

## **EXPLANATORY STATEMENT**

### *Food Standards Australia New Zealand Act 1991*

#### ***Food Standards (Application A1315 – Chitosan and (1,3)- $\beta$ -glucans from *Agaricus bisporus* as a food additive) 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 A1315, which sought to amend the Code to permit the use of a combination of chitosan and (1,3)- $\beta$ -glucans extracted from *Agaricus bisporus* as a food additive for use as a preservative in food and beverage products. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation – the *Food Standards (Application A1315 – Chitosan and (1,3)- $\beta$ -glucans from *Agaricus bisporus* as a food additive) Variation* (the approved draft 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 approved 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.

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 permit a combination of chitosan and (1,3)-

β-glucans (mushroom chitosan) extracted from *Agaricus bisporus* to be used as a food additive in a range of food, including beverages, in accordance with the Code. The amendments include:

- Amending Schedule 16 of the Code to list ‘mushroom (*Agaricus bisporus*) chitosan’ as an additive permitted at GMP.
- Inserting a new specification for mushroom chitosan extracted from *Agaricus bisporus* in Schedule 3 of the Code.
- Amending Schedule 8 of the Code to list ‘mushroom chitosan’ as the food additive name that must be listed in the statement of ingredients for food containing mushroom chitosan in accordance with section 1.2.4—7.

#### **4. Documents incorporated by reference**

The approved draft variation does not incorporate any documents by reference.

However, the approved draft variation will vary Schedule 3 of the Code which does incorporate documents by reference. Section 1.1.1—15 of the Code requires certain substances (such as substances used as food additives) to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code (or sold for such use).

Schedule 3 incorporates documents by reference to set specifications for various substances in the circumstances specified in that Schedule. The documents incorporated include: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition); and the Commission Regulation (EU) No 231/2012.

#### **5. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority’s consideration of application A1315 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for over a consultation period from 25 March 2025 until 6 May 2025. 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](http://www.foodstandards.gov.au).

Changes have been made to the impact analysis requirements by the Office of Impact Analysis (OIA)<sup>1</sup>. Impact analysis is no longer required to be finalised with the OIA. Under the new approach to impact analysis, FSANZ will assess whether an application requires a Regulatory Impact Statement (RIS).

FSANZ’s assessment is that a RIS is not required for this application. Prior to these changes, the OIA advised FSANZ that a RIS was not required for applications relating to food additives. This is because applications relating to permitting the use of food additives that have been determined to be safe are considered to be minor and/or deregulatory in nature, as their use will be voluntary if the draft variation concerned is approved.

FSANZ’s decision not to develop a RIS for application A1315 is consistent with the OIA’s prior advice.

#### **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*.

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<sup>1</sup> Formerly known as the Office of Best Practice Regulation (OBPR)

## 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 A1315 – Chitosan and (1,3)- $\beta$ -glucans from *Agaricus bisporus* as a food additive) 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.

**Items [1] and [2]** of the Schedule to the variation amend Schedule 3 of the Code.

Schedule 3 contains specifications for the purposes of section 1.1.1—15 of the Code.

Section 1.1.1—15 requires certain substances, e.g. substances used as food additives, to comply with any relevant identity and purity specifications listed in Schedule 3 when added to food in accordance with the Code or sold for use in food.

Specifications include those set out in provisions which are listed in the table to subsection S3—2(2) (see paragraph S3—2(1)(a)).

**Item [1]** inserts a new entry into the table to subsection S3—2(2) consisting of the substance 'mushroom (*Agaricus bisporus*) chitosan' in alphabetical order in column 1 and its associated provision 'section S3—55' in column 2. These new references relate to the new provision that would be inserted by **item [2]** below.

**Item [2]** inserts a new section S3—55 into Schedule 3 which sets out the specifications relating specifically to mushroom chitosan from *Agaricus bisporus*, which includes the substance sought to be permitted by the applicant.

*Agaricus bisporus* is the species name of several varieties of mushrooms, including white button mushrooms.

Consequently, the permission for this mushroom chitosan to be used as a food additive is subject to the requirement in section 1.1.1—15 that the substance must comply with these specifications when added to food in accordance with the Code or sold for use in food.

**Items [3] and [4]** of the Schedule to the variation amend Schedule 8 of the Code.

Schedule 8 contains the food additive names and code numbers that are required to be used on the statement of ingredients in accordance with subsection 1.2.4—7(1); and for the definition of code number in section 1.1.2—2.

**Items [3] and [4]** amend Schedule 8 by inserting 'mushroom chitosan' into each of the following tables to section S8—2:

- the table titled 'Food additive names—alphabetical listing'—to be inserted in alphabetical order
- the table titled 'Food additive names—numerical listing'—to be inserted after the table item dealing with 'Monk fruit extract or luo han guo extract'.

No INS number (or code number as it is referred to in Schedule 8) is included in those entries as there is no current INS number for mushroom chitosan from *Agaricus bisporus*. So, a dash (-) is included in place of an INS or code number in both tables.

**Items [5] and [6]** of the Schedule to the variation amend Schedule 16 of the Code.

Schedule 16 of the Code sets out 'additives permitted at GMP' (in alphabetical and numerical listings). 'GMP' or Good Manufacturing Practice is defined in section 1.1.2—2 of the Code.

Subsection 1.3.1—3 provides that a substance may be used as a food additive in relation to

food if (among other things):

- the substance is permitted to be used as a food additive for that food by Schedule 15; and
- any restrictions on the use of that substance as a food additive set out in this Standard or in Schedule 15 are complied with.

Schedule 15 lists a range of foods, including beverage products, in which ‘additives permitted at GMP’ may be used as food additives.

**Items [5] and [6]** amend Schedule 16 by inserting ‘mushroom (*Agaricus bisporus*) chitosan’ into each of the following tables to section S16—2:

- the table titled ‘Additives permitted at GMP—alphabetical listing’—to be inserted in alphabetical order
- the table titled ‘Additives permitted at GMP—numerical listing’—to be inserted after the table item dealing with ‘Monk fruit extract (luo han guo extract)’.

No INS number is included in those entries as there is no current INS number for mushroom chitosan from *Agaricus bisporus*. So, a dash (-) is included in place of an INS or code number in both tables.

The effects of amendments in **items [5] and [6]** are:

- mushroom chitosan from *Agaricus bisporus* is an ‘additive permitted at GMP’,
- as an ‘additive permitted at GMP’, mushroom chitosan from this source is permitted to be used as a food additive in a range of food, including beverage products, as set out in Schedule 15, in accordance with the Code,

This permission is subject to the condition that an ‘additive permitted at GMP’ permitted to be used as a food additive by Schedule 15 may be present in a food for sale as a result of use in accordance with GMP (see subsection 1.3.1—4(1) of the Code).