

13 November 2018

[63-18]

Approval report – Application A1158

Rosemary extract as a food additive

Food Standards Australia New Zealand (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.

On 20 July 2018, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received 10 submissions.

FSANZ approved the draft variation on 31 October 2018. The Australia and New Zealand Ministerial Forum on Food Regulation was notified of FSANZ's decision on 12 November 2018.

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

The following document which informed the assessment of this Application are available on the FSANZ website:

SD1 Risk and technical assessment report (at Approval)

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 permission 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. FSANZ has reviewed the scientific evidence including the reproductive and developmental toxicity study that will likely be submitted to JECFA, and concluded that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment.

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) estimates of exposure were under the ADI. However this scenario used highly conservative assumptions resulting in a likely overestimate of exposure for this population group.

Based on the safety assessment (Supporting document 1), FSANZ concluded that there are no public health and safety concerns associated with adding 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.

The FSANZ Board has approved a draft variation to Standard 1.3.1 and Schedules 8 and 15 of the Code to permit the use of rosemary extract as a food additive with the technological purpose of an antioxidant. This permission is limited to the specific food groups proposed by the applicant. It will be listed in the table to section S15—5 and is subject to maximum permitted levels as indicated.

1 Introduction

1.1 The applicant

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

1.2 The application

The applicant was seeking permission for the use of rosemary extract as an antioxidant. The applicant proposed using 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) were 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 sought 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 sought 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.

Rosemary extract is currently permitted for use as a food additive flavouring substance. Schedules 15 and 16 provide specific food additive permissions for permitted flavouring substances. Section 1.1.2—2 defines the term *permitted flavouring substance* to include 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, respectively¹.

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

The international and national permissions for the use of rosemary extract as a food additive antioxidant that are relevant to this application are summarised below.

1.3.1.1 Codex Alimentarius

The use of rosemary extract as a food additive is not yet included in the General Standard for

¹ https://www.femaflavor.org/sites/default/files/3.%20GRAS%20Substances%282001-3124%29_0.pdf

Food Additives (GSFA)². 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 toxicity³.

1.3.1.2 Other regulations

Rosemary extract is 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 the 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 was assessed under the General Procedure.

1.6 Decision

The draft variation as proposed following assessment was approved with amendments after consideration of submissions. The approved draft variations are at Attachment A. The variation takes effect on gazettal.

The related 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.

The draft variation on which submissions were sought is at Attachment C.

² Codex Alimentarius General Standards for Food Additives.
http://www.fao.org/gsaonline/docs/CXS_192e.pdf

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

2 Summary of the findings

2.1 Submissions

2.1.1 Specific issues raised in submissions

FSANZ sought public comments on the draft variation between 22 July 2018 and 31 August 2018.

Ten submissions were received:

- **Four** from government agencies (Department of Health South Australia, Queensland Health, New Zealand Ministry of Primary Industries – not supported; Victoria Department of Health and Human Services and Department of Economic Development, Jobs, Transport, and Resources – supported)
- **Five** from industry or industry associations (Kalsec, Kellogg's, Australian Food and Grocery Council, New Zealand Food and Grocery Council, Global Organization for EPA and DHA Omega-3s – all supported); and
- **One** from a consumer organisation (Food Intolerance Network – not supported).

Individual issues raised in submissions and FSANZ's responses are detailed in Table 1.

Table 1: Summary of issues

Issue	Submitter	Response
<p>The submitter questions whether food manufacturers are using a concentrated substance for a technological purpose without approval. The submitter indicates that rosemary extract is already being used as an antioxidant in the Australian food supply and that FSANZ is covering the legal liability of manufacturers by approving a food additive that is already being used.</p>	<p>Food Intolerance Network (FIN)</p>	<p>FSANZ has assessed the application as required by the <i>FSANZ Act 1991</i> and not for purposes of covering the legal liability of manufacturers. FSANZ's understanding is that use of rosemary extract as a food additive antioxidant is not currently permitted in the Food Standards Code. However, FSANZ is not a regulator. Any issues regarding the enforcement or interpretation of that Code as applied by Australian and New Zealand food laws remain the responsibility of the jurisdictional authorities which administer those laws.</p>
<p>The submitter questions whether rosemary extract has been added as an ingredient in the past but if approved as a food additive will now require labelling with number 392.</p>	<p>FIN</p>	<p>Should rosemary herb be added as an ingredient, then general labelling requirements for the statement of ingredients apply (Standard 1.2.4). The use of rosemary extract as a flavouring agent is permitted under Standard 1.1.2—2 and Schedules 15 and 16 and must be included in the list of ingredients according to subsection 1.2.4—7 (4). The INS number 392 would not be used if rosemary extract was used for flavour purposes. This application seeks approval to use rosemary extract as an antioxidant. Rosemary extract as a food additive antioxidant would be subject to the labelling requirements outlined in Section 2.3.4 of this Approval report.</p>
<p>The submitter is concerned that studies relevant to humans are not available and that dietary exposure estimates for high consumers in the US and EU may exceed the ADI upper bound by 2.7-fold.</p>	<p>FIN</p>	<p>The rosemary plant has a long history of use as a culinary herb. The two human studies that were reviewed by FSANZ did not indicate cause for concern.</p> <p>Regarding the exceedance of the ADI in EU and USA high consumers, the submitter cites the evaluation made by JECFA in the full toxicology report published in 2017⁴. In this report, JECFA stated that based on the conservative nature of the dietary exposure assessments, in which it was assumed that all foods contained rosemary extracts at the maximum use level, the Committee concluded that this exceedance of the temporary ADI does not necessarily represent a safety concern. (See also Section 2.1.2.5)</p>
<p>The submitter is concerned that rosemary extract is very high in salicylates and persons with salicylate intolerance may react to the substance.</p>	<p>FIN</p>	<p>FSANZ is aware that salicylates are a class of substances associated with pharmacological food intolerance and that salicylates are found in many fruits, vegetables, nuts, herbs and spices, and wines. Rosemary extract (if approved) added to food to perform the technological function of antioxidant will be required to be declared as an ingredient (see Section 2.3.4). This will help consumers to make informed choices</p>

⁴ JECFA, 2017. *Rosemary Extract in Safety evaluation of certain food additives: prepared by the Eighty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA)*, Geneva: World Health Organization (WHO Food Additive Series No. 73).

<p>The submitters indicate that FSANZ should ‘stop the clock’ pending completion of the developmental and reproductive safety study and the JECFA decision on the temporary status of the ADI.</p>	<p>NZ MPI SA Health QLD Health FIN</p>	<p>about foods to manage intolerance reactions.</p> <p>FSANZ is required to assess the application in accordance with the FSANZ Act and Australian administrative law. The latter require, among other things, FSANZ to have regard to the need for standards to be based on risk analysis that use the best <i>available</i> scientific evidence. The FSANZ Act permits FSANZ to ‘stop the clock’ in very limited circumstances, none of which were applicable in this case.</p> <p>FSANZ has a policy of endeavouring to harmonise with Acceptable Daily Intakes (ADI) established by JECFA where possible.⁵ A comprehensive review of the best available scientific evidence did not identify any information that would justify a change to the JECFA temporary ADI of 0 - 0.3 mg/kg bw/day established in 2017.</p> <p>SD1 has been updated after the CFS to include a recently submitted reproductive and development toxicity screening study in rats using rosemary extract conducted according to OECD test guideline 421. FSANZ has evaluated this study and concluded that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment (see SD1).</p> <p>Based on the information provided in the application, the additional studies reviewed in FSANZ’s safety assessment, and data provided in the new study, there is no information gap that prevents FSANZ from completing the assessment.</p>
<p>The submitter queried whether a component based safety assessment for mixtures is appropriate and excludes the relevance of sensitivity reactions to food-based plant extracts.</p>	<p>SA Health</p>	<p>The FSANZ evaluation has taken into account dietary exposure from both rosemary extract (at the proposed maximum permissible levels and the usual use levels) and from rosemary leaves and rosemary extract combined. For the usual use scenarios, mean dietary exposures to carnosic acid plus carnosol for consumers only were 15 – 30% of the ADI and P90 exposures were 30 – 60% of the ADI, depending on the population group being assessed. Moreover, market share information, if applied, would dramatically reduce these dietary exposure estimates (see Section 2.3.2).</p> <p>FSANZ has not conducted an assessment of aggregate exposure from other routes (e.g. dermal) and does not hold data to conduct such an assessment.</p> <p>FSANZ has conducted a search of Pubmed, Embase and Cochrane databases and not identified any case studies of food allergy related to rosemary or rosemary extract. To date, no entries for rosemary allergens have been submitted to the AllergenOnline (University of Nebraska – Lincoln; http://www.allergenonline.org/) or WHO Allergen</p>

⁵ FSANZ (2014) Risk analysis in food regulation. Food Standards Australia New Zealand. Canberra. <http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx>

		Nomenclature Sub-Committee (http://www.allergen.org/) databases. The Australasian Society of Clinical Immunology and Allergy (ASCI) and Allergy and Anaphylaxis Australia websites make no reference to allergy through consumption of rosemary.
<p>The submitter raised concerns about</p> <ul style="list-style-type: none"> whether relevant safety studies associated with the proprietary extract were conducted, and change in the paradigm of assessment for food additives typically from well characterised substance(s) to the assessment of poorly defined mixtures with limited supporting safety data 	SA Health	<p>The test substances used in toxicological studies and their relation to the material intended to be marketed are described in Sections 3.1 and 3.2 of SD1. The assessed data included studies on purified carnosic acid, rosemary leaves and solvent-based (ethanolic) extracts of rosemary leaves. These studies were considered appropriate to assess the toxicity of rosemary extract because:</p> <ul style="list-style-type: none"> Carnosol and carnosic acid are primarily responsible for the antioxidant properties of rosemary extract. Carnosol is a metabolite of carnosic acid. Rosemary leaves would be expected to contain carnosic acid and carnosol as well as a range of other compounds The application concerns rosemary extracts made using solvent extraction with acetone or ethanol, that meet the specifications of the tentative monograph by JECFA (WHO 2017) and the Food Chemicals Codex 10th edition (FCC 2016). <p>Water soluble extracts were not considered to be relevant because they are unlikely to be comparable to rosemary extracts made using ethanol or acetone.</p> <p>FSANZ notes that rosemary extract has assigned an INS number and a specification set by Food Chemicals Codex which meets the requirements of the Code.</p>
<p>The submitter questions whether a broad interpretation of 'history of safe use' for the safety assessment has been applied.</p>	SA Health	<p>FSANZ assessed data on rosemary extract including information on toxicokinetics and metabolism, genotoxicity, toxicity in laboratory animals, and studies in human volunteers. The submitted data, together with the assessment by JECFA (WHO 2017) were considered suitable to assess the hazard of rosemary extract. FSANZ also noted that rosemary plant has a long history of human use as a culinary herb and as a folk medicine (as cited in SD1 - Ulbricht et al. 2010; Begum et al. 2013; Ribeiro-Santos et al. 2015; WHO 2017).</p>
<p>Extend permissions -The submitters suggest that permitted food categories and MPLs should align with international regulations.</p>	NZFGC NZMPI	<p>FSANZ's assessment was conducted based on foods and MPLs provided in the application. In its application, the applicant removed some food categories being sought for use and reduced some MPLs compared to EU regulations to reduce the overall estimated exposure while the additional toxicity studies are completed (see Application page 12). The assessment was conducted within the scope of this request.</p>
<p>Extend permissions - The submitters request an extension to food category 20.2 permissions to include processed nut products not less than 20% processed nuts. This is to enable mixed food products (such as nut-based snack bars) to have enough</p>	Kalsec Kellogg's	<p>This extension is out of scope.</p> <p>The permission sought by the application being assessed was for <i>Foods not included in items 0 to 14</i> (ie, Item 20 in the table to section S15—5), specifically <i>Food other than beverages</i> (Item 20.2), and was for processed nuts only and subject to an MPL or maximum concentration of 50 mg/kg. By virtue of section 1.3.1—3(2), this permission</p>

<p>rosemary extract in the finished food to have an antioxidant effect.</p>		<p>would allow carry over to foods containing processed nuts.</p> <p>The extension to category 20.2 requested by these submitters would mean that rosemary extract would be permitted to be added to mixed foods for which there is no definition in the Code.</p>																				
<p>Extend permissions - An increase of the MPL for certain meat categories was proposed in the submission by the applicant. The applicant indicates an error in their application whereby the proposed maximum concentrations were calculated on the fat content of the meat rather than the whole mass of the food for meats with less than 10% fat, dried meat and sausages. The requested corrected MPLs are aligned with the limits in EU regulations (Regulation (EC) 1333/2008)</p>	<p>Kalsec</p>	<p>The requested corrected MPLs for the meat food categories are listed below.</p> <table border="1" data-bbox="981 411 1944 699"> <thead> <tr> <th>Food Cat. No.</th> <th>Description</th> <th>Current Proposed MPL (ppm CA+CN)*</th> <th>Requested Corrected MPL (ppm CA+CN)</th> </tr> </thead> <tbody> <tr> <td>8.2</td> <td>Processed meat, poultry and game products in whole cuts or pieces (fat ≤ 10%)</td> <td>1.5</td> <td>15</td> </tr> <tr> <td>8.2</td> <td>Processed meat, poultry and game products in whole cuts or pieces (fat > 10%)</td> <td>37.5</td> <td>37.5 (no change)</td> </tr> <tr> <td>8.2.3</td> <td>Dried Meat</td> <td>37.5</td> <td>150</td> </tr> <tr> <td>8.3.2</td> <td>Sausage and sausage meat containing raw, unprocessed meat</td> <td>50</td> <td>100</td> </tr> </tbody> </table> <p>These three increased MPLs were applied to the scenarios used in the dietary exposure assessment. The overall exposures were slightly increased with the increased MPLs and did not change FSANZ's risk assessment conclusion that public health and safety are not at risk. SD1 and drafting have been amended accordingly.</p>	Food Cat. No.	Description	Current Proposed MPL (ppm CA+CN)*	Requested Corrected MPL (ppm CA+CN)	8.2	Processed meat, poultry and game products in whole cuts or pieces (fat ≤ 10%)	1.5	15	8.2	Processed meat, poultry and game products in whole cuts or pieces (fat > 10%)	37.5	37.5 (no change)	8.2.3	Dried Meat	37.5	150	8.3.2	Sausage and sausage meat containing raw, unprocessed meat	50	100
Food Cat. No.	Description	Current Proposed MPL (ppm CA+CN)*	Requested Corrected MPL (ppm CA+CN)																			
8.2	Processed meat, poultry and game products in whole cuts or pieces (fat ≤ 10%)	1.5	15																			
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8.2.3	Dried Meat	37.5	150																			
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	50	100																			
<p>The submitter seeks a 24 month transition period to permit updates to packaging.</p>	<p>Kellogg's</p>	<p>Rosemary extract added to food for the purpose of antioxidant is a new food additive permission. Therefore a transition period to allow changeover of labels should not be necessary.</p>																				

2.1.2 Further considerations

Submitters indicated several more general risk assessment and risk management issues that are explained below. Additional risk management considerations that were discussed in the call for submissions paper are found in Section 2.3 of this report.

2.1.2.1 Robustness of the risk assessment

Some submitters questioned the adequacy of the risk assessment.

FSANZ conducted a comprehensive risk assessment following internationally accepted processes as specified in the *IPCS Environmental Health Criteria 240 Principles and Methods for the Risk Assessment of Chemicals in Food* and the *Joint FAO/WHO Expert Committee on Food Additives Guidance document for WHO monographers and reviewers evaluating food additives (excluding enzyme preparations and flavouring agents)*.

The risk assessment was based on the best available scientific evidence as legislatively required. The risk assessment processes included a comprehensive literature review, critical assessments of the studies provided by the applicant, identification of new studies not provided by the applicant or previously reviewed by JECFA, and a comprehensive dietary exposure assessment for Australian and New Zealand consumers that employed conservative assumptions and gave overestimates of likely exposure.

FSANZ has a policy of endeavouring to harmonise with Acceptable Daily Intakes (ADI) established by JECFA where possible.⁶ A comprehensive review of the best available scientific evidence did not identify any information that would necessitate a change to the JECFA temporary ADI of 0 - 0.3 mg/kg bw established in 2017. Supporting document 1 (SD1) has been updated after the Call for Submission (CFS) to include a reproductive and development toxicity screening study in rats using rosemary extract conducted according to OECD test guideline 421. FSANZ has evaluated this study and concluded that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment.

2.1.2.2 Interpretation of a temporary ADI

Submitters queried FSANZ's reference to the temporary ADI in its risk assessment.

JECFA has set temporary ADIs in a number of situations and the significance of the temporary ADI is explained in the FAO/WHO publication on the principles and methods for the risk assessment of chemicals in food⁷. This document addresses the issue in several sections and states that a temporary ADI is allocated to:

“permit the acceptance of substances where there are sufficient data to conclude that the use of the substance is safe over the relatively short period of time required to produce further safety data, but are insufficient to conclude that the use of the substance is safe over a lifetime.”

Additionally, a temporary ADI is allocated on the stipulation that further safety data is submitted by a specified deadline. It also incorporates an increased uncertainty factor (i.e. usually an additional uncertainty factor of 2) as further assurance that the temporary ADI is protective of public health. If data is submitted, JECFA then re-evaluates the substance in

⁶ FSANZ (2014) Risk analysis in food regulation. Food Standards Australia New Zealand. Canberra. <http://www.foodstandards.gov.au/publications/riskanalysisfoodregulation/Pages/default.aspx>

⁷ <http://www.who.int/foodsafety/publications/chemical-food/en/>

light of the study results. If the data is not submitted, the temporary ADI may be withdrawn or can be extended if information from longer term outcomes is needed. In previous examples of a temporary ADI being allocated, it was emphasised that withdrawal of a temporary ADI does not indicate a potential health hazard, only that insufficient information was available at the time of review that enable the Committee *to conclude with reasonable certainty that there is no likelihood of adverse effects on health resulting from ingestion over a prolonged period.*

For rosemary extract, a temporary ADI was allocated pending data from a developmental and reproductive toxicity study to be submitted by December 2018. As indicated in the application, the study is being conducted by Kalsec (the applicant) along with several other laboratories. At the time of the public consultation for A1158, FSANZ was aware of progress on the study but results were not available. However, a draft study report to be submitted to JECFA was provided to FSANZ. On the basis of data provided, which has been summarised in SD1 (see section 3.2.5), FSANZ concluded that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment.

FSANZ understands that the final study report will be submitted to JECFA by the deadline and will be considered by JECFA at its next meeting (June 2019). However this does not preclude FSANZ from making a decision before JECFA completes its deliberations. As an example, FSANZ approved advantame in 2011 whereas JECFA did not assess advantame until 2013.

2.1.2.3 Safety assessments of a substance which is a mixture

FSANZ also reiterates the findings in FSANZ's Risk and Technical Assessment (SD1) indicating that rosemary extract is a well-characterised food additive. Its antioxidant and chemical properties are well understood, and it has been reviewed by JECFA, assigned an INS number, approved in multiple jurisdictions, and has a specification set by Food Chemicals Codex which meets the requirements of the Code.

2.1.2.4 Rosemary extract added as an ingredient for a technological purpose

Submitters queried the addition of rosemary extract to foods as a flavouring or an ingredient when it is intended to perform a technological purpose listed in Schedule 14.

FSANZ is aware that there are a number of ingredients that provide a function in food but may not be regarded as food additives or added as such. Generally if the active component(s) is extracted from the source material, it is then regarded as an additive requiring permission before use in foods. Examples include lemon juice/extract versus citric acid (INS 330) or vinegar versus acetic acid (INS 260). Although the reason for the addition of a substance should be justified by food manufacturers, FSANZ acknowledges the lack of clarity that can be created by these distinctions. However, FSANZ also considers that the issue of clarity is not a regulatory problem from a public health and safety perspective. Several international regulators have determined rosemary extract to be a food additive, hence an INS number has been assigned and a FCC specification has been set. As such, and for the reasons stated in this report and the findings of the risk assessment (SD1), it is appropriate for FSANZ to also designate rosemary extract as a food additive for the technological purpose of an antioxidant.

2.1.2.5 New information on dietary exposure to carnosol and carnosic acid

Rosemary extract has been authorised for use as a food additive in the EU since 2008⁸.

⁸ EU permissions include a greater range of foods and, in some cases, at higher permitted levels than

Recently, EFSA published a refined exposure assessment of rosemary extract (carnosol plus carnosic acid) as a food additive based on reported use levels provided by industry and using several modelling scenarios.⁹ The most relevant scenario estimated mean exposures to be < 0.01 – 0.09 mg/kg bw/day and a maximum exposure of 0.2 mg/kg bw/day for children aged 3-9 years at the 95th percentile consumption. EFSA considered these exposures were likely overestimates of the exposure.

Carnosol and carnosic acid exposures from naturally occurring sources (dried or fresh leaves from rosemary or sage) were also estimated in the EFSA assessment. In this case, exposures at the 95th percentile across all population groups were 0.0 - 1.6 mg/kg bw/day, indicating that exposures from natural sources are significantly greater than that from food additive use. In comparison, FSANZ's dietary exposure assessment also included a *naturally occurring* scenario which was calculated on the basis of rosemary leaves only (dried or fresh). The mean dietary exposures in this scenario were 8 – 60% of the ADI and P90 exposures were 25 – 100% of the ADI, depending on the population group being assessed (see SD1 Section 4.3).

Overall, the EFSA assessment is consistent with FSANZ's conclusion that, based on the safety and dietary exposure assessments, there is no evidence of a public health and safety concern associated with adding rosemary extract as an antioxidant to the requested foods.

In summary, FSANZ considers the assessment has used the best available evidence to reach a conclusion on whether to permit the addition of rosemary extract to the requested food categories at the specified MPLs. On this basis, FSANZ determined that the requested permission should be approved. The permission includes higher MPLs requested for processed meat, poultry and game products in whole cuts or pieces (fat ≤ 10%), dried meat, and sausage and sausage meat containing raw, unprocessed meat as requested by the applicant Kalsec in their submission (and explained above in Table 1). The permission for the higher MPLs required a change to the draft food regulatory measure that was released at call for submissions stage. The revised draft food regulatory measure is at Attachment A.

2.2 Risk assessment

The submitted data, and information from other sources, were considered sufficient to define the hazard of rosemary extract. Oral bioavailability of carnosic acid (which is oxidised to carnosol) is estimated to ≥65% and metabolism occurs through common pathways with several metabolites detected in urine and faeces of rats. The 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. However there was no evidence of genotoxicity in the two genotoxicity assays that were available to FSANZ, and the unpublished study reports reviewed by JECFA did not identify any lesions that might lead to cancer by non-genotoxic mechanisms. Therefore chronic/carcinogenicity studies are not considered necessary. There is limited information on the developmental and reproductive safety of rosemary extract in the conventional experimental species, but 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. In addition, rosemary has a long history of use as a culinary herb.

Following the Call for Submissions, the Applicant provided FSANZ with a draft final report of

that requested in application A1158.

⁹ EFSA Panel on Food Additives and Nutrient Sources added to Food (2018) Refined exposure assessment of extracts of rosemary (E 392) from its use as food additive. EFSA Journal 16(8) 5373. <https://www.efsa.europa.eu/en/efsajournal/pub/5373>

a reproductive and development toxicity screening study in rats using rosemary extract conducted according to OECD 421 test guideline. The NOAEL for reproductive parameters of parental (P) generation, and the NOAEL for maternal toxicity, was the highest dose tested, equivalent to 316.2 mg/kg bw/day rosemary extract for males and 401.2 mg/kg bw/day rosemary extract for females. When these values are converted to the sum of carnosic acid and carnosol, they are 149.3 mg/kg bw/day for males and 189.4 mg/kg bw/day for females. The NOAEL for offspring toxicity was 166.7 mg/kg bw/day, equivalent to 78.7 mg/kg bw/day carnosic acid and carnosol, on the basis of low group mean serum thyroxine (T4) and thyroid stimulating hormone (TSH) in pups at higher doses on postnatal day 13. The reproductive, maternal and offspring NOAELs are more than 200-fold greater than the JECFA temporary ADI. Therefore FSANZ considers that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment.

Two scenarios were modelled in the dietary exposure assessment. Conservative assumptions were applied in both scenarios (see SD1 section 4.2.1). All estimates of dietary exposure (expressed as a percentage of the ADI) in the modelled scenarios were well under the ADI except for one¹⁰, 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.

The risk assessment concluded that, based on the safety and dietary exposure assessments, there is no evidence of a public health and safety concern associated with adding rosemary extract as an antioxidant to the requested foods.

2.3 Risk management

Based on the results of FSANZ's risk and technical assessment, it is appropriate to accept the applicant's request to permit rosemary extract as a food additive antioxidant in the specified foods. The following points were considered in determining appropriate risk management options.

2.3.1 Use of the temporary ADI

The conclusion of the risk assessment at Call for Submissions was based on the temporary ADI set by JECFA. The temporary status of the ADI is pending the outcomes of a developmental and reproductive toxicology study being conducted at the time of the A1158 assessment. FSANZ has now evaluated this study and concluded that the JECFA temporary ADI for rosemary extract remains appropriate for the purposes of this assessment (see Section 2.1.2.2)

2.3.2 Dietary exposure estimates

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 extract¹¹. 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 substantially reduced if this

¹⁰ The MPL scenario modelled dietary exposure using concentrations of carnosic acid plus carnosol in all requested foods at the proposed MPL.

¹¹ 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

market share information was applied.

2.3.3 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.

Two changes to the applicant's requested permissions were made by FSANZ and 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) was 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)' was changed to category 2.2.1.3 '*Margarine and similar products*' to reflect the requested food category of margarines.

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

During public consultation on the Call for Submissions, the applicant lodged a submission requesting an increase to three MPLs due to a calculation error in the application (see Section 2.1 – Submissions). The new MPLs for these categories have been amended in Attachments A and B.

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.

2.3.4 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 sought 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).

2.3.5 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 is needed in Schedule 3 and rosemary extract used as an antioxidant would need to comply with the identity and purity requirements of the Codex specification.

2.4 Risk communication

2.4.1 Consultation

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions on this application. Every submission was considered by the FSANZ Board. All comments are valued and contribute to the rigour of our assessment.

FSANZ developed and applied a basic communication strategy to this application. The call for submissions was 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.

The applicant, individuals and organisations that made submissions on this application were notified at each stage of the assessment.

2.5 FSANZ Act assessment requirements

2.5.1 Section 29

2.5.1.1 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 was 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 considered whether to approve or reject the application (retain the status quo). A consideration of costs and benefits was included in the call for submissions (CFS) report based on the information and data held at that time. No further information has been received in the consultation process to date that influenced the findings from the analysis of costs and benefits in the CFS.

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 waste. 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.

2.5.1.2 Other measures

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

2.5.1.3 Any relevant New Zealand standards

The approved draft variations to Standard 1.3.1 and Schedules 8 and 15 will apply in both Australia and New Zealand. There were no relevant New Zealand only Standards.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 Protection of public health and safety

FSANZ concluded that there are no safety concerns associated with the addition of rosemary extract as an antioxidant to the requested foods.

2.5.2.2 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 2.3.4 – Labelling considerations. These requirements provide information to enable consumers to make informed food choices

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 Subsection 18(2)

FSANZ also had regard to:

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

FSANZ 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 identified and used by FSANZ in assessing the application.

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

Rosemary extract is permitted as a food additive in several other countries. 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](#)¹² 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')
- 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 determined that permitting the use of rosemary extract as an antioxidant for the foods listed in Attachment B is consistent with the specific order principles.

Attachments

A. Approved draft variations to the Australia New Zealand Food Standards Code

¹² <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/pages/default.aspx>

B. Explanatory Statement

C. Draft variation/s to the *Australia New Zealand Food Standards Code* (call for submissions)

Attachment A – Approved draft variations 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]

Glen Neal
General Manager, Risk Management and Intelligence Branch

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) 15	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 8.2.3 of the table to section S15—5, after the entry for 'Nitrites (potassium and sodium salts)'		
392	Rosemary extract	150	
[3.10]	inserting in item 8.3.2 of the table to section S15—5, after the entry for 'Ethyl lauroyl arginate'		
392	Rosemary extract	100	Only dried sausages
[3.11]	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.
[3.12]	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

[3.13] 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

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

20.2.0.5 ***Soup bases (the maximum permitted levels apply to soup made up as directed)***

950 Acesulphame potassium 3 000

954 Saccharin 1 500

956 Alitame 40

962 Aspartame-acesulphame salt 6 800

20.2.0.6 ***Starch based snacks (from root and tuber vegetables, legumes and pulses)***

392 Rosemary extract 20

Attachment B – 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.

The Authority 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	15	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	150	
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	100	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

* 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.

Attachment C – Draft variation/s to the *Australia New Zealand Food Standards Code* (call for submissions)



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
------------------	-----

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

392	Rosemary extract
-----	------------------

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

20.2.0.5 *Soup bases (the maximum permitted levels apply to soup made up as directed)*

950	Acesulphame potassium	3 000
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954	Saccharin	1 500
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956	Alitame	40
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962	Aspartame-acesulphame salt	6 800
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20.2.0.6 *Starch based snacks (from root and tuber vegetables, legumes and pulses)*

392	Rosemary extract	20
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