

Attachment B – Explanatory Statement

EXPLANATORY STATEMENT

Food Standards Australia New Zealand Act 1991

Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) 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 A1254 which seeks to amend the Code to extend the permission to use rosemary extract as a food additive to additional foods. The Authority considered the Application in accordance with Division 1 of Part 3 and has approved a draft variation - the *Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) 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 amending Schedule 15 of the Code to extend the permitted use of rosemary extract as a food additive to additional foods, subject to maximum permitted levels.

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 would prescribe identity and purity specifications for the food additive to be permitted by the approved draft variation. Section 1.1.1—15 of the Code requires substances used as food additives to comply with any relevant identity and purity specifications listed in Schedule 3 of the Code. Section S3—2 of Schedule 3 incorporates by reference the specifications listed in the Joint FAO/WHO Expert Committee on Food Additives (JECFA) Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021)), the United States Pharmacopeial Convention Food Chemicals Codex (13th edition, 2022), and the Commission Regulation (EU) No 231/2012. These include specifications for the identity and purity parameters of rosemary extract.

5. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1254 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 17 November 2023 for a 4-week consultation 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 analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised the Authority that a Regulatory Impact Statement (RIS) was not required for the 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 deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, the Authority's assessment is that a RIS is 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*.

¹ Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies: <https://oia.pmc.gov.au/resources/guidance-impact-analysis/regulatory-impact-analysis-guide-ministers-meetings-and-national>

7. Variation

Clause 1 of the variation provides that the name of the variation is the *Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) 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.

7.1 Item [1] – [5]

Items [1] to [5] of the Schedule to the variation amends the table to section S15—5 in Schedule 15. Each amendment made to the table is explained below.

The amendments made by Items [1] to [5] each set an MPL for rosemary extract. That MPL is calculated as the sum of carnosic acid and carnosol (expressed in mg/kg) (see paragraph 1.3.1—4(6)(k) of the Code).

Item [1] repeals the table item dealing with rosemary extract under the heading ‘*2.1 Edible oils essentially free of water*’ in the table to subsection S15—5; and substitutes the repealed item with a new table item dealing with rosemary extract. The new table item consists of:

‘392	Rosemary extract	50’
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The effect of this amendment is to permit rosemary extract (INS number 392) to be used as a food additive in all edible oils essentially free of water up to an MPL of 50 mg/kg.

Item [2] repeals the table item dealing with rosemary extract under the heading ‘*6.4 Flour products (including noodles and pasta)*’ in the table to subsection S15—5; and substitutes the repealed item with a new table item dealing with rosemary extract. The new table item consists of:

‘392	Rosemary extract	(a) 10	Only flour based snacks e.g. pretzels, fritters, and crackers; and cooked or instant noodles and pasta
		(b) 40	Only wheat or corn based tortilla’

The effects of this amendment are to:

- retain the permission to use rosemary extract as a food additive in ‘Only flour based snacks e.g. pretzels, fritters, and crackers’, with an MPL of 10 mg/kg; and
- add a new permission to use rosemary extract as a food additive in ‘cooked or instant noodles and pasta’, with an MPL of 10 mg/kg; and
- add a new permission to use rosemary extract as a food additive in ‘wheat or corn based tortilla’, with an MPL of 40 mg/kg.

Item [3] inserts a new entry, consisting of a heading and corresponding item into the table to subsection S15—5, after the table item dealing with Steviol glycosides under the heading ‘7.1.1 Fancy Breads’. The new entry consists of:

'7.1.2	Breadcrumbs	
392	Rosemary extract	40'

The effect of this amendment is to permit rosemary extract (INS number 392) to be used as a food additive in a class of food identified as 'Breadcrumbs' with an MPL of 40 mg/kg.

Item [4] inserts a new item into the table to subsection S15—5, after the table item dealing with Nitrates (potassium and sodium salts) under the heading '8.3.1 Fermented, uncooked processed comminuted meat products'. The new table item consists of:

'392	Rosemary extract	40'
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The effect of this amendment is to permit rosemary extract (INS number 392) to be used as a food additive in 'fermented, uncooked processed comminuted meat products' with an MPL of 40 mg/kg.

Item [5] repeals the item dealing with rosemary extract under the heading '8.3.2 Sausage and sausage meat containing raw, unprocessed meat' in the table to subsection S15—5; and substitutes the repealed item with a new table item dealing with rosemary extract. The new table item consists of:

'392	Rosemary extract	(a) 40	Only sausage containing raw, unprocessed meat
		(b) 100	Only dried sausages'

The effects of this amendment is to:

- (a) permit the use of rosemary extract as a food additive in 'sausage containing raw unprocessed meat' with an MPL of 40 mg/kg; and
- (b) retain the current permission to use rosemary extract as a food additive in 'dried sausages' with an MPL of 100 mg/kg.

7.2 Item [6]

Item [6] removes the numbered heading for class '*20.2.06 Starch based snacks (from root and tuber vegetables, legumes and pulses)*' and replaces it with a new numbered heading. The effect of the amendment is to correct an error in the subheading by changing the heading number from 20.2.06 to 20.2.0.6 and by italicising '*Starch based snacks (from root and tuber vegetables, legumes and pulses)*'