14 May 2025
340-25

Approval report – Application A1307

Milk fat globule membrane as a nutritive substance in infant formula products

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Food Standards Australia New Zealand (FSANZ) has assessed an application made by Arla Foods Ingredients Group P/S to amend the Australia New Zealand Food Standards Code to permit the use of bovine milk fat globule membrane-enriched whey protein concentrate as a nutritive substance in infant formula products.

On 12 December 2024, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 10 submissions.

FSANZ approved the draft variation on 30 April 2025. The Food Ministers' Meeting[1] was notified of FSANZ's decision on 14 May 2025.

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 1 (SD1)

The following document which informed the assessment of this application is available on the A1307 page on the FSANZ website:

SD1 Risk and technical assessment – Application A1307 (at Approval)

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 a nutritive substance in infant formula products.

The applicant also requested an exclusive use permission under the brand name 'Lacprodan® MFGM-10' for a period of 15 months after gazettal.

The substance MFGM-WPC has been concentrated from bovine milk through substantially different techniques and technology to those considered traditional, for the purpose of providing a nutritive benefit to the formula-fed infant. In accordance with the FSANZ Act and Code requirements, the substance therefore meets the definition of 'used as a nutritive substance' and must undergo pre-market assessment.

FSANZ's safety assessment concluded that MFGM-WPC is an appropriate source of phospholipids for inclusion in infant formula products and does not pose a safety risk to infants. While more data is needed to substantiate improved mental development compared to standard infant formula products, there is evidence MFGM-WPC may be beneficial for infant gut microbiota development.

The associated health benefits from the addition of MFGM-WPC to infant formula products for infants include:

1. an anti-pathogenic effect
2. immunomodulation, and
3. development of the gut microbiome through increased *Bifidobacterium* expression.

Following assessment and preparation of a draft variation, FSANZ called for submissions from 12 December 2024 to 6 February 2025. Ten submissions were received, seven of which supported the assessment and draft variation.

For the reasons set out in this report, FSANZ has approved the draft variation proposed at the call for submissions with amendments. The effect of the approved draft variation is that MFGM-WPC will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code. The approved draft variation will:

- Amend Schedule 29 of the Code to permit the voluntary use of 'milk fat globule membrane-enriched whey protein concentrate' as a nutritive substance in infant formula products at a concentration of 0.14 g/100 kJ to 0.28 g/100 kJ. 'Bovine milk fat globule membrane-enriched whey protein concentrate' is the permitted form.

- Include an exclusive use permission linked to the applicant's brand name 'Lacprodan® MFGM-10' for period of 15 months.

- Insert a specification for MFGM-WPC into Schedule 3 of the Code which includes a specified sphingomyelin range and with which MFGM-WPC would have to comply when used as a nutritive substance in infant formula products for sale (or sold for such use).

The effect of those amendments is that the applicant's MFGM-WPC will be permitted to be used as a nutritive substance in infant formula products in accordance with the Code.

1 Introduction

1.1 The applicant

Arla Foods Ingredients Group P/S (AFI) is a Danish food ingredient manufacturer supplying dairy based ingredients to the infant and medical nutrition manufacturing industry.

1.2 The application

The application sought permission for the use of bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) as a nutritive substance in infant formula products. The applicant's MFGM-WPC will be sold under the commercial name Lacprodan® MFGM-10.

Bovine MFGM-WPC is a source of polar lipids such as glycerophospholipids and sphingolipids, and membrane-specific proteins. These substances, present in human milk and in cow milk, are important for the healthy development of the infant. Whey protein concentrate (WPC) is a common source of phospholipids, fatty acids and protein in infant formula products. The phospholipid components (phosphatidyl ethanolamine or PE, phosphatidyl serine or PS, phosphatidyl inositol or PI, phosphatidyl choline or PC, and sphingomyelin or SM) can be enriched in the MFGM fraction of WPC through processing and are the key characterising components associated with its physiological benefits.

The permission will provide infant formula products with bovine MFGM-WPC added as a nutritive substance. Bovine MFGM-WPC as a source of lipids is expected to partially replace, or be added in addition to, vegetable oils which are normally used in infant formula products and do not have the nutritive composition that MFGM-WPC isolated from bovine milk would have.

The permission will apply to all categories of infant formula products as an optional nutritive substance.

1.3 The current standard

Australian food laws require food for sale to comply with relevant provisions in the Australia New Zealand Food Standards Code (the Code). The provisions relevant to this application are summarised below.

1.3.1 Permitted use

Paragraph 1.1.1—10(6)(b) of Standard 1.1.1 requires that, unless expressly permitted, a food for sale must not have as an ingredient or component, a substance that is used as a nutritive substance. This requirement extends to foods that are infant formula products.

*S*ection 1.1.2—12 sets out when a substance is used as a nutritive substance for the purposes of the Code. It provides that a substance is 'used as a nutritive substance' in relation to a food if each of the following criteria are met:

- It is added to that food to achieve a nutritional purpose.
- It is a substance identified in subsection 1.1.2—12(2). The substances listed in that subsection include 'any substance … that has been concentrated, refined or synthesised to achieve a nutritional purpose when added to a food'.

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 currently no relevant specification for bovine MFGM-WPC in Schedule 3. The approved draft variation will insert a specification specifically for bovine MFGM-WPC into Schedule 3 with which bovine MFGM-WPC will have to comply in accordance with section 1.1.1—15.

1.3.3 Infant formula products

Revised regulation of infant formula products came into effect on 13 September 2024 and applies in Australia only.[2]

Infant formula products in Australia are regulated by Standard 2.9.1 which sets out specific requirements for the following infant formula products:

- infant formula (for infants aged 0 to <12 months)
- follow-on formula (for infants aged from 6 to <12 months)
- special medical purpose product for infants[3] (from birth).

1.3.3.1 Composition of infant formula products

Subsection 2.9.1—9(1) provides that a substance in the table to section S29—7 may be used as a nutritive substance in infant formula provided that the amount of the substance in the formula (including any naturally-occurring amount) is no less than any minimum amount; and no more than any maximum amount, specified in the table.

Subsection 2.9.1—9(2) provides that a substance listed in the table to section S29—8 may be used as a nutritive substance in follow-on formula provided that the amount of the substance in the formula (including any naturally-occurring amount) is no less than any minimum amount; and no more than any maximum amount, specified in the table.

Section 2.9.1—37 provides that a substance listed in the table to section S29—7 may be used as a nutritive substance in a SMPPi provided that the amount of the substance in the product (including any naturally-occurring amount) is no less than any minimum amount; and no more than the maximum amount, specified in the table.

For nutritive substances that are not vitamins, minerals or electrolytes and are used in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9, paragraph 2.9.1—10(b) provides that such substances must be added in a permitted form listed in the table to section S29—9. The same requirement is set in section 2.9.1—38 for SMPPi.

Section 2.9.1—10A requires a permitted nutritive substance in an infant formula product to comply with any conditions of use listed in the table to section S29—9A for that substance in its permitted form.

Section 2.9.1—7 for infant formula and follow-on formula and section 2.9.1—34 for SMPPi set restrictions on fatty acid composition. The relevant requirement in relation to this application is a restriction on the total phospholipid content of 72 mg/100 kJ set in subsections 2.9.1—7(3) and 2.9.1—34(3).

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[2] For further information on any relevant New Zealand standard see section 2.5.1.3.
[3] Abbreviated as SMPPi

1.3.3.2 Microbiological limits

Section 1.6.1—2 provides unacceptable microbiological limits for foods listed in Schedule 27. The table to section S27—4 restricts levels or *Cronobacter* and *Salmonella* in powdered infant formula; and *Salmonella* in powdered follow-on formula.

1.3.3.3 Labelling of infant formula products

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 ingredients to 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 requirements for making voluntary nutrition, health and related claims about food. Paragraph 1.2.7—4(b) states a nutrition content claim or health claim must not be made about an infant formula product.

Division 3 of Standard 2.9.1 provides the labelling and packaging requirements for infant formula and follow-on formula. This includes specific requirements relating to the statement of ingredients, a mandated Nutrition Information Statement (NIS) which must contain specific information and be declared in a prescribed format, and prohibited representations. Paragraph 2.9.1—28(1)(i) prohibits the label on a package of infant formula or follow-on formula to contain information relating to the presence of certain substances, including a substance used as a nutritive substance, except for a reference in a statement of ingredients, or in a declaration or statement expressly permitted or required by the Code, such as in the NIS.

Labelling requirements that apply to SMPPi are set out in Division 4 of the same standard. Some of these requirements differ to the provisions for infant formula and follow-on formula. For example, subsection 2.9.1—53(1) specifies the nutrition information required to be declared for a SMPPi, including a substance used as a nutritive substance, expressed per given amount of the product.

1.4 International standards

1.4.1 Codex standards

The current Codex Alimentarius Standards for Infant Formula and Formulas for Special Medical Purposes Intended for Infants Standard 72-1981 (Codex Alimentarius 2020) and Follow-up formula for Older Infants and Product for Young Children - Standard 156-1987 (Codex Alimentarius 2023) do not contain specific provisions for MFGM-WPC. However, these standards contain provisions for ‘optional ingredients’ which would apply to the addition of substances such as MFGM-WPC.

1.4.2 International regulations

MFGM-WPC has been used overseas as an optional ingredient in infant formula products for many years. In most countries MFGM is considered to be a component of bovine WPC, a

common protein source ingredient in infant formula products and has not required premarket assessment in these countries. According to the application, infant formula products containing MFGM-WPC are currently on the market in Argentina, Bulgaria, Brazil, Canada, Colombia, Czech Republic, Denmark, Ecuador, Finland, Hong Kong, India, Indonesia, Japan, Latvia, Lithuania, Malaysia, Mexico, Nigeria, Norway, Panama, Peoples Republic of China, Peru, Philippines, Poland, Portugal, Russia, Singapore, South Korea, Spain, Sri Lanka, Sweden, Taiwan, Thailand, United States of America (USA) and Vietnam. The product is listed as an ingredient as 'whey protein concentrate' or 'whey protein concentrate (containing MFGM)'.

1.4.2.1 Canada

As of 1 March 2024, the applicant's Lacprodan® MFGM-10 has been approved for use as a bioactive nutrient in infant formula available for sale in Canada. The listing of this ingredient came about through Health Canada's process for premarket notification for a New Infant Formula Ingredient (NIFI)[4].

1.4.2.2 European Union and the United Kingdom

The use of bovine milk-derived MFGM 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 has been in infant formula products sold in the EU for 15 years. It is similarly permitted for use in the United Kingdom.

1.4.2.3 People's Republic of China

According to the application, addition of MFGM-enriched ingredients (i.e. WPC) is permitted as an optional ingredient to infant formula. Inclusion of MFGM in whey protein powders (a permitted ingredient in infant formulas) is specified in a standard (QB/T 5805-2023) which sets requirements for the raw materials, sensory and physicochemical characteristics, and testing of milk (whey) protein powder with milk fat globule membranes.

1.4.2.4 United States

MFGM ingredients are considered to be a component of WPC and have not required premarket approval. However, infant formula manufacturers in the USA are required to register a new infant formula product with a New Infant Formula Notification (NIFN) before the product can be introduced to the market[5]. This is separate to the 'generally recognised as safe' (GRAS) process used for novel ingredients. According to the application, safety, physiological and technical requirements of the premarket NIFN for MFGM ingredients were supported by clinical trial studies.

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), and
- it related to a matter that warranted the variation of a food regulatory measure.

[4] See Appendix 1A and guidance in Guidance: Transition strategy to prepare for the expiration of Health Canada's interim policy to mitigate the infant formula shortages - Canada.ca

[5] See Regulations and Information on the Manufacture and Distribution of Infant Formula | FDA

1.6 Procedure for assessment

The application was assessed under the General Procedure requirements of the FSANZ Act.

1.7 Decision

For the reasons outlined in this report, including the Supporting Document (SD1), FSANZ approved the draft variation proposed at the call for submissions with the following amendments:

- an amendment to remove the condition of use relating to sphingomyelin in the table to section S29—9A in item [6] of the approved draft variation (the reasons for this amendment are set out in section 2.3.4.2 of this report)
- amendments to correct numbering in items [1] and [2] of the approved draft variation, and
- an amendment to correct formatting of the heading of the new section in item [2] of the approved draft variation.

The approved draft variation will:

- Amend Schedule 29 of the Code to permit the voluntary use of 'milk fat globule membrane-enriched whey protein concentrate' as a nutritive substance in infant formula products at a concentration of 0.14 g/100 kJ to 0.28 g/100 kJ. 'Bovine milk fat globule membrane-enriched whey protein concentrate' is the permitted form.
- Include an exclusive use permission linked to the applicant's brand name 'Lacprodan® MFGM-10' for a period of 15 months.
- Insert a specification for MFGM-WPC into Schedule 3 of the Code which includes a specified sphingomyelin range and with which MFGM-WPC would have to comply when used as a nutritive substance in infant formula products (or sold for such use).

The approved draft variation takes effect on gazettal and 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.

2 Summary of the findings

2.1 Summary of issues raised in submissions

FSANZ called for submissions from 12 December 2024 to 6 February 2025. Ten submissions were received (six industry, one non-government organisation, one government agency and two individuals). Seven submitters supported and three submitters did not support FSANZ's assessment and the draft variation. Most submitters provided comments on FSANZ's assessment and/or the draft regulatory measure which are summarised and addressed in Table 1.

Table 1: Summary of issues

Submitter comment	Submitter(s)[6]	FSANZ Response
Issue: Code requirements for nutritive substances		
Supported FSANZ's approach to regulate MFGM-WPC as a nutritive substance but noted that expansion of the capture as a nutritive substance to a preparation made up of various constituents increases regulatory uncertainty and ambiguity of the over-arching definition of '*used as a nutritive substance'.	NSW FA	FSANZ notes this comment. 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: • Is added to food to achieve a nutritional purpose • Is a substance that has been concentrated, refined or synthesised to achieve a nutritional purpose. 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 beneficial effects if added to infant formula products. See also section 2.3.2 of this report. Amending the Code to clarify the definition of a nutritive substance is out of scope for this application.
Queried why the whole MFGM-WPC is categorised as a nutritive substance rather than just the phospholipid components. The submitter referred to the parallel case of Application A1186 – soy leghaemoglobin where only part of the nutritive substance was regulated rather than the entire preparation.	NSW FA	MFGM-WPC is a mixture manufactured from cows milk to be composed of unique polar lipids and membrane-specific proteins. The phospholipid composition is variable depending on the methods used to isolate, purify and analyse its components. Individual components are not easily separated, purified/concentrated and/or quantified. To list only the phospholipid component of MFGM as the nutritive substance requires an evidence base to support that. The approach to list MFGM-WPC as the nutritive substance is consistent with FSANZ's

[6] Abbreviations: The a2 Milk Company Limited = a2MC; Arla Foods Ingredients Group P/S = AFI; Danone Nutricia Australia Pty Limited = DN; Dietitians Australia = DA; Fonterra Co-operative Group Limited = FCG; Individual 1 = Ind1; Individual 2 = Ind2; Infant Nutrition Council = INC; Mead Johnson Nutrition = MJN; NSW Food Authority = NSW FA

Submitter comment	Submitter(s)[6]	FSANZ Response
		risk and technical assessment of the application, and the evidence base supporting MFGM-WPC as the nutritive substance. Application A1186 was dissimilar in that the genetically modified (GM) cell lysate preparation and soy leghemoglobin allowed for separation and corresponding regulation in Schedule 26 (food produced using gene technology) and Schedule 17 (nutritive substance) respectively. The safety, food technology and nutrition assessments for A1186 supported this approach.
Considered there to be ambiguity in the definition 'used as a nutritive substance' and whether substances naturally present in bovine milk, when concentrated and used in infant formula products, required pre-market approval. Submitter requested clarification on: • Would the proposed permission for MFGM-WPC as a nutritive substance, including exclusive use permission, prohibit the use of any other WPC (whether meeting the proposed specification in S3—53) in infant formula products as an ingredient? • Would the use of bovine milk fat components including MFGM in infant formula products require FSANZ's pre-market approval, when the infant formula product is compliant with the existing fat requirements in Standard 2.9.1 including total phospholipid level in subsection 2.9.1–7(3)?	NSW FA	Revision of the definition of a nutritive substance is out of scope for this application. Responding to each dot point: • No, the permission will not prohibit the use of other WPC. Application A1307 is permitting a specific preparation of bovine MFGM-WPC as a nutritive substance. Through processing of the whey protein fraction of bovine milk, it is enriched in specific nutrients (as listed in the Schedule 3 specification) to achieve a nutritional purpose (see section 2.3.5). The permission will allow bovine MFGM-WPC to be added in the range of 0.14 – 0.28 g/100 kJ. Standard 2.9.1—9 requires naturally-occurring amounts of the nutritive substances to be include in the specified range. However there are no endogenous amounts of the nutritive substance MFGM-WPC as it is produced through a specific manufacturing process and to a specific composition listed in the Schedule 3. As it is an approved optional nutritive substance, it must be labelled by listing in the NIS. Other forms of bovine MFGM (i.e. with a composition that differs from the form permitted as a nutritive substance) or any of the individual lipids and proteins comprising bovine MFGM also may be present in infant formula products as they are constituents of cow milk which is an ingredient for infant formula products. The composition of other forms of bovine MFGM will vary depending on how the milk is processed. If another form of bovine MFGM meets the requirements of the permission for the nutritive substance MFGM-WPC, then it may be added and must be labelled as such. However, if there is no express permission for

Submitter comment	Submitter(s)[6]	FSANZ Response
		addition of other forms of bovine MFGM (or constituents thereof) as a nutritive substance they may still be present but then 1.1.1—10(7) would apply. Under subsection 1.1.1—10(7) the requirement for an express permission for a nutritive substance does not apply to the substance that is in the food by natural occurrence. This also applies for any individual lipids and proteins comprising bovine MFGM that do not have an express permission to add as a nutritive substance. • Bovine milk fat components including MFGM which are concentrated, refined or synthesised through substantially different techniques and technology to those considered traditional, for the purpose of providing a nutritive benefit to the formula-fed infant, meet the definition of 'used as a nutritive substance' and must undergo pre-market assessment. Subsections 2.9.1–7(3) (for infant formula) and 2.9.1—34(3) (for follow on formula) are not intended to operate as a permission to add phospholipids as a nutritive substance[7], noting the requirement in paragraph 1.1.1—10(6)(b) that there must be an 'express' permission to add a nutritive substance. A permission to add phospholipids (specific or a mixture of) as a nutritive substance, if different to that specified in Schedule 3, would require pre-market assessment.
Concerned that this application and previous application A1253 – Bovine lactoferrin in infant formula products sets a precedent to regulate a food ingredient containing substances naturally present in bovine milk as optional nutritive substances in infant formula products, without explicitly determining the functional difference between an ingredient (permitted without specific Code listing) and a nutritive substance (only permitted if specifically listed in the Code).	NSW FA	FSANZ notes this comment. FSANZ has assessed this application in accordance with the FSANZ Act and Code requirements, as well as the Ministerial Policy Guideline to ensure that 'substances' added for a nutritive or technological purpose undergo pre-market assessment. As discussed above, 'milk fat globule membrane-enriched whey protein concentrate' meets the definition for 'used as a nutritive substance' (section 1.1.2—12), in that it is a substance that has been concentrated and refined and then added for the purpose of providing a nutritive benefit to the formula-fed infant. The response to the

[7] See Proposal P1028 Approval Report (pg. 187) or section 4.6 of SD2 to the 2nd CFS at P1028 - Infant Formula | Food Standards Australia New Zealand

Submitter comment	Submitter(s)[6]	FSANZ Response
		previous issue clarifies the difference between MFGM added as the nutritive substance versus MFGM that may be present as a component of cow milk used as an ingredient. Further clarification of the functional difference between an ingredient and a nutritive substance would need to be undertaken independently of this application (i.e. through a proposal) as this may have implications for other food categories.
Suggested the current regulatory environment (requiring NIS listing of permitted nutritive substances, exclusive use permission, and approval of 'substances' naturally present in a common ingredient) is incentive for the infant formula industry to submit an application about a food ingredient containing substances naturally present in bovine milk as a nutritive substance. This is not the intent of the nutritive substance permission in the Code.	NSW FA	FSANZ notes this comment. Proposal P1028 considered the regulatory approach for declaring nutrition information in the NIS. Under paragraph 2.9.1—24(3)(e)(i), a permitted nutritive substance added to an infant formula product requires the substance to be declared in the NIS. The requirement enables caregivers to use the NIS to identify particular nutrients and substances and their levels (including those which are voluntary additions), as well as to make product comparisons. See P1028 Approval Report (pg. 263-264), SD3 of the 2nd CFS (pg. 27) or Section 3.3. of SD3 to the 1st CFS.
To address the confusion between an 'ingredient' and a 'nutritive substance', including comments outlined above, submitters supported reactivation of Proposal P1024 to review the regulatory framework for nutritive substances (including the definition) in the Code.	NSW FA, INC	FSANZ notes this comment.
Requested confirmation that that the MFGM-WPC specification would only be required to be met when used as a nutritive substance.	INC	Section 1.1.1—15 requires that the permitted nutritive substance must comply with relevant specifications set out in Schedule 3 when added to food in accordance with the Code, or sold for use in food the substance.
Issue: Proposed permission for MFGM-WPC		
Requested stronger justification to support MFGM-WPC concentrations in infant formula products up to 7 g/L. • For 'the widespread use of MFGM-WPC in infant formula products internationally', is the international use level of	NSW FA	Responding to each dot point: • See section 1.4.2 of this report. In most countries, MFGM is considered to be a component of WPC and unlike Australia, would not be regulated as a nutritive substance. Internationally, the use of

Submitter comment	Submitter(s)[6]	FSANZ Response
MFGM-WPC in infant formula products comparable to the proposed concentration of 4 to 7 g/L? • Information in SD1 does not seem to support 'consistency with human milk' where: o In SD1 page 6, FSANZ concluded that 'the phospholipid composition MFGM-WPC is sufficiently similar to human milk'. The submitter notes that MFGM-WPC used at 7g/L would give rise to phospholipid concentrations that would far exceed levels that are normally found in human milk. o SD1 pages 17-18 presented estimated phospholipid concentrations in infant formula products containing MFGM-WPC based on the proposed use levels being higher than that in human milk as below: □ the maximum concentrations of phospholipids from MFGM-WPC in infant formula products as 0.7 g/L, and □ the range of mean phospholipid concentrations in mature human milk from mothers of full-term infants as 0.147 – 0.26 g/L (14.7 – 26.0 mg/100 mL).		MFGM-WPC in infant formula products varies, but the proposed concentration of 4 to 7 g/L is within the range used in products to ensure they contain levels of phospholipids, sphingolipids, gangliosides, and membrane proteins that are closer to those found in human milk. The proposed concentration of 4 to 7 g/L MFGM-WPC in infant formula products reflects the best available evidence and is considered safe and beneficial for infant development. • FSANZ's comparison of phospholipids is intended to show that the relative proportions of each phospholipid are similar in human milk versus the applicant's MFGM-WPC (SD1, Figure 1). FSANZ disagrees that if MFGM-WPC is added at the maximum permitted amount, then the level of phospholipids would 'far exceed levels normally found in human milk'. o In Table 1 (page 6 of SD1), total phospholipids in the applicant's MFGM-WPC is 6.7%. Assuming this composition, the maximum concentration of phospholipids from MFGM-WPC in infant formula is 0.47 g/L which is approximately 2-fold greater than the highest mean concentration of phospholipids in mature human milk (0.26 g/L) as presented on page 18. The phospholipid amount in a product containing MFGM-WPC at the maximum permission is well below the regulatory limit of total phospholipids from all sources of 72 mg/100 kJ (subsection 2.9.1—7(3)). o The dietary intake calculation (section 3.5.3 of SD1) is based on **maximum** concentration of phospholipids from MFGM-WPC in infant formula products (0.7 g/L) (see Table 3 of SD1). At this concentration, mean and P90 dietary intakes of phospholipids from added MFGM-WPC is approximately 3-fold greater than dietary intakes from human milk. Calculated dietary intakes based on the minimum concentration of phospholipids from added MFGM-WPC (0.26 g/L) will be lower (data not shown). The estimated dietary intake range based on the minimum and maximum concentrations of phospholipids from added

Submitter comment	Submitter(s)[6]	FSANZ Response
		MFGM-WPC is comparable to intake based on the range of phospholipids intakes from human milk. Based on the above, FSANZ has concluded that phospholipid composition MFGM-WPC is sufficiently similar to human milk to be used as a source of phospholipids in infant formula products. No change is required to SD1.
Queried how FSANZ views enforcement of the provision and requests whether formulation records outlining dosage would be a feasible way to demonstrate compliance to the Schedule 29 provision.	FCG, INC, a2MC	Paragraph 2.9.1—9(1)(b) (for infant formula) and paragraph 2.9.1—9(2)(b) (for follow on formula) specifies minimum and maximum permitted amounts of a nutritive substance listed in the tables to sections S29—7 and S29—8 respectively. The amount of the nutritive substance in the formula includes any naturally occurring amounts of the nutritive substance. Subparagraph 2.9.1—24(3)(e)(i) also requires the average quantity of a substance used as a nutritive substance in infant formula or follow on formula to be declared in the NIS expressed in grams, micrograms or milligrams per 100 mL of formula. Therefore, average quantity of MFGM-WPC will have to be declared in the NIS, in accordance with the Code, when it is used voluntarily as a nutritive substance in infant formula and follow-on formula. 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.
Stated MFGM lacks triglycerides needed for infant growth and therefore the industry may be focusing on the wrong nutrient to improve brain function. The submitter further noted that if formula still includes vegetable oils that were sprayed with pesticides, which is detrimental to brain formation and function, then the addition of MFGM will not make this product analogous to the optimum option of breast milk.	Ind2	Due to the limitations in the available data, FSANZ was not satisfied that the evidence demonstrated improvement in neural development and cognitive function in infants. The assessment concluded that additional evidence would be required to make a definitive conclusion. Consideration of the benefit of other nutrients would be out of scope for the assessment of this application. As reaffirmed in the recent comprehensive review of infant formula

Submitter comment	Submitter(s)[6]	FSANZ Response
		product regulations (Proposal P1028)[8], vegetable oils are permitted to be used in infant formula products and no changes to the fat requirements of infant formula (Standard 2.9.1—7) will occur from the approval of this Application A1307. The fat requirements include minimum amounts of fatty acids required for infant growth. Chemicals such as pesticides in food are regulated through maximum residue limits, see Chemicals in food - maximum residue limits | Food Standards Australia New Zealand.
Stated the processing and separation of MFGM from the milk fat globule may interrupt satiety causing an increase in formula consumed, resulting in overweight infants or obesity issues. The submitter further suggested MFGM could displace other nutrients and it could cause deficiencies or over consumption.	Ind2	SD1 section 3.2 addressed the effect of MFGM-WPC on absorption of other nutrients and found no concerns. Assessment on growth effects (section 3.3. of SD1) found that formula enriched with MFGM-WPC at a concentration up to 5 g/L is unlikely to affect growth of infants when compared to standard formula between 14 days and 12 months of age. FSANZ notes no evidence was provided by the submitter to support the assertion that processing of MFGM alters infant satiety or displaces other nutrients causing deficiency or over-consumption. FSANZ undertook a related Pubmed search and no studies that considered the effect of satiety in formula-fed infants were identified.
Issue: Sphingomyelin content as a condition in the permission		
Suggested amending 'condition 1' to clarify that the permitted range up to 6.4 mg/100 kJ for MFGM-WPC and 7.5 mg/100 kJ for the total sphingomyelin level in infant formula products containing MFGM-WPC. This would assist enforcement agencies by providing clarity on the regulatory limit of the total sphingomyelin level in infant formula products if MFGM-WPC is added, but also provide an indicator of boosted sphingomyelin levels in products without added MFGM-WPC. This would be useful during the exclusivity period proposed.	NSW FA	FSANZ notes the submitter comments for this issue and has clarified the intent in section 2.3.4.2. The proposed specified sphingomyelin range as a condition of use in the table to section S29—9A was not to represent a regulatory limit that would unnecessarily restrict the amount of sphingomyelin that may be present naturally in other infant formula ingredients. Having had regard to the submissions and on further consideration of the available evidence, FSANZ decided to remove the condition of use for sphingomyelin in the table to section S29–9A and has amended the explanatory statement accordingly.
Requested clarity on the presence of sphingomyelin in infant formula products from other ingredients (permitted without	NSW FA	

[8] See the FSANZ website at P1028 - Infant Formula | Food Standards Australia New Zealand

Submitter comment	Submitter(s)[6]	FSANZ Response
specific Code listing). For example, if an infant formula product contains sphingomyelin at the range of 1.8 - 7.5 mg/L or over from dairy ingredients other than MFGM-WPC, would this make the infant formula product non-compliant, provided the total phospholipid level is within the regulatory limit?		
Requested clarity on the intent of the sphingomyelin range in the MFGM-WPC nutritive substance outlined in S29-9A. If the intent is that this is to represent the level of sphingomyelin in: • the nutritive substance, then we would recommend the unit is aligned to the specification "*Contains sphingomyelin in the range of 1.3-2.3%.*". • the infant formula product (from all sources) when MFGM-WPC is used as a nutritive substance, clarity could be provided by adding the conditions "*Contains sphingomyelin in the range of 1.8-7.5 mg/100 kJ in the infant formula product*."	FCG, INC, a2MC	
Noted the comment in draft explanatory statement: "*the amount of sphingomyelin in the infant formula product must be no less than 1.8 mg/100 kJ, but not greater than 7.5 mg/100 kJ*" suggests the intent of the drafting was to apply the limits on the final infant formula. If this was the case, clarity could be provided by adding to the conditions "*Contains sphingomyelin in the range of 1.8-7.5 mg/100 kJ in the infant formula product."* clearly indicating if these limits are to apply to total sphingomyelin levels in the end product.	INC	
Raised concerns about the use of the minimum sphingomyelin as a marker for enforcement activities in infant formula products containing the MFGM-WPC nutritive substance. The submitter noted situations where infant formula products may contain sphingomyelin from other milk-based ingredients at a level similar to the proposed.	FCG, INC	

Submitter comment	Submitter(s)[6]	FSANZ Response
Stated the sphingomyelin range of 1.8 – 7.5 mg/100 kJ range provides insufficient flexibility to account for natural variation of sphingomyelin presence and analytical variability of sphingomyelin in raw materials and infant formula. The submitter requested for consideration to increase the maximum level to 10 mg/100 kJ to account for aforementioned variation factors.	FCG	
Issue: Benefit assessment on cognitive effects		
Noted their disappointment that FSANZ have opted not to support the effect of MFGM-WPC on neurodevelopment and cognitive function as the primary beneficial health effect and most important function.	AFI	As described in section 4.1 of SD1, the available evidence was insufficient to definitively conclude that MFGM-WPC improved the neural development or cognitive function in infants. Two of the infant studies used an instrument that identifies cognitive delay in infants but does not predict cognitive ability above normal ranges. Therefore no conclusions relating to improved cognitive function can be drawn from these studies. A third study that used an instrument that measures intelligence in young children did not identify any differences between children that consumed MFGM-WPC as infants and those that did not.
Agreed with the assessment conclusion that there is not enough evidence to support claimed beneficial effects on neural development.	NSW FA	FSANZ notes this comment.
Provided new evidence to support the cognitive benefits of MFGM supplementation in infant formula. The submitters further noted that individual studies, as well as the totality of the evidence, provide sufficient support for the effect of bovine milk fat globule membrane on brain development and cognitive function.	MJN, INC	Additional studies provided during submissions have been discussed in section 4.1.4 of SD1 (at Approval). Due to limitations in study design and uncertainty in the findings, the additional papers provided do not alter FSANZ's previous conclusions
Stated that the research does not show strong evidence for claims MFGM increases neurological or cognitive function. The submitter suggested that given the desired effect of increased brain function and the nutrient claim are not supported, this	Ind2	FSANZ has assessed that, in accordance with the FSANZ Act and Code requirements:

Submitter comment	Submitter(s)[6]	FSANZ Response
should be classed as a Novel Food.		• 'Milk fat globule membrane-enriched whey protein concentrate' meets the definition for '*used as a nutritive substance (section 1.1.2—12), and • the substance has a substantiated benefit in normal growth and development. The application was assessed having regard to Ministerial Policy Guideline[9] whereby substances used in infant formula products should have a substantiated beneficial role in the normal growth and development of infants. The assessment showed that infant formula supplemented with MFGM-WPC supported the development of a microbiota that more closely resembles that of breastfed infants (see SD1, section 4.2). The submitter notes that the nutrient claim (of increased neurological or cognitive function) is not supported. FSANZ notes that Standard 1.2.7 provides that a nutrition content claim or health claim must not be made about infant formula products. The Note to Division 3 of Standard 2.9.1 provides a signpost to this prohibition.
Issue: Benefit assessment on gut microbiome effects		
Stated the claim of improved gut microbiota through increased Bifidobacterium expression lack sufficient human studies to validate these outcomes.	DA	FSANZ notes three human infant studies were included in its assessment. An additional two human infant studies were identified and provide further evidence supporting MFGM-WPC supplementation may shift microbiota and metabolic profiles closer towards that of breastfed infants. The evidence shows that MFGM-WPC or its components support increased abundance and metabolic activity of infant-specific beneficial bacteria including *Bifidobacterium*. To support FSANZ's approach to assess the gut microbiome effects, additional information and clarification has been added in section 4.2 of SD1.
Issue: Safety and technological concerns		

[9] See "Policy guideline on infant formula products" at: https://www.foodregulation.gov.au/resources/publications/policy-guideline-infant-formula-products

Submitter comment	Submitter(s)[6]	FSANZ Response
Noted infants, particularly those under six months of age, as well as the elderly, often have compromised immune systems, making them more susceptible to infections and other health issues. While MFGM may offer certain benefits, its consumption by these vulnerable groups could pose significant health risks, especially if the product is not properly tested for safety and contamination.	Ind1	The permission to add MFGM-WPC only applies to infant formula products, for infants aged 0-12 months, not the elderly. FSANZ's safety assessment (section 3.1 of SD1), found that MFGM-WPC has an established history of safe use in many countries, with no case reports of adverse effects, and concluded that MFGM-WPC does not pose a safety risk to infants. FSANZ notes that Proposal P1028 introduced a regulatory framework consisting of a new category of infant formula products for unhealthy infants, such as those that are immune compromised. This new category, special medical purpose products for infants (SMPPi), is based on the principle that compositional requirements are compliant with the baseline composition (including voluntary permissions) for infant formula, **unless deviation is required for a particular medical purpose.** Risk of inappropriate use of SMPPi is mitigated through restricted sale, labelling and use under medical supervision. Regarding contaminants in infant formula products, FSANZ notes that: • Contaminants in infant formula products were reviewed in the recent comprehensive review of infant formula product regulations (Proposal P1028)[6]. Requirements based on FSANZ's assessment are summarised in the Approval Report for P1028 and are listed in S19. • Limits on microbiological contaminants are listed in the Code under Standard 1.6.1. It is the responsibility of the manufacturer of the food for sale to ensure the food satisfies the Code requirements.
Stated the potential transmission of diseases within the bovine sector is a serious consideration. Bovine diseases, such as tuberculosis, BSE (bovine spongiform encephalopathy), and antibiotic-resistant infections, could be transmitted through contaminated milk or milk-derived products. The introduction of such pathogens into the food chain, particularly if sourced from unverified or insufficiently tested origins, could have adverse	Ind1	FSANZ notes the recommendations from the World Health Organisation (WHO) stating tests on milk from BSE-infected animals did not show any BSE infectivity, and that milk and milk products are considered safe. Additionally, during manufacturing MFGM-WPC is subjected to heat treatment, which inactivates infectious pathogens, including bovine tuberculosis. The raw material used in the manufacture of the applicant's MFGM-

Submitter comment	Submitter(s)[6]	FSANZ Response
public health consequences.		WPC conforms to the European regulations 854/2004. This regulation states in section IX, Chapter I, section I, subsection 1 clause a): "[Raw milk must come from animals:] that do not show any symptoms of infectious diseases communicable to humans through milk". Food safety requirements for food businesses handling dairy are specified in Chapter 3 of the Code, and by Standard 4.2.4.
Stated a hidden market exists for imported food-related raw products in Australia, despite claims of Australian origin. This market, driven by complex supply chains involving multiple intermediaries, increases the difficulty in tracking the safety and quality of ingredients. Without proper oversight, this could result in the use of substandard or potentially hazardous raw materials, undermining consumer confidence in the integrity of the food supply.	Ind1	This issue is an enforcement issue, which is outside of FSANZ's statutory functions and the scope of this application. All imported food intended for sale in Australia must be safe and meet requirements in the Code. The Australian Government Department of Agriculture, Fisheries and Forestry (DSAFF) is responsible for regulating food that is imported to Australia for sale to check it is safe and compliant with requirements in the Code. Information about those requirements can be found on the Australian Government Department of Agriculture, Fisheries and Forestry website: see Importing food into Australia - DAFF.
Called for stronger regulatory measures to ensure that ingredients, especially those from high-risk sectors such as dairy, are subject to thorough testing and certification processes. Improved supply chain traceability, along with stricter import controls, could significantly enhance food safety and prevent the inclusion of contaminated or non-compliant raw materials in the marketplace.	Ind1	Regarding stronger regulatory measures, FSANZ has just completed a comprehensive review of infant formula product regulations (Proposal P1028)[6] which considered the latest scientific evidence, market developments, changes in international regulations and revised Australian and New Zealand policy. The review culminated in the gazettal of a new standard covering all aspects of compositional requirements and labelling provisions. Compliance with the standard including testing and certification processes is the responsibility of state and territory enforcement authorities. Information about the Imported Food Inspection Scheme, as it relates to infant formula (including biosecurity requirements) can be found on the Australian Government, Department of Agriculture, Fisheries and Forestry website.[10]

[10] See Infant formula (powdered) - DAFF. See also Biosecurity Import Conditions system (BICON) - DAFF.

Submitter comment	Submitter(s)[6]	FSANZ Response
Raised concerns about processing to produce MFGM and stated the application should provide more detail to understand fully all the chemicals used or possible contaminations and detailed changes to the molecules in question. Suggested spray drying with low temperatures or above 40°C causes MFMG to lose polar charge, be denatured and susceptible to oxidation damage, which would be damaging to the infant consuming formula with MFGM.	Ind2	The manufacturing process used to produce MFGM-WPC (see section 2.3 in SD1) are similar to those used to produce standard WPC that has been used safely for many years. The only additional steps are two additional filtration steps and one additional concentration step to produce higher concentrations of the whey protein compared to WPC. These additional processing steps are not expected to produce the changes referred to in the submission as they do not require additional unique spray drying steps compared to what is used to produce WPC. The production of WPC already undergoes a heating using spray drying step. No evidence is provided by the submitter explaining how the changes referred to would happen due to the additional filtration and concentration steps.
Suggested the addition of highly processed MFGM could be damaging and change brain structure and function with a detrimental outcome for the infant. This may not be obvious under 12 months - that the limited studies consider. Issues may not be evident until adulthood and then it is unlikely to be linked to infant formula and years of damage to infants, toddlers and children could ensue.	Ind2	The components of the applicant's MFGM-WPC are normal components of breastmilk. 12-and 24-week studies of MFGM supplementation in rodents, equivalent to decades of human life, do not show any adverse effects on neurological function. See section 3.1 of SD1 to this report for further details.
Noted precautions should be taken due to the delicate and vulnerable target cohort. Thus it is important to not modify foods in formula without clear evidence of no long term harm and not make claims made about unproven nutritive benefits on the cognition of human mammals.	Ind2	FSANZ's safety assessment (section 3.1 of SD1) concluded that MFGM-WPC does not pose a safety risk to infants. FSANZ's safety assessment was based on the best available evidence and conducted in accordance with the FSANZ Act. Under paragraph 1.2.7—4(b), nutrient content and health claims are prohibited in infant formula products.
Suggested MFGM may alter gut microbiota in number (up or down), species diversity, or introduce new novel pathogenic microbes. This is especially important for infants that are born preterm, those on formula from birth and those infants with disease states or immune disorders.	Ind2	As summarised in section 4.2 of SD1, FSANZ has conducted a comprehensive risk assessment on effects of MFGM-WPC on the development of the gut microbiota. FSANZ's decisions are based on the best available evidence, ensuring public health and safety are upheld. Regarding microbiological safety risks (see section 3.4 of SD1), FSANZ determined that no additional microbiological safety risks arise

Submitter comment	Submitter(s)[6]	FSANZ Response
		from addition of MFGM-WPC to powdered infant formula products beyond those encountered with infant formula products that are not supplemented with MFGM-WPC. As noted above, Proposal P1028 introduced a regulatory framework with a new category of infant formula products called SMPPi. The category regulates products for unhealthy infants, such as those mentioned by the submitter. The SMPPi category is based on the principle that compositional requirements are compliant with the baseline composition (including voluntary permissions) for infant formula, **unless deviation is required for a particular medical purpose.** Risk of inappropriate use of SMPPi is mitigated through restricted sale, labelling and use under medical supervision.
Suggested MFGM is a Novel Food substance with presumed higher levels of fat concentrations than in breast milk or than in normal whey protein- caution and more research should be taken before approving and adding MFGM to Infant Formula. Lack of evidence of safety of MFGM and presence in products is not sufficient proof of safety.	Ind2	Regulation of MFGM-WPC as nutritive substance has been discussed (see above and section 2.3.2 of this report).. As explained, the intended use of the substance in question is addition to food (infant formula products) to achieve a nutritional purpose. The substance has also been concentrated, refined or synthesised, to achieve [that] nutritional purpose when added to a food. FSANZ's assessment, based on the best available evidence, concluded that the substance (which is concentrated from bovine milk) will achieve a nutritional purpose when added to a food. As such, the substance falls within the ambit of the Code's provisions regulating nutritive substances as opposed to those regulating novel foods. Fat requirements are prescribed in section 2.9.1—7 (for infant formula and follow-on formula) and section 2.9.1—34 (for special medical purpose products for infants). FSANZ's safety assessment (section 3 of SD1) concluded that MFGM-WPC does not pose a safety risk to infants.
Issue: Labelling		
Considered that declaring MFGM-WPC under the 'Additional' subheading within the NIS is not typical for a nutritive substance and it raises the following issues:	NSW FA INC	FSANZ agrees that MFGM-WPC differs from several permitted nutritive substances insofar that it comprises of more than one nutrient. However, for reasons stated in this report, FSANZ has assessed

Submitter comment	Submitter(s)[6]	FSANZ Response
• It represents an ingredient declaration rather than a component or singular nutrient. Under the current Code, existing nutritive substances are singular nutrients with relatively high purity where their declaration can be directly linked to their average quantity. • It is inconsistent with the regulatory approach that prohibits the declaration of ingredients within the NIS (e.g. fish oil). • It will contribute to the 'Protein' and 'Fat' content of the food product (for protein, it may be up to 30% of the total protein present), and therefore be reflected in those average quantities. It will also contribute to 'Whey' content, which may be voluntarily declared. The result of these contributions is that a separate declaration of MFGM-WPC under the 'Additional' subheading would constitute double counting of protein, whey and fat in the NIS. • MFGM-WPC may be wrongly viewed by consumers as a single nutrient given that information for parents and carers on the FSANZ website explains listings under the 'Additional' subheading as 'non-mandatory nutrients'. • A declaration of MFGM-WPC (which includes 'whey protein' as part of its name) under the 'Additional' subheading may give consumers the false impression of additional benefit, over and above the mandatory protein declaration. Such a declaration would be at odds with average consumer understanding that WPC is a protein rich ingredient.	a2MC FCG	MFGM-WPC as a nutritive substance. The issue raised by these submitters relates to existing labelling requirements relating to nutritive substances for infant formula and follow-on formula. The permission to add the nutritive substance to these foods is subject to those requirements. The regulatory approach for declaring optional nutritive substances differs to that of other ingredients. If added to infant formula or follow-on formula, the Code requires the average quantity of any substance used as a nutritive substance to be expressed in grams, micrograms or milligrams per 100 mL formula in the NIS (subparagraph 2.9.1—24(3)(e)(i) of the Code) and for it to be declared under the subheading 'Additional' and in the same format as specified in the table for that substance (subsection 2.9.1—25(3) of the Code). Unless elsewhere provided in the Code, the NIS must not contain information other than is required by section 2.9.1—24. The regulatory intent is for the average quantity of MFGM-WPC to be declared under the 'Additional' subheading and the contributions to protein, whey (if declared) and fat from that nutritive substance to be captured under the 'Protein', 'Whey' (voluntary) and 'Fat' subheadings. This approach standardises the content and format of the NIS to assist caregivers to make quicker product comparisons and aid their understanding of the nutrition information relating to the product. This regulatory approach was based on consumer evidence and stakeholder feedback. For more information describing the rationale underpinning this regulatory approach for infant formula and follow-on formula, see Table 5, item B4 in SD3 to the 2nd CFS for P1028 Infant formula[6]. The Code does not specify formatting requirements for the declaration of nutritive substances added to SMPPi. The use of a nutritive substance ingredient still needs to meet the overall prescribed composition of an infant formula or follow-on formula, and the requirement to declare a nutritive substance separately in the NIS allows for this to be transparent for caregivers.

Submitter comment	Submitter(s)[6]	FSANZ Response
		FSANZ acknowledges that its website information for parents and caregivers 'Nutrition information statement on infant formula and follow-on formula' refers to 'non-mandatory nutrients'. This phrase was considered as more consumer friendly than 'nutritive substance'. FSANZ notes the submitter provided no evidence that caregivers will view MFGM-WPC as a single nutrient. As noted above in the previous response, the regulatory approach for declaring optional nutritive substances under the 'Additional' subheading is based on consumer research. This research indicates: • grouping vitamins, minerals and optional substances under subheadings in the NIS is preferred because it helps caregivers identify what the nutrients are and enables product comparisons across the categories. • the NIS format assists caregivers to make faster product comparisons. (see Table 5, item B4 in SD3 to the 2nd CFS for P1028 Infant formula). FSANZ also notes that separating nutrition declarations for optional nutritive substances from declarations for mandatory nutrients is a means of informing caregivers of the main compositional differences between products. In response to the comment that a MFGM-WPC declaration under the subheading 'Additional' may give consumers a false impression of additional benefit, FSANZ agrees Australian and New Zealand caregivers are likely to be familiar with WPC because of its common use as an ingredient in infant formula and follow-on formula. However, FSANZ considers it is unlikely consumers will be aware of MFGM-WPC given that it is currently not permitted for use in the domestic market, and if it is permitted, the declaration under the NIS subheading 'Additional' would alert caregivers that it is something new. As it is not currently permitted for addition, it is unknown whether caregivers will view a MFGM-WPC declaration as providing additional benefit in relation to protein content of the product (i.e. the nutritive substance provides protein that is supplementary to standard protein

Submitter comment	Submitter(s)[6]	FSANZ Response
		compositional parameters for infant formula and follow-on formula). However, a caregivers' impression of additional benefit would not be totally misplaced since FSANZ's assessment concluded MFGM may be beneficial for infant gut microbiota development (see SD1 report).
Recommended that FSANZ consider labelling for sphingomyelin as the marker compound for MFGM-WPC under the 'Additional' subheading in the NIS for the following reasons: • The declaration would help minimise confusion with consumers, for example removing the issue of double counting protein and not exaggerate the perceived benefit of the added optional substance. • A declaration of sphingomyelin would reflect the sphingomyelin present in the final product from all sources (that is, from MFGM-WPC and other dairy based ingredients), but would only be permitted to be declared when the MFGM-WPC is added as a nutritive substance. • Considered this approach would align with the condition of use for SM in S29—9A, but is dependent on FSANZ's interpretation of the condition for use.	FCG, INC, a2MC	FSANZ does not agree that sphingomyelin should be declared in the NIS when MFGM-WPC is added as an optional nutritive substance to infant formula or follow-on formula. The submitter's reference to the condition for use for sphingomyelin in the table to section S29—9A is no longer applicable as the condition has been removed from the approved draft variation. See section 2.3.4.2 of this report. Responding to each dot point: • See above for FSANZ's response regarding 'double counting' and perceived benefit. • As noted above, the permission will be for MFGM-WPC as an optional nutritive substance. Permissions for use will reside in the table to section S29—7 (for infant formula and SMPPi) and in the table to section S29—8 (for follow-on formula). Declaration requirements subparagraph 2.9.1—24(3)(e)(i) relate to permitted nutritive substances rather than any components or constituents of them. • In regard to submitter comments about declaring sphingomyelin to minimise consumer confusion, neither the submitters nor the applicant provided evidence of caregiver understanding of sphingomyelin including that it can be derived from other dairy sources. FSANZ also considers there would be a disconnect between the declarations in the statement of ingredients and the NIS, which may cause caregiver confusion. The applicant noted that in overseas markets where Lacprodan® MFGM-10 is permitted, it is declared in the ingredient list. This regulatory approach suggests caregivers in other countries are unlikely to be aware of sphingomyelin because it would not be declared.
Noted that neither the ingredient name nor the name of the	NSW FA	FSANZ agrees. The regulatory approach for nutritive substances is to

Submitter comment	Submitter(s)[6]	FSANZ Response
nutritive substance as declared in the NIS is prescribed. This means that industry can determine the name used on label for MFGM-WPC. This submitter supported FSANZ's position in section 2.2.8.1 of the CFS that the name that includes the phrase 'a source of' (e.g. 'Whey protein concentrate* (*a source of MFGM)') would be prohibited due to the implication as a nutrition content claim.		not prescribe the names for declaration on product labels. This approach applies to the use of nutritive substances in any special purpose food. As noted by the submitter, this approach was explained in section 7 Labelling of Appendix 3 to the P1028 Approval Report[6].
Considered FSANZ should require stronger evidence for health claims, such as high-quality, independent human studies, before approving any claims related to the ingredient's health benefits. Evidence from in vitro and animal studies should not be the sole basis for these claims.	DA	FSANZ notes the comment, however the Code provides that nutrition content and health claims must not be made about infant formula products. The Note to Division 3 of Standard 2.9.1 Infant formula products provides a signpost to the claim prohibition in Standard 1.2.7 Nutrition, health and related claims. This prohibition will remain in place.
Recommended clear labelling is needed to acknowledge the processes required to create this synthetic form of MFGM and allow those consumers with reactions or allergies such as acute otitis media or eczema to navigate products easily.	Ind2	FSANZ acknowledges these comments, however it considers additional labelling regarding the production process for MFGM-WPC to be unnecessary. FSANZ undertook a robust safety assessment and concluded that, with the exception of infants with milk protein allergies, there were no public health and safety concerns relating to the applicant's MFGM-WPC (see section 2.2 of this report and section 3.1.11 in SD1). In section 2.3.8.2 of this report, FSANZ states that a mandatory allergen declaration for milk will apply to MFGM-WPC, if added to an infant formula product. Milk is one of the 23 food allergens and substances required to be listed if it is present in a food for sale. For more information about generic Code requirements, see FSANZ's webpage Allergen labelling for consumers | Food Standards Australia New Zealand. Further, food labelling requirements in the Code are outcome-based (that is, they relate to the food for sale). FSANZ does not usually develop standards that encompass specific production methods used in the manufacture of food or food ingredients.

Submitter comment	Submitter(s)[6]	FSANZ Response
Issue: Exclusive use permission		
Suggested an exclusive use permission is unnecessary for an ingredient already available internationally, would likely serve only to consolidate market dominance for the applicant and potentially drive up cost, with no clear benefits to Australian consumers.	DA	The applicant provided evidence of their investment in preparing this application. Much of this was confidential commercial information (CCI) and was used in FSANZ's assessment. FSANZ considers it appropriate to grant a limited conditional exclusive use permission for the applicant's MFGM-WPC to be added to infant formula products in this instance. The granting of an exclusive use permission does not preclude other manufacturers from applying for permission to add their MFGM-WPC to infant formula products, including within the 15 month exclusive permission period. Further, the approved draft variation relates to an ingredient that infant formula products manufacturers may purchase. The approved draft variation does not apply any restrictions on who may purchase the applicant's MFGM-WPC during the 15 month exclusive use period.
Issue: New Zealand standards		
Confused by the statement at clause 2.4.1.3, which states: "*There are no relevant New Zealand Standards*". New Zealand's current standard for infant formula is the Standard 2.9.1 that was gazetted in 2002. This remains the New Zealand standard, and as such, we believe that any application to change the Food Standards Code needs to consider the New Zealand domestic standard, as per the obligations contained in s29 of the FSANZ Act. This would be irrespective of whether the application permission only applies to Australia.	INC, a2MC	See section 2.5.1.3 of this report.
Issue: Cost/benefit assessment		
Recommended FSANZ evaluate the potential impact of this decision on the cost of infant formula products and prioritise affordability for families. Any claims of benefit should be justified by robust evidence to prevent unnecessary cost	DA	The potential for the decision to result in a price premium is noted within the cost and benefit analysis. More robust analysis is not possible at present, due to the difficulty inherent in modelling product markets to estimate the impact on product pricing, and a lack of

Submitter comment	Submitter(s)[6]	FSANZ Response
increases.		information about products containing MFGM-WPC (or ingredients that could be a proxy for MFGM-WPC when modelling price changes).
Issue: Quality of evidence		
Requested FSANZ ensure transparency and independence by critically assessing the objectivity of the evidence presented, and managing conflicts of interest, especially for industry funding studies. Independent, peer-reviewed research should be required for regulatory decisions. The reliance on industry-funded studies further raises concerns about the objectivity of the evidence presented, as such studies are often associated with conflicts of interest.	DA	FSANZ conducted a comprehensive risk assessment according to internationally accepted methods and principles for the risk assessment of substances in foods. The assessment included a literature review and identification of additional studies not provided by the applicant, critical assessments of the studies provided by the applicant (including study methodology), and a dietary intake assessment for Australian consumers. FSANZ also notes the following: • Regarding transparency: In addition to evidence provided by the applicant, FSANZ undertakes a comprehensive search of the scientific literature to identify any additional relevant studies to be considered in the body of evidence. FSANZ provides details of that search and the date on which it was undertaken. • Regarding objectivity: When undertaking a scientific assessment FSANZ considers the evidence from a range of sources including (but not limited to) peer reviewed literature and reports. FSANZ independently assesses the data in these studies and reports any limitations in that literature when drawing its conclusions.
Suggested the evidence provided to support the gut microbiome health benefits is speculative and primarily based on in vitro and animal studies, which are not directly applicable to human populations. Furthermore, language in the evidence provided in the research findings, such as “may” and “could,” underscore the inconclusive findings and support from commercial interests. This points to the need to examine possible conflicts of interest.	DA	As above. FSANZ also notes that the microbiological benefit of MFGM-WPC was assessed using the best available scientific evidence, drawing the appropriate conclusion that infant formula supplemented with MFGM may support the development of a microbiota that more closely resembles that of breastfed infants. The conclusion is based on *in vitro* and *in vivo* mechanistic studies, animal studies and human intervention studies. See section 4.2 of SD1.
Issue: Correction/clarification		
In regards to section 1.6.2 of the Application, the submitter	AFI	The sentence in section 1.4.2 of the Approval Report has been

Submitter comment	Submitter(s)[6]	FSANZ Response
noted that a market update from the USA has confirmed that AFI's MFGM-WPC is not Lacprodan® MFGM-10, but another MFGM containing product. In addition, MFGM-WPC ingredients from other manufacturers are available in the USA.		amended to reflect this information.

2.2 Risk assessment

FSANZ compared the phospholipid composition of the MFGM-WPC with reported concentrations in human milk and is satisfied that the phospholipid composition of the MFGM-WPC is sufficiently similar to human milk to be used in infant formula products.

Specifications for MFGM-WPC will be added to Schedule 3 of the Code. The applicant has provided sufficient evidence to demonstrate that the MFGM-WPC preparation would comply with those specifications when sold for use in infant formula products, and that sphingomyelin can be used as a marker to quantify the addition of MFGM-WPC in infant formula products.

The safety assessment found that MFGM-WPC has an established history of safe use in many countries as an ingredient in infant formula products, with no case reports of adverse effects. MFGM-WPC has no more allergenic potential than other infant formula products based on bovine milk. FSANZ does not have concerns regarding the effect of MFGM-WPC in infant formula products on the absorption of other nutrients, nor were any adverse effects of MFGM-WPC on weight-based growth outcomes observed when compared to formula-fed infants in studies with MFGM-added up to a concentration of 5 g/L. No additional microbiological safety risks arise from addition of MFGM-WPC to powdered infant formula products.

The dietary intake assessment estimated the intake of phospholipids from MFGM-WPC in infant formula and follow-on formula assuming the maximum use level proposed by the applicant. Although higher than the estimated intakes of phospholipids by infants who consume mature human milk, estimated intakes of phospholipids from MFGM-WPC in infant formula and follow-on formula do not exceed estimated intakes assuming the regulatory limit of phospholipids specified in the Code.

FSANZ considered the evidence for the effect of MFGM-WPC in infant formula products on improved neural development and cognitive function. Due to the limitations in the available data, FSANZ was not satisfied that the evidence demonstrated improvement in neural development and cognitive function in infants. The assessment concluded that additional evidence would be required to make a definitive conclusion.

FSANZ also considered evidence for the effect of MFGM-WPC in infant formula products on improved development of the infant gut microbiota, anti-pathogenic effects, and immunomodulation effects for a formula-fed infant. FSANZ is satisfied that there is evidence the addition of MFGM-WPC to infant formula products may support the development of a gut microbiome that more closely resembles that of breastfed infants.

Taken together, FSANZ is satisfied that MFGM-WPC is an appropriate source of phospholipids for inclusion of infant formula products and does not pose a safety risk to infants. While more data is needed to substantiate improved neural development and cognitive function compared to standard infant formula products, there is evidence MFGM-WPC may be beneficial for infant gut microbiota development.

2.3 Risk management

Breastfeeding is the recommended way to feed infants. However, a safe and nutritious substitute for human milk is needed for infants when breastfeeding is not possible. As infants are a vulnerable population group, infant formula products are regulated by prescriptive provisions for composition and labelling. Any changes to the composition of these products must be established as safe prior to being permitted.

Following assessment, FSANZ prepared a draft variation and called for submissions on the draft variation from 12 December 2024 to 6 February 2025 (the submission period). The risk management options available to FSANZ after the submission period were to:

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

For reasons set out in this report, FSANZ has decided to approve the draft variation proposed at the call for submissions with amendments.

2.3.1 Regulatory approval

The draft variation prepared by FSANZ listed MFGM-WPC in the tables to sections S29—7 and S29—8 as an optional nutritive substance in infant formula products, with 'bovine milk fat globule membrane-enriched whey protein concentrate' as a permitted form in the table to section S29—9.

The applicant sought to permit the use of MFGM-WPC as a nutritive substance in infant formula products with an amendment to Schedule 29 to provide permission for sphingomyelin as an analytical marker for MFGM-WPC. While FSANZ's risk and technical assessment confirmed sphingomyelin as a suitable analytical marker for MFGM-WPC and that the applicant's range of 1.8 – 7.5 mg/100 kJ sphingomyelin in the final infant formula product was consistent with human milk concentrations, FSANZ considered it appropriate that the permission in Schedule 29 should reflect the nutritive substance MFGM-WPC, rather than a single component.

The approved draft variation therefore provides a permission for MFGM-WPC in Schedule 29 as a nutritive substance, with sphingomyelin content specified in the specification to be inserted into Schedule 3. The approved draft variation will list MFGM-WPC as the nutritive substance is consistent with FSANZ's risk and technical assessment and the evidence base supporting MFGM-WPC as the nutritive substance.

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

2.3.2 MFGM-WPC as a nutritive substance in infant formula products

In considering the proposed permission, FSANZ acknowledges that breastfeeding is the recommended way to feed infants and the intent of Standard 2.9.1 is not to replace human milk but to provide a safe, nutritionally replete, functional alternative for those infants for whom breastfeeding is not possible. Given this, and in accordance with the Ministerial Policy Guideline on infant formula products[11], infant formula products' composition should aim as closely as possible for nutritional equivalence to human milk.

To assess the suitability of compositional changes to the Code, FSANZ recognises the importance of demonstrating a link between physiological, biochemical or functional effects of the proposed ingredient to specific health outcomes for formula-fed infants, with appropriate evidence, and to use human milk as the primary reference for determining the composition of infant formula products as per specific policy principles (d) - (h) of the Ministerial Policy Guideline[9].

[11] Policy guideline on infant formula products at: Policy guideline on infant formula products | Food Regulation

The applicant's MFGM-WPC is manufactured using standard whey processing techniques, with additional filtration steps to concentrate MFGM components from whey to higher levels than found in standard WPC. As noted in section 1.4.2 of this report, infant formula products containing MFGM are already available in overseas markets, and MFGM is considered in many countries to be a component of WPC. As a protein source derived from cow milk, use of WPC in infant formula products is already common practice in Australia and internationally and is regulated under Standard 2.9.1—6 of the Code.

While MFGM-WPC components are present in low levels in cow milk-based infant formula products, this application is seeking to add MFGM-WPC at higher concentrations. FSANZ has determined that, given the intention is for use as a nutritive substance, pre-market assessment is required. This is consistent with requirements in the Code and relevant Ministerial Policy Guidelines.

Overall, FSANZ's assessment found that bovine MFGM-WPC is a safe and suitable ingredient in infant formula products, and that its proposed use as a nutritive substance in infant formula products:

- enables infant formula products to be better aligned with human milk by providing nutritionally important lipids normally removed during WPC processing, and
- is associated with beneficial health effects.

These findings are discussed in detail below.

2.3.3 Public health and safety considerations of MFGM-WPC in infant formula products

FSANZ's risk and technical assessment at SD1 reported no microbiological or toxicological safety concerns with the use of the applicant's MFGM-WPC in infant formula products at the proposed concentrations.

FSANZ's assessment also concluded MFGM-WPC is unlikely to affect growth of formula-fed infants compared to standard formula at concentrations up to 5 g/L. Due to a lack of available studies, FSANZ was not able to assess the impact of MFGM-WPC on infant growth at higher concentrations. However, given the widespread use of MFGM-WPC in infant formula products internationally and FSANZ's assessment outcomes (no toxicological safety concerns and consistency with human milk concentrations), FSANZ considered it unlikely that MFGM-WPC would adversely affect infant growth at concentrations up to 7 g/L, as requested in the application.

Infant formula products containing the applicant's MFGM-WPC is subject to existing fat and protein compositional requirements in Standard 2.9.1, including the maximum limit of total phospholipids of 72 mg/100 kJ. Phospholipids are naturally occurring constituents of milk and the intent of the restriction is to ensure phospholipids are not added to infant formula products at levels above those naturally occurring in milk. There is no existing permission in Standard 2.9.1 or Schedule 29 for 'phospholipids' to be used as a nutritive substance - it is strictly a restriction related to fatty acid composition.

At the MFGM-WPC maximum concentration of 7 g/L, estimated intakes of total phospholipids from MFGM-WPC in infant formula products were higher than estimates of total phospholipid intakes from mature human milk but do not exceed estimated intakes based on the regulatory limit for phospholipids in Standard 2.9.1 (see section 3.5 of SD1).

The maximum phospholipid amount of 72 mg/100 kJ (or 2 g/L) was introduced in Standard 2.9.1 through Proposal P1028. The previous standard did not include a maximum limit for

total phospholipid in infant formula products. In FSANZ's P1028 assessment, it was noted that total phospholipid concentration in mature human milk ranged from 0.20 – 0.25 g/L and that the maximum limit set in international regulations (EU and Codex) was aligned at 2 g/L (FSANZ, 2021, section 5.6.3). The prescribed maximum level of 2 g/L, despite being approximately 10-fold higher than the human milk concentration, is set to allow for the naturally occurring amounts of phospholipids in dairy milk. Therefore, FSANZ has no concerns with intakes of total phospholipids from MFGM-WPC being higher than human milk intakes as long as the prescribed maximum phospholipid amount for infant formula products is not exceeded.

The maximum limit for phospholipids in the Code applies to the total phospholipid content of infant formula products, which is inclusive of phospholipids from all sources (e.g. lecithin, LC-PUFA, vegetable oils, milk fat). As such the total phospholipids amount in infant formula products containing MFGM-WPC would need to include any other sources of phospholipids added such as lecithin.

FSANZ concluded there are no public health and safety concerns from the addition of bovine MFGM-WPC when used as a nutritive substance in infant formula products at the proposed concentration of 4 to 7 g/L.

2.3.4 Specific phospholipids

2.3.4.1 Comparison with human milk

MFGM-WPC is a mixture of unique polar lipids and membrane-specific proteins. The main polar lipids in MFGM are glycerophospholipids and sphingolipids, which are collectively referred to in FSANZ's assessment as phospholipids. The structure and proportion of different phospholipids in MFGM is discussed in section 2.2 of SD1.

FSANZ's risk and technical assessment (SD1) compared concentrations of the five most abundant phospholipids (PE, PS, PI, PC, and SM)[12] present in human milk to the applicant's MFGM-WPC. FSANZ concluded the phospholipid composition of MFGM-WPC to be sufficiently similar to human milk for use as a source of phospholipids in infant formula products.

FSANZ considers the contribution of other constituents of MFGM-WPC (protein, triglycerides, cholesterol, and other fatty acids) are managed through the existing Code requirements and therefore these were not compared to concentrations in human milk.

- Protein content and amino acid composition are regulated under section 2.9.1—6 and cow milk protein is a permitted protein source in infant formula products (subsection 2.9.1—6(1)).
- The Code does not restrict fat sources for use in infant formula products but sets compositional requirements for fatty acids in section 2.9.1—7 for infant formula and follow-on formula and section 2.9.1—34 for SMPPi. This includes minimum amounts of essential fatty acids, and restrictions on amounts of specific fatty acids, such as trans fatty acids and docosahexaenoic acid.

2.3.4.2 Sphingomyelin content as a condition in the permission

FSANZ's assessment at CFS considered the suitability of sphingomyelin as an analytical marker, noting that MFGM-WPC is a mixture of substances and not easily quantified.

[12] PE = phosphatidyl ethanolamine, PS = phosphatidyl serine, PI = phosphatidyl inositol, PC = phosphatidyl choline, SM = sphingomyelin.

Sphingomyelin is one of the major phospholipids present in MFGM-WPC, and standardised methods are available to assay its content in MFGM-WPC and infant formula products. FSANZ's assessment concluded that sphingomyelin is a useful analytical marker to differentiate as well as quantify the addition of MFGM-WPC to infant formula products (section 2.5 of SD1). Based on this conclusion, FSANZ proposed at CFS to include a condition in the table to section S29—9A that if used, MFGM-WPC must provide a concentration range of sphingomyelin in infant formula products of 1.8 – 7.5 mg/100 kJ (the section S29—9A condition).

However, submitters to the CFS raised concerns in relation to the proposed condition, including:

- Enforcement issues due to the lack of consistency between the maximum amount of sphingomyelin specified in Schedule 3 (1.3 – 2.3% which converts to 1.8 – 6.4 mg/100 kJ)[13] and the maximum amount specified in the section S29—9A condition (7.5 mg/100 kJ).
- Uncertainty around whether sphingomyelin from other dairy ingredients is included in the section S29—9A condition and whether that represents the maximum amount of sphingomyelin in the nutritive substance or the infant formula product.
- That the condition imposes a regulatory limit of sphingomyelin in the final infant formula product and provides insufficient flexibility to account for natural variation of sphingomyelin in other infant formula ingredients.

FSANZ notes that the condition of use proposed at CFS aligned with the application which requested permission for sphingomyelin as the nutritive substance. However, as concluded in the CFS, this permission was not supported by the evidence base which showed that the health outcome is based on studies conducted with MFGM-WPC, not isolated or purified sphingomyelin. The decision at CFS to set this range as a condition of use in the table to section S29—9A was to indicate sphingomyelin as a defining measurable characteristic of the nutritive substance MFGM-WPC (i.e. as an analytical marker) and as a quality assurance measure for phospholipid composition of the nutritive substance MFGM-WPC.

The concentration range for sphingomyelin in the condition of use (which applies to the infant formula product) provides an additional 1.1 mg/100 kJ above the amount of sphingomyelin as derived from the specification in Schedule 3. According to the application, this would allow for naturally occurring amounts of sphingomyelin in other ingredients used in infant formula products. FSANZ has since obtained information that sphingomyelin in standard WPC ingredients may be present at concentrations greater than 1.1 mg/100 kJ.[14]

In light of submitter comments, FSANZ has reconsidered the approach from CFS and removed Condition 1 from the *Conditions of use* column in the draft variation's amendment to the table to section S29—9A, as proposed at CFS. In removing the condition, the sphingomyelin amount in the nutritive substance is sufficiently restricted by the level specified in Schedule 3 (1.3 – 2.3%) where the sphingomyelin amount in the infant formula product from addition of MFGM-WPC would be in the range of 1.8 – 6.4 mg/100 kJ[11]. Removing the condition of use allows for greater flexibility when sphingomyelin is present in other ingredients. This change is further complemented by the existing fat compositional requirements in Standard 2.9.1, including the maximum limit of total phospholipids of 72 mg/100 kJ which ensures phospholipids are not added to infant formula products at levels above those naturally occurring in milk.

[13] Calculated based on MFGM-WPC added in the range of 0.14 – 0.28 g/100 kJ (4 – 7 g/L) and the Standard 2.9.1 energy range of 2510 – 2930 kJ/L.
[14] The submission from Fonterra Co-operative Group Limited indicated that an infant formula product made predominantly with "standard" WPC would contain approx. 3 mg/100 kJ of sphingomyelin.

2.3.5 Substantiated health benefit

A demonstrable health effect in conjunction with bringing the composition of infant formula products closer to that of human milk is aligned with the principles of the Ministerial Policy Guideline in infant formula products[9]. This also aligns with specific policy principle (j) of the guideline, which states that substances added to infant formula products should have a substantiated beneficial role in the normal growth and development of infants, or a technological role. FSANZ is required to consider these principles in assessing the beneficial health effect of the applicant's MFGM-WPC.

The fraction of bovine milk that contains MFGM is largely removed during normal processing to manufacture infant formula and other dairy products. To meet energy and composition requirements in the Code, vegetable oils are commonly used as a fat source in infant formula products. Vegetable oils lack some lipids found in human milk fat. Based on the lipid composition of the applicant's MFGM-WPC (see Figure 1, SD1), infant formula products with MFGM-WPC added at the proposed amount will contain levels of lipids that better align with levels in human milk.

Based on FSANZ's assessment of beneficial health effects, FSANZ concluded that infant formula products supplemented with MFGM-WPC may support improved neural development and cognitive function in infants, with some studies reporting an increase in developmental scores compared to controls fed infant formula products with no added bovine MFGM-rich ingredient. However, the body of evidence is limited (see section 4.1 of SD1).

The applicant also provided evidence on the benefits of MFGM-WPC on the development of the gut microbiota. FSANZ's assessment concluded that infant formula products containing MFGM-WPC allow for a microbiota that more closely resembles that of breastfed infants. The associated health benefits from MFGM-WPC for infants include:

1. an anti-pathogenic effect
2. immunomodulation, and
3. development of the gut microbiome through increased *Bifidobacterium* expression (see section 4.2 of SD1).

Evidence reviewed by FSANZ (from both the applicant and independent third parties, as well as from FSANZ's own literature search) demonstrated that MFGM-WPC added to infant formula products has physiological and functional effects that can be beneficial to formula-fed infants. FSANZ considers that the evidence supports the proposed voluntary compositional permission, noting the proposed addition is safe and will provide an infant formula product that is more comparable to human milk.

2.3.6 Permitted range and units of expression

The permitted range of MFGM-WPC is based on consideration of the safety, technical and beneficial health effects assessments, including estimated dietary intakes and naturally occurring levels in human milk. FSANZ's risk assessment did not identify any safety concerns of MFGM-WPC at the proposed concentration range of 4 to 7 g/L.

As noted in section 2.2 of this report, at the maximum concentration of 7 g/L, estimated intakes of phospholipids in infant formula products containing MFGM-WPC would be higher than intakes in infants who are breastfed (based on the maximum concentration of phospholipids in the applicant's MFGM-WPC) but are well below the intakes estimated based on the maximum amount of phospholipids permitted to be in infant formula products under subsection 2.9.1— 7(3) (72 mg/100 kJ). Given that phospholipids are a naturally occurring component of cow milk and the conclusions of the safety assessment, FSANZ considered the maximum proposed concentration of bovine MFGM-WPC of 7 g/L to be appropriate.

Generally, the rationale for setting minimum levels for optional nutritive substances to infant formula products has been to ensure that these substances, if added, would be present at levels sufficient to achieve their intended purpose. In many cases permissions for optional substances (e.g. human identical milk oligosaccharides), the available evidence is not sufficient to establish an effective minimum dose and therefore, no minimum was set in the Code. In this application the minimum concentration of 4 g/L in infant formula products is comparable to the amounts used in test formulas to assess potential beneficial health outcomes.

For consistency with other permissions in the Standard 2.9.1 and Schedule 29, FSANZ based the minimum and maximum amounts of MFGM-WPC on mg/100 kJ units. This allows for the actual amount of MFGM-WPC in infant formula products to vary depending on the energy content of the formula. The application sought permission to add MFGM-WPC to infant formula products at a level of 4 to 7 g/L. Using the required energy range of 2510 – 2930 kJ/L, this converts to a range of 0.14 – 0.28 g/100 kJ.

As previously detailed, the lipid composition for MFGM-WPC is prescribed by the permitted ranges for phospholipids and sphingomyelin listed in the specification to be inserted in Schedule 3 (see section 2.3.8).

2.3.7 Labelling

Division 3 of Standard 2.9.1 provides specific labelling requirements for infant formula and follow-on formula. Labelling requirements that apply to SMPPi are set out in Division 4 of the same standard. FSANZ refers to the relevant requirements below that will apply to the applicants' MFGM-WPC if it is added to infant formula products.

2.3.7.1 Statement of ingredients

Infant formula and follow-on formula

Standard 1.2.4 requires food for sale to be labelled with a statement of ingredients unless exempt. The label on a package of infant formula or follow-on formula must contain a statement of ingredients. Should manufacturers choose to add the applicant's MFGM-WPC to infant formula or follow-on formula, then this substance must be declared in the statement of ingredients.

Generic ingredient labelling provisions in section 1.2.4—4 require ingredients to be identified using a name by which they are commonly known, or a name that describes its true nature, or a generic ingredient name if one is specified in Schedule 10 *Generic names of ingredients and conditions for their use*. A generic ingredient name for bovine MFGM has not been specified. These ingredient naming requirements will apply to the applicant's MFGM-WPC.

The applicant proposed some options for how their nutritive substance could be listed in the statement of ingredients. These included:

- 'Milk fat globule membrane-enriched whey protein concentrate'
- 'Phospholipid enriched whey protein concentrate'.

The wording of the above options would be consistent with the substance name proposed for the permission of the applicant's MFGM-WPC as an optional nutritive substance for infant formula and follow-on formula (see the table to Schedule S29—7 and the table to Schedule S29—8 of the approved draft variation).

However, FSANZ noted that some of the proposed ingredient name options asterisk bracketed information, where that information states 'a source of' (e.g. *'Whey protein concentrate* (*a source of MFGM)'*). It is unclear whether the asterisked bracketed information would be included as part of the ingredient declaration or elsewhere on the label of the package. However, the use of the text 'a source of' would be a prohibited nutrition content claim, irrespective of whether it appeared in the statement of ingredients or not.

Special Medical Purpose Products for infants (SMPPi)

Section 2.9.1—51 sets the requirement for information relating to ingredients in SMPPi. This section specifies that ingredient information may be provided on the label of a package of SMPPi in a statement of ingredients (in accordance with the Code), or ingredient information that complies with either the EU or US regulations. The regulatory approach in the Code is intended to facilitate the importation of highly specialised SMPPi that are manufactured in low volumes in Europe and in the United States. Therefore, for the use of the applicant's MFGM-WPC in SMPPi, the ingredient naming requirements of either the Code, or the EU or USA would apply.

2.3.7.2 Mandatory allergen declarations

Infant formula and follow-on formula

The applicant's MFGM-WPC is derived from bovine milk. FSANZ considers the potential for allergenicity of infant formula that includes this nutritive substance is anticipated to be similar to that of other bovine milk-derived infant formula products (see section 3.1.9 of SD1).

Allergen declaration requirements in Division 3 of Standard 1.2.3 will apply to infant formula and follow-on formula. In accordance with these Code requirements, the term 'milk' is the required name[15] and must be declared in conjunction with the applicant's MFGM- WPC in the statement of ingredients and in a summary statement.

SMPPi

Paragraph 2.9.1—50(h) of Standard 2.9.1 of the Code states SMPPi are subject to allergen declaration requirements specified by section 1.2.3—4. Either the term 'milk' or another name by which the food is commonly known must be declared, but other declaration requirements in Division 3 (e.g. for formatting and location) will not apply to SMPPi.

2.3.7.3 Mandatory nutrition information

Infant formula and follow-on formula

Section 2.9.1—24 sets requirements for the declaration of nutrition information in a NIS on the label of a package of infant formula or follow-on formula. The NIS is a single statement that must be set out in the same format as specified in the table to section S29—10, and in accordance with section 2.9.1—25.

Subparagraph 2.9.1—24(3)(e)(i) requires any substance used as a nutritive substance in infant or follow-on formula to be declared in the NIS expressed in grams, micrograms or milligrams per 100 mL of formula. Therefore, the applicant's MFGM-WPC must be declared in the NIS when it is used voluntarily in infant formula and follow-on formula. Subsection 2.9.1—25(3) requires the declaration to be made under the heading 'Additional' in the NIS,

[15] ***Required name***, of a particular food, means the name declared by section 1.2.3—5 as the required name for that food for the purposes of Division 3 of Standard 1.2.3 (section 1.1.2—2).

using the format specified in the table to section S29—10.

The Code also requires the average quantity of fat and protein to be declared and permits the average quantities of whey and casein to be declared in the NIS (paragraph 2.9.1—24(3)(b) and subsection 2.9.1—24(4), respectively). The amount of fat, protein and whey protein from the applicant's MFGM-WPC must be included as part of these declarations.

SMPPi

Paragraph 2.9.1—53(1)(c) requires the declaration of a substance used as a nutritive substance expressed per given amount of the product and that has been added to the SMPPi to achieve its intended medical purpose. Should manufacturers choose to add the applicant's MFGM-WPC, then this provision will apply. However, there are no formatting requirements for this nutrition information, as labelling provisions for SMPPi are generally more flexible compared to infant formula and follow-on formula to ensure the importation of SMPPi is not impeded.

Name of nutritive substance

As stated in section 2.3.1 of this report, FSANZ is proposing to permit the use of 'Milk fat globule membrane-enriched whey protein concentrate' as an optional nutritive substance in infant formula products. FSANZ notes the applicant proposed several options for declaring the sphingomyelin component in the NIS (for example, 'Milk fat globule membrane sphingomyelin'). These proposed options were based on the permission sought by the applicant for the sphingomyelin component as an analytical marker for MFGM-WPC. However, as noted above, FSANZ considers the permission should reflect the nutritive substance, rather than a single component. If added to infant formula products, the declaration in the NIS should reflect the name of the permitted nutritive substance.

2.3.7.4 Prohibited representations and prohibited claims

Paragraph 2.9.1—28(1)(i) prohibits information relating to the presence of a nutritive substance except for a reference in a statement of ingredients or in a declaration or statement expressly permitted or required by the Code, such as a NIS, on the label of a package of infant formula or follow-on formula.

For SMPPi, subsections 2.9.1—46(1) and (2) set out explicit prohibitions for:

- claims that –
  - refer to the prevention, diagnosis, cure or alleviation of a disease, disorder or condition; or
  - compare the product with a good that is:
    - represented in any way to be for therapeutic use, or
    - likely to be taken to be for therapeutic use, whether because of the way in which the good is presented or for any other reason; and.
- nutrition content and health claims.

These prohibitions will apply in relation to the applicant's MFGM-WPC where it is used voluntarily in SMPPi. However, the prohibitions will not apply in relation to:

- a claim that is expressly permitted by this Code; or
- declaration that is required by an application Act.

2.3.7.5 Voluntary representations

Paragraph 1.2.7—4(b) states that a nutrition content or health claim must not be made about an infant formula product. This provision will apply to infant formula products that contain the applicant's MFGM-WPC.

2.3.8 Specification

Section 1.1.1—15 requires that a substance used as a nutritive substance must comply with any relevant specification set out in Schedule 3 when added to food in accordance with this Code, or sold for use in food. There are no relevant specifications for MFGM-WPC in Schedule 3. Therefore, in the absence of an appropriate published specification, a new specification for MFGM-WPC is required for addition to Schedule 3.

The applicant provided their manufacturing specification and batch analysis results. FSANZ assessed the information and developed a specification for inclusion in Schedule 3. While the specification is based on the parameters provided in the application, FSANZ is of the view that these are sufficiently generic to allow for future innovation. As noted in section 2.4 of SD1, FSANZ only included the analytes considered important for a regulatory specification for identity and purity reasons. When used as a nutritive substance in infant formula product (or MFGM-WPC sold for such use) would have to comply with the specification listed in Schedule 3.

The specification for MFGM-WPC includes an amount of sphingomyelin that is not less than 1.3% and not more than 2.3%. This converts[12] to a possible range of sphingomyelin from the added nutritive substance MFGM-WPC of 1.8 mg/100 kJ to 6.4 mg/100 kJ in the final infant formula product. As previously discussed, sphingomyelin is one of the major phospholipids present in MFGM-WPC, and standardised methods are available to assay its content in MFGM-WPC and infant formula products. Sphingomyelin content may provide a useful analytical marker to differentiate as well as quantify the addition of MFGM-WPC to infant formula products (see section 2.5 of SD1).

2.3.9 Exclusivity

An applicant may request exclusive use permission to use and sell a food (including a substance) for a certain period of time to recognise the investment made in developing that food, and the need to achieve return on this investment, thereby supporting innovation..[16]

The applicant requested an exclusive use permission for their specific brand of MFGM-WPC.

FSANZ has decided to grant the applicant with an exclusive use permission for MFGM-WPC for a 15-month period commencing on the date of gazettal of the approved draft variation.

This means that, during that 15-month period, MFGM-WPC can only be sold under the brand Lacprodan® MFGM-10 in accordance with the Code.

Once the 15-month exclusive use period ends, the permission to use MFGM-WPC will revert to a general permission i.e., become generic and non-brand specific, meaning that MFGM-WPC under any brand may then be sold for use as a nutritive substance in an infant formula product in accordance with the Code.

[16] See FSANZ website: Exclusivity of use for novel foods and nutritive substances | Food Standards Australia New Zealand

An exclusive use permission in the Code does not, and cannot, prevent approval of second or subsequent applications under the Code, either within the exclusive use period or during the progression of an application, for the use of the same food or ingredient by other food companies, providing the application process is undertaken.

2.3.10 Risk management conclusion

Having considered all aspects of the assessment against the statutory requirements, including relevant Ministerial Policy Guidelines, FSANZ has decided to approve the draft variation proposed at the call for submissions with amendments (see section 1.7 of this report), to permit the use of MFGM-WPC as a nutritive substance in infant formula products in accordance with the Code.

The applicant's MFGM-WPC will be subject to relevant requirements and conditions in the Code, which include the following:

- The nutritive substance MFGM-WPC may be voluntarily added at a minimum level of 0.14 g/100 kJ up to a maximum level of 0.28 g/100 kJ.
- The MFGM-WPC when used as a nutritive substance in infant formula products (or sold for such use) must be sourced from bovine milk (the permitted form) and must meet the specification listed in section S3—53.
- Meeting the specification includes that the added MFGM-WPC contains an amount of sphingomyelin (among other substances) consistent with the specification.
- Subsections 2.9.1—7(3) and 2.9.1—34(3) already restrict the total phospholipid content in the respective infant formula products to not more than 72 mg/100 kJ. This restriction will apply to phospholipids added as MFGM-WPC and from any other sources.
- Existing generic and specific labelling requirements in the Code will apply to infant formula products containing MFGM-WPC used as a nutritive substance.
- An exclusive use permission will be granted to the applicant, so that 'MFGM-WPC' may only be sold under the applicant's brand name 'Lacprodan® MFGM-10' during a period of 15 months, commencing on the date of gazettal of the approved draft variation.

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. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's digital channels and Food Standards News.

The process by which FSANZ considers standards development matters is open, accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. 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 call for submissions period.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

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

2.5.1.1 Consideration of costs and benefits

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the application outweigh the costs to the community, government or industry that would arise from the development or variation of the food regulatory measure.

Background

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[17]. Impact Analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to the voluntary addition of nutritive substances to foods (OIA Reference: OIA23-06224).

This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have 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 (paragraph 29(2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where the status quo is rejecting the application). This analysis considered the costs and benefits of permitting the proposed use of the applicant's MFGM-WPC as a nutritive substance in infant formula products.

The consideration of the costs and benefits in this section was 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 sought 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 a nutritive substance in infant formula products.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

Consumers

[17] Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

The permission to add MFGM-WPC has been assessed in Australia only (see section 1.3.3 and 2.5.1.3). FSANZ's risk assessment concluded that there are no safety concerns, and therefore no negative impacts are expected. Australian infants may benefit from the addition of MFGM-WPC. The health benefits to consumers are described in this report.

It is possible that industry may achieve some price premium for this product in the short-term. 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.

The purpose of granting an exclusive use period is to encourage industry innovation and allow applicants to achieve commercial rewards through higher returns on their investment. Any commercial reward from this application's exclusive use period could come at the expense of consumers in the short-term, through other businesses not being able to compete to supply the applicant's MFGM-WPC at lower prices during the exclusivity period. However, without this incentive this innovation may not have taken place. It is assumed that the greater incentive to innovate will lead to greater benefits in the medium to long term for consumers as more products come to market that may benefit them.

Industry

The permission to add MFGM-WPC has been assessed in Australia only (see section 1.3.3 and 2.5.1.3). Manufacturers of infant formula products that contain MFGM-WPC for export to Australia will be permitted to sell their products in Australia (where they fully comply with the Code).

Given the applicant's MFGM-WPC is already approved in some overseas countries, the permission will favour trade and any growth of overseas markets for exporters of infant formula products in Australia. The permission may also support innovation in infant formula products.

Producers of infant formula products in Australia may however face greater competition in the Australian infant formula products market from overseas-based producers that can also supply Australia with infant formula products containing MFGM-WPC. Any such impacts to domestic producers are assumed to be outweighed by benefits to consumers from greater industry competition.

Granting an exclusive use period will prevent other businesses from producing MFGM-WPC in the short-term. There may also be short-term restrictions on numbers of businesses that can access sale of MFGM-WPC, relative to if the exclusive use period had not been granted. However, the granting of an exclusive use period does not preclude any other company from applying to amend the Code in relation to the same food or ingredient. Therefore, the market for this additional source of the milk fat globule membrane could be opened during the 15-month exclusivity for any other companies willing to make an application.

Government

The approval of this application may result in a small but likely inconsequential cost to Australian governments in terms of monitoring for compliance.

Overall conclusion

FSANZ's assessment is that the direct and indirect benefits that will arise from permitting 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

Paragraph 29(c) of the FSANZ Act requires FSANZ to have regard to any relevant New Zealand standards.

As explained above, the draft approved variation will amend Schedule 29 of the Code to provide a permission for bovine MFGM-WPC to be added as a nutritive substance for the purposes of Standard 2.9.1 of the Code.

Standard 2.9.1 of the Code is an Australian only standard[18]. Schedule 29 of the Code lists the compositional requirements (e.g. permissions, limits, calculations, permitted forms etc.) for the purposes of that Australia only Standard 2.9.1 as well as Standards 2.9.2 to 2.9.5 of the Code. Standards 2.9.2 to 2.9.5 are joint standards that apply in both Australia and New Zealand.

Standard 2.9.1 as it was in force immediately prior to the gazettal of the variations made by Proposal P1028 remains in force in New Zealand as part of New Zealand law (the New Zealand standard). That is, as it previously had been adopted by the New Zealand Government under the *Food Act 2014* (NZ) and no action has been taken to date by that Government to amend or revoke it under section 400 of that Act.

The New Zealand standard is not part of the Code for the purposes of the FSANZ Act. Nor is it covered by the 'Australian New Zealand Food Standards System' established by the Treaty and for which FSANZ is authorised to develop draft standards in accordance with the FSANZ Act.

FSANZ also understands that the consequential amendments made by Proposal P1028 to Standards 1.1.2, 1.2.3, 1.3.1, 1.5.1, 2.9.2, 2.9.3, 2.9.5, and Schedules 8, 15, 19, 25 and 29 of the Code have not been adopted in New Zealand under the *Food Act 2014* (NZ).

The application, interpretation and amendment of the New Zealand standard is a matter for the New Zealand Government.

Approved draft variation's amendment of Schedule 3

As explained, the draft approved variation will also amend Schedule 3 of the Code by adding to that Schedule a specification for 'bovine milk fat globule membrane-enriched whey protein concentrate'. If the draft approved variation is approved, the latter will be the permitted form of MFGM-WPC when used a nutritive substance for the purposes of Standard 2.9.1 and Schedule 29.

Section 1.1.1—15 of the Code provides that food additives, processing aids, nutritive substances and novels foods must comply with a relevant specification in Schedule 3 when added to food in accordance with the Code (i.e. a joint Standard), or when sold for such use.

[18] On 5 August 2024, the New Zealand Government formally opted out of Standard 2.9.1 under *Annex D* of *The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*.

Standard 1.1.1 and Schedule 3 of the Code are joint standards that apply in both Australia and New Zealand.

FSANZ is not aware of any provisions of the joint Code that currently permit the use or sale of MFGM-WPC as a food additive, processing aid, nutritive substance or novel food.

The application of the approved draft's specification to and in New Zealand remains a matter for the New Zealand Government.

Advice about the application of the approved draft variation to infant formula products sold in New Zealand can be obtained from the New Zealand Ministry for Primary Industries.

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 this, FSANZ considered the evidence of any public health and safety risk associated with the intake of MFGM-WPC as well as potential beneficial health effects to infants who are consuming infant formula products. FSANZ's assessment concluded MFGM-WPC added at a level of 4 to 7 g/L (equivalent to the permitted range of 0.14 g/100 kJ to 0.28 g/100 kJ) is an appropriate source of phospholipids for inclusion in infant formula products and does not pose a safety risk to infants. While more data is needed to substantiate improved mental development compared to standard infant formula products, there is evidence MFGM-WPC may be beneficial for infant gut microbiota development.

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 2.3.7 of this report will apply to infant formula products containing added MFGM-WPC and provide adequate information to enable consumers to make an informed choice.

2.5.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 2.3.7.4, that aim to prevent misleading or deceptive conduct, will apply to infant formula products containing added 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[19], FSANZ has considered the best available scientific evidence to reach its conclusions on the safety, technical and beneficial health outcomes of MFGM-WPC in infant formula products.

- **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. MFGM-WPC is permitted for addition to infant formula products equivalent products in many overseas jurisdictions. The proposed permission will promote consistency between domestic and a number of international food standards.

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

The proposed permission will support an internationally competitive food industry (see section 2.5.1.1 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**

As part of A1307, FSANZ had regard to both high order and specific policy principles in the following Ministerial Policy Guidelines:

  - Regulation of Infant Formula Products
  - Intent of Part 2.9 of the Food Standards Code – Special Purpose Foods.

Noting the the food technology aspects, safety, associated health benefits and nutritional impact assessed in SD1 and section 2.2 of this report, FSANZ considers these policy guidelines have been met.

3 References

Codex Alimentarius (2020) Standard for Infant Formula and Formulas for Special Medical Purposes Intended for Infants. (CXS 72, adopted in 1981. Amendment: 1983, 1985, 1987, 2011, 2015, 2016 and 2020, Revision: 2007). Rome, Italy: Codex Alimentarius Commission. Available at: https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B72-1981%252FCXS_072e.pdf

Codex Alimentarius (2023) Standard for Follow-up formula for Older Infants and Product for Young Children. (CXS/156, adopted in 1987. Amendment: 1989, 2011, 2017, Revision: 2023. Rome, Italy: Codex Alimentarius Commission. 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 (2021) Consultation Paper 2 – Nutrient Composition. Proposal P1028 – Infant Formula. FSANZ, Canberra. Available online at: P1028 - Infant Formula | Food Standards Australia New Zealand

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

Attachments

A. Approved draft variation to the *Australia New Zealand Food Standards Code*
B. Explanatory Statement

Attachment A – Approved draft variation to the *Australia New Zealand Food Standards Code*

Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table)

Insert:

Bovine milk fat globule membrane-enriched whey protein concentrate	section S3—53

[2] After section S3—52

Insert:

S3—53 Specification for bovine milk fat globule membrane-enriched whey protein concentrate

(1) In this section, bovine milk fat globule membrane-enriched whey protein concentrate is a preparation of cow's milk consisting of lipids and proteins.

(2) For bovine milk fat globule membrane-enriched whey protein concentrate, the specifications are the following:

(a) description—off white powder;
(b) total protein—not less than 69.0% and not more than 76.0%;
(c) lactose—not more than 2.0%;
(d) fat—not less than 16.0% and not more than 22.0%;
(e) phospholipids—not less than 6.0% and not more than 10.0%;
(f) sphingomyelin—not less than 1.3% and not more than 2.3%;
(g) ash—not more than 3.0%;
(h) moisture—not more than 5.0%;
(i) arsenic—not more than 0.2 mg/kg;
(j) cadmium—not more than 0.1 mg/kg;
(k) lead—not more than 0.05 mg/kg;
(l) mercury—not more than 0.02 mg/kg;
(m) microbial limits:
  (i) total plate count (30°C)—not more than 10000 cfu/g;
  (ii) total plate count (55°C)—not more than 1000 cfu/g;
  (iii) *Bacillus cereus*—not more than 50 cfu/g;
  (iv) Sulphite-reducing *Clostridia*—not more than 10 cfu/g;
  (v) *Enterobacteriaceae*—not more than 10 cfu/g;
  (vi) Coagulase-positive *staphylococci*—absent in 1 g;
  (vii) Yeast and moulds—not more than 10 cfu/g.

Schedule 29—Special purpose foods

[3] Section S29—7 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g

[4] Section S29—8 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g

[5] Section S29—9 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate

[6] Section S29—9A (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate	1. During the exclusive use period, may only be sold under the brand Lacprodan® MFGM-10 for *use as a nutritive substance in an infant formula product. 2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) 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 A1307 which seeks to permit the use of bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) as a nutritive substance in infant formula products. The application also sought a 15 month exclusive use permission for the Applicant's brand of MFGM-WPC. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) 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 approved the draft variation to:

- amend Schedule 29 to permit the use of MFGM-WPC as a nutritive substance in infant formula products in accordance with the Code subject to certain conditions, including specified minimum and maximum amounts and an exclusive use permission for a period of 15 months for the applicant's brand of MFGM-WPC; and
- insert a prescribed specification for MFGM-WPC into Schedule 3, with which MFGM-WPC would have to comply when added to infant formula products in accordance with the Code, or sold for such use.

4. Documents incorporated by reference

The approved draft variation does not incorporate any documents by reference.

However, the approved draft variation would vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as nutritive substances) to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food. Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1307 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 12 December 2024 for a 8-week consultation period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA).[20]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

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*.

[20] Formerly known as the Office of Best Practice Regulation (OBPR)

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 A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation.*

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

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

Items [1] and [2]

Items [1] and **[2]** of the Schedule to the variation would amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code. Section 1.1.1—15 requires certain substances, e.g. substances used as nutritive substances, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code, or sold for use in food. Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

Item [1] would amend the table to subsection S3—2(2) by inserting, in alphabetical order, a new entry for 'Bovine milk fat globule membrane-enriched whey protein concentrate' and a corresponding reference to new section S3—53 (see **item [2]** below).

Item [2] would insert new section S3—53 into Schedule 3 after section S3—52. The new section sets out a specification for the substance 'bovine milk fat globule membrane-enriched whey protein concentrate', which contains identity and purity specifications for that substance.

Consequently, when MFGM-WPC is used as a nutritive substance in infant formula products in accordance with the Code (or sold for such use), it must comply with these specifications.

Items [3], [4], [5] and ***[6]***

Items [3], [4], [5] and [6] of the Schedule to the variation would amend Schedule 29.

Item [3]

Subsection 2.9.1—9(1) and section 2.9.1—37 provide for the use of optional nutritive substances in infant formula, and in special medical purpose products for infants, respectively. Those sections provide that a substance listed in Column 1 of the table to section S29—7 may be used as a nutritive substance in infant formula or a special medical purpose product for infants, provided the amount of the substance (including any naturally-occurring amount) in the formula or product (as the case may be) is no less than any minimum amount specified in Column 2 of the table; and no more than any maximum amount specified in Column 3 of the table.

Item [3] would amend the table to section S29—7 by inserting, in alphabetical order, a new entry for MFGM-WPC into the table as follows:

Column 1 – ‘Milk fat globule membrane-enriched whey protein concentrate’ as the substance;

Column 2 – ‘0.14 g’ as the minimum amount of the substance (per 100 kJ); and

Column 3 – ‘0.28 g’ as the maximum amount of the substance (per 100 kJ).

Item [4]

Subsection 2.9.1—9(2) provides for the use of optional nutritive substances in follow-on formula. The section provides that a substance listed in Column 1 of the table to section S29—8 may be used as a nutritive substance in follow-on formula, provided the amount of the substance (including any naturally-occurring amount) in the formula is no less than any minimum amount specified in Column 2 of the table; and no more than any maximum amount specified in Column 3 of the table.

Item [4] would amend the table to section S29—8 by inserting, in alphabetical order, a new entry for MFGM-WPC into the table as follows:

Column 1 – ‘Milk fat globule membrane-enriched whey protein concentrate’ as the substance;

Column 2 – ‘0.14 g’ as the minimum amount of the substance (per 100 kJ); and

Column 3 – ‘0.28 g’ as the maximum amount of the substance (per 100 kJ).

Item [5]

Section 2.9.1—10 requires that a substance used as a nutritive substance in infant formula or follow-on formula in accordance with section 2.9.1—8 or 2.9.1—9 must be added in a permitted form listed in: the table to section S29—23 if a vitamin, mineral or electrolyte, or in any other case, the table to section S29—9.

Section 2.9.1—38 requires that a substance used as a nutritive substance in a special medical purpose product for infants in accordance with section 2.9.1—36 or 2.9.1—37 must be added in a permitted form listed in: the table to section S29—23 if a vitamin, mineral or electrolyte, or in any other case, the table to section S29—9.

Item [5] would amend the table to section S29—9 by inserting, in alphabetical order, a new entry for MFGM-WPC into the table as follows:

Column 1 – ‘Milk fat globule membrane-enriched whey protein concentrate’ as the substance; and

Column 2 – ‘Bovine milk fat globule membrane-enriched whey protein concentrate’ as the permitted form of the substance.

Item [6]

Section 2.9.1—10A provides that a substance that is:

- used as a nutritive substance in an infant formula product; and
- listed in Column 1 of the table to section S29—9A; and
- in a permitted form listed in Column 2 of that table for that substance,

must comply with any corresponding conditions specified in Column 3 of the table to section S29—9A for that substance in that permitted form.

Section S29—9A sets out a table headed 'Conditions of use for permitted nutritive substances'. The table has three Columns listing the substance, the permitted form of the substance, and conditions of use for the substance respectively.

Item [6] would amend the table to section S29—9A by inserting, in alphabetical order, a new entry for MFGM-WPC into the table as follows:

Column 1 - 'Milk fat globule membrane-enriched whey protein concentrate'

Column 2 - 'Bovine milk fat globule membrane-enriched whey protein concentrate'; and

Column 3 –
'

1. During the exclusive use period, may only be sold under the brand Lacprodan® MFGM-10 for* use as a nutritive substance in an infant formula product.
2. For the purposes of condition 1 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards* (*Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products*) *Variation* and ending 15 months after that date.'

The effect of the approved draft variation

The effect of the approved draft variation will be that MFGM-WPC is permitted to be used as a nutritive substance in infant formula products (i.e., infant formula, follow-on formula and special medical purpose products for infants) in accordance with the Code, subject to the following conditions:

- the amount of MFGM-WPC in an infant formula product must be no less than 0.14 g/100 kJ, but not greater than 0.28 g/100 kJ; and
- the permitted form of MFGM-WPC is 'Bovine milk fat globule membrane-enriched whey protein concentrate'; and
- the following exclusive use permission applies:
  - MFGM-WPC may only be sold under the brand 'Lacprodan® MFGM-10' for use as a nutritive substance in an infant formula product during the exclusive use period i.e. the period commencing on the date of gazettal of the variation and ending 15 months after that date, and
  - once that period ends, the permission would revert to a general permission, i.e. MFGM-WPC under any brand may then be sold for use as a nutritive substance in an infant formula product in accordance with the Code.

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 A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation

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

Dated [To be completed by the Delegate]

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

Note:

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

1 Name

This instrument is the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) 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.

4 Effect of variations made by this instrument

Section 1.1.1—9 does not apply to the variations made by this instrument.

Schedule

Schedule 3—Identity and purity

[1] Subsection S3—2(2) (table)

Insert:

Bovine milk fat globule membrane-enriched whey protein concentrate	section S3—53

[2] After section S3—52

Insert:

S3—53 Specification for bovine milk fat globule membrane-enriched whey protein concentrate

(1) In this section, bovine milk fat globule membrane-enriched whey protein concentrate is a preparation of cow's milk consisting of lipids and proteins.

(2) For bovine milk fat globule membrane-enriched whey protein concentrate, the specifications are the following:

(a) description—off white powder;
(b) total protein—not less than 69.0% and not more than 76.0%;
(c) lactose—not more than 2.0%;
(d) fat—not less than 16.0% and not more than 22.0%;
(e) phospholipids—not less than 6.0% and not more than 10.0%;
(f) sphingomyelin—not less than 1.3% and not more than 2.3%;
(g) ash—not more than 3.0%;
(h) moisture—not more than 5.0%;
(i) arsenic—not more than 0.2 mg/kg;
(j) cadmium—not more than 0.1 mg/kg;
(k) lead—not more than 0.05 mg/kg;
(l) mercury—not more than 0.02 mg/kg;
(m) microbial limits:
  (i) total plate count (30°C)—not more than 10000 cfu/g;
  (ii) total plate count (55°C)—not more than 1000 cfu/g;
  (iii) *Bacillus cereus*—not more than 50 cfu/g;
  (iv) Sulphite-reducing *Clostridia*—not more than 10 cfu/g;
  (v) *Enterobacteriaceae*—not more than 10 cfu/g;
  (vi) Coagulase-positive *staphylococci*—absent in 1 g;
  (vii) Yeast and moulds—not more than 10 cfu/g.

Schedule 29—Special purpose foods

[3] Section S29—7 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g

[4] Section S29—8 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	0.14 g	0.28 g

[5] Section S29—9 (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate

[6] Section S29—9A (table)

Insert:

Milk fat globule membrane-enriched whey protein concentrate	Bovine milk fat globule membrane-enriched whey protein concentrate	1. Contains sphingomyelin in the range of 1.8 – 7.5 mg/100 kJ. 2. During the exclusive use period, may only be sold under the brand Lacprodan® MFGM-10 for *use as a nutritive substance in an infant formula product. 3. For the purposes of condition 2 above, **exclusive use period** means the period commencing on the date of gazettal of the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation* and ending 15 months after that date.