

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1279 – Lentinula edodes (Shiitake mushroom) mycelia as a processing aid) 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 A1279 which sought to amend the Code to permit a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia for use as a processing aid in the fermentation of pea protein, rice protein and pea and rice protein. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft Variation - the *Food Standards (Application A1279 – Lentinula edodes (Shiitake mushroom) mycelia as a processing aid) Variation*.

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the draft variation.

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).

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 sunset 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 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 the draft variation to amend Standard 1.3.3 of the Code to permit the use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid in the fermentation of pea protein, rice protein and pea and rice protein; and to set conditions for that substance's use as a processing aid.

4. Documents incorporated by reference

The draft variation 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 A1279 included one round of public consultation following an assessment, and the preparation of a draft variation and associated assessment summary. A call for submissions (including the draft variation) was open for an eight-week period. Further details of the consultation process, the issues raised during consultation and by whom, and the Authority's response to these issues are available in an approval report published on the Authority's website at www.foodstandards.gov.au.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)¹. Impact analyses are no longer required to be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to processing aids. This is because applications relating to permitting the use of processing aids that have been determined to be safe are considered to be minor and deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS was not required for this application.

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

References to 'variation' in this section are references to the approved draft variation.

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1279 – Lentinula edodes (Shiitake mushroom) mycelia as a processing aid) Variation*.

Clause 2 of the variation provides that the Code is amended by the Schedule to the variation.

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

¹ <https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national>

Item [1] of the Schedule to the draft variation amends Standard 1.3.3 of the Code.

Item [1] inserts a new section 1.3.3—14, titled ‘Fermentation aid—a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.

New subsection 1.3.3—14(1) provides that, for the purposes of section 1.3.3—14, a ‘fermented preparation’ means a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia.

New subsection 1.3.3—14(2) provides that the fermented preparation may be used as a processing aid for the technological purpose of a fermentation aid in the fermentation of any of the following: pea protein, rice protein or pea and rice protein. The new subsection provides an express permission for the purposes of paragraph 1.1.1—10(6)(c) of the Code. That paragraph provides that a food for sale cannot contain, as an ingredient or component, a substance used as a processing aid unless that substance’s use as a processing aid is expressly permitted by the Code.

New subsection 1.3.3—14(3) sets a condition for use of the fermented preparation as a processing aid. That is, that the proportion of the fermented preparation that is used is no more than the maximum level necessary to achieve, under conditions of ‘GMP’, its technological purpose as a fermentation aid in the fermentation of pea protein, rice protein or pea and rice protein. ‘GMP’ or ‘Good Manufacturing Practice’ is defined in subsection 1.1.2—2(3) of the Code

New subsection 1.3.3—14(4) also sets a condition for use of the fermented preparation as a processing aid. The subsection provides that the permission provided by subsection 1.3.3—14(2) is limited to a fermented preparation that is produced from a glycerol stock of *Lentinula edodes* (shiitake mushroom) mycelia that meets each of the specifications prescribed in subsection 1.3.3—14(4).

The effect of item [1] of the Schedule to the variation is to permit the proposed use of a fermented preparation of *Lentinula edodes* (shiitake mushroom) mycelia as a processing aid in accordance with the Code.