

## **EXPLANATORY STATEMENT**

*Food Standards Australia New Zealand Act 1991*

### ***Food Standards (Application A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans 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 A1251 which sought to amend the Code to:

- remove the prohibition on the addition of 2'-fucosyllactose (2'-FL) to infant formula products (IFP) in combination with galacto-oligosaccharides (GOS) and/or inulin-type fructans (ITF); and
- thereby allow forms of 2'-FL that are currently permitted by the Code to be added to IFP in combination with GOS and/or ITF in accordance with applicable limits and conditions currently set by the Code.

The Application also sought a 15-month exclusive use permission. That is, an amendment to the Code to provide that IFP may not be sold containing 2'-FL together with added ITF and/or GOS unless: the IFP is manufactured by Nutricia Australia Pty Ltd; and the 2'-FL in question is the 2'-FL developed and owned by Chr. Hansen A/S and contains Nutricia Australia Pty Ltd's blend of short-chain GOS and long chain FOS, namely scGOS/lcFOS (9:1).

The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation to the Code - *the Food Standards (Application A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans 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 standard or draft variation of a standard.

#### **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](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunset 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 sunset 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 sunseting 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 section 2.9.1—7, to remove the prohibition on the addition of 2'-FL to IFP in combination with GOS and/or ITF; and.
- provide the exclusive use permission requested by Application A1251.

### **4. Documents incorporated by reference**

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

### **5. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1251 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 22 July 2022 for a four-week consultation period.

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement (RIS) for permitting genetically modified foods (OBPR correspondence dated 24 November 2010, reference 12065) and for the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943). The OBPR also advised in this case that a RIS was not required as: FSANZ will be ensuring the safety of any fortification permitted; and the proposed change allows business to voluntarily combine ingredients for fortification, rather than making it mandatory (OBPR advice to FSANZ, dated 9 November 2021; OBPR Reference: OBPR21-01118).

### **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**

Item [1] of the Schedule to the variation will amend subsection 2.9.1—7(2) of the Code.

Subsection 2.9.1—7(2) prohibits an IFP to which an ITF and/or a GOS is added from also containing either 2'-FL or a combination of 2'-FL and lacto-N-neotetraose.

Item [1] will replace subsection 2.9.1—7(2) with new subsections 2.9.1—7(2), (3) and (4).

New subsection 2.9.1—7(2) will provide that an IFP to which an ITF and/or a GOS is added must not contain lacto-N-neotetraose as an added substance. Subsection 2.9.1—7(2) will no longer prohibit an IFP to which an ITF and/or a GOS is added from also containing 2'-FL. The removal of that prohibition will in effect allow those forms of 2'-FL that are currently permitted by the Code to be added to IFP in combination with GOS and/or ITF in accordance with applicable limits and conditions currently set by the Code.

New subsections 2.9.1—7(3) and (4) will provide the exclusive use permission requested by Application A1251. The new subsections will impose a condition of use on the addition of 2'-FL to IFP in combination with GOS and/or ITF. This condition will be that, during the exclusive use period, IFP may not be sold containing 2'-FL together with added ITF and/or GOS unless the IFP:

- is manufactured by Nutricia Australia Pty Ltd; and
- contains, as a nutritive substance, 2'-FL sourced from *Escherichia coli* BL21 containing the gene for alpha-1,2-fucosyltransferase from *Escherichia coli* O126. That is, the 2'-FL in question is the 2'-FL developed by Chr. Hansen A/S and permitted as a result of Application A1190; and
- contains Nutricia Australia Pty Ltd's blend of *short-chain galacto-oligosaccharides and long chain fructo-oligosaccharides, namely scGOS/lcFOS (9:1)*.

New subsection 2.9.1—7(4) will provide that, for the purposes of the above, the exclusive use period will be the period commencing on the date of gazettal of the *Food Standards (Application A1251 – 2'-FL combined with galacto-oligosaccharides and/or inulin-type fructans in infant formula products) Variation* and ending 15 months after that date. On the expiry of this 15 month period, the condition of use will lapse and IFP may be sold containing any form of 2'-FL permitted by the Code in combination with GOS and/or ITF (subject to applicable limits and conditions set by the Code).

The amendments made by item [1] will not make any substantive change to *existing* permissions and to other requirements in the Code relating to food produced using gene technology and nutritive substances.