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Supporting document 1

Risk and technical assessment – Application A1344

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

Executive summary

Food Standards Australia New Zealand (FSANZ) received an application from Arla Foods Ingredients P/S (AFI) to amend the Australia New Zealand Food Standards Code (the Code) to permit bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) for use as an optional nutritive substance in formulated supplementary foods for young children (FSFYC). MFGM-WPC is currently permitted in Standard 2.9.1 of the Code for use as an optional nutritive substance in infant formula, special medical purpose products for infants and follow-on formula.

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

The applicant has provided evidence that their MFGM-WPC can comply with the existing identity and purity specifications in the Code. The assessment confirmed that sphingomyelin, as set out in the existing specification, is an appropriate marker to quantify the presence of MFGM-WPC to FSFYC.

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

The nutrition assessment in Application A1344 found that the proposed use of MFGM-WPC in FSFYC does not raise nutrition concerns for children aged 1–3 years. Estimated phospholipid intakes from MFGM-WPC in FSFYC, based on the maximum proposed use level, do not exceed those based on the regulatory limit for phospholipids established for infant formula products in the Code. These limits provide a relevant benchmark for assessing phospholipids exposure in children aged 1–3. FSANZ has also assessed that the potential benefits of adding bovine MFGM-WPC to infant formula products would also apply if MFGM-WPC is added to FSFYC. These include an anti-pathogenic effect, immunomodulation and

development of the gut microbiome through supporting growth of *Bifidobacteria* spp, although the magnitude of these effects may differ in young children due to their more diverse diets and more established gut microbiome.

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

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

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1 Introduction

Food Standards Australia New Zealand (FSANZ) received an application from Arla Foods Ingredients P/S (AFI) to amend the Australia New Zealand Food Standards Code (the Code) to permit bovine milk fat globule membrane-enriched whey protein concentrate (MFGM-WPC) for use as an optional nutritive substance in formulated supplementary foods for young children (FSFYC). The applicant proposed a maximum use level of 2.3 g per serve, with no more than 40 mg of sphingomyelin per serve.

FSANZ previously assessed an application from AFI to permit MFGM-WPC as a nutritive substance in infant formula products (Application A1307) (FSANZ 2024). MFGM-WPC is currently permitted in Standard 2.9.1 and Schedule 29 of the Code for use as an optional nutritive substance in infant formula, special medical purpose products for infants and follow-on formula. The MFGM-WPC assessed in this application is the same as that previously assessed.

2 Food technology assessment

2.1 Introduction

The proposed use of MFGM-WPC is as an optional nutritive substance in FSFYC. The intended purpose for the addition of MFGM-WPC is to restore and enrich milk fat globule membrane-derived components and support immune function in young children. This is in noting that MFGM constituents are generally removed during the production of dairy ingredients (such as skim milk powder), before these are added to FSFYC.

2.1.1 Objectives

The objectives of the food technology assessment were to:

- assess the stability of MFGM-WPC under the intended conditions of use and recommended storage conditions in FSFYC (using information and data provided for infant formula as a proxy for FSFYC where appropriate); and
- determine whether the applicant's MFGM-WPC is consistent with the existing specification.

2.1.2 Existing permissions in the Code

With regards to FSFYC, currently approved nutritive substances for optional addition include lutein derived from *Tagetes erecta L* (Standard 2.9.3) and a range of vitamins and minerals listed in Schedule 29. However, unlike these permitted substances, the subject of this application seeking to amend Standard 2.9.3 is a nutritive substance which takes the form of a preparation made up of various constituents, rather than a single component substance.

2.1.3 Scope of the assessment

This food technology assessment considers the applicant's nutritive substance (i.e. MFGM-WPC), including comparing it with bovine milk and standard whey protein concentrate (WPC) where appropriate, in relation to:

- chemical and physical properties, which are unchanged from Application A1307
- manufacturing process, including whether that process introduces any safety concerns or impurities

- incorporation into the relevant food matrix (i.e. FSFYC)
- stability of the product itself and of the finished products in which it has been incorporated.

2.2 Chemical and physical properties

2.2.1 Milk fat globule membrane

Detailed information regarding the typical structure and composition of bovine MFGM has been previously reported (FSANZ 2024).

Bovine milk typically contains approximately 3 to 5% fat which is secreted into the milk as droplets or globules roughly 2 to 6 µm in diameter (Lucey, Otter, and Horne, 2017). These take the form of extracellular vesicles (EVs) and milk fat globules (MFGs). EVs consist of a single membrane bilayer comprising sphingolipids and cholesterol, whereas MFGs are enclosed by a more complex membrane structure comprising a phospholipid-cholesterol monolayer with embedded proteins, surrounded by an outer phospholipid bilayer (Sprenger et al. 2024). For simplicity, membrane components derived from both MFGs and EVs are collectively referred to as the MFGM.

Approximately 25-70% of bovine MFGM is protein, depending on factors such as the extraction method and globule size (Dewettinck et al. 2008; Singh 2006; Guerin et al. 2019). The main protein present in the MFGM is the glycoprotein butyrophilin, which comprises approximately 40% of the total MFGM protein content by weight. This is followed by xanthine oxidase (20%). Other MFGM proteins are present at concentrations of 5% or less (Singh 2006). MFGM proteins contribute 1-4% of total bovine milk protein (Cavaletto et al. 2008).

The total lipid content ranges between 50-80% of the MFGM (Table 2-1 of the application); the main lipid being triacylglycerols, the content of which ranges between 20-80% of MFGM weight (Smoczyński, Staniewski and Kiełczewska 2012). Polar lipids of the MFGM also include phospholipids, sphingolipids (including sphingomyelin) and glycolipids (including gangliosides) and cholesterol (Smoczyński, Staniewski and Kiełczewska 2012; Singh, 2006). Of these, the two main ones are phospholipids and sphingolipids (Guerin et al. 2019). Approximately 65% of milk's phospholipids comes from the MFGM. But the total phospholipid content of bovine milk is approximately only 0.8% of milk's total lipid content (MacGibbon and Taylor 2006).

Major phospholipids and their typical proportions reported in MFGM include phosphatidyl choline (PC) (35%), phosphatidyl ethanolamine (PE) (30%), phosphatidyl inositol (PI) (5%) and phosphatidyl serine (PS) (3%) (Dewettinck et al. 2008). Table 2-1 of the application includes further details of the typical phospholipid fractions of bovine MFGM and their range, as a percentage of total phospholipids. They are broadly consistent with the types and relative proportions of phospholipids reported in bovine milk, as evidenced in Table 2-2 of the application.

The major sphingolipid present in MFGM is sphingomyelin (25%) (Dewettinck et al. 2008). For this and other reasons detailed in section 2.5, sphingomyelin can be used as a marker to quantify the addition of MFGM-WPC in formula products. Other lipid components of MFGM include glucosylceramide, lactosylceramide and gangliosides, which are present in trace amounts (Dewettinck et al. 2008).

Since MFGM is comprised of various components it does not have a unique chemical name, a Chemical Abstracts Service (CAS) registry number or a structural formula.

2.2.2 Comparison of the applicant's MFGM-WPC with bovine milk

The applicant has proposed a maximum use level of 2.3 g MFGM-WPC and not more than 40 mg of sphingomyelin per serving of FSFYC. The application stated a serving size is equal to 200 mL. Therefore, when expressed in grams per litre, this corresponds to a maximum addition rate of MFGM-WPC of 11.5 g/L of FSFYC. The applicant states this addition rate restores MFGM levels equivalent to those in a FSFYC formula made using whole milk.

FSANZ has calculated the proposed maximum addition rate of 11.5 g/L equates to approximately 771 mg phospholipids (based on phospholipid content of 6.7% of MFGM-WPC noted in the application) and 200 mg sphingomyelin per litre of FSFYC, assuming the MFGM-WPC is the sole source of these constituents in the FSFYC. These levels are higher than those reported in bovine milk, which range from approximately 303-412 mg phospholipids and 40-45 mg sphingomyelin per litre of bovine milk (Pimentel et al. 2016; Graves et al. 2007). An addition rate of approximately 4.5-6 g/L MFGM-WPC to FSFYC would result in levels that are in the range of those reported for bovine milk.

2.2.3 Comparison of the applicant's MFGM-WPC with standard WPC

The applicant's manufacturing process enables them to produce a MFGM-WPC (e.g. Lacprodan® MFGM-10) from bovine milk with phospholipid, sphingolipid and membrane protein levels that are higher compared to those in standard WPC.

A detailed compositional comparison of MFGM-WPC against standard WPC has been previously provided (FSANZ 2024). In summary, whilst MFGM-WPC is essentially a whey powder, it is reported to contain 2 to 4 times higher concentrations of major lipid and protein components of the MFGM compared to standard WPC (e.g. Lacprodan® WPC 80). Table 2-6 of the application highlights the compositional differences and, in particular, higher levels of the 4 phospholipids PC, PE, PI and PS and the sphingolipid sphingomyelin.

The major protein components of MFGM-WPC are also present at higher levels compared to other typical standard WPC ingredients. However, the protein and amino acid profiles are relatively similar. There are no unique proteins specific to MFGM-WPC compared to standard WPC.

2.2.4 Incorporation of MFGM-WPC into FSFYC

MFGM-WPC is manufactured as a free-flowing spray dried powder of homogenous composition with a similar particle size distribution to standard WPC.

When added to wet mixes in FSFYC production, it is solubilised and uniformly distributed into the mix. Subsequent dairy processes including homogenisation ensure the resultant spray-dried powder remains homogeneous. In dry blend manufacturing applications, MFGM-WPC is blended with the other ingredients to achieve uniform distribution in the FSFYC preparation and readily dissolves upon reconstitution.

2.3 Manufacturing process

Detailed information, including a schematic, regarding the manufacture of MFGM-WPC has been previously reported (FSANZ 2024).

MFGM-WPC is produced from bovine whey dominant streams, which are by-products of cheese and casein production. The manufacturing process is similar to standard WPC, with the main differences being two additional filtration steps and an additional concentration step using reverse osmosis. These additional steps result in a whey stream with increased

MFGM-related proteins and lipids and lower levels of other components such as lactose, minerals and water.

The liquid-filtered and concentrated whey stream undergoes additional pasteurisation and is then spray-dried. The resulting powder is sieved and bagged in a similar manner to standard WPC.

2.3.1 Stability results

The applicant has provided data to demonstrate that MFGM-WPC powder is stable over 18 months at ambient conditions (21°C and 45±5% relative humidity). Parameters analysed included colour, moisture content, water activity, pH, peroxide values, lipid and protein content, and several sensory properties. Microbiological parameters were also assessed. All assessed parameters, including those that form part of the MFGM-WPC specification for identity and purity, remained within acceptance limits up to 18 months of storage[1].

The applicant has also provided summary results of three independent stability trials demonstrating the stability of MFGM-WPC powder incorporated into commercially available nutritional formula powders. These were provided by the applicant as examples only, to illustrate the characteristics of MFGM-WPC in representative products. The stability of any finished product containing MFGM-WPC is assessed by the product manufacturer, and will depend on the final formulation, processing practices and types of packaging, which vary between product type, manufacturers and production facilities.

The stability trials investigated macronutrients, susceptible fatty acids and vitamins, oxidative stability and sphingomyelin (noting its use as an analytical marker) in infant and follow-on formula. For the latter, stability in toddler formula was also investigated. The addition level of MFGM-WPC was 5-6 g/L in infant formula and 2.5 g/L for follow-on formula. For the sphingomyelin stability trial, the addition rate of MFGM-WPC was 6 g/L for infant and follow-on formulas, and 2.5 g/L in toddler formula.

Results indicated acceptable stability of all parameters assessed through the label claim period of 24 months, providing assurance that the addition of MFGM-WPC to nutritional formulas has no impact on the stability of macronutrients, fatty acids, and vitamins studied, nor on oxidative stability. Results of the trial assessing sphingomyelin concentrations in infant, follow-on and toddler formulas demonstrated that sphingomyelin concentration does not appreciably alter with storage conditions of up to 18 months when stored at 25°C and 60% humidity. This provides confirmatory evidence that sphingomyelin concentration can be used as an analytical marker for added MFGM-WPC in these formula products. Further details on these studies have been previously provided by the applicant and assessed by FSANZ (FSANZ 2024).

During the assessment, the applicant advised FSANZ it was aware of formula products that have been developed using MFGM-WPC at higher addition levels (i.e. approximately 10–12 g/L), which are close to the proposed maximum addition rate of 11.5 g/L in FSFYC, but stability data for the finished products are commercially confidential and not available. As mentioned in section 2.2.2 of this report, an addition rate of 11.5 g/L in FSFYC would result in substantially higher levels of phospholipid and sphingomyelin compared with those reported for bovine milk. However, the applicant states that adding MFGM-WPC at higher levels than those assessed in the above stability trials (i.e. 2.5 g/L in toddler formula) is not

[1] At the time the stability study was performed, the shelf-life specification acceptance level for moisture content was ≤6%. Results were in the range of approximately 4.7-5.5% over an 18-month storage period. The specification has since been reduced to ≤5%. The applicant has provided certificates of analysis from 2018-2025 for non-consecutive batches of their MFGM-WPC (Lacprodan® MFGM-10) – all of which meet the specification for moisture content.

expected to introduce new stability risks, as it does not introduce inherently unstable components nor materially change proximate composition targets.

2.3.1.1 Stability results for infant formula as a proxy for formula-type FSFYC

During the assessment, the applicant provided additional information to support its assertions that, whilst most of the stability studies were conducted on MFGM-WPC in infant formula powders, these are a suitable proxy for formula-type FSFYC. This is due to their overall compositional similarity, commonalities in their processing methods, and the fact that FSFYC poses a less challenging oxidative environment compared with infant formula. The applicant provided supporting data and information, including information relating to the different pro-oxidant mineral load and potential for lipid oxidation across the formula types. Taken together, stability studies of MFGM-WPC in infant formula can be considered a scientifically valid and conservative proxy for assessing stability in formula-type FSFYC.

Stability data for MFGM-WPC powder in FSFYC products other than formula-type FSFYC have not been provided by the applicant nor assessed by FSANZ. As noted above, stability evaluations are conducted by the manufacturers of the finished products. FSANZ's conclusions on the stability of MFGM-WPC in finished products are therefore limited to its stability in formula-type FSFYC only, in line with the available information and data.

2.4 Specifications

Paragraph 1.1.1—15(1)(c) and subsection 1.1.1—15(2) of the Code require that a substance used as a nutritive substance must comply with any relevant specification set out in Schedule 3 – Identity and Purity.

Section S3—53, copied below, provides a specification for bovine MFGM-WPC. This specification was inserted following approval of Application A1307, permitting the applicant's same MFGM-WPC as a nutritive substance in infant formula products.

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.

The applicant has provided analytical results for 4 non-consecutive batches of MFGM-WPC which met the specification. This information has been deemed confidential commercial information (CCI) under Section 114 of the Act and, as such, full details cannot be disclosed.

2.5 Analytical methods for detection

Analytical methods for detection of MFGM-WPC have been previously reported (FSANZ 2024). As noted in earlier sections, the applicant proposes using sphingomyelin as a marker lipid for checking and quantifying MFGM-WPC in formulated products. This is because it is one of the major phospholipids present in MFGM-WPC, there are standardised methods of analysis available, and it is only present at very low levels in standard WPC and FSFYC made without MFGM-WPC.

2.6 Food technology conclusions

The applicant states the addition of their MFGM-WPC to FSFYC is to replace and supplement MFGM to levels found in regular bovine milk and to contribute to the support of immune function in young children.

MFGM-WPC is similar to standard WPC but differs in composition particularly with respect to glycerophospholipid and sphingomyelin content. Sphingomyelin is used as an analytical marker to differentiate as well as quantify the addition of MFGM-WPC to food products.

MFGM-WPC is manufactured in a similar manner to that of standard WPC, but with additional purification and concentration steps, resulting in a WPC with substantially higher concentrations of membrane lipid and protein components.

Given their comparable physical attributes, MFGM-WPC can be incorporated into food matrices in the same manner as standard WPC. Stability studies in infant formula products containing MFGM-WPC powder provide a suitable proxy for formula-type FSFYC, and demonstrate acceptable stability in all parameters assessed.

A relevant identity and purity specification for bovine MFGM-WPC already exists in Schedule 3 of the Code. The applicant's MFGM-WPC would have to meet this specification when added to FSFYC in accordance with the Code or sold for such use.

3 Safety assessment

3.1 Toxicology assessment

The purpose of this assessment was to consider whether there are any toxicological concerns associated with the consumption of MFGM-WPC in FSFYC at the proposed use levels. The scope of the assessment was limited to information not already considered as a part of Application 1307.

3.1.1 Previous FSANZ evaluation

FSANZ's previous toxicological assessment of MFGM-WPC concluded that MFGM-WPC has an established history of safe use in many countries, including 15 years of consumption in infant and follow-on foods in the European Union, with no reports of adverse effects.

The major components of MFGM WPC are the same as those normally found in MFGM of human milk and/or bovine milk and would be expected to be metabolised in same way. No

toxicity studies in experimental animals were found in comprehensive literature searches.

An increased incidence of eczema was reported in only one of several studies of MFGM-WPC supplementation of infants, and was considered unlikely to be related to the supplementation. MFGM-WPC is not considered to carry greater allergenic potential than other infant formula products based on bovine milk.

No other potential safety concerns were identified.

3.1.2 New studies assessed

The applicant provided a report of literature searches for safety/toxicity studies of MFGM in animals (conducted in 2024) and safety studies in young children (conducted in 2024 and updated in 2025). No animal studies were found investigating the safety of MFGM, while the search for studies with young children found one relevant study that has not previously been assessed by FSANZ. A literature search conducted by FSANZ on PubMed on 9 April 2026[2] did not identify further studies relevant to the safety assessment.

The application included several animal studies designed to investigate potential beneficial effects of dietary MFGM or MFGM-WPC. No evidence of adverse effects of MFGM supplementation were reported in any of these studies.

In a prospective double-blind, randomised controlled trial, healthy children aged 2.5 – 6 years were assigned to consume a 200 mL chocolate milk drink with or without MFGM (0.25 g/100 mL) daily for 120 days. No adverse events were observed and it was concluded the milk containing MFGM was safe and well-tolerated (Veereman-Wauters et al. 2012).

3.1.3 Safety assessment reports prepared by international agencies or other national government agencies

No safety assessments by other agencies were found.

3.1.4 Conclusions of the toxicology assessment

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

3.2 Microbiology assessment

The objective of this assessment was to review the microbiological safety of MFGM-WPC when added to FSFYC. FSANZ has previously assessed the microbiological risk and health benefit assessment of MFGM-WPC when added to infant formula products in Application A1307.

3.2.1 Microbiological assessment

The production process described by AFI includes controls to reduce the risk of microbial contamination. The whey dominant streams used to produce MFGM-WPC are by-products of

[2] Search terms: ("milk fat globule" OR "milk fat globule membrane" OR "MFGM") AND ("toxic*" or "safety" or "adverse")

cheese or casein production from pasteurised milk. Before the manufacture of MFGM-WPC the whey dominant streams are stored at 5°C to control microbial growth. Selective separation by micro- and ultra-filtration is used to generate the MFGM enriched whey stream, which is further concentrated by reverse osmosis. This material is then heat treated at 60-70°C for approximately 20 seconds before being spray-dried. Spray drying removes the majority of the water resulting in a powdered final product. Additionally, the applicant implements quality control systems in accordance with current Good Manufacturing Practice (cGMP) and applies hazard analysis and critical control points (HACCP)-based principles to reduce microbiological hazards.

The effectiveness of microbiological controls is determined by regular microbiological testing. The microbiological testing should align with the guidance in FSANZ's "Compendium of Microbiological Criteria for Food" which identified *Salmonella* spp. and *B. cereus* as pathogens of interest for dried powders derived from milk (FSANZ 2025b). Full microbiological specifications for bovine MFGM-WPC are listed in Schedule 3–53.

Microbiological data provided by the applicant were considered to inform the microbiological risk assessment. AFI tests every batch of MFGM-WPC against microbiological criteria, which includes tests for the presence of *Salmonella* spp. and *B. cereus*. Data for 8 final batch tests were provided and assessed by FSANZ. Additionally, the applicant provided data on a stability trial, confirming that after 18 months of storage the final product was still able to meet their microbiological criteria.

Given the identical chemical structure and that the requested use levels are below those assessed in A1307, FSANZ has concluded that there are no microbiological concerns with the use of MFGM-WPC in FSFYC. This is supported by FSANZ's evaluation of the production process and the data provided.

3.2.2 Microbiological Benefit

A comprehensive benefit assessment of MFGM-WPC in infant formula was completed as part of the assessment of Application A1307, which identified (1) an anti-pathogenic effect; (2) immunomodulation and (3) development of the gut microbiome through supporting growth of *Bifidobacteria* spp. While the mechanisms are expected to be relevant to young children, the magnitude of the effect of MFGM-WPC in FSFYC may differ due to the more diverse diet and more established gut microbiome in children aged 1-3 years.

3.3 Nutrition assessment

3.3.1 Scope of assessment

The proposed use of MFGM-WPC is as an optional nutritive substance in FSFYC, where it is used as a replacement for dairy-derived ingredients, such as WPC. FSFYC are intended to supplement a varied diet for young children and are not relied upon as a sole source of nutrition.

The applicant has proposed a maximum use level of 2.3 g MFGM-WPC per serving of FSFYC. When expressed relative to the minimum permitted energy content of 330 kJ per serve, this corresponds to approximately 0.7 g MFGM-WPC per 100 kJ.

3.3.2 Objectives

The objectives of the nutrition assessment were to:

- determine whether the addition of MFGM-WPC to FSFYC results in any new or disproportionate dietary intake concerns for children aged 1–3 years; and
- determine whether there is any new evidence, beyond previous assessments, indicating that MFGM-WPC can inhibit or modify the absorption of other nutrients.

3.3.3 Nutrition profile of MFGM-WPC

MFGM-WPC is a WPC powder with a protein content of approximately 75% and a fat content of approximately 19%. As noted in section 2.2.3, the key compositional difference is the enrichment of MFGM components, particularly phospholipids, which are naturally present in standard WPC but at lower concentrations.

Also as outlined in section 2.2.3, MFGM-WPC has a similar protein and amino acid profile to standard WPC. Accordingly, the addition of MFGM-WPC is not expected to alter protein quality or amino acid balance relative to standard WPC in the diet of young children.

The major phospholipid classes present in MFGM-WPC and standard WPC are the same, with five phospholipids (PC, PE, PI, PS and sphingomyelin) accounting for more than 98% of total phospholipids in both products. While the absolute concentration of phospholipids is higher in MFGM-WPC, the relative distribution of individual phospholipids as a proportion of total fat is similar between MFGM-WPC and standard WPC.

3.3.4 Assessment of potential changes in dietary intakes

FSFYC are intended to supplement a varied diet and may be consumed as an alternative to, or alongside other dairy foods. The proposed use of MFGM-WPC is intended to replace standard dairy-derived ingredients within FSFYC formulations and is not expected to materially alter the frequency or volume of FSFYC consumption.

As noted in Section 2.2.2 of this report MFGM-WPC has a higher phospholipid concentration than bovine milk. The proposed maximum addition rate of MFGM-WPC, together with an upper limit on sphingomyelin content, constrains dietary intake of MFGM phospholipids. Estimated dietary intake of phospholipids based on the limits provided by the applicant is provided in Section 3.4 of this report.

3.3.5 Effect on absorption of other nutrients

FSANZ undertook a literature search in PubMed on 30 March 2026[3] to determine whether new evidence was available, since Application A1307, indicating that MFGM-WPC inhibits or modifies the absorption of other nutrients. A recent review article describes potential mechanisms by which sphingomyelin may modulate intestinal lipid absorption (Park et al., 2025), consistent with the evidence considered in Application A1307 (FSANZ 2024). No new evidence was identified that would change FSANZ's conclusions, and FSANZ does not have concerns regarding nutrient absorption under the proposed conditions of use.

3.3.6 Conclusion

FSANZ concludes that the use of MFGM-WPC as an optional nutritive substance in FSFYC is not expected to result in new or disproportionate dietary intake concerns for children aged 1–3 years. No new evidence was identified since Application A1307 to indicate concerns regarding the effects of MFGM-WPC on nutrient absorption.

[3] Search terms: ("milk fat globule OR milk fat globule membrane OR MFGM") AND ("antinutrient" or "antinutritional" or "anti-nutrient" or "anti-nutritional" or "absorbed" or "absorption")

3.4 Dietary intake assessment

3.4.1 Objective of the dietary intake assessment

The objective of this dietary intake assessment was to estimate the dietary intake of phospholipids from the proposed use of MFGM-WPC in FSFYC.

There is a regulatory limit in the Code (72 mg/100 kJ) for phospholipids in infant formula and follow-on formula. FSFYC could be considered as proxy foods for infant formula and follow-on formula. Hence, the same regulatory limit for phospholipids was considered for intake of phospholipids from FSFYC for this assessment for comparison purpose only.

3.4.2 Approach for the dietary intake assessment

Dietary intake assessments require data on the concentrations of the chemical of interest in the foods requested, as well as any naturally occurring sources and any current permissions for additions to food; and consumption data for the foods which are usually collected through a national nutrition survey.

A summary of the general FSANZ approach to conducting dietary intake assessments is on the FSANZ website. A detailed discussion of the FSANZ methodology and approach to conducting dietary intake assessments is set out in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2024).

3.4.2.1 Population groups assessed and consumption data used

The hazard identification and characterisation did not identify any population sub-groups for which there were specific safety considerations in relation to the intake of phospholipids. Based on the food category relevant to this application the population groups that were used for the dietary intake assessment were:

- Infants aged 12 months – representing infants who consume food as well as FSFYC.
- Children aged 2-3 years – representing children who consume food as well as FSFYC.

The food consumption data used for the dietary intake assessments were:

- 2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS), one 24 hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (ABS 2015). Only those respondents who had two days of food consumption data (n=7,735) were used in the assessment of dietary intakes of phospholipids. This data set was used for the assessment for 2-3 year old children.

The design of this nutrition surveys and the key attributes, including survey limitations, are set out on the FSANZ website. The dietary intake assessment for the 2-3 year old children was undertaken using FSANZ's dietary modelling computer program Harvest.

Whilst data from the 2023 NNPAS (ABS 2025) has been released by the ABS, only summary food consumption statistics at the food group level have been published to date. At the time of this assessment the raw data from the survey that allows extraction of consumption for specific foods was not available to FSANZ, therefore the 2023 NNPAS data were not able to be used for this assessment.

As there are no national consumption data for Australian children younger than two years of age, the dietary intake assessment for the infants aged 12 months was conducted using a

model diet. The model diet was constructed to represent the consumption of FSFYC and solid foods by that age group. How the model diet was constructed is outlined further below.

There are no national consumption data for New Zealand children aged 2-3 years as the 2002 National Children's nutrition survey included respondents from 5 years of age and above. Therefore, it was assumed that the model diet for infants aged 12 months, and the assessments for 2-3 year old Australian children are representative of New Zealand infants and young children.

3.4.2.2 Construction of the model diet

The model diet for infants aged 12 months was constructed following the methodology explained in the supporting document 1 (SD1) of A1155 (FSANZ 2018). The details are provided below.

Infants aged under 12 months should be breastfed or fed a commercial infant/follow on formula as their main drink, not cow's milk (National Health and Medical Research Council (Australia) 2013). From 12 months of age, infants can drink cow's milk (or other appropriate substitute). FSFYC (these are captured as toddler milks in the AUSNUT database (FSANZ 2025a)) are not a requirement for healthy children (National Health and Medical Research Council (Australia) 2013). Infants aged 12 months consume a mixed diet. The model diet was constructed based on the recommended energy intake for a 12 month old boy (335 kJ/kg bw/day) at the 50th percentile weight (9.6 kg) for the same age and sex (FSANZ 2018). It was assumed that 35% of energy intake was derived from FSFYC as their sole source of milk and 65% from solid foods and other fluids (Hitchcock 1986).

As the model diet is based on mean food consumption amounts only, a distribution of food consumption was not available. Therefore, 90th percentile (P90) dietary intake was estimated to be double the mean intake as per the calculation used by FSANZ (WHO et al 1985).

The energy content of FSFYC was required for the calculation of the amount of these foods in the model diets. AUSNUT is the latest nutrient dataset published for Australian foods (FSANZ 2025a). In this dataset, the energy content of FSFYC, made with water is 262 kJ/100 g.

3.4.2.3 Concentrations of phospholipids

The application seeks permission to add MFGM-WPC to FSFYC (as prepared or ready-to-feed) at a maximum use level of 2.3 g/serve. The proposed specification for phospholipids in MFGM-WPC preparation is 6.0 – 10.0%, with the applicant's MFGM-WPC containing a total phospholipid concentration of 6.7% (see the application for details). Therefore, intakes of phospholipids for this assessment were estimated using the proposed maximum use level of MFGM-WPC and the highest specification for phospholipids in MFGM-WPC.

The maximum concentrations of phospholipids from MFGM-WPC (in g/L and g/kg) in different serves of FSFYC, assuming the proposed maximum use level of MFGM-WPC in FSFYC and the maximum specification for phospholipids in MFGM-WPC are provided in Table 1.

Table 1 Maximum concentrations of phospholipids from MFGM-WPC in FSFYC per serve*

FSFYC serve size (as prepared or ready-to-feed)	Maximum concentration of phospholipids from MFGM-WPC	
	g/L	g/kg
200 mL suggested by the applicant	1.15	1.1
250 mL reported in the 2023 AUSNUT (FSANZ 2025a)	0.92	0.88

*Calculated using the proposed maximum use level of MFGM-WPC in FSFYC (2.3 g/serve), the maximum specification for phospholipids in MFGM-WPC (10%), and the density of FSFYC (1 L prepared FSFYC is equivalent to 1.050 kg (FSANZ 2025a)).

3.4.2.4 Assumptions and limitations of the dietary intake assessment

The aim of the dietary intake assessment was to make the most realistic estimation of dietary intakes of phospholipids as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the estimated dietary intake was not an underestimate of intake.

Assumptions made in the dietary intake assessment included:

- FSFYC contain phospholipids at the concentrations specified in Table 1
- there is 100% market penetration of the FSFYC containing phospholipids from MFGM-WPC
- 1 litre of FSFYC equals 1,050 grams
- the smallest serving size for FSFYC is 200 mL (suggested by the applicant)
- the largest serving size for FSFYC is 250 mL (reported in the 2023 AUSNUT)
- infants aged 12 months and children aged 2-3 years consume FSFYC
- infants aged 12 months and children aged 2-3 years are no longer consuming breast milk
- consumption of foods as outlined in the model diets represent current food consumption amounts for Australian and New Zealand infants aged 12 months
- the amount of FSFYC consumed by children aged 2-3 years is as per the 2011-12 NNPAS
- the estimated consumption of FSFYC also included consumers of infant formula. There is evidence that caregivers may not always provide the correct formula product for their child's age (FSANZ 2023) and therefore all formulas consumed by children aged 2–3 years were included. This assumption also results in a larger dataset that provides more reliable consumption data.
- mean consumption of FSFYC on day one of the 2011-12 NNPAS reflects longer term daily consumption
- consumption of FSFYC by Australian children 2-3 years is the same for New Zealand children aged 2-3 years.

In addition to the specific assumptions made in relation to this dietary intake assessment, there are a number of limitations associated with the nutrition surveys from which the food consumption data used for the assessment are based. A discussion of these limitations is included in Section 6 of the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2024).

3.4.3 Estimated dietary intakes of phospholipids

3.4.3.1 Estimated dietary intakes of phospholipids from MFGM-WPC in FSFYC

Infants aged 12 months

The mean and P90 intakes of phospholipids from MFGM-WPC in FSFYC were estimated for 12-month-old infants considering two serve sizes (200 mL and 250 mL). For these two scenarios, the estimated mean and P90 intakes of phospholipids from MFGM-WPC in FSFYC range between 0.38-0.47 g/day and 0.8-0.9 g/day respectively for 12-month-old infants.

On a grams per kilogram body weight per day basis, the estimated mean and P90 dietary intakes of phospholipids from MFGM-WPC in FSFYC range between 0.04-0.05 g/kg bw/day and 0.08-0.10 g/kg bw/day respectively for 12-month-old infants (Table 2).

Table 2 Estimated dietary intakes of phospholipids from MFGM-WPC in FSFYC for infants aged 12 months based on the model diet and different serve sizes

Item	Unit	Serve size	
		200 mL	250 mL
Recommended energy intake[1]	kJ/kg bw/day	335	335
P50 body weight[2]	kg	9.6	9.6
Recommended energy intake	kJ/day	3216	3216
Amount of FSFYC required to meet 35% of energy requirements[3]	g/day	430	430
Number of FSFYC serves required to meet 35% of energy requirements [4,5,6]	n/a*	2	1.6
Mean dietary intake of phospholipids from FSFYC[7]	g/day	0.47	0.38
	g/kg bw/day	0.05	0.04
P90 dietary intake phospholipids from FSFYC[8]	g/day	0.9	0.8
	g/kg bw/day	0.10	0.08

[1]United Nations University et al. 2004.
[2]World Health Organization 2006.
[3]Energy content of FSFYC is 262 kJ/100 g (FSANZ, 2025a).
[4]The smallest serve size for FSFYC is 200 mL (210 g).
[5]The largest serve size for FSFYC is 250 ml (263 g).
[6]The density of FSFYC (1 L prepared FSFYC is equivalent to 1.050 kg (FSANZ 2025a).
[7]The maximum concentration of phospholipids from MFGM-WPC in FSFYC is 0.23 g/serve.
[8] P90 dietary intake is equal to double the mean dietary intake (WHO et al 1985).
*Not applicable.

Children aged 2-3 years

The mean and P90 intakes of phospholipids from MFGM-WPC in FSFYC were estimated for children aged 2-3 years considering the two serve sizes (200 mL and 250 mL). For these two scenarios, the estimated mean and P90 intakes of phospholipids from MFGM-WPC in FSFYC range between 0.37-0.47 g/day and 0.75-0.94 g/day respectively for 2-3 year old children.

On a grams per kilogram body weight per day basis, the estimated mean and P90 dietary intakes of phospholipids from MFGM-WPC in FSFYC range between 0.02-0.03 g/kg bw/day and 0.05-0.06 g/kg bw/day respectively for 2-3 year old children (Table 3).

Table 3 Estimated dietary intakes of phospholipids from MFGM-WPC in FSFYC for children aged 2-3 years based on the estimated consumption amounts and different serve sizes

Item	Unit	Serve size	
		200 mL	250 mL
P50 body weight[1]	kg	16	16
Mean consumption amount of FSFYC[2]	g/day	428	428
Number of FSFYC serves required to meet the mean consumption amount[3,4]	n/a*	2	1.6
Mean dietary intake of phospholipids from FSFYC[5]	g/day	0.47	0.37
	g/kg bw/day	0.03	0.02
P90 dietary intake of phospholipids from FSFYC[6]	g/day	0.94	0.75
	g/kg bw/day	0.06	0.05

[1]2011-12 NNPAS (ABS 2015).
[2]2011-12 NNPAS (ABS 2015). Consumption data for infant formula and follow-on formula were also considered assuming caregivers provide any formula at any age and due to small number of consumers for FSFYC only. Survey sample weighting factors are used to adjust survey data to better reflect the results that would have been obtained if a truly representative sample had been able to be obtained (FSANZ 2024).
[3]The smallest serve size for FSFYC is 200 mL (210 g).
[4]The largest serve size for FSFYC is 250 ml (263 g).
[5]The maximum concentration of phospholipids from MFGM-WPC in FSFYC is 0.23 g/serve
[6] P90 dietary intake is equal to double the mean dietary intake (WHO et al 1985).
*Not applicable

3.4.3.1 Estimated dietary intakes of phospholipids from FSFYC for infants aged 12 months assuming the regulatory limit in the Code[4]

The estimated mean and P90 intakes of phospholipids from FSFYC assuming the regulatory limit in the Code are 0.8 g/day and 1.6 g/day for 12-month-old infants. On a grams per kilogram body weight per day basis, the estimated mean and P90 dietary intakes of phospholipids from FSFYC are 0.08 g/kg bw/day and 0.17 g/kg bw/day for 12-month-old infants (Table 4).

Table 4 Estimated dietary intakes of phospholipids from FSFYC for infants aged 12 months assuming the regulatory limit in the Code[3]

Item	Unit	
Recommended energy intake[1]	kJ/kg bw/day	335
P50 body weight[2]	kg	9.6
Recommended energy intake	kJ/day	3216
100% energy requirements	kJ/day	3216
35% energy requirements	kJ/day	1126
Mean dietary intake of phospholipids from FSFYC[3]	g/day	0.8
	g/kg bw/day	0.08
P90 dietary intake of phospholipids from FSFYC[4]	g/day	1.6
	g/kg bw/day	0.17

[1]United Nations University et al. 2004.
[2]World Health Organization 2006.
[3]The regulatory limit of phospholipids in infant formula and follow-on formula in the Code is 72 mg/100 kJ. FSFYC were considered as proxy foods for infant formula and follow-on formula for this assessment.
[4] P90 dietary intake is equal to double the mean dietary intake (WHO et al 1985).

[4] The regulatory limit of phospholipids in infant formula and follow-on formula in the Code is 72 mg/100 kJ. FSFYC were considered as proxy foods for infant formula and follow-on formula for this assessment.

3.4.4 Conclusion

Based on the proposed maximum use level of MFGM-WPC in FSFYC by the applicant and the maximum specification for phospholipids in MFGM-WPC, the estimated mean and P90 intakes of phospholipids from MFGM-WPC in FSFYC are 0.37 and 0.94 g/day respectively. These intakes do not exceed the estimated mean and P90 intakes of phospholipids from FSFYC assuming the regulatory limit of phospholipids specified for infant formula and follow-on formula in the Code (0.8 and 1.6 g/day respectively).

4 Conclusions

After reviewing the information supplied by the applicant and available data in the scientific literature, FSANZ is satisfied that MFGM-WPC is an appropriate source of phospholipids for inclusion in FSFYC and consistent with its intended purpose to restore and enrich MFGM-derived components and support immune function, does not raise safety or nutrition concerns for children aged 1–3 years. MFGM-WPC has no more allergenic potential than other foods based on bovine milk. No microbiological safety concerns associated with MFGM-WPC when added to FSFYC were identified. There are existing identity and purity specifications for MFGM-WPC in the Code, with which this product must comply. Sphingomyelin can be used as an analytical marker to differentiate and quantify the addition of MFGM-WPC to FSFYC.

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