Explanatory Statement

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.

FSANZ accepted Application A1120 which seeks to permit an agarose ion exchange resin as a processing aid. The resin will be used in the production of high purity lactoferrin from bovine milk and milk-related products. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared a draft variation to the Code.

Following consideration by the Australia and New Zealand Ministerial Forum on Food Regulation, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunsetting under the *Legislation Act 2003*.

2. Purpose

Ion exchange resins used in processing and manufacturing food are considered to be processing aids. Only those processing aids listed in Schedule 18 of the Code are permitted to be used in producing food sold in Australia and New Zealand. The Authority has proposed that the agarose ion exchange resin is permitted as a processing aid for lactoferrin production by adding this resin to the table to subsection S18—9(3) in Schedule 18.

Permissions for processing aids are also linked to their specification for identity and purity, provided in Schedule 3 of the Code. Since there are no specifications for the agarose ion exchange resin for lactoferrin production in any of the monographs in Schedule 3 (subsections S3—2 and S3—3), a new specification will be written into Schedule 3.

3. Documents incorporated by reference

The approved draft variation incorporates a specification by reference to a specific document in force or existing at the commencement of the variation.

The incorporated specification is an extraction regime described in the 2014 compilation of the United States Code of Federal Regulation. The latter is referred to in order to provide technical detail required to support the provisions of the Code. This reference by incorporation is consistent with the current practice in the Code, particularly Schedule 3 which itself already incorporates the same document by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1120 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. A call for submissions (including the draft variation) occurred for a six-week consultation period.

A Regulation Impact Statement was not required because the proposed variation to Schedule 18 and Schedule 3 is likely to have a minor impact on business and individuals.

5. 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 94 of the FSANZ Act.

6. Variation

6.1 Variation to Schedule 3

Item [1] varies Schedule 3.

Subitem [1.1] omits the words 'agarose ion exchange resin' from the table to subsection S3—2(2), and substitutes those words with 'amine agarose ion exchange resin'.

Subitem [1.2] inserts a reference to 'sulphonate agarose ion exchange resin' into the table to subsection S3—2(2) in alphabetical order, together with a reference to the provision that sets a specification for that substance ('section S3—34').

Subitem [1.3] omits the words 'agarose ion exchange resin' from the heading to section S3—6, and substitutes those words with 'amine agarose ion exchange resin'.

Subitem [1.4] inserts new section S3—34, which sets a specification for a sulphonate agarose ion exchange resin. The new section is numbered S3—34 to take account of another variation which will insert section S3—33 into Schedule 3.

6.2 Variation to Schedule 18

Item [2] varies Schedule 18.

Subitem [2.1] omits the definition of 'agarose ion exchange resin' in subsection S18—9(2).

Subitem [2.2] inserts in subsection S18—9(2), in alphabetical order, definitions for the following terms used in section S18—9:

- 'amine agarose ion exchange resin'; and
- 'sulphonate agarose ion exchange resin'.

Subitem [2.3] omits the words 'Agarose ion exchange resin' from the table to subsection S18—9(3), and substitutes those words with 'Amine agarose ion exchange resin'.

Subitem [2.4] inserts in the table to subsection S18—9(3), in alphabetical order, a new entry for 'Sulphonate agarose ion exchange resin'. The effect of this amendment is that sulphonate agarose ion exchange resin is permitted as a processing aid where:

- its technological purpose is the production of lactoferrin from bovine milk and milk-related products; and
- its maximum levels are consistent with good manufacturing practice (GMP).