EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1253 – Bovine Lactoferrin 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 A1253 which seeks to permit the addition of bovine lactoferrin (bLf) as a nutritive substance in infant formula products (IFP). The Application also sought a 15 month exclusive use permission for the Applicant's brand of bLf. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - *Food Standards (Application A1253 – Bovine Lactoferrin in Infant Formula Products) Variation.*

Following consideration by the Food Ministers' Meeting, 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 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 approved a draft variation to the Code to:

- amend Schedule 29 and Standard 2.9.1 to permit the addition of bLf as a nutritive substance for use in IFP in accordance with the Code subject to certain conditions, including not exceeding the specified maximum amount and an exclusive use period of 15 months for the Applicant's brand of bLf; and
- insert prescribed specifications for bLf into Schedule 3, with which bLf would have to comply.

The approved draft variation includes consequential amendments to the Code as a result of the above amendments.

4. Documents incorporated by reference

The approved draft variation prepared by the Authority 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. 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 A1253 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 6 October 2022 for a five-week consultation period.

The Office of Impact Analysis (OIA), formerly the Office of Best Practice Regulation (OBPR), granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for the Applications relating to voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943). This standing exemption was provided as permitting the new nutritive substance is deregulatory and their use will be voluntary if the Application concerned is approved. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

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

7.1 Item [1]

Item [1] of the Schedule to the approved draft variation amends subsection 2.9.1—5(1).

Subsection 2.9.1—5(1) provides for the use of nutritive substances in IFP. The subsection provides that a substance listed in Column 1 of the table to section S29—5 may be used as a nutritive substance in an IFP only if the following two conditions are met:

(a) it is in a permitted form listed in Column 2 of the table; and

(b) the amount of the substance in the product (including any naturally-occurring amount) is no more than the corresponding amount listed in Column 4 of the table.

In particular, **item [1]** substitutes existing paragraph 2.9.1—5(1)(b), which is currently the end of the subsection, with a new version of the paragraph ending with '; and' which allows for the insertion of new paragraph 2.9.1—5(1)(c).

New paragraph 2.9.1—5(1)(c) sets out an additional condition which a substance listed in Column 1 of the table to section S29—5 must meet to be able to be used as a nutritive substance in an IFP—the substance complies with any conditions listed in section S29—5A in relation to that substance.

7.2 Items [2] and [3]

Items [2] and **[3]** of the Schedule to the approved draft variation amends Schedule 3.

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. 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 [2] amends the table to subsection S3—2(2) by inserting, in alphabetical order, a new entry for 'bovine lactoferrin' and a corresponding reference to new section S3—46 (see **item [3]** below).

Item [3] inserts, in numerical order, new section S3—46 into Schedule 3. The new section sets out a specification for the substance 'bovine lactoferrin', which contains identity and purity specifications for that substance.

7.3 Items [4] and [5]

Items [4] and **[5]** of the Schedule to the approved draft variation amend Schedule 29.

Item [4] amends the table to section S29—5 by inserting, in alphabetical order, a new entry for bLf into the table as follows:

Column 1 – 'Lactoferrin' as the substance;

Column 2 – 'Bovine lactoferrin' as the permitted form of the substance; and

Column 4 – '40 mg' as the maximum amount of the substance in an IFP (per 100 kJ).

Item [5] inserts new section S29—5A into Schedule 29. The new section sets out the conditions of use of permitted nutritive substances in IFP.

Subsection S29—5A(1) refers to the table to subsection S29—5A(2) and provides that a substance that is:

- listed in Column 1 of the table to subsection (2); 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 that table for that permitted form.

Subsection S29—5A(2) 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 permitted form of the substance respectively.

'Lactoferrin' is listed as the substance in Column 1.

'Bovine lactoferrin' is listed as permitted form of the substance in Column 2.

The following two conditions (related to an exclusive use permission) are listed in Column 3:

1. During the exclusive use period, bLf may only be sold under the brand Synlait for use as a nutritive substance in an IFP.
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 A1253 – Bovine Lactoferrin in Infant Formula Products) Variation* and ending 15 months after that date.

The effect of the approved draft variation is to permit the use of bLf as a nutritive substance in IFP in accordance with the Code.