

Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1260 – 2-Methyloxolane 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 A1260 which sought to amend the Code to permit 2-methyloxolane (2-MeOx) as a processing aid for the purpose of an extraction solvent in relation to food. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation: the *Food Standards (Application A1260 – 2-Methyloxolane as a processing aid) 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 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 amending Schedule 3 and the table to section S18—8 of the Code to permit the use of 2-MeOx as a processing aid for the purpose of being an extraction solvent in relation to food. 2-MeOx can be used to extract and separate oils and proteins from plant-based products, including oilseeds. It can also be used to extract other components including flavours, fragrances and colours from plant-based sources. This permission is subject to the condition that 2-MeOx must not be present in the food at a level greater than the maximum permitted level indicated in the corresponding row of the table (3 mg/kg in Infant formula products; 5 mg/kg in Foods for infants and Formulated supplementary foods for young children; 20 mg/kg in all other foods). As a substance used as a processing aid, 2-MeOx will also have to comply with relevant specifications set out in Schedule 3 of the Code when added to food in accordance with the Code, or sold for use in food.

4. Documents incorporated by reference

The approved 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 A1260 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. FSANZ called for submissions on the draft variation from 26 August to 20 September 2024. 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 analysis no longer must be finalised with the OIA. Prior to these changes, the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not needed 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 minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under this 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 'the variation' in this section are references to the approved draft variation.

¹ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis (pmc.gov.au)

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1260 – 2-Methyloxolane 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 commences on the date of gazettal of the instrument.

Schedule to the variation

Items [1] and [2] of the Schedule to the variation amends 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 processing aids, 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)). This table lists entries consisting of substances for which there are specifications in Schedule 3 (column 1); and their associated provisions (column 2).

Item [1] amends the table to subsection S3—2(2) by inserting a new entry into the table before the table item dealing with ‘Nicotinamide riboside chloride’. The new entry consists of ‘2-Methyloxolane’ in column 1 of the table and ‘section S3—52’ in column 2 of the table.

This amendment is consequential to the amendment in **item [2]** (see below).

Item [2] inserts new section S3—52 into Schedule 3, which sets out identity and purity specifications specifically for 2-MeOx.

Amendments in **items [1] and [2]** are related to the amendment in **item [3]** below, which will permit the use of 2-MeOx as a processing aid for certain technological purposes in accordance with the Code.

The effect of amendments in **items [1] and [2]** will be that when 2-MeOx is added to food in accordance with the Code, or sold for use in food, 2-MeOx will have to comply with the new specification in section S3—52, in addition to any other relevant specification in Schedule 3.

Item [3] of the Schedule to the variation amends Schedule 18 of the Code.

Schedule 18 lists substances that are permitted to be used as processing aids for the purposes of the Code.

In particular, **item [3]** inserts a new entry into the table to subsection S18—8 of the Code. This table lists substances that are permitted to function as extraction solvents in relation to food for the purposes of section 1.3.3—10 of the Code.

According to section 1.3.3—10, a substance listed in section S18—8 may be used as a processing aid to perform the technological purpose of an extraction solvent if the substance satisfies both of the following conditions – the substance:

- is used in relation to a food listed in the corresponding row of the table; and
- is not present in the food at a level greater than the maximum permitted level specified

in the corresponding row of the table.

The term 'used as a processing aid' is defined in section 1.1.2—13 of the Code.

The new entry will be inserted into the table to subsection S18—8 before the table item dealing with 'Propane'; and consist of the following:

'2-Methyloxolane' is the substance listed in column 1 of the table.

The associated foods for this substance are listed in column 2 of the table as 'Infant formula products', 'Foods for infants', 'Formulated supplementary foods for young children' and 'All other foods'.

The maximum permitted level corresponding to each food is set out in column 3 of the table as follows:

- 3 mg/kg (Infant formula products);
- 5 mg/kg (Foods for infants);
- 5 mg/kg (Formulated supplementary foods for young children); and
- 20 mg/kg (All other foods).

The amendment in **item [3]** will permit the proposed use of 2-MeOx as a processing aid in accordance with the Code.