EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

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

1. Authority

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

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

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

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

2. Variation is a legislative instrument

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

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

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

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

3. Purpose

The Authority approved the draft variation to:

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

4. Documents incorporated by reference

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

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

5. Consultation

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

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)[1]. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement was not required for applications relating to nutritive substances OIA Reference: OIA23-06224. This is because applications relating to permitting the use of nutritive substances that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

6. Statement of compatibility with human rights

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

7. Variation

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

In this section, references to ‘the variation’ are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1307 – Milk fat globule membrane as a nutritive substance in infant formula products) Variation.*

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

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

Items [1] and [2]

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

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

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

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

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

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

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

Item [3]

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

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

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

substance;

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

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

Item [4]

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

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

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

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

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

Item [5]

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

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

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

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

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

Item [6]

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

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

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

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

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

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

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

Column 3 –
'

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

The effect of the approved draft variation

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

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