

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.

The Authority prepared Proposal P1042 to develop a food regulatory measure to permit seeds of low delta 9-tetrahydrocannabinol (low THC) varieties of *Cannabis sativa*, and certain products derived from those seeds, to be a food for sale or used as an ingredient in a food for sale. The Authority considered the Proposal in accordance with Division 2 of Part 3 and has approved a draft variation of a standard.

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 sunseting under the *Legislation Act 2003*.

2. Purpose and operation

The Authority has prepared a draft variation to Standards 1.2.7 and 1.4.4 to permit certain types of seeds and seed products from *Cannabis* species to be sold as a food or used as an ingredient in a food provided that certain conditions are met.

3. Documents incorporated by reference

The variation does not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 2 of Part 3 of the FSANZ Act, the Authority's consideration of the Proposal included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 28 July 2016 for a four-week consultation period.

A Regulation Impact Statement was not required because the proposed variation is likely to have only a minor regulatory impact on business, community organisations or 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

Item [1] amends Standard 1.2.7 by inserting a Note after section 1.2.7—4. The Note provides a reference in Standard 1.2.7 to the prohibition imposed by subsection 1.4.4—7(3) on health claims and nutrition content claims in relation to cannabidiol in hemp food products.

Item [2.1] amends Standard 1.4.4 by omitting the Note to section 1.4.4—2 and substituting three new Notes. Note 1 provides a reference in Standard 1.4.4 to sections 1.1.2—2 and 1.1.2—3, which define certain terms used in Standard 1.4.4 including in new sections 1.4.4—6 and 1.4.4—7.

Note 2 provides a reference in Standard 1.4.4 to the definition in section 1.1.2—9 of the term 'nutrition content claim'. Section 1.4.4—7 includes a reference to nutrition content claims made in relation to cannabidiol in hemp food products and foods that contain hemp food products as ingredients.

Note 3 provides a reference to Standard 1.2.7 and the requirements in that Standard for making health claims and nutrition content claims. Section 1.4.4—7 refers to health claims and nutrition content claims made in relation to cannabidiol in hemp food products and foods that contain hemp food products as ingredients.

Item [2.2] amends Standard 1.4.4 by inserting sections 1.4.4—6, 1.4.4—7 and 1.4.4—8 into the Standard.

Section 1.4.4—6 provides a permission for the purposes of paragraphs 1.1.1—10(5)(a) and 1.1.1—10(6)(e) of the Code to allow certain seeds and seed products from low THC varieties of *Cannabis sativa* to be sold as food or added to food.

Subsection 1.4.4—6(1) provides that *Cannabis sativa* seeds may be a food for sale or used as an ingredient in a food for sale only if each of the following conditions is met:

- the seeds are of a *Cannabis sativa* plant, the leaves and flowering heads of which contain no more than 1% delta 9-tetrahydrocannabinol.
- the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the seeds does not exceed 5 mg per kg of seeds.
- the only cannabinoids present in the seeds are naturally occurring in or on the seeds.
- if for retail sale – the seeds are non-viable and hulled (that is, the outer coat has been removed).

Subsection 1.4.4—6(2) provides permission for three specific types of products derived from seeds of low THC varieties of *Cannabis sativa*.

Paragraph 1.4.4—6(2)(a) permits oil extracted from the seeds of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for sale if the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the oil does not exceed 10 mg per kg of oil.

Paragraph 1.4.4—6(2)(b) permits a beverage derived from the seeds of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for sale if the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the beverage does not exceed 0.2 mg per kg of the beverage.

Paragraph 1.4.4—6(2)(c) permits any other product that is extracted or derived from the seeds of low THC *Cannabis sativa* to be a food for sale or used as an ingredient in a food for sale if the total combined amount of delta 9-tetrahydrocannabinol and delta 9-tetrahydrocannabinolic acid in the product does not exceed 5 mg per kg of the product.

Subsection 1.4.4—6(3) requires that the only cannabinoids present in a product listed in subsection 1.4.4—6(2) must be those that were naturally present in or on the seeds from which the product was extracted or derived. The purpose of this requirement is to prevent the fortification of seed products with cannabinoids.

Subsection 1.4.4—6(4) provides that the seed products permitted by subsection 1.4.4—6(2) may be derived or extracted from hulled, unhulled, viable or non-viable seeds.

Subsection 1.4.4—6(5) defines certain terms for the purposes of section 1.4.4—6.

Subsection 1.4.4—6(6) defines the phrase 'low THC *Cannabis sativa*' for the purposes of section 1.4.4—6.

Section 1.4.4—7 restricts how food for sale that consists of, or has as an ingredient, a hemp food product, may be packaged, labelled, advertised or sold.

Subsection 1.4.4—7(1) provides that section 1.4.4—7, and the restrictions imposed by it, apply only in relation to a food for sale that consists of, or has as an ingredient, a hemp food product. Subsection 1.4.4—7(5) defines the term 'hemp food product' for the purposes of subsection 1.4.4—7(1).

Subsection 1.4.4—7(2) provides that such a food for sale must not be labelled or otherwise presented for sale in a form which expressly or by implication suggests that the product has a psychoactive effect. Subsection 1.4.4—7(5) defines the term 'psychoactive effect' for the purposes of subsection 1.4.4—7(2).

Subsection 1.4.4—7(3) imposes restrictions in relation to the label for the food for sale.

Paragraph 1.4.4—7(3)(a) provides that the label must not include a nutrition content claim about cannabidiol.

Paragraph 1.4.4—7(3)(b) provides that the label must not include a health claim about cannabidiol.

Paragraph 1.4.4—7(3)(c) provides that the label must not include an image or representation of any part of the *Cannabis sativa* plant (including the leaf of that plant) other than the seed.

Paragraph 1.4.4—7(3)(d) provides that the label must not include the words 'cannabis', 'marijuana' or words of similar meaning.

Subsection 1.4.4—7(4) provides that, notwithstanding subsection 1.4.4—7(3), the label for the food for sale may include the word 'hemp'.

Subsection 1.4.4—7(5) defines certain terms for the purposes of section 1.4.4—7.

Section 1.4.4—8 provides that food for sale must not contain cannabidiol in excess of 75 mg/kg. The purpose of this requirement is to provide a compliance value to support the prohibition in section 1.4.4—6 on the fortification of seeds and products with cannabinoids and to ensure foods do not contain CBD at a level that would not be expected to be naturally present.