raise health or safety concerns for children aged 1–3 years. |
| *Sphingomyelin as a condition* | | |
| Supported applying the same specification for MFGM-WPC as already defined in S3—53 of the Code. | Fonterra | FSANZ notes this support. |
| Supported that it is not necessary to include a condition of use that limits the total amount of sphingomyelin from both added MFGM-WPC and | a2MC, Fonterra, INC | FSANZ notes the submitter’s comments. |

| Issue | Raised by[5] | FSANZ response |
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| naturally occurring sources to 40 mg per serving or supported sphingomyelin as set out in the S3—53 as an appropriate marker to quantify the presence of MFGM-WPC to FSFYC. | | |
| Considered that the proposed 2.3 g per serving limit and declaration requirement cannot be reliably measured or verified because MFGM-WPC is a variable mixture and sphingomyelin levels do not correspond to a single quantity of the ingredient. Considered the meaning of "naturally occurring" unclear for MFGM-WPC. They requested clarification of how compliance and labelling should be established, clarification of the treatment of naturally occurring components, reinstatement of a measurable 40 mg sphingomyelin limit per serving, and consistent naming and units for declaration. | Individual (XW) | The A1307 assessment noted sphingomyelin as one of the major phospholipids present in MFGM-WPC and that standardised methods are available to assay its content in MFGM-WPC and infant formula products. The A1344 assessment concluded that sphingomyelin is a useful analytical marker to differentiate, as well as quantify, the addition of MFGM-WPC to FSFYC.<br>For the reasons set out in section 2.3.5 of this report, FSANZ considers that the sphingomyelin content is sufficiently constrained by the specification in section S3—53 of the Code. This also ensures consistency in the Code.<br>Requiring both naturally occurring and added amounts of a nutritive substance to be accounted for when added to FSFYC is consistent with the requirement for addition of nutritive substances to other products, including the addition of MFGM-WPC to infant formula products.<br>FSANZ does not provide advice on compliance with the Code. Interpretation and enforcement of Code requirements are the responsibility of Australian and New Zealand food enforcement agencies. |
| *Labelling* | | |
| Supported the proposed requirement to declare MFGM-WPC in the NIP because it:<br>• is a clear and factual way to communicate its presence.<br>• provides meaningful and relevant information to consumers and healthcare professionals.<br>• maintains consistency with the Code's existing claims and labelling framework. | Danone, Fonterra, INC, NZFS | FSANZ notes this support. |
| Questioned the proposed labelling approach because MFGM-WPC is not a singular nutrient and declaration of an ingredient within the NIP is not typical. | a2MC | FSANZ acknowledges that MFGM-WPC is not a single nutrient but a preparation of several protein and lipid components. However, FSANZ assessed MFGM-WPC as the whole preparation, rather than assessing its individual components as separate nutritive substances. The permission therefore applies to MFGM-WPC as the nutritive substance and not to any individual component, such as sphingomyelin.<br>Accordingly, the proposed NIP declaration would identify and quantify the permitted nutritive substance (MFGM-WPC). This approach is consistent with FSANZ's risk and technical assessment and with the regulatory approach |

| Issue | Raised by[5] | FSANZ response |
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| | | adopted for MFGM-WPC in infant formula products (refer to section 2.1, Table 1 in the A1307 Approval Report). |
| Supported the revisions and restructure of the labelling framework as proposed. | Danone, NZFS | FSANZ notes this support. |
| Opposed the labelling approach because it exceeded the scope of A1344 and considered the change in NIP declaration requirements for FSFYC requires broader consideration for the following reasons:<br>• The applicant did not request changes to existing labelling requirements.<br>• Considered the proposed labelling approach as a policy change affecting the whole FSFYC category, rather than a measure necessary to accommodate MFGM-WPC.<br>• The proposed labelling approach would treat newly permitted nutritive substances differently from lutein, which generally requires NIP declaration only when a claim is made.<br>• Disputed that the proposed labelling approach aligns with declaration requirements for other special purpose foods.<br>• Considered related but different changes under A1344 and P1066 may create confusion for industry and regulators.<br>Recommended considering mandatory NIP declaration of voluntarily added nutritive substances under P1066, so that a consistent approach can be developed and applied to relevant products. | NSW FA | When assessing applications seeking permission for a new nutritive substance, FSANZ considers whether existing Code labelling provisions remain appropriate or whether amendments are required. The labelling provisions outlined in this Approval Report establish a declaration mechanism for MFGM-WPC as a condition of its permission for use. At the time of approval, this requirement applies only to MFGM-WPC. For the reasons set out in section 2.3.7.2 of this report, FSANZ considered it was appropriate to address the declaration requirements applying to MFGM-WPC through Application A1344. Lutein was permitted under Application A597 and is subject to existing requirements arising from that regulatory history. Those requirements are unchanged by A1344. Proposal P1066 may consider whether broader changes to existing permissions, including lutein, are warranted.<br>MFGM-WPC is the only nutritive substance listed in the table and requiring declaration in the NIP. Any future permissions for nutritive substances, and the requirements associated with those permissions, would be assessed on a case-by-case basis through the relevant application or proposal process.<br>See section 2.3.7.2 of this report for further discussion of the NIP declaration requirements. |
| Sought confirmation that, under proposed subsection 2.9.3—8(1A), any newly permitted nutritive substance (including MFGM-WPC) would be required to be declared in the NIP whenever added to FSFYC, irrespective of whether a claim is made, while lutein would remain excluded from this requirement. | INC | As noted in the previous response, future permissions for nutritive substances, and the requirements associated with those permissions (such as a NIP declaration requirement), would be assessed on a case-by-case basis. |
| Considered the requirement in subsection 2.9.3—8(6) of the Code, that lutein be present at not less than 30 micrograms per serving when its presence is | INC | FSANZ notes this suggestion. Existing requirements for lutein are being considered as part of Proposal P1066. |

| Issue | Raised by[5] | FSANZ response |
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| indicated, to be equivalent to a minimum level for a nutrition content claim.<br>Requested that all regulatory parameters applying to nutritive substances permitted in FSFYC be consolidated in the table to section S29—15A for regulatory clarity. This would include the specific lutein requirement noted above, potentially recorded in a new 'minimum claim' column. | | |
| Noted the following issues pertaining to claims:<br>• that nutrition content and health claims are currently permitted on FSFYC where they comply with Standard 1.2.7, while Proposal P1066 is separately considering a prohibition on claims for young child formula.<br>• that the application indicates an intention to make claims about MFGM-WPC or MFGM both on- and off-pack.<br>• questioned whether evidence for MFGM-WPC assessed under Application A1307 would substantiate equivalent health claims for children aged 1–3 years and whether claims concerning anti-pathogenic effects or immunomodulation could be prohibited therapeutic claims.<br>• did not support claims that are inconsistent with the supplementary purpose of FSFYC. It was recommended that FSANZ has a broader consideration of claim eligibility, consumer perceptions and market trends for this food category. | NSW FA | FSANZ notes the submitter's concerns about nutrition content and health claims about FSFYC containing MFGM-WPC. As indicated in section 1.3.3.3 of the CFS, Standard 1.2.7 sets out the restrictions, requirements and conditions applying to voluntary nutrition, health and related claims and would apply to any FSFYC containing MFGM-WPC. The permission being sought concerns the addition of MFGM-WPC as an optional nutritive substance; it does not itself authorise claims about MFGM-WPC, MFGM or their components.<br>Under the approach proposed in the CFS, the nutritive substance permitted by the Code (the MFGM-WPC, not any component of it) would be declared in accordance with the applicable ingredient and nutrition information requirements. Any voluntary claim would need to independently comply with Standard 1.2.7, including the applicable conditions for nutrition content or health claims.<br>The broader question of whether claims should be permitted on young child formula is outside the scope of Application A1344 and is being considered under Proposal P1066.<br>FSANZ's assessment under Application A1307 considered evidence of potential benefit in the context of the policy principles in the Ministerial Policy Guideline for Infant Formula Products. That assessment did not establish food–health relationships for the purposes of general level health claims about anti-pathogenic effects, immunomodulation or development of the gut microbiome. Under Standard 1.2.7, the food business is responsible for substantiating any food–health relationship relied on for a general level health claim and for ensuring that the claim meets all applicable requirements.<br>FSANZ also notes the concern that claims referring to anti-pathogenic effects or immunomodulation may be therapeutic in nature. Section 1.2.7—8 prohibits claims that refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition, or compare a food with a good that is represented to be or may be taken to be for therapeutic use. Any claim made for an FSFYC |

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| | | containing MFGM-WPC must therefore be framed and substantiated so that it does not contravene these prohibitions. |
| Drawing inferences from previous assessments on infant formula (Application A1307) is insufficient and not consistent with the requirements for making a general level health claim. The results of a full systematic review of the purported effects should have been part of the application to inform assessment and response to the consultation. | HFSA | As noted above, Application A1344 sought to extend the use of MFGM-WPC from infant formula products to FSFYC. The A1344 risk and technical assessment considered the outcomes of the assessment for Application A1307, as a relevant assessment conducted for MFGM-WPC.<br>FSANZ's assessment of Application A1344 does not establish a pre-approved food-health relationship for inclusion in Schedule 4 of the Code. Any business wishing to make a general level health claim about an FSFYC product containing MFGM-WPC may do so under the existing framework in Standard 1.2.7, provided they substantiate the relevant food-health relationship in accordance with that standard, including through a systematic review where required. |
| Noted it would be helpful to specify which of the two names used in the draft variation is to be declared in the NIP under subsection 2.9.3—8(1A) of the draft variation:<br>• 'milk fat globule membrane-enriched whey protein concentrate' (the Table to section S29—15A of the draft variation)<br>• 'bovine milk fat globule membrane-enriched whey protein concentrate' (the Table to section S29—15B of the draft variation). | Individual (XW) | The draft variation does not prescribe a specific name that must be used when declaring MFGM-WPC under subsection 2.9.3—8(1A).<br><br>Subsection 2.9.3—8(1A) requires 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, except lutein, that:<br>(a) is listed in Column 1 of the table to section S29—15A; and<br>(b) is used as a nutritive substance in the food.<br><br>Column 1 of the table to section S29—15A lists 'Milk fat globule membrane-enriched whey protein concentrate' as the name of the substance.<br>'Bovine milk fat globule membrane-enriched whey protein concentrate' is listed in the table to section S29—15B as the permitted form of that substance.<br>FSANZ considers labelling terminology for nutritive substances on a case-by-case basis during pre-market assessment. The Code does not impose specific naming requirements for most permitted nutritive substances. Consistent with this approach, the Application Handbook requires applicants to provide proposed labelling information, including statements relating to the presence of the nutritive substance. A specific naming restriction would generally be imposed only where needed to address an identified regulatory issue, as occurred for human milk oligosaccharides in Application A1155. |
| Suggested it would be helpful to specify the units in which the average quantity is to be expressed. | Individual (XW) | FSANZ agrees and has amended the draft variation. See section 2.3.7.2 of this report for discussion on this issue. |

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| *Cost benefit analysis* | | |
| Considered that the cost-benefit analysis should more fully recognise the benefits of the proposed permission.<br>In particular, the assessment appears to understate the potential consumer benefit of enabling access to an ingredient assessed as safe and suitable for young children, including its recognised role in supporting immune function.<br>The cost-benefit analysis should also more explicitly recognise the broader regulatory benefits of clear and proportionate permissions, including their role in enabling responsible product innovation, supporting investment certainty and maintaining regulatory competitiveness across Australia and New Zealand.<br>Requested FSANZ reflect these considerations in the final approval report. | Danone, INC | FSANZ assessed the potential costs and benefits of the approved draft variation in accordance with the FSANZ Act, in particular, section 29 of the FSANZ Act<br>Applications to permit the voluntary use of nutritive substances that have been determined to be safe are generally considered minor in impact or deregulatory in nature. Therefore, the cost-benefit analysis focuses on the potential advantages and disadvantages of changing the status quo by allowing the applicant's MFGM-WPC to be used as an optional nutritive substance in FSFYC. |
| *Alignment with other work on the FSANZ workplan* | | |
| P1066 has identified the need for greater regulatory clarity to ensure composition, labelling and representation of young child formula are consistent with their intended role as special purpose foods.<br>Approving MFGM-WPC at this time risks undermining the work of P1066 by facilitating the introduction of novel ingredients that can be used to reinforce perceptions of superiority, despite limited evidence of a corresponding public health benefit.<br>Requested more guidance as to how the MFGM-WPC permission sits within the wider context. | FHA, HFSA, Individual (NB), Individual (SM), NZFGC, QLDH | Proposal P1066 will review the regulatory provisions applying to young child formula as special purpose foods with a focus on regulatory definitions, composition, labelling, product representation and safety.<br>Under the FSANZ Act, FSANZ cannot defer the assessment of applications to amend the Code due to a proposal on a related topic. Applications are assessed on their own merits against the regulatory framework in force at the time of assessment and the applicable legislative requirements.<br>Application A1344 is expected to be assessed within the relevant statutory timeframe and prior to the completion of Proposal P1066. Accordingly, A1344 will be assessed under the existing regulatory framework applicable to that food. P1066 will review the Code as in force at the time of the proposal, including any relevant Code amendments that occur during review. |
| Stated that if there are changes to the general labelling provisions for young child formula as a result of Proposal P1066, then these changes should apply to young child formula with added MFGM-WPC. | a2MC, INC, NZFS | As outlined above, Proposal P1066 will review the regulatory provisions applying to young child formula as special purpose foods. Any regulatory changes resulting from the assessment of P1066 will apply to the Code as in force at the time of the proposal, including any relevant Code amendments that occur during review. |
| Recommended that given the emerging products containing MFGM-WPC for infants and young | NSW FA | FSANZ notes this comment. |

| Issue | Raised by[5] | FSANZ response |
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| children, FSANZ start consideration of how to appropriately regulate the use and advertising of 'functional' substances such as MFGM in commercial foods for infants and young children in the review included in the FSANZ Roadmap to 2030. | | |
| Requested reactivation of Proposal P1024.<br>One submitter commented that extending the precedent set by Application A1307, Application A1344 uses the Code's nutritive substance definition to amend the status of a particular WPC when used in FSFYC from an ingredient to a nutritive substance, whilst all other 'standard' WPC remains as an ingredient.<br>The other submitter commented that the nutritive substance definition creates ambiguity and requests the reactivation of P1024 to provide industry and stakeholders regulatory clarity. | INC, NSW FA | FSANZ has assessed, in accordance with the FSANZ Act and Code requirements, 'Milk fat globule membrane-enriched whey protein concentrate' meets the definition for *used as a nutritive substance (section 1.1.2—12) as it:<br>• is added to food to achieve a nutritional purpose<br>• is a substance that has been concentrated, refined or synthesised to achieve a nutritional purpose.<br>The substance, in this instance, is a preparation made up of a number of protein and lipid components. The components are concentrated through manufacturing to produce a 'substance' that has a nutritional purpose.<br>Amending the Code to clarify the definition of a nutritive substance is out of scope for this application but will be considered as part of P1024 which is expected to formally recommence in 2027. |
| *Other issues* | | |
| Stated that non-human animal milks are not appropriate for the human diet and FSANZ should not consider applications involving animal fats or proteins. | Individual (BL) | FSANZ notes the comment. The source of an ingredient is not, in itself, a basis for approval or refusal. Applications are assessed on their merits within the existing regulatory framework, including consideration of safety, nutritional impacts and the proposed use of the ingredient. |