

Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1247 – D allulose as a novel food) 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 A1247 which sought to amend the Code to permit the use of D-allulose as a novel food from enzymatic conversion of fructose by D-psiocose 3-epimerase contained in *M. foliorum*. The Authority considered the application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1247– D-allulose as a novel food) 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 (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 a draft variation to amend Standards 1.1.2, 1.2.3, 1.2.7, 1.2.8, 2.6.2 and Schedules 2, 4, 11, 18 and 25 to permit, subject to certain specified conditions: the sale and use of D-allulose as a novel food; and the use of a particular enzyme – the D-psicose 3-epimerase from *M. foliorum* - as a processing aid in the production of D-allulose.

4. Documents incorporated by reference

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

However, existing provisions of the Code incorporate documents by reference that will prescribe identity and purity specifications for the D-allulose and D-psicose 3-epimerase to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as novel foods and processing aids to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code.

Subsection S3—2(1) incorporates by reference the United States Pharmacopeial Convention (2022) Food chemicals codex (13th edition), which establishes specifications for 'Allulose'.

Subsection S3—3(g) incorporates by reference The Merck Index, 15th Edition, being a secondary source within S3—3, which establishes a specification for 'D-psicose' (O'Neil et al 2013).

Section S3—2 of Schedule 3 incorporates by reference the specifications listed in: the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)); and in the United States Pharmacopeial Convention (2022) Food Chemicals Codex (13th edition). Both include general specifications for the identity and purity of enzyme preparations used in food processing. These will be relevant for D-psicose 3-epimerase.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of application A1247 included one round of public consultation following an assessment and the preparation of a draft variation and associated report. Submissions were called for on 8 November 2023 for a 6-week consultation period.

The Office of Best Practice Regulation (OBPR), now called the Office of Impact Analysis (OIA), exempted FSANZ from the need to undertake a formal Regulation Impact Statement (RIS) in relation to the regulatory change proposed in response to application A1247 (OBPR correspondence dated 6 May 2022, OBPR Reference: OBPR22-02203). That is because the OBPR considered the proposed change was unlikely to have a more than minor regulatory impact.

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

Clause 1 provides that the name of the approved draft variation is the *Food Standards (Application A1247 – D-allulose as a novel food) Variation*.

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

Clause 3 provides that the approved draft variation will commence and take effect immediately after the commencement of the *Food Standards (Proposal P1063 – Code Revision (2024) – Added Sugar(s) Claims) Variation* (the P1063 variation). The P1063 variation amends many of the same provisions that the approved draft variation amends. The P1063 variation removes a redundant term from those provisions. For that reason, clause 3 provides that the approved draft variation shall take effect immediately after the P1063 variation takes effect.

Items [1] to [11] of the Schedule of the approved draft variation amend the Code.

Item [1]

Item [1] amends paragraph (a) of the definition of “sugars” in subsection 1.1.2—2(3) of the Code. It repeals the paragraph and substitutes it with the following new paragraph (a):

“(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D allulose) and disaccharides; and”

The effect of this amendment is to expressly exclude D-allulose from the definition of “sugars” for the purposes of Standard 1.2.7, Standard 1.2.8 and Schedule 4.

The amendments made to the Code by Items [3] – [5], and [7] are as a consequence of this amendment.

Item [2]

Item [2] amends Section 1.2.3—2 of the Code. It repeals paragraph 1.2.3—2(2)(c) and substitutes it with the following new paragraphs:

- (c) one or more of the substances listed in paragraph (a), in combination with one or more of the substances listed in paragraph (b), at a level of or in excess of 10 g/100 g; or
- (d) added D-allulose as an ingredient and the food is one of the following:
 - (i) a bakery product;
 - (ii) bubble gum;
 - (iii) chewing gum;
 - (iv) breakfast cereal;
 - (v) confectionery (but not chocolate);
 - (vi) a dessert (with or without gelatine);
 - (vii) ice cream;
 - (viii) edible ice;
 - (ix) a non-alcoholic water based flavoured drink (as defined in the table to section S25—2);
 - (x) yoghurt.

Section 1.2.3—2 of the Code provides that the labelling of certain foods must include certain statements in accordance with Standard 1.2.1. Subsection 1.2.3—2(2) lists the foods that, in accordance with Standard 1.2.1, must have an advisory statement to the effect that excess consumption may have a laxative effect. The amendment made by Item [2] will in effect require such an advisory statement to appear on or in the labelling of a food for sale in accordance with Standard 1.2.1 if the food for sale: is a food listed in subparagraphs 1.2.3—2(2)(d)(i) – (x); and contains added D-allulose as an ingredient.

Item [3]

Item [3] amends the definition of “sugars” in Note 1 of section 1.2.7—2 by repealing the paragraph and substituting it with the following new paragraph:

“**sugars**, in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).”

This amendment reflects the amendment in item [1] above.

Item [4]

Item [4] amends the definition of “sugars” in Note 1 of section 1.2.8—4 by repealing the paragraph and substituting it with the following new paragraph:

“**sugars**, in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides. (Elsewhere in the Code it has a different definition).”

This amendment also reflects the amendment in item [1] above.

Item [5]

Item [5] amends paragraph (a) of the definition of “sugars” in Note 1 of section 2.6.2—2 by repealing the paragraph and substituting it with the following new paragraph (a):

“(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides; and”

This amendment mirrors the amendment in item [1] above.

Item [6]

Item [6] amends Schedule 2 of the Code. It inserts the following entry into the table to section S2—2 after table item dealing with ‘w/v’ (weight per volume):

“w/w	weight per weight”
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Schedule 2 sets out the meanings of certain symbols used in the Code. This amendment is needed as the amendment in item [11] below refers to “w/w”. Schedule 2 does not currently contain a meaning for that symbol.

Weight per weight (w/w) is a reference to the weight of each component being used to calculate levels of addition, irrespective of whether either is a solid or a liquid. In the case of a liquid, the volume is ignored. Instead, the weight of that liquid is used in the calculation.

Item [7]

Item [7] amends Schedule 4 of the Code by repealing paragraph (a) of the definition of “sugars” in the Note to section S4—2 and substituting it with the following new paragraph (a):

“(a) in Standard 1.2.7, Standard 1.2.8 and Schedule 4—means monosaccharides (other than D-allulose) and disaccharides; and”

This amendment mirrors the amendment in item [1] above.

Item [8]

Item [8] amends Schedule 4 of the Code. It amends the conditions listed in column 4 of the table to section S4—3 for making “no added sugars” nutrition content claims. The amendment replaces the words (“hexose monosaccharides and disaccharides”) in condition (f)(i) with “hexose monosaccharides (other than D-allulose) and disaccharides”.

The amendment’s effect is provides that conditions (a) and (b) listed in the table to section S4—3 for making a “no added sugars” nutrition content claim do not apply to D-allulose, which is a hexose monosaccharide.

Item [9]

Item [9] amends Schedule 11 of the Code by inserting the following new entry into the table to subsection S11—2(3) (above the table item dealing with ‘erythritol’):

“D-allulose	2”
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The effect of this amendment is to assign D-allulose an energy factor of 2 kJ/g to be used in the calculation of “average energy content” for the purposes of Standard 1.2.8 and Schedule 11.

Item [10]

Item [10] amends the table to subsection S18—9(3) in Schedule 18 of the Code. The table lists substances permitted by the Code to be used as a processing aid for a specific technological purpose. The amendment inserts, in alphabetical order, a new entry into the table.

The new entry lists in column 1 of the table the permission to use the following enzyme as a processing aid: “D-psicose 3-epimerase (EC 5.1.3.30) contained in *Microbacterium foliorum*”.

The new entry lists in column 2 of the table the specific permitted technological purpose for which this enzyme may be used as a processing aid: “For use in the manufacture of D-allulose”.

The permission is subject to the condition, as prescribed in column 3 of the table, that the maximum permitted level or amount of this enzyme that may be present in a final food must be consistent with *GMP* or *Good Manufacturing Practice* (as defined in section 1.1.2—2 of the Code).

The effect of the amendment is to permit the proposed use of the above-mentioned enzyme as a processing aid in accordance with the Code.

Item [11]

Item [11] amends the table to section S25—2 of Schedule 25 of the Code

Paragraphs 1.1.1—10(5)(b) and 1.1.1—10(6)(f) of the Code provide that, unless expressly permitted by the Code, a food offered for retail sale must not be a novel food or have a novel food as an ingredient. Section 1.5.1—3 of the Code provides that the express permission required by those paragraphs. The section provides that a food offered for retail sale may consist of, or have as an ingredient, a novel food if:

- (a) the novel food is listed in the table to section S25—2;
- (b) any conditions of use specified in that table are complied with.

The table to section S25—2 of the Code lists permitted novel foods together with their conditions for use.

Item [11] inserts a new entry into the table. The new entry:

- permits D-allulose as a novel food to be a food for retail sale or to be present as an ingredient in a food for retail sale; and
- specifies seven conditions of use for D-allulose as a permitted novel food.

The conditions specified are as follows.

Condition 1 provides that D-allulose may only be a food for retail sale if that food is a tabletop sweetener. That is, D-allulose itself may be sold at retail sale only as a tabletop sweetener.

Condition 2 provides that D-allulose may only be added to a food listed in condition 4. That is, D-allulose must not be added to any food which is not listed in condition 4.

Condition 3 provides that food listed in condition 4 must not contain added D-allulose in an amount or at a level greater than the limit, if any, specified in that condition for that food.

Condition 4 lists the foods to which D-allulose may be added and the maximum permitted amount for D-allulose in each food. As explained above, condition 3 requires that the amount of D-allulose present in the relevant food not exceed that specified limit.

A Note is provided following condition 4 which directs the reader to the advisory statement required by subsection 1.2.3—2(2). The Note states that an advisory statement to the effect that excess consumption may have a laxative effect is required for certain foods for sale containing D-allulose.

Condition 5 clarifies, for the purposes of the permission to add D-allulose to non-alcoholic water based flavoured drinks, as per the condition at 4(n), that the meaning of a non-alcoholic water based flavoured drink:

- (a) includes: a brewed soft drink; a non-brewed soft drink; a cola type drink; a formulated caffeinated beverage; a fruit drink; a tea beverage; a coffee beverage; a powdered drink concentrate; and a liquid drink concentrate; and
- (b) does not include: a food standardised in Part 2.9 of the Code; a dairy analogue; a fruit juice; a vegetable juice; a formulated beverage; an electrolyte drink; and an electrolyte drink base.

Condition 6 provides that, during the exclusive use period as defined by condition 7, only D-allulose sold under the brand *Nexweet* may be:

- a food for retail sale in accordance with condition 1 above; or
- added to food in accordance with conditions 2 to 5 above.

Condition 7 defines the term “exclusive use period” for the purposes of condition 6 as the period commencing on the date of gazettal of the *Food Standards (Application A1247 – D-allulose as a novel food) Variation* and ending 15 months after that date. On the expiry of the exclusive use period, condition 6 will automatically cease to have effect. At that point, the D-allulose novel food permission provided by the new entry will apply to - and permit - any and all brands of D-allulose that comply with the Code.