12 December 2024
321-24

Call for submissions – Application A1307

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

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 and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

Submissions on this application need to be made through the Consultation Hub (https://consultations.foodstandards.gov.au/).

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

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

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

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

DEADLINE FOR SUBMISSIONS: 11:59pm (Canberra time) 6 February 2025

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

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

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

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

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Supporting document

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

Executive summary

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

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

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 could 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.

For reasons set out in this report, FSANZ has prepared a draft variation to the Code to permit the use of MFGM-WPC as a nutritive substance in infant formula products in accordance with the Code. If approved, the draft variation would:

- 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.

- set a condition of use that MFGM-WPC must contain sphingomyelin in the range of 1.8 to 7.5 mg/100 kJ. Sphingomyelin has been identified as a suitable analytical marker for MFGM-WPC.

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

- insert a specification for MFGM-WPC into Schedule 3 of the Code, with which MFGM-WPC would have to comply when used as a nutritive substance in infant formula products (or sold for such use).

The proposed permission, if approved, would apply to Australia only. The use of MFGM-WPC in infant formula products would be subject to labelling requirements specified in Standard 2.9.1.

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

1 Introduction

1.1 The applicant

Arla Foods Ingredients 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 seeks 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 is 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 are substances present in human milk and in cow milk, which 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 and are the key characterising components associated with its physiological benefits.

If approved, the permission will provide infant formula products with bovine MFGM-WPC added as a nutritive substance. Bovine MFGM 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.

If approved, the permission will apply to all categories of infant formula products.

1.3 Relevant standards

The Australia New Zealand Food Standards Code (the Code) sets a number of requirements for the addition of nutritive substances to infant formula products, as 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.

Section 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. There is currently no specification in Schedule 3. The draft variation, if approved, would insert a

specification specifically for bovine MFGM-WPC into Schedule 3 with which bovine MFGM-WPC, would have to comply.

1.3.3 Infant formula products

Standard 2.9.1 sets specific compositional and labelling requirements for 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 Products for infants (SMPPi, for infants aged 0 to <12 months).

A review of infant formula product requirements was recently completed under Proposal P1028[1]. The proposal reviewed the regulatory requirements for all infant formula products, including infant formula, follow-on formula, and SMPPi (formerly special dietary use products).

The revised regulation of infant formula products came into effect on 13 September 2024 and applies in Australia only. New Zealand opted out of this regulation under *Annex D of The Agreement between the Government of Australia and the Government of New Zealand Concerning a Joint Food Standards System*. Therefore, the permission for addition of MFGM-WPC, if approved, would apply in Australia only as per the Code currently in force.

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; and no more than any maximum 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; and no more than any maximum 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 formula (including any naturally-occurring amount) is no less than any minimum; and no more than any maximum specified in the table.

For nutritive substances that are not vitamins, minerals or electrolytes, paragraph 2.9.1—10(b) provides that the permitted forms are listed in the table to section S29—9. A substance used in infant formula or follow-on formula must be added in a permitted form.

Section 2.9.1—10A requires a permitted nutritive substance to comply with any conditions of use listed in S29—9A for that substance.

Section 2.9.1—7 for infant formula and follow-on formula and Section 2.9.1—34 for SMPPi sets 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).

[1] See P1028 - Infant Formula | Food Standards Australia New Zealand

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 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 and their derivatives when they are present in a food for sale.

Section 1.2.4—2 requires food products to be labelled with a statement of ingredients. Section 1.2.4—4 requires ingredients to be declared 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.

Standard 1.2.7 sets out the requirements and conditions for voluntary nutrition, health and related claims made 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 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 a substance used as a nutritive substance except for a reference in a statement of ingredients or 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, without specific format requirements.

1.4 International regulations

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 as an optional ingredient in infant formula equivalent products overseas 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. It has not required premarket assessment in these countries. According to the application, infant formula products containing the applicant’s Lacprodan® MFGM-10 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, 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)[2].

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 consumed in infant formula products sold in the EU for the past 15 years. It is similarly permitted for use in the United Kingdom.

1.4.2.3 Peoples 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 United States (US) 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[3]. 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 A1307

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.

1.6 Procedure for assessment

The application is being assessed under the General Procedure.

[2] 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

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

2 Summary of the assessment

2.1 Risk assessment

FSANZ has compared the phospholipid composition of the MFGM-WPC with reported oncentrations 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 up to a concentration of 5 g/L of MFGM-WPC. 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 in four human and five animal studies. Due to the limitations in the available data, FSANZ concludes that MFGM-WPC supplemented infant formula may improve neural development and cognitive function in infants, but 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 could 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 could be beneficial for infant gut microbiota development.

2.2 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.

2.2.1 Risk management options

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

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

For the reasons set out in this report, FSANZ decided to prepare a draft variation to the Code to permit the use of MFGM-WPC as a nutritive substance for use in infant formula products, subject to certain conditions. If approved, the proposed permission would have to be exercised in accordance with the Code.

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

2.2.2 MFGM-WPC 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[4], 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 Policy Guideline on infant formula products.[4]

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. Use of WPC in infant formula products as a protein source is already common practice in Australia and internationally and is regulated under Standard 2.9.1 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 FSANZ Act requirements 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.

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

These findings are discussed in detail below.

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

FSANZ's risk and technical assessment at Supporting Document 1 (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. 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 considers it unlikely that MFGM-WPC would adversely affect infant growth at concentrations up to 7 g/L.

Infant formula products containing the applicant's MFGM-WPC would be 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 in fatty acid composition.

At the MFGM-WPC maximum proposed 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 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 concludes there are no public health and safety concerns from the addition of bovine MFGM-WPC to infant formula products at the proposed concentration of 4 to 7 g/L.

2.2.4 Specific phospholipids: consistency with human milk

MFGM-WPC is a mixture of unique polar lipids and membrane-specific proteins. The two main polar lipids in MFGM being 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 compared the concentration of the five most abundant phospholipids (PE, PS, PI, PC, and SM) 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's assessment also considered the suitability of sphingomyelin as an analytical marker, noting that MFGM-WPC is a mixture of ingredients and not easily quantified. Sphingomyelin is one of the major phospholipids present in MFGM-WPC, and standardised methods are available to assay its content in MFGM-WPC and final 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 food products such as infant formula products (section 2.5 of SD1).

FSANZ considers the contribution of other constituents of MFGM-WPC are managed through the existing Code requirements and 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.

2.2.5 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 Policy Guideline in infant formula products[4]. This also aligns with specific policy principle (j) of the Policy 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 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. 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 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.

2.2.6 Proposed regulatory approval

FSANZ is proposing to list MFGM-WPC in 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.

This application sought to permit the use of MFGM-WPC as a nutritive substance in infant formula products and requested 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, FSANZ considers it appropriate that the permission should reflect the nutritive substance MFGM-WPC, rather than a single component.

The draft variation prepared by FSANZ therefore provides a permission for MFGM-WPC in Schedule 29 as a nutritive substance, with sphingomyelin content included as a condition of use in the table to S29—9A. The proposed approach to 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.

2.2.7 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 2.2.4, at the maximum concentration of 7 g/L, estimated intakes of phospholipids in infant formula products containing MFGM-WPC are higher than intakes in infants who are breastfed but are within the intakes estimated based on the maximum phospholipid limit set in the Code of 72 mg/100 kJ. Given that phospholipids are a naturally occurring component of cow milk and the conclusions of the safety assessment, FSANZ considers 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 proposes to base the minimum and maximum amounts of MFGM-WPC on mg/100 kJ units. This would allow for the actual amount of MFGM-WPC in infant formula products to vary depending on the energy content of the formula. The application seeks 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.

The lipid composition would be prescribed by the permitted ranges for phospholipids and sphingomyelins listed in the proposed specification (see section 2.2.9).

2.2.8 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 would apply to the applicants' MFGM-WPC if it was added to infant formula products.

2.2.8.1 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 would have to 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 would 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 draft variation).

However, FSANZ notes 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. 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.

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. These regulatory labelling requirements are 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 the Code, or the EU or US could apply.

2.2.8.2 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 would apply to infant formula and follow-on formula. In accordance with these Code requirements, the term 'milk' would be the required name[5] and would need to 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 would need to be declared, but other declaration requirements in Division 3 (e.g. for formatting and location) would not apply to SMPPi (paragraph 1.2.3—6(4)(b) and subsection 1.2.3—6(5) of Standard 1.2.3 of the Code).

2.2.8.3 Mandatory nutrition information

Infant formula and follow-on formula

Section 2.9.1—24 regulates 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 in the form of a table, as indicated in section 2.9.1—25 and in accordance with section S29—10.

Subparagraph 2.9.1—24(3)(e)(i) requires any substance used as a nutritive substance to be declared in the NIS. Therefore, the applicant's MFGM-WPC would need to 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, using the format specified in section 29—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 would need to be included as part of these mandatory and voluntary 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 would 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

[5] ***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.

SMPPi is not impeded.

Name of nutritive substance

As stated in section 2.2.6 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.

2.2.8.4 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 NIS on the label of a package of infant formula or follow-on formula.

For SMPPi, subsection 2.9.1—46 sets out an explicit prohibition for nutrition content, health claims and claims that compare the product with a good that is represented in any way to be for therapeutic use. This prohibition would apply in relation to the applicant's MFGM-WPC where it is used voluntarily in SMPPi.

2.2.8.5 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 would apply to infant formula products that contain the applicant's MFGM-WPC.

2.2.9 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. There are no specifications for MFGM-WPC in Schedule 3. Therefore, in the absence of an appropriate published specification, a new specification for MFGM-WPC would be required for addition to Schedule 3.

The applicant provided their manufacturing specification and batch analysis results. FSANZ assessed the information and developed a proposed specification for inclusion in Schedule 3. While the specifications are 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 proposes to only include the analytes considered important for a regulatory specification for identity and purity reasons.

The proposed specification for MFGM-WPC includes an amount of sphingomyelin that is not less than 1.3% and not more than 2.3%. This converts[6] to a possible range of sphingomyelin of 1.8 mg/100 kJ to 6.4 mg/100 kJ, which is within the range of the sphingomyelin content as proposed in the draft variation in the table to S29—9A (i.e. 1.8 to 7.5 mg/100 kJ).

The application seeks permission to add WPC-MFGM 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.

[6] Using the required energy range of 2510 – 2930 kJ/L and the concentration range of MFGM-WPC of 4 to 7 g/L.

The draft variation would insert a new specification relating specifically to the applicant's MFGM-WPC. All infant formula products using MFGM-WPC as a nutritive substance (or MFGM-WPC sold for such use) would have to comply with this specification.

2.2.10 Exclusivity

An applicant may request exclusive 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.[7]

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

FSANZ is proposing to provide the applicant with a 15 month exclusive use period for MFGM-WPC commencing on the date of gazettal of the draft variation (if approved).

If the draft variation is approved, this means that, during that 15 month period, the permission would apply exclusively to that substance 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 would revert to a general permission, meaning that the permission would apply to all brands of MFGM-WPC in accordance with the Code.

An exclusive use period 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.

2.2.11 Risk management conclusion

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

If the draft variation is approved, the applicant's MFGM-WPC would be subject to relevant requirements and conditions in the Code, which include the following:

- It may be voluntarily added up to a maximum level of 0.28 g/100 kJ and at a minimum level of 0.14 g/100 kJ.
- The amount of sphingomyelin must be no less than 1.8 mg/100 kJ, but not greater than 7.5 mg/100 kJ.
- 'Bovine milk fat globule membrane-enriched whey protein concentrate' is the permitted form.
- Existing generic and specific labelling requirements in the Code would apply to infant formula products containing the applicant's MFGM-WPC.
- Schedule 3 of the Code would set a specific specification for bovine MFGM-WPC with which it must comply when used as a nutritive substance in infant formula products (or sold for such use).

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

- An exclusive use period to use 'MFGM-WPC' would apply for 15 months, linked to the applicant's brand name 'Lacprodan® MFGM-10', commencing on the date of gazettal of the approved draft variation.

2.3 Risk communication

2.3.1 Consultation

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

FSANZ developed and applied a standard communication strategy to this application. All calls for submissions are notified via the FSANZ Notification Circular, media release, through FSANZ's social media channels and Food Standards News.

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

Subscribers and interested parties are also notified about the availability of reports for public comment. The draft variation will be considered for approval by the FSANZ Board taking into account all public comments received on this call for submissions.

The applicant and individuals and organisations that make submissions on this application will be notified at each stage of the assessment.

2.3.2 World Trade Organization (WTO)

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

There are not any relevant international standards and amending the Code to permit the use of bovine MFGM to infant formula products is unlikely to have a significant effect on international trade as the substance is already permitted in similar products overseas. Therefore, a notification to the WTO under Australia's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

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

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

Background

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[8]. 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

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

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 regulatory impact statement 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 considers 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 is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the potential positives and negatives of moving away from the status quo by permitting the proposed use of the applicant's MFGM-WPC as a nutritive substance in infant formula products.

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

Consumers

Products containing the milk fat globule membrane would be permitted to be sold in Australia only.

FSANZ's risk assessment concludes 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 call for submissions document.

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 to come to market that may benefit them.

Industry

Products containing the applicant's MFGM-WPC will be permitted to be sold in Australia only. 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 Standard 2.9.1).

Given the applicant's MFGM-WPC is already approved in some overseas countries, the permission would favour trade and any growth of overseas markets for exporters of infant formula products in Australia and New Zealand[9]. The proposed permission may also support innovation in infant formula products.

Producers of infant formula products in Australia and New Zealand, 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 as proposed would 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 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 months' 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.

Conclusion

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

2.4.1.2 Other measures

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

2.4.1.3 Any relevant New Zealand standards

There are no relevant New Zealand Standards. The regulatory measure relates to the current Standard 2.9.1 and Schedule 29 which applies to Australia only.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

[9] Where New Zealand products are manufactured to comply with Standard 2.9.1, which applies to products sold in Australia only.

during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ completed a risk and technical assessment (SD1) which is summarised in Section 2.1 of this report. In doing 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 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 mental development compared to standard infant formula products, there is evidence MFGM could be beneficial for infant gut microbiota development.

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

Current labelling requirements outlined in section 2.2.6 of this report would apply to infant formula products containing added MFGM-WPC and provide information to enable consumers to make an informed choice.

2.4.2.3 The prevention of misleading or deceptive conduct

Current labelling requirements, including prohibited representations described in section 2.2.6.4 that aim to prevent misleading or deceptive conduct, would apply to infant formula products containing added MFGM-WPC.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

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

Using the risk analysis framework[10], 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 would promote consistency between domestic and a number of international food standards.

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

The proposed permission would support an internationally competitive food industry (see Section 2.2.5 of this report).

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

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

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

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

FSANZ has had regard to both high order and specific policy principles in relevant Ministerial Policy Guidelines. Two Ministerial Policy Guidelines specifically applied to this application:

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

Noting the assessment in SD1 and the assessment above of FSANZ Act requirements, FSANZ considers these Policy Guidelines would be met by the proposed permission, if approved.

3 Draft variation

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

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

4 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

Attachments

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

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

Food Standards (Application 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.

Attachment B – Draft Explanatory Statement

DRAFT 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 period for the Applicant's brand of MFGM-WPC. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft variation - the *Food Standards (Application A1312– Milk fat globule membrane as a nutritive substance in infant formula products) Variation* (the draft variation).

2. Variation will be a legislative instrument

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

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

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

part of those food laws.

3. Purpose

The Authority has prepared a draft variation to the Code to:

- Amend Schedule 29 to permit MFGM-WPC for use 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 period of 15 months for the applicant's brand of MFGM-WPC.
- Insert a prescribed specification for MFGM-WPC into Schedule 3, with which MFGM-WPC would have to comply.

4. Documents incorporated by reference

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

However, the 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 will include one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) will be open for an 8-week period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA). 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

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

7. Variation

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

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1312 – 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.

Clause 4 of the variation provides that a stock-in-trade period of 12 months does not apply.

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, the proposed permission for MFGM-WPC to be used as a nutritive substance in infant formula products (or sold for such use) would be subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications

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

Items [3], [4], [5] and [6] of the Schedule to the draft 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 and special medical purpose product for infants, provided the amount of the substance (including any naturally-occurring amount) 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) 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. 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.

If the draft variation is approved, the effect of the draft variation would be that MFGM-WPC would be permitted to be used as a nutritive substance in infant formula products (including 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 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; and
- the following exclusive use period 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.