

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 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

FSANZ prepared Proposal P1025 to revise the Code. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft revised Code.

Following consideration by the Legislative and Governance Forum on Food Regulation¹, 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 sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved variations of Chapters 1 and 2 of the Code.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference. The variations update some references to documents that are incorporated by reference.

4. Consultation

In accordance with the procedure in Subdivision F of Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of Proposal P1025 included two rounds of public comment following an assessment and the preparation of a draft Standard and associated reports. Submissions were called for on 23 May 2013 for a 12-week period, and on 10 July 2014 for an eight-week period.

A Regulation Impact Statement was not required, because the proposed variations to the Code are 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 (Chapter 1—Introduction and standards that apply to all foods, Part 5—Foods requiring pre-market clearance)

Standard 1.5.2 – Food produced using gene technology

New section 1.5.2 Name

This section establishes that the instrument is the *Australia New Zealand Food Standards Code – Standard 1.5.2 – Food produced using gene technology*.

¹ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

New section 1.5.2—2 Definitions

This section has no operative part. It provides note references to the definitions for food produced using gene technology and gene technology in section 1.1.2—2.

New section 1.5.2—3 When food produced using gene technology is permitted for sale

The basic prohibition on the use of food produced using gene technology is in section 1.1.1—10. This new section restates the provision, currently in clause 2 of Standard 1.5.2, which provides that food produced using gene technology can be used in a food for sale if the food is listed in the schedule and complies with any conditions that are imposed or is a food additive or processing aid that is permitted for use. The conditions of approval are set out in Schedule 26.

New section 1.5.2—4 Requirement to label food as ‘genetically modified’

This new section re-states, with modification, the current content of parts of clauses 1, 4 and 5 of Standard 1.5.2, consolidating the requirements for labelling a food that contains a food produced using gene technology in one provision. The current provisions of clause 7 have not been repeated as they have no operative effect.

The definition of ‘altered characteristics’ in the current Code is not required in the redraft. The concept of altered characteristics was used to identify the characteristics that led to labelling conditions being imposed regardless of the presence of novel DNA or novel protein. Those foods are now clearly identified by having labelling conditions imposed in subsections S26—3(2) and (3).

The basic requirements to label a food or to display information to indicate that a food for retail sale is a food produced using gene technology are in paragraphs 1.2.1—8(1)(k), for a food required to bear a label, and 1.2.1—9(3)(b), for food that is or is not required to bear a label, respectively.

The labelling requirements apply to foods that consist of or contain a food produced using gene technology that contains either DNA or protein that has been modified using gene technology, where the DNA or protein is different in chemical sequence or structure from DNA or protein present in counterpart food that has not been produced using gene technology. An exception is made for protein that is a food additive or processing aid and has an amino acid sequence that is found in nature.

The genetically modified labelling requirement does not apply to a food if:

- the food has been highly refined with the effect of the refining process being to remove any novel DNA or novel protein. This exception does not apply to a food that is subject to a condition that it be labelled as genetically modified; that is, food that was previously categorised as having altered characteristics.
- a food additive or processing aid that is a food produced using gene technology leaves no novel DNA that or novel protein in the food.
- the food produced using gene technology is a flavouring that is in the food at a concentration of no more than 1g of flavouring for each kilogram of food.
- the food produced using gene technology is not intentionally present in the food and is present in a quantity of no more than 10g for each kilogram of an ingredient.
- the food is for immediate consumption and is prepared and sold by a food business of a type mentioned in subparagraph 1.5.2—4(1)(e)(ii).

The information that is to be provided is the statement ‘genetically modified’ followed by the name of the food produced using gene technology. If the food produced using gene technology is an ingredient, the statement may be made in a statement of ingredients. Conditions requiring such labelling can also be imposed as a condition of approval for foods produced using gene technology that do not contain novel DNA or novel protein².

² See, for example, the conditions imposed in section S26—3.

Further additional labelling requirements can also be imposed as a condition of approval for foods produced using gene technology.

Subsection (4) repeats the current content of clause 6 of Standard 1.5.2.

New subsection (5) provides new definitions for novel DNA, novel protein and genetically modified food, which are applicable in this labelling section only. The new definitions for 'novel DNA' and 'novel protein' replace the single definition for 'novel DNA and/or protein'. They provide a definition for 'novel protein' that deals more effectively with protein-engineered food additives or processing aids that can, in practice, have no counterpart (the term used in the current definition) but do have natural equivalents.