

20 July 2018
[54–18]

Call for submissions – Application A1158

Rosemary extract as a food additive

FSANZ has assessed an application made by Kalsec Inc to permit the use of rosemary extract as a food additive with the technological purpose of an antioxidant and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

Under section 114 of the FSANZ Act, some information provided to FSANZ cannot be disclosed. More information about the disclosure of confidential commercial information is available on the FSANZ website at [information for submitters](#).

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

There is no need to send a hard copy of your submission if you have submitted it by email or via the FSANZ website. FSANZ endeavours to formally acknowledge receipt of submissions within 3 business days.

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 31 August 2018

Submissions received after this date will not be considered unless an extension had been given before the closing date. Extensions will only be granted due to extraordinary circumstances during the submission period. Any agreed extension will be notified on the FSANZ website and will apply to all submitters.

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

Hard copy submissions may be sent to one of the following addresses:

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Supporting documents

The following document¹ which informed the assessment of this application is available on the FSANZ website:

SD1 Risk and technical assessment report

¹ <http://www.foodstandards.gov.au/code/applications/Pages/A1158-Rosemaryextractasafoodadditive.aspx>

Executive summary

Kalsec Inc submitted an application in January 2018 to amend the Australian New Zealand Food Standards Code to permit the use of rosemary extract as a food additive.

The applicant is seeking permission to use rosemary extract as an antioxidant in a range of foods. Antioxidants prevent oxidation of food components such as fats and oils, thus helping to stabilise food products and extend shelf life. Rosemary extract is sourced from the leaves of the rosemary plant using a solvent extraction method that concentrates the amounts of two main antioxidant substances (carnosic acid and carnosol) in rosemary leaves. The extract has antioxidant properties that are comparable to other permitted food antioxidants but without the strong flavouring substances that are also present in rosemary leaves.

Dried or fresh rosemary leaves have a long history of safe consumption in the human diet as a seasoning herb. Rosemary extract has permissions to be used as a preservative or antioxidant food additive in EU, Japan, Singapore and China. Rosemary extract as a food additive is not yet included in the General Standard for Food Additives (GSFA). The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated rosemary extract and set a temporary Acceptable Daily Intake (ADI) pending submission of new studies on developmental and reproductive toxicity.

The submitted data, together with the recent JECFA evaluation and other sources, were used to assess the risk of rosemary extract. No human health and safety concerns were identified. On the basis of toxicological studies, FSANZ also found no evidence to indicate that the use of rosemary extract is of public health concern and that its ADI should be different to the temporary ADI established by JECFA.

The applicant is seeking permission for rosemary extract as a food additive with a maximum permitted level (MPL) specified for each requested food category. A dietary exposure assessment for the Australian and New Zealand population was conducted using various modelling scenarios. In all but one scenario (New Zealand 5-14 year old children, 90th percentile, see below) estimates of exposure were under the ADI. However the assessment used highly conservative assumptions resulting in a likely overestimate of exposure for New Zealand 5-14 year old children in the 90th percentile (high consumers) exposure group.

On the basis of the safety assessment (Supporting document 1), FSANZ concluded that there is no evidence of public health and safety risk associated with the addition of rosemary extract as an antioxidant to the requested foods.

All substances used as food additives must be listed in the statement of ingredients on most packaged foods.

FSANZ therefore prepared a draft variation to the Code to permit the use of rosemary extract as a food additive in certain foods with the technological purpose of antioxidant.

1 Introduction

1.1 The applicant

The applicant is Kalsec Inc, a supplier of products derived from herbs and spices located in Kalamazoo, Michigan, USA.

1.2 The application

The applicant is seeking permission for the use of rosemary extract as an antioxidant. The applicant proposes to use the extract in foods in the categories of edible oils, fruit and vegetable spreads, icings and frostings, breakfast cereals and cereal bars, flour-based snacks, biscuits and cakes, processed meats, sausage meats, sauces and toppings, processed nuts, and potato chips. Maximum permitted levels (MPL) are specified for each food category.

Rosemary extracts are isolated from the dried leaves of the rosemary plant. Dried or fresh rosemary leaves have a long history of consumption in the human diet as a seasoning herb and the extract has also been used as a flavour in food preparations. This application seeks to permit the use of rosemary extract as an antioxidant and thus stabilise product formulations and provide longer shelf-life.

Rosemary extract as a food additive has the Codex Alimentarius International Numbering System (INS) for food additives of number 392. This refers to the extract composed of the compounds carnosol and carnosic acid, the two main antioxidants present in rosemary extract. Unless otherwise noted the common name of rosemary extract will be used throughout the report.

The applicant seeks to add rosemary extract to Schedule 15 (Substances that may be used as food additives) and to Schedule 8 (Food additive names and code numbers (for statement of ingredients)) in the Australia New Zealand Food Standards Code (the Code)

1.3 The current standard

Australian and New Zealand food laws require food for sale to comply with the following Code requirements.

Permitted use

Paragraph 1.1.1—10(6)(a) of the Code provides that food for sale cannot contain, as an ingredient or component, a substance ‘used as a food additive’ unless that substance’s use as a food additive is expressly permitted by the Code.

Section 1.3.1—3 details which substances are permitted to be used as a food additive for the purposes of the Code. The permitted food additives for different food categories are listed in the table to section S15—5 of the Code.

Section 1.1.2—11 also provides that a substance is ‘used as a food additive’ if it is added to a food to perform one or more technological functions listed in Schedule 14 of the Code and is one of the following: a substance identified in the table to section S15—5 as permitted food additive; a substance identified in section 16—2 as an additive permitted at GMP; a substance identified in section 16—3 as an a colouring permitted at GMP; a substance identified in section 16—4 as an a colouring permitted at a maximum level; or a prescribed non-traditional food.

Schedule 14 lists the permitted technological purposes of food additives. The table in section S14—2 of that Schedule provides that use as an antioxidant is a permitted purpose.

Schedules 15 and 16 list the specific food additive permissions for different categories of food products.

The Code does not currently permit the use of rosemary extract as a food additive antioxidant.

Under Section 1.1.2-2 (Permitted flavouring substance (a)(i)) of the Code, rosemary extract is permitted as a flavouring substance. This section defines *permitted flavouring substance* as a substance that is listed in the Generally Recognised as Safe (GRAS) lists of flavouring substances published by the Flavour and Extract Manufacturers' Association (FEMA) of the United States. Rosemary and rosemary oil is included on the GRAS lists under GRAS reference numbers 2991 and 2992, respectively².

Labelling

Paragraph 1.1.1—10(8) of the Code provides that food for sale must comply with all relevant labelling requirements imposed by the Code for that food.

Standard 1.2.4 of the Code generally requires food products to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) of that Standard requires food additives to be declared in the statement of ingredients.

Schedule 7 (Food additive class names (for statement of ingredients)) lists prescribed food additive class names. 'Antioxidant' is a prescribed class name.

Schedule 8 (for statement of ingredients) lists the names and code numbers of food additives that are to be used for labelling purposes.

Schedule 8 does not refer to rosemary extract as this substance is not currently permitted to be added to food as a food additive.

Identity and purity requirements

Paragraph 1.1.1—15(1)(a) 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. Food Chemicals Codex (Codex) is listed in section S3—2 of Schedule 3 as a primary source of specifications for this purpose. Codex contains a specification for rosemary extract (FCC 2016).

1.3.1 International standards

1.3.1.1 Codex Alimentarius

The use of rosemary extract as a food additive is not yet included in the General Standard for Food Additives (GSFA)³. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) evaluated rosemary extract at the 82nd meeting in June 2016 and set a temporary Acceptable Daily Intake (ADI) pending submission of studies on potential developmental and reproductive toxicity⁴.

² https://www.femaflavor.org/sites/default/files/3.%20GRAS%20Substances%282001-3124%29_0.pdf

³ Codex Alimentarius General Standards for Food Additives.

http://www.fao.org/gsaonline/docs/CXS_192e.pdf

⁴ Summary report of the eighty-second meeting of JECFA. <http://www.fao.org/3/a-bl839e.pdf>

1.3.1.2 Other regulations

Rosemary extract has been permitted for use as a food additive in a number of national and international regulations, as listed below.

- **United States** - Rosemary extract is allowed in the United States as a flavour and it appears on some food labels as a preservative. The applicant is pursuing a self-affirmed GRAS position for rosemary antioxidant extract that is based upon the EU and JECFA evaluations.
- **European Union** - Rosemary extract (E392) is approved in the EU additives regulation No. 1129/2011. It was evaluated by the European Food Safety Authority (EFSA) in 2008 (EFSA, 2008) and then again in 2015 to extend its uses to fat based spreads (EFSA, 2015). A list of permitted uses was provided in Appendix 3 of the application.
- **Japan** - Rosemary extract appears as additive #365 in the Japanese Existing Additives List (see Appendix 4 of the application). There are no specific use limits.
- **China** - China has published a specification that is largely aligned with the EU except that some additional extraction solvents (such as hexane and methanol) are permitted. See Appendix 5 of the application.
- **Singapore** - Rosemary extract is permitted for use as an antioxidant in foods and beverages in Singapore. Singapore adopts the EU and Codex specification and permitted uses are listed in Appendix 6 of the application.

1.4 Reasons for accepting application

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2)
- it related to a matter that warranted the variation of a food regulatory measure.

1.5 Procedure for assessment

The application is being assessed under the General Procedure.

2 Summary of the assessment

2.1 Risk assessment

The submitted data, and information from other sources, were considered adequate to define the hazard of rosemary extract. Oral bioavailability of carnosic acid (which is oxidised to carnosol) is estimated to $\geq 65\%$ and metabolism occurs through common pathways with several metabolites detected in urine and faeces of rats. Acute toxicity of carnosic acid was demonstrated in rats and mice to be low. No chronic or carcinogenicity studies of rosemary extract, carnosic acid, or carnosol were identified. No evidence of genotoxicity was identified in two genotoxicity assays that were available to FSANZ. There is limited information on the reproductive and developmental safety of rosemary extract. FSANZ identified several studies involving carnosic acid supplementation of the diet of pregnant and lactating dairy ewes and goats. No adverse effects were identified in these studies. No concerns were identified in human studies. Rosemary has a long history of use as a culinary herb.

On the basis of a no-observed-adverse-effect level (NOAEL) identified in a 90 day toxicity study in rats, the Joint FAO/WHO Expert Committee on Food Additives (JECFA) established a temporary acceptable daily intake (ADI) of 0 - 0.3 mg/kg bw for rosemary extract, expressed as the sum of carnosic acid and carnosol. The ADI is temporary pending the submission of data on the reproductive and developmental safety of rosemary extract to JECFA. FSANZ has found no evidence to suggest that the ADI should be different to that of

the temporary ADI established by JECFA.

Two scenarios were modelled in the dietary exposure assessment. Conservative assumptions were applied in both scenarios (see section 4.2.1 in SD1). All estimates of dietary exposure (expressed as a percentage of the ADI) in the modelled scenarios were well under the ADI except for one⁵, that being the 90th percentile of consumers aged 5–14 years in New Zealand. In this case, the estimated exposure was 110% of the ADI. As explained in section 4.5.3.1 of SD1, this is a highly conservative scenario that is not expected to occur and the dietary exposure is likely to be over-estimated.

2.2 Risk management

The main risk management options available to FSANZ are to approve or reject the request to amend the Code and, if approved, to impose conditions that may be appropriate (e.g. limit the number of food categories and/or lower the specified MPL). In addition to the conclusions of the risk and technical assessment, the following points have been taken into account in determining appropriate risk management options.

2.2.1 Use of the temporary ADI

The conclusion of the risk assessment was based on a temporary ADI set by JECFA. The application indicated that the temporary status of the ADI is pending the outcomes of a toxicology study on the reproductive and developmental effects of carnosic acid plus carnosol. FSANZ has confirmed that these studies are nearing completion, with study results expected to be submitted to JECFA by the end of 2018. Nevertheless, the FSANZ hazard assessment found no additional evidence that the temporary ADI should be changed. This included two reproductive and developmental studies (not included in the evidence base used to establish the JECFA ADI) in which no adverse effects were identified. Therefore, FSANZ considers that the temporary status of the ADI does not preclude a determination of the safety of rosemary extract as an antioxidant.

FSANZ may reconsider the safety of using rosemary extract as an antioxidant if the temporary ADI is amended by JECFA upon their evaluation of the reproductive and developmental study.

2.2.2 Dietary exposure estimates

If approved, rosemary extract used as an antioxidant could be used instead of other (already permitted) antioxidants. According to the application, less than 2% of the food products launched in the EU and USA between 2013–2017 include added rosemary extract⁶. This market share value is based on product categories that are comparable to those used in the dietary exposure assessment (see appendices 8 and 9 of the application). A market share scenario using this percentage of foods using rosemary extract as an antioxidant was not included in the dietary exposure assessment. Dietary exposure estimates would be dramatically reduced if this market share information was applied.

2.2.3 Requested permissions

The application sought permission to use rosemary extract as a food additive in specific categories of food products listed in section S15—5. These are listed in the table at Attachment B. The requested MPL for each category is indicated.

⁵ The MPL scenario modelled dietary exposure using concentrations of carnosic acid plus carnosol in all requested foods at the proposed MPL.

⁶ The Innova Database is an online food and beverage product database that collect the latest data on food product trends from more than 70 countries. www.innovadatabase.com/Home/Index

Two changes to the applicant's requested permissions have been included in the table at Attachment B:

- As a consequence of MPLs to be expressed as the sum of carnosic acid and carnosol, an insertion to Standard 1.3.1—4(6) has been proposed to include 'rosemary extract calculated as the sum of carnosic acid and carnosol'. This is consistent with other food additives in S15—5 that require a calculation for application of an MPL.
- The requested category of 2.2.2 'Oil emulsions (<80% oil)' has been changed to category 2.2.1.3 '*Margarine and similar products*' to reflect the requested food category of margarines.

Neither of these changes affect the permissions being sought by the applicant.

FSANZ's food technology assessment (section 2.1.3 of SD1) confirmed the efficacy of rosemary extract used as an antioxidant in a concentration range that was consistent with the proposed MPLs.

Compared to the EU regulations, the application relates to fewer food categories for which rosemary extract can be used and, in some categories, at a lower MPL. These measures were applied to reduce the overall dietary exposure while the additional toxicological studies are completed and submitted to JECFA. If rosemary extract is approved for use as requested, dietary exposure for carnosic acid plus carnosol would be expected to be less for Australian and New Zealand populations compared to European populations.

2.2.4 Labelling considerations

Food additives must be listed in the statement of ingredients in accordance with requirements set out in section 1.2.4—7 of the Code. This application seeks permission to use rosemary extract as an antioxidant, which is a prescribed class name included in Schedule 7 (Food additive class names (for statement of ingredients)). The presence of rosemary extract in a food, when used as an antioxidant, must therefore be declared using the class name 'antioxidant', followed in brackets by the name or code number of the substance as listed in Schedule 8 (392 for rosemary extract).

There are some exemptions to the above requirements for foods for sale that are not required to bear a label. These exemptions are set out in section 1.2.1—6 of the Code, and include foods that are made and packaged on the premises from which it is sold and foods that are packaged in the presence of the purchaser.

2.2.5 Specifications

Subsection 1.1.1—15(2) of the Code requires that a substance used as a food additive (paragraph 1.1.1—15(1)(a)) must comply with a relevant specification in Schedule 3 – Identity and purity. Food Chemicals Codex (Codex) contains a specification for rosemary extract (FCC 2016). Codex is a primary source of specifications as listed section S3—2. Therefore no specification would be needed to be included in Schedule 3 and rosemary extract used as an antioxidant would need to comply with the identity and purity requirements of the Codex specification.

2.2.6 Risk management conclusions

Based on the above points, and the conclusions from the risk and technical assessment, it is appropriate to accept the applicant's request to permit rosemary extract as an antioxidant.

FSANZ has there prepared a draft variation to permit the use as a food additive in certain foods of rosemary extract for the technological purpose of an antioxidant. A copy of that draft variation is at Attachment A.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a basic communication strategy to this application. All calls for submissions are notified via the Food Standards Notification Circular, media release, FSANZ's social media tools and Food Standards News.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the application and the impacts of regulatory options.

The draft variation will be considered for approval by the FSANZ Board taking into account public comments received from this call for submissions

2.3.2 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO members where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are no relevant international standards (i.e. Codex) for rosemary extract as a food additive antioxidant. Amending the Code to approve rosemary extract as a food additive is unlikely to have a significant effect on international trade as the food additive meets international specifications for rosemary extract in the United States Pharmacopeial Convention (2017) Food Chemicals Codex (online edition). Therefore, a notification to the WTO as per Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 FSANZ Act assessment requirements

When assessing this application and the subsequent development of a food regulatory measure, FSANZ has had regard to the following matters in section 29 of the FSANZ Act:

2.4.1 Section 29

2.4.1.1 Consideration of costs and benefits

The Office of Best Practice Regulation (OBPR) granted FSANZ a standing exemption from the requirement to develop a Regulatory Impact Statement for permitting new food additives in the Code (OBPR correspondence dated 24 November 2010, reference 12065). This standing exemption was provided as permitting food additives is machinery in nature and their use, once permitted, is voluntary. This standing exemption relates to the introduction of a food to the food supply that has been determined to be safe.

FSANZ, however, has given consideration to the costs and benefits that may arise from the proposed measure for the purposes of meeting FSANZ Act considerations. The FSANZ Act requires FSANZ to have regard to whether costs that would arise from the proposed measure outweigh the direct and indirect benefits to the community, government or industry that would arise from the proposed measure (see paragraph 29(2)(a) of that Act).

The purpose of this consideration is to determine if the community, government, and industry

as a whole is likely to benefit, on balance, from a move from the status quo. This analysis is to consider permitting the use of rosemary extract as a food additive. FSANZ is of the view that no other realistic food regulatory measures exist, however information received may result in FSANZ arriving at a different outcome.

The consideration of the costs and benefits in this section is not intended to be an exhaustive, quantitative economic analysis of the proposed measures and, in fact, most of the effects that were considered cannot easily be assigned a dollar value. Rather, the assessment seeks to highlight the likely positives and negatives of moving away from the status quo by permitting the use of rosemary extract as a food additive.

Costs and benefits of permitting rosemary extract as a food extract

Consumers will benefit from the antioxidant function of rosemary extracts that will provide a longer shelf-life, helping to reduce food wastage. Consumers wishing to avoid synthetic ingredients may benefit from the choice of an additional range of food products having a naturally derived antioxidant.

There are no identified costs to consumers.

Due to the voluntary nature of the permission, industry will only use the extract where it believes a net benefit exists. Industry will benefit from having additional antioxidants available to them. Rosemary extract will provide a longer shelf-life for food products, helping to reduce food waste and reduce associated costs. Rosemary extract is approved as a food additive in several other countries which may be a business opportunity for Australia and New Zealand industries, although there may also be competing imports from these countries into the domestic market.

There are no identified costs to industry.

Permitting the extract may result in a small cost to government in terms of adding it to the current range of extracts that are monitored for compliance.

Conclusions from cost benefit considerations

FSANZ's assessment is that the direct and indirect benefits that would arise from permitting the use of rosemary extract as a food additive most likely outweigh the costs arising from maintaining status quo of not permitting the extract.

2.4.1.2 Other measures

There are no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the application.

2.4.1.3 Any relevant New Zealand standards

The Standards being amended apply in both Australia and New Zealand. There are no relevant New Zealand only Standards.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2. Subsection 18(1)

FSANZ has also considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment.

2.4.2.1 Protection of public health and safety

FSANZ has undertaken a safety assessment (SD1) and concluded that there is no evidence of public health and safety risk associated with the addition of rosemary extract as an antioxidant to the requested foods.

2.4.2.2 The provision of adequate information relating to food to enable consumers to make informed choices

The labelling requirements for rosemary extract used as an antioxidant are discussed in section 2.2.2 – Labelling considerations. These requirements provide information to enable consumers to make informed food choices.

2.4.2.3 The prevention of misleading or deceptive conduct

There are no issues identified with this application relevant to this objective.

2.4.3 Subsection 18(2) considerations

FSANZ has also had regard to:

- **the need for standards to be based on risk analysis using the best available scientific evidence**

FSANZ has used the best available scientific evidence to conduct the risk analysis, which is provided in SD1. The applicant submitted a dossier of scientific studies as part of their application. Other technical information, including scientific literature, was also used in assessing the application.

- **the promotion of consistency between domestic and international food standards**

Rosemary extract is permitted as a food additive in several national food regulations. Permitting the use of rosemary extract for the proposed purpose will promote consistency of food regulations between Australia and New Zealand and international standards.

- **the desirability of an efficient and internationally competitive food industry**

The proposed variation is expected to have a positive effect by allowing Australian and New Zealand food manufacturers an alternative antioxidant to preserve food and extend shelf life.

- **the promotion of fair trading in food**

No issues were identified for this application relevant to this objective.

- **any written policy guidelines formulated by the Forum on Food Regulation**

The [Policy Guideline for the Addition to Food of Substances other than Vitamins and Minerals](#)⁷ includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

- the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the ‘stated purpose’)

⁷ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

- the addition of the substance to food is safe for human consumption
- the amounts added are consistent with achieving the technological function
- the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- no nutrition, health or related claims are to be made in regard to the substance.

FSANZ has determined that permitting the use of rosemary extract as an antioxidant for the foods listed in Table 1 is consistent with the specific order principles.

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation.

Attachments

- A. Draft variation to the *Australia New Zealand Food Standards Code*
- B. Draft Explanatory Statement

Draft variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1158 – Rosemary Extract as a Food Additive) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of the variation.

Dated [To be completed by the Delegate]

Insert Delegate Title

Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of the above notice.

1 Name

This instrument is the *Food Standards (Application A1158 – Rosemary Extract as a Food Additive) Variation*.

2 Variation to a Standard in the *Australia New Zealand Food Standards Code*

The Schedule varies standards in the *Australia New Zealand Food Standards Code*.

3 Commencement

The variation commences on the date of gazettal.

Schedule

[1] **Standard 1.3.1** is varied by omitting paragraph 1.3.1—4(6)(j), substituting

- (j) sulphur dioxide and sulphites, including hydrosulphites, bisulphites and metabisulphites, are calculated as sulphur dioxide;
- (k) rosemary extract is calculated as the sum of carnosic acid and carnosol.

[2] **Schedule 8** is varied by

[2.1] inserting in the table to section S8—2 entitled ‘Food additive names—alphabetical listing’, in alphabetical order

Rosemary extract	392
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[2.2] inserting in the table in section S8—2 entitled ‘Food additive names—numerical listing’, in numerical order,

392	Rosemary extract
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[3] **Schedule 15** is varied by

[3.1] inserting in item 2.1 of the table to section S15—5, after the entry for ‘Colourings permitted to a maximum level’

392	Rosemary extract	50	Only fish oils and algal oils
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[3.2] inserting in item 2.2.1.3 of the table to section S15—5, after the entry for ‘Colourings permitted to a maximum level’

392	Rosemary extract	75
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[3.3] inserting in item 4.3.4 of the table to section S15—5, after the entry for ‘Calcium propionate’

392	Rosemary extract	50	Only nut butters and nut spreads
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[3.4] inserting in item 5.4 of the table to section S15—5, after the entry for ‘Benzoic acid and sodium, potassium and calcium benzoates’

392	Rosemary extract	20	
[3.5]	inserting in item 6.3 of the table to section S15—5, after the entry for ‘Annatto extracts’		
392	Rosemary extract	50	Only grain bars, breakfast bars and breakfast cereals
[3.6]	inserting in item 6.4 of the table to section S15—5, after the entry for ‘Propionic acid and sodium and potassium and calcium propionates’		
392	Rosemary extract	10	Only for flour based snacks e.g. pretzels, fritters, and crackers; Not for noodles and pasta
[3.7]	inserting in item 7.2 of the table to section S15—5, after the entry for ‘Sulphur dioxide and sodium and potassium sulphites’		
392	Rosemary extract	40	
[3.8]	inserting in item 8.2 of the table to section S15—5, after the entry for ‘Propionic acid and sodium and potassium and calcium propionates’		
392	Rosemary extract	(a) 1.5	For meat with <10% fat; Not for dried sausages
		(b) 37.5	For meat with >10% fat; Not for dried sausages
[3.9]	inserting in item 8.3.2 of the table to section S15—5, after the entry for ‘Ethyl lauroyl arginate’		
392	Rosemary extract	50	Only dried sausages
[3.10]	inserting in item 12 of the table to section S15—5, above item 12.1		
392	Rosemary extract	40	Not for condiment sauces e.g. ketchup, mayonnaise, mustard, and relishes.
[3.11]	inserting in item 20.2 of the table to section S15—5, after the entry for ‘Annatto extracts’		
392	Rosemary extract	50	Only processed nuts
[3.12]	inserting in item 20.2.0.4 of the table to section S15—5, after the entry for ‘Calcium disodium EDTA’		
392	Rosemary extract	50	

[3.13] omitting item 20.2.0.5 of the table to section S15—5, substituting

20.2.0.5	<i>Soup bases (the maximum permitted levels apply to soup made up as directed)</i>	
950	Acesulphame potassium	3 000
954	Saccharin	1 500
956	Alitame	40
962	Aspartame-acesulphame salt	6 800
20.2.0.6	<i>Starch based snacks (from root and tuber vegetables, legumes and pulses)</i>	
392	Rosemary extract	20

Attachment B – Draft Explanatory Statement

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.

FSANZ accepted application A1158 which seeks to permit use of rosemary extract as a food additive to perform the technological purpose of an antioxidant. The Authority considered the application in accordance with Division 1 of Part 3 and has prepared a draft Standard.

2. Purpose

The Authority has prepared a draft amendment to the table at section S15—5 in Schedule 15 to permit the use of rosemary extract as a food additive to perform the technological purpose of an antioxidant in the food groups and at the maximum concentrations (expressed as the sum of carnosic acid and carnosol in mg/kg) as listed in the table below.

Food category no.	Description	Maximum concentration** (mg/kg)	Included Foods
2.1	Edible oils essentially free of water	50	Fish oil and algal oil only
2.2.1.3	Oil emulsions (<80% oil)	75	Margarines (solid and liquid) only
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	50	Nut butters and nut spreads only
5.4	Icings and frostings	20	
6.3	Processed cereals and meal products	50	Grain bars, breakfast bars, breakfast cereals only
6.4	Flour products	10	Excluding pasta and noodles
7.2	Biscuits, cakes and pastries	40	
8.2	Processed meat, poultry and game products in whole cuts or pieces	1.5	Meat with a fat content not higher than 10%, excluding dried sausages
		37.5	Meat with a fat content > 10%, excluding dried sausages
8.2.3	Dried Meat	37.5	
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	50	Dried sausages only
12	Salts and condiments	40	
20.2.04	Sauces and toppings (including mayonnaises and salad dressings)	50	
20.2	Foods not included in items 0 to 14 - Food other than beverages	50	Processed nuts only
20.2	Foods not included in items 0 to 14 - Food other than beverages	20	Potato chips, including starch based snacks from roots and tubers, pulses

* Table is reproduced from the application (see page 34, Table 5 of application).

** Based on the whole food expressed as the sum of carnosic acid plus carnosol

As a consequence to amendments to Schedule 15, the Authority has also prepared a draft amendment to Standard 1.3.1—4(6) to list rosemary extract as the sum of carnosic acid and carnosol.

The Authority has also prepared an amendment to Schedule 8 to prescribe the use of the words “rosemary extract” and INS number 392 to describe the permitted antioxidant food additive for labelling purposes

3. Documents incorporated by reference

The approved draft variations to food regulatory measures do not incorporate any documents by reference.

Existing provisions of the Code incorporate a document by reference that will 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 Food Chemicals Codex (10th edition). This includes a specification for rosemary extract.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority’s consideration of Application A1158 will include 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) will occur for a six-week consultation period.

5. 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 94 of the FSANZ Act.

6. Variation

Item [1] varies subsection 1.3.1—4(6) of Standard 1.3.1. to insert a new entry for rosemary extract calculated as the sum of carnosic acid and carnosol.

Item [2] varies the tables in section S8—2 of Schedule 8 to insert references to rosemary extract and to its INS Number 392 in the alphabetical and numerical lists of food additives names used for labelling purposes.

Item [3] varies the table to section S15—5 in Schedule 15 to insert permissions for rosemary extract to be added as a food additive in specific classes of foods subject to the maximum permitted level (expressed as the sum of carnosic acid and carnosol in mg/kg) specified for each class.