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 A1186 which sought to permit the voluntary use of a soy leghemoglobin, produced by microbial fermentation of a GM yeast (*Pichia pastoris*), in a soy leghemoglobin preparation to meat analogue products at levels not more than 0.8% weight for weight (w/w[1]) in raw product. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved 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

The Authority has approved a draft variation amending the Code to permit iron in the form of soy leghemoglobin, produced in a particular way, to be used as a nutritive substance in meat analogue products to which section S17—4 applies, up to a specified maximum level.

The soy leghemoglobin must be in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with corresponding conditions listed in that Schedule.

The draft variation includes amendments to Standard 1.3.2, and Schedules 3, 17 and 26 to achieve this purpose.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents 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 A1186 included a total of two public and one targeted consultation rounds following an assessment and the preparation of a draft variation and associated assessment summaries.

Submissions were first called for on the Authority's safety and risk assessment, and preliminary regulatory position on 20 December 2020 for an eight week consultation period, after which the Authority undertook targeted consultation with interested Australian enforcement agencies and the New Zealand Ministry of Primary Industries

[1] %'weight for weight' or %'w/w' means g/100 g.

A second consultation was undertaken on the Authority's proposed draft variation to the Code on 6 August 2020 for a 6 week consultation period.

A Regulation Impact Statement (RIS) was not required because the Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption, permitting:

- the voluntary use of genetically modified food (OBPR correspondence dated 24 November 2010, reference 12065), and
- the voluntary addition of nutritive substances to foods (OBPR correspondence dated 16 April 2013, reference 14943).

The use of soy leghemoglobin in a soy leghemoglobin preparation as a nutritive substance in meat analogue products, as proposed, is voluntary. In addition, permissions in the draft variation are likely to have only a minor impact on business and individuals because they are minor, deregulatory changes that allow for the introduction of a food product to the food supply which has been determined to be safe.

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

Item [1]

Item [1] varies Standard 1.3.2 by inserting after section 1.3.2—7, new section 1.3.2—8, which lists conditions for the permitted use of soy leghemoglobin as a nutritive substance. The conditions are:

- iron in the form of soy leghemoglobin must not be used as a nutritive substance in food other than meat analogue products to which section S17—4 applies; and
- soy leghemoglobin must not be present in a meat analogue product in its raw state at a concentration greater than 0.8%.

Item [2]

Item [2] makes the following amendments to Schedule 3.

Sub-item [2.1] varies Note 1 of Schedule 3 by omitting the words 'Section 1.1.1—15 requires', and substituting 'Sections 1.1.1—15 and S26—3 require'. The effect of this amendment is to explain that section S26—3 requires certain food produced using gene technology, for example—the soy leghemoglobin preparation, to comply with any relevant specifications in Schedule 3. This is in addition to the same requirement in section 1.1.1—15 applying to other types of substances.

This amendment is consequential to the amendments made to the table to subsection S26—3(7) in sub-item [4.2] below.

Sub-item [2.2] varies the table to subsection S3—2(2) by inserting the substance 'soy leghemoglobin preparation' in column 1 of the table in alphabetical order, and 'section S3—42' as the corresponding provision in column 2 of the table.

Sub-item [2.3] varies Schedule 3 by inserting a new section S3—42 after section S3—41. The new section sets out specifications for a soy leghemoglobin preparation. A note is also included explaining that subsections S26—3(5) and (7) require a soy leghemoglobin preparation to comply with the specifications set out in section S3—42.

Item [3]

Sub-item [3.1] varies the table to subsection S17—3 by inserting 'Soy leghemoglobin in a soy leghemoglobin preparation that is listed in Schedule 26 and complies with any corresponding conditions listed in that Schedule', alphabetically into Column 2 of the table under the entry for the mineral 'Iron' in column 1 of the table.

The effect of this amendment is that this *particula*r soy leghemoglobin is a permitted form of iron for the purposes of subsection S17—3.

Sub-item [3.2] varies the table to section S17—4 under the heading 'Analogues derived from legumes' by omitting 'Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains 5 g protein per serve of the food' and substituting with, 'Analogues of meat, where no less than 12% of the energy value of the food is derived from protein, and the food contains no less than 5 g protein per serve of the food'.

The effect of the amendment in item [3.2] is that the vitamins and minerals (and their corresponding maximum claim amounts) listed for analogues of meat under the heading 'Analogues derived from legumes' in the table to section S17—4, will now relate to analogues of meat with the following properties:

- no less than 12% of the energy value of the food is derived from protein; and
- the food contains *no less than* 5 g protein per serve of the food.

Item [4]

Sub-item [4.1] varies subsection S26—2(2) by inserting the definition for 'soy leghemoglobin preparation' into that subsection, in alphabetical order. 'Soy leghemoglobin preparation' is defined as a cell lysate preparation with the following components—the preparation:

- derives from *Pichia pastoris* containing the gene for leghemoglobin c2 from *Glycine max*; and
- contains soy leghemoglobin.

Sub-item [4.2] varies the table to subsection S26—3(7) by inserting as **item 3** in column 1 of that table, the substance 'soy leghemoglobin preparation', in numerical order (by item number indicating the order in which the substance is permitted by the Code).

Note: The table to subsection S26—3(7) does not currently exist in the Code, but is proposed in the drafting of A1155, which is yet to be gazetted. The drafting of A1155 also inserts two substances into the new table. At the point of preparing this Explanatory Statement, the soy leghemoglobin preparation is the third substance inserted into the table to subsection S26—3(7).

Sub-item [4.2] also inserts in column 2 of the table to subsection S26—3(7), the source of the permitted soy leghemoglobin preparation as '*Pichia pastoris* containing the gene for leghemoglobin c2 from *Glycine max*'. In other words, only a soy leghemoglobin preparation from that source is permitted under the Code.

Last, sub-item [4.2] inserts the following conditions, corresponding to the soy leghemoglobin preparation, in column 3 of the table to subsection S26—3(7):

- the preparation may only be added to a meat analogue product to enable the use, in that product, of soy leghemoglobin as a nutritive substance in accordance with Standard 1.3.2; and
- the preparation must comply with the specifications set out in section S3—42.

A soy leghemoglobin preparation listed in the table to subsection S26—3(7) must comply with both of those conditions (this requirement is included in the A1155 drafting)