

**26 March 2024**  
**286-24**

Approval report – Application A1254

## Rosemary extract as a food additive – extension of use

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Kalsec Inc. to extend the permission to use rosemary extract as a food additive to additional foods.

On 17 November 2023, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received five submissions, plus one late submission.

After having regard to the submissions received, FSANZ approved the draft variation, subject to amendments, on 13 March 2024. The Food Ministers' Meeting<sup>1</sup> was notified of FSANZ's decision on 26 March 2024.

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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<sup>1</sup> Formerly referred to as the Australia and New Zealand Ministerial Forum on Food Regulation

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## Supporting document

The [following document](#) which informed the assessment of this application is available on the FSANZ website:

SD Risk and technical assessment report (at approval)

## Executive summary

Kalsec Inc. (Kalsec) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to permit the use of rosemary extract as a food additive (an antioxidant) in a number of foods. The applicant also requested maximum permitted levels (MPLs) for rosemary extract in each of the foods. Rosemary extract is already permitted in the Code for use as a food additive in certain foods up to specified MPLs.

Kalsec provided a range of studies that demonstrated the efficacy of rosemary extract as an antioxidant in a variety of foods, including some of the foods for which permission to add rosemary extract was requested. The use of the antioxidant properties of rosemary extract in food is well documented in the scientific literature. The main components of rosemary extract that impart the antioxidative properties are carnosic acid and carnosol. There are relevant identity and purity specifications for rosemary extract in the Code.

There was no evidence of a public health and safety concern associated with extending the use of rosemary extract as a food additive at the requested MPLs to the list of foods requested by the applicant. However, consistent with the current approach in the Code for raw meat, FSANZ decided not to permit the use of rosemary extract as a food additive in ground poultry. This was to reduce the risk of consumers being misled about the quality, and potentially the safety, of the product from the antioxidant effect of rosemary extract giving a false appearance of freshness.

Following assessment and the preparation of the draft variation, FSANZ called for submissions regarding the draft variation. FSANZ received 5 submissions and one late submission. The majority of submitters supported extending the use of rosemary extract to the requested foods. One submitter raised concerns related to the complexity and prescriptive regulatory approach regarding the addition of rosemary extract to colouring and flavouring preparations.

Following further consideration, FSANZ decided to amend the draft variation, to remove the permission to use rosemary extract as a food additive in colourings and flavourings. The applicant was supportive of these changes being made to the draft variation. Attachment A contains the amended draft variation.

For reasons set out in this report, FSANZ has decided to approve the amended draft variation to the Code. The approved draft variation will amend Schedule 15 of the Code to extend the permission to use rosemary extract as a food additive to the following foods, in accordance with the Code:

- edible oils essentially free of water
- cooked or instant noodles or pasta
- breadcrumbs
- tortillas (wheat or corn based)
- sausages containing raw unprocessed meat, and
- fermented, uncooked processed comminuted meat products.

The permissions will be subject to specified MPLs for rosemary extract, calculated as the sum of carnosic acid and carnosol, that may be present in each food.

The approved draft variation will not permit the use of rosemary extract as a food additive in colourings and flavourings.

# 1 Introduction

## 1.1 The applicant

The applicant is Kalsec Inc (Kalsec), a supplier of ingredients to the food industry.

## 1.2 The application

The purpose of the application was to amend the Australia New Zealand Food Standards Code (the Code) to extend permissions to use rosemary extract as a food additive (antioxidant) to the following additional foods:

- colourings (colouring preparations)
- flavourings (flavouring preparations)
- fats and oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils
- noodles and pasta (specifically precooked or instant noodles with oil added, such as ramen, chow mein, wonton and other similar styles)
- breadcrumbs
- tortillas (wheat or corn)
- ground poultry
- raw meat sausages
- fermented, uncooked processed comminuted meat products.

Kalsec also requested specific maximum permitted levels (MPLs) for rosemary extract in each food.<sup>2</sup> These are listed in Table A1 of the Appendix to the Supporting Document (SD).

Rosemary extract is currently permitted by the Code to be used as a food additive in a number of foods up to specific MPLs, but not the foods that are the subject of this application.

## 1.3 The current Standard

Australian and New Zealand food laws require food for sale to comply with relevant requirements in the Code. The requirements relevant to this application are summarised below.

### 1.3.1 Permitted use

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

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met: the substance is added to the food to perform one or more technological functions listed in Schedule 14; and the substance is identified in subsection 1.1.2—11(2) – this includes (among other things) a substance identified in the table to section S15—5 as a permitted food additive.

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<sup>2</sup>Paragraph 1.3.1—4(6)(k) of the Code specifies that rosemary extract is calculated as the sum of carnosic acid andarnosol. References to MPLs of rosemary extract in this report therefore mean the sum of carnosic acid andarnosol.

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

Section 1.3.1—3 details when substances are permitted to be used as food additives in food. The table to section S15—5 of Schedule 15 lists the specific food additive permissions for different classes of foods. Rosemary extract is listed in that table as a permitted food additive for fish oils, algal oils, margarine and similar products, nut butters, nut spreads, icings, frostings, grain bars, breakfast bars, breakfast cereals, flour based snacks, biscuits, cakes, pastries, meat with less than 10% fat, dried meat, dried sausages, salts, condiments (not including condiment sauces), processed nuts, sauces, toppings and soup bases.

The table to section S15—5 also lists the MPLs in relation to rosemary extract that may be present in each food. Paragraph 1.3.1—4(6)(k) specifies that 'in this Standard' rosemary extract is calculated as the sum of carnosic acid and carnosol.

Schedule 16 sets out the types of substances that may be used as food additives in any food at Good Manufacturing Practice (GMP) levels. As rosemary extract is not such a food additive, it is not listed in Schedule 16.

### **1.3.2 Identity and purity requirements**

Paragraph 1.1.1—15(1)(a) requires substances used as food additives to comply with any relevant identity and purity specifications set out in Schedule 3. Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the:

- Joint FAO/WHO Expert Committee on Food Additives (JECFA) Combined Compendium of Food Additive Specifications (FAO JECFA Monographs 26 (2021))
- United States Pharmacopeial Convention (2022) Food chemicals codex (13<sup>th</sup> edition)
- Commission Regulation (EU) No 231/2012.

These all include specifications for rosemary extract.

### **1.3.3 Labelling requirements**

Subsection 1.1.1—10(8) provides that food for sale must comply with all relevant labelling requirements in the Code.

Standard 1.2.1 sets out the labelling requirements for food for sale, including whether certain foods have to bear a label or not, and the labelling provisions that apply in each case.

Standard 1.2.4 generally requires packaged food to be labelled with a statement of ingredients. Subsection 1.2.4—7(1) requires substances used as food additives to be declared in the statement of ingredients in one of the following ways: if the food additive can be classified into a class of additives listed in Schedule 7 – Food additive class names (for statement of ingredients) by referring to the relevant class name, followed in brackets by the name or code number of the food additive indicated in Schedule 8 – Food additive names and code numbers (for statement of ingredients); or otherwise, by referring to the name of the food additive as indicated in Schedule 8.

## **1.4 International standards**

### **1.4.1 Codex Alimentarius and other international standards**

In developing food regulatory measures, FSANZ must have regard to the promotion of consistency between domestic and international food standards. In terms of food safety, the

relevant international standard setting body is the Codex Alimentarius (Codex).

Codex STAN 192-1995 (also referred to as the General Standard for Food Additives, or GSFA) contains food additive listings, by food category.<sup>3</sup> Rosemary extract as a food additive is not yet included in the GSFA. Only food additives that have been assigned an Acceptable Daily Intake (ADI) or determined, on the basis of other criteria, to be safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA) and have an International Numbering System (INS) designation by Codex are considered for inclusion in the GSFA. JECFA evaluated rosemary extract at their 82<sup>nd</sup> meeting in June 2016 and set a temporary Acceptable Daily Intake (ADI).<sup>4</sup>

#### **1.4.2 Other regulations**

Rosemary extract is permitted for use as a food additive in a number of countries overseas. The applicant provided a summary of the permissions and maximum permitted use levels in the following countries and regions: European Union, Brazil, Central America, China, Eurasian Union, Indonesia, Mexico, Singapore, Taiwan, Vietnam and Japan (see Table 1 in the application).

In the European Union, rosemary extract 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), and in 2018 to refine the dietary exposure assessment (EFSA, 2018).

In Japan, rosemary extract is listed in the Japanese Existing Additives List<sup>5</sup>. There are no specific limits on its use in foods.

### **1.5 Reasons for accepting application**

The application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), and
- it related to a matter that warranted the variation of a food regulatory measure.

### **1.6 Procedure for assessment**

The application was assessed under the General Procedure in the FSANZ Act.

### **1.7 Decision**

For the reasons outlined in this report, FSANZ decided to approve an amended version of the proposed draft variation that was set out in the call for submissions. The amendments were as follows:

- removal of Item [1] of the Schedule to the draft variation (i.e. removal of proposed amendments to sections 1.3.1—7 and 1.3.1—8 of the Code)
- removal of Item [10] of the Schedule to the draft variation (i.e. removal of proposed new section S15—6 of the Code)

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<sup>3</sup> Codex Alimentarius General Standards for Food Additives. [Food Additives DB \(GSFA Online\) | CODEXALIMENTARIUS FAO-WHO](#)

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

<sup>5</sup> Available at [https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou\\_iryuu/shokuhin/syokuten/index\\_00012.html](https://www.mhlw.go.jp/stf/seisakunitsuite/bunya/kenkou_iryuu/shokuhin/syokuten/index_00012.html)

These amendments removed the proposed permissions to use rosemary extract as a food additive in colourings and flavourings.

The approved draft variation amends the Code to extend the permission to use rosemary extract as a food additive to the following foods:

- edible oils essentially free of water
- cooked or instant noodles or pasta
- breadcrumbs
- tortillas (wheat or corn based)
- sausages containing raw unprocessed meat, and
- fermented, uncooked processed comminuted meat products.

The permissions will be subject to specified MPLs of rosemary extract, calculated as the sum of carnosic acid and carnosol, that may be present in each food.

The approved draft variation takes effect on gazettal and is at Attachment A. 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 Summary of the findings

### 2.1 Summary of issues raised in submissions

FSANZ called for submissions on a draft variation to the Code from 17 November to 15 December 2023.

Six submissions including a late submission from the Victorian departments of Health and Energy, Environment and Climate Action (Victorian departments) were received as follows:

- **One** from a consumer organisation (Food Intolerance Network);
- **Two** from industry or industry associations (Sherratt Ingredients, New Zealand Food and Grocery Council); and
- **Three** from government agencies (New Zealand Food Safety (NZFS), New South Wales Food Authority and the Victorian departments).

The summary of submissions and FSANZ's response to issues raised in the submissions are provided in Table 1.

**Table 1: Summary of issues**

Issue	Submitter	Response
<p><b>The submitter is concerned that rosemary extract is very high in chemicals resembling salicylates.</b></p>	<p>Food Intolerance Network</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 added to food to perform the technological function of antioxidant will be required to be declared as an ingredient (see section 2.4.2). This will help consumers to make informed choices about foods to manage intolerance reactions.</p>
<p><b>The submitter is concerned that no new evidence has been presented since 2018, and the temporary (JECFA) ADI remains unsupported by other than desk top population assessments of intake in the general population. The submitter comments the requested extension of use is based on the old rat studies on development or reproductive toxicity plus guesses as to how much people might eat.</b></p>	<p>Food Intolerance Network</p>	<p>JECFA established a temporary ADI of 0 to 0.3 mg /kg bw for rosemary extract, expressed as the sum of carnosic acid and carnosol, at their 82<sup>nd</sup> meeting. This ADI was based on a 90-day study in rats, which was not a reproductive or developmental study. The JECFA ADI was temporary pending additional information on developmental and reproductive safety.</p> <p>FSANZ’s first assessment of rosemary extract (A1158) included a reproductive and developmental toxicity study in rats that had been conducted since the JECFA assessment. The paternal, maternal and offspring No Observed Adverse Effect Levels in that study were all more than 200-fold greater than the JECFA ADI, and therefore did not indicate any need to alter the ADI.</p> <p>As part of the current assessment, FSANZ undertook a comprehensive review of the scientific literature published since the previous assessment (A1158). No new information was found that would justify a change to the JECFA temporary ADI of 0 to 0.3 mg/kg bw/day established in 2017.</p>
<p><b>Regarding the addition of rosemary extract to colouring and flavouring food additive preparations, the submitter expressed concerns about the relatively complex and prescriptive regulatory approach. The submitter questions how new sections 1.3.1—7 and 1.3.1—8 will work in practice for industry and enforcement agencies - for example, ingredient suppliers will need to be aware of the restriction of use and provide detailed composition information to</b></p>	<p>NZFS</p>	<p>Noted.</p> <p>Following further consideration, FSANZ has decided to amend the draft variation to remove the permissions to add rosemary extract to colourings and flavourings. See section 2.4.1.1 for the fuller explanation of changes made to the draft variation as an outcome of considering this issue.</p>



<p>manufacturing clients. The submitter noted that if rosemary extract is used in a colouring or flavouring preparation it is unlikely to appear in the ingredient list for the final food. The submitter noted that while domestic food production is subject to a food control plan that may ensure compliant ingredients are used, compliance of imported foods will be particularly difficult to determine and enforce.</p> <p>The submitter would therefore prefer a simpler regulatory approach and requests that FSANZ revisits these specific provisions with the applicant. If the permissions via colourings and flavourings are removed, the new permissions are limited to S15—5 alone.</p>		
<p><b>Extend permissions - The submitter requests an extension to food category 8.5 Animal protein products (in Schedule 15)</b></p>	<p>Sherratt Ingredients</p>	<p>This extension is out of scope of the application. The permissions sought by the application did not include food category 8.5. A new application is required to consider permitting the use of rosemary extract as a food additive in animal protein products.</p>
<p><b>Fully supports the proposed drafting for amendment to the Code</b></p>	<p>New Zealand Food and Grocery Council</p>	<p>Noted</p>
<p><b>Support FSANZ’s proposal not to permit the use of rosemary extract as a food additive in raw ground poultry (unprocessed).</b></p>	<p>New South Wales Food Authority (NSW FA)  NZFS</p>	<p>Noted</p>
<p><b>The submitter requests further commentary from FSANZ on the rationale for permitting the use of rosemary extract in ‘fermented, uncooked processed comminuted meat products’ and ‘sausage containing raw, unprocessed meat’. The submitter queries if the use of rosemary extract in these specific</b></p>	<p>NSW FA</p>	<p>FSANZ notes that the two food classes identified are 8.3.1 and 8.3.2, being subclasses of 8.3. Food class 8.3 permits a number of antioxidants (including those within S16—2, such as ascorbic acid and the various ascorbate salts). Food class 8.3 also permits a number of preservatives, such as nisin, and nitrates and nitrites. Food additive permissions in food class 8.3 apply also to lower subclasses 8.3.1 and 8.3.2 (due to S15—2). Permitting the use of rosemary extract as a food additive with the technological function of antioxidant for these food classes is therefore consistent with current</p>

<b>raw meat products may also result in disguising the effects of spoilage from microbial growth.</b>		permissions for other antioxidants. As stated above, raw ground poultry sold as such is not permitted to contain rosemary extract as a food additive.
<b>The submitter supports the restrictions under new sections 1.3.1—7 and 1.3.1—8, given that rosemary extract is a food additive with an ADI of 0-0.3 mg.kg.</b>	NSW FA	Noted (noting that under the revised approach at Approval, proposed sections 1.3.1—7 and 1.3.1—8 are removed from the approved draft variation).
<b>The submitter requests clarification regarding ‘carry-over’ in the example of fish and fish products coated with breadcrumbs.</b>	NSW FA	As noted above, proposed sections 1.3.1—7, 1.3.1—8 and S15—6 are removed from the approved draft variation. The carry-over provision remains unchanged in the Code.
<b>The submitter suggests reviewing the proposed MPL for ‘vegetable protein products’. The proposed MPL in S15—6 is 40 mg/kg, whereas the dietary exposure used 10 mg/kg.</b>	NSW FA	Noted. However, under the revised approach at approval, proposed section S15—6 is removed from the approved draft variation, therefore the submitter comment is no longer applicable.
<b>The submitter generally supports the progression of the application, but questioned the need for rosemary extract in foods inherently low in fat.</b>	Victorian departments	Noted. Under the approach at call for submission, the foods inherently low in fat were not permitted to contain rosemary extract by direct addition, only via a colouring and/or flavouring preparation. The rosemary extract was therefore performing its technological function in a colouring or flavouring preparation.  To note, as stated above, under the revised approach at approval, the permissions for these foods (i.e. the foods inherently low in fat that were listed in the proposed section S15—6) are removed from the approved draft variation.
<b>Agrees that due to the ADI of 0-0.3 mg/kg bw, the use of rosemary extract does not result in intakes that exceed the ADI.</b>	NZFS	Noted

## 2.2 Food technology assessment

Kalsec provided a range of studies that demonstrated the efficacy of rosemary extract as an antioxidant in a variety of foods, including some of the foods for which permission to add rosemary extract was requested. The MPLs for rosemary extract that each food may contain as requested by the applicant were not comparable with the amounts used in the studies in all instances. The use of the antioxidant properties of rosemary extract in food is, however, well reported in the scientific literature. The main components of rosemary extract that impart the antioxidative properties are carnosol and carnosic acid.

There are relevant identity and purity specifications for rosemary extract in the Code. For further details, refer to the SD.

## 2.3 Risk assessment

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed rosemary extract at their 82<sup>nd</sup> meeting and established a temporary ADI of 0 - 0.3 mg/kg bw for rosemary extract, expressed as the sum of carnosic acid and carnosol (WHO 2017). FSANZ assessed the safety of rosemary extract as a food additive in Application A1158 – Rosemary extract as a food additive and concluded that the temporary ADI set by JECFA was protective of human health and safety. As part of the current assessment FSANZ conducted a literature search to determine if any new publications, not considered in A1158, would justify setting an ADI less than 0 – 0.3 mg/kg bw. It was concluded that there is no recent evidence that would justify decreasing the ADI from the temporary ADI set by JECFA.

Dietary exposures to carnosic acid plus carnosol were estimated for a number of scenarios that included current permissions for the use of rosemary extract as a food additive, permissions as requested in the application, MPLs and Usual Use Levels. Requested permissions included a range of food classes in Schedule 15 of the Code, use of rosemary extract in colourings and flavourings and carry over from this use to final foods. Dietary exposures were estimated for both Australian and New Zealand population groups. Of all the population groups and scenarios assessed, the ADI was exceeded (110% and 150%) only in two scenarios, both in the New Zealand population aged 5-14 years and only for the 90<sup>th</sup> percentile dietary exposures when MPLs were used. This is due to a number of reasons including lower body weights for that age group and one day of food consumption data being used for the estimate.

The dietary exposure estimates based on MPLs were highly conservative and are not likely to occur in reality. The Usual Use Level scenarios represent more likely estimates of dietary exposure. The P90 dietary exposures based on Usual Use Levels were 60% and 95% of the ADI respectively for the New Zealand population aged 5-14 years. For the Australian population aged 2 years and above, and the New Zealand population aged 15 years and above, the highest P90 exposures were 85% and 75% respectively based on MPLs.

As a conservative approach, the dietary exposure estimates assumed 100% market penetration. However, according to the data provided by the applicant, the proportion of food products labelled as containing rosemary extract as an ingredient out of the total number of food products in respective food categories in the Mintel<sup>6</sup> database as a whole for each year from 2018 to 2022 was ≤ 4% and ≤ 8% for Australia and New Zealand, respectively.

Exposure to carnosic acid plus carnosol as a result of use of rosemary as a culinary herb contributes very little to the overall exposure.

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<sup>6</sup> [Mintel - A Global Market Intelligence & Research Agency](#)

Based on the safety and dietary exposure assessments, there is no evidence of a public health and safety concern associated with extending the use of rosemary extract as a food additive at the requested MPLs. This includes an extension of the use of rosemary extract as a food additive to the requested foods/food categories and to the food categories the applicant suggested could include flavourings and colourings containing rosemary extract.

For further details, refer to the SD.

## **2.4 Risk management**

As set out above, the conclusions from the risk and technical assessment were that the proposed extension of use of the food additive is technologically justified, with no safety concerns identified.

FSANZ therefore initially considered it appropriate to prepare a draft variation to the Code to extend the existing permissions for rosemary extract to be used as a food additive to the following additional foods: preparations of food additives that are colourings and flavourings (with limitations on the foods they can be used in), edible oils essentially free of water, cooked or instant noodles or pasta, breadcrumbs, tortillas (wheat or corn based), sausages containing raw unprocessed meat, and fermented, uncooked processed comminuted meat products.

The risk management options available to FSANZ following the call for submissions are to either:

- approve the draft variation proposed following assessment, or
- approve that draft variation subject to such amendments as FSANZ considers necessary, or
- reject that draft variation.

Having regard to all submissions received, and for the reasons set out in this report, FSANZ considers it appropriate to approve an amended version of the draft variation (Attachment A). An explanation of each amendment is provided below in section 2.4.1.1.

The approved draft variation permits the use of rosemary extract as a food additive in the below list of foods:

- edible oils essentially free of water
- cooked or instant noodles or pasta
- breadcrumbs
- tortillas (wheat or corn based)
- sausages containing raw unprocessed meat, and
- fermented, uncooked processed comminuted meat products.

The approved draft variation does not include a permission to use rosemary extract as a food additive in colourings or flavourings.

The permission to use rosemary extract as a food additive is subject to MPLs. Other risk management considerations for this application are discussed below.

### **2.4.1 Regulatory approval**

FSANZ has approved a draft variation to extend the permission to use rosemary extract as a food additive in the above bullet list of foods, in accordance with the Code.

The approved draft variation inserts each of the new permissions into the relevant food or food category in the table to subsection S15—5 of the Code, including each associated MPL.

#### **2.4.1.1 Preparations of food additives that are colourings and flavourings**

The applicant initially requested permission for rosemary extract to be used as a food additive in preparations of colourings and flavourings as outlined in Table 2. Colourings and flavourings are themselves used as food additives. Such food additive preparations sometimes require the use of food additives for technological reasons.

**Table 2: Initial request for permission to use rosemary extract in colourings and flavourings**

<b>Class number and description (Schedule 15)</b>	<b>Proposed MPL mg/kg*</b>	<b>Comments</b>
0.2 Colourings	1000	Not to exceed 5 mg/kg in the final food
0.3 Flavourings	1000	Not to exceed 5 mg/kg in the final food

\*expressed as the sum of carnosol and carnosic acid

The applicant originally requested permission to use rosemary extract as a food additive in colourings and flavourings which could then be added to any other food. In the risk assessment (SD) however, FSANZ used a combined total of 10 mg rosemary extract (calculated as the sum of carnosic acid and carnosol) per kg of the final food containing the colouring or flavouring with added rosemary extract in specified food classes only, as agreed with the applicant (see section 4.3.3 of the SD and as explained in the call for submissions, section 2.3.1.1).

At the call for submissions stage, the reason for proposing the limited permission for adding rosemary extract to colouring and flavouring preparations subsequently added to certain food classes was to limit the dietary exposure to rosemary extract. A general permission allowing colouring and flavouring preparations with added rosemary extract to be added to all food classes that allow such preparations would have increased the risk of exposure for different populations and scenarios to potentially exceed the ADI.

Limiting the permissions of colouring and flavouring preparations containing rosemary extract to use in certain specific food classes required very specific detailed drafting as proposed within the call for submission report (see Attachment C).

In one of the submissions received by FSANZ, a jurisdictional enforcement agency raised concerns regarding the complexity of the proposed regulatory approach to the use of rosemary extract as a food additive in colouring and flavouring preparations. The agency questioned how they would be able to enforce the proposed new permissions and MPLs (specifically the amendments to sections 1.3.1—7, 1.3.1—8 and the proposed new section S15—6). In relation to enforcement difficulties, the agency noted that ingredient suppliers (of rosemary extract) would need to be aware of the restrictions on use, and that where rosemary extract was used in a colouring or flavouring food additive preparation, it is unlikely to be included in the ingredient list for the final food.

After careful consideration of the difficulties raised by the jurisdictional agency regarding the enforcement of the proposed drafting, FSANZ decided to remove permissions for the use of rosemary extract as a food additive in colouring and flavouring preparations from the draft variation, as follows:

- removal of Item [1] of the Schedule to the draft variation (i.e. removal of proposed amendments to sections 1.3.1—7 and 1.3.1—8 of the Code)
- removal of Item [10] of the Schedule to the draft variation (i.e. removal of proposed new section S15—6 of the Code)

The applicant was supportive of these changes being made to the draft variation.

FSANZ further notes that the dietary exposure assessment performed and detailed in the SD for the call for submission included exposures to rosemary extract due to its use in colouring and flavouring preparations added to a limited number of food classes. As noted within the SD and as summarised in section 2.3 of this report, there is no evidence of a public health and safety concern. This conclusion is associated with extending the use of rosemary extract as a food additive at the requested MPLs for the requested food classes, as well as those food classes proposed to be permitted to contain rosemary extract via flavourings and colourings. Removing the limited number of food classes permitted to have colourings and flavouring containing rosemary extract reduces the dietary exposure further. Due to this fact FSANZ did not conduct an updated dietary exposure assessment with such food classes removed.

#### **2.4.1.2 Ground poultry**

The applicant requested permission for rosemary extract to be used as a food additive in 'ground poultry'. FSANZ clarified with the applicant that by 'ground poultry' they meant ground (or minced) poultry that is later cooked. The applicant also agreed that ground/minced poultry fitted appropriately in the food class 8.1.1 – Poultry, which comes under the class 8.1 Raw meat, poultry and game in Schedule 15.

Food additives are not generally permitted to be used in unprocessed raw meat, with the exception of sodium acetate in poultry. The use of antioxidants in raw meat may preserve the colour and texture of the raw meat and disguise the effects of spoilage from microbial growth.

Consistent with the current approach in the Code for raw meat, FSANZ decided not to include a permission for the use of rosemary extract as a food additive in raw ground poultry (unprocessed) in the draft variation included in the call for submissions report. This was to reduce the risk of consumers being misled about the quality, and potentially the safety, of the product from the antioxidant effect of rosemary extract giving a false appearance of freshness. None of the submissions disagreed with this decision.

#### **2.4.1.3 Tortillas and class in Schedule 15**

The applicant requested permission for rosemary extract to be used as a food additive in tortillas (wheat or corn) and questioned whether the permission fitted under class 7 – Bread and bakery products in Schedule 15.

The approved draft variation will permit rosemary extract to be used as a food additive in tortillas (wheat or corn) up to the requested MPL of 40 mg per kg. Tortillas are not currently specifically identified in a food class in Schedule 15. FSANZ considers they are most accurately described by class 6.4 Flour products (including noodles and pasta), and the approved draft variation contains a permission to use rosemary extract as a food additive in tortillas under that class number and description.

#### **2.4.1.4 Specifications**

There are relevant identity and purity specifications in primary sources of specifications listed in Schedule 3 which rosemary extract used as a food additive would need to comply with

(refer to section 1.3.2 above).

## **2.4.2 Labelling requirements**

The labelling requirements that apply to the existing permitted uses of rosemary extract, as outlined below, will also apply to its use in additional foods.

Food additives must be listed in the statement of ingredients in accordance with requirements set out in section 1.2.4—7 in conjunction with Schedules 7 and 8 of the Code (see section 1.3.3 of this report). 'Antioxidant' is a prescribed class name included in Schedule 7, and 'rosemary extract' with the code number 392 is listed in Schedule 8. The use of rosemary extract in a food as an antioxidant must therefore be declared in the statement of ingredients using one of the following names:

- Antioxidant (rosemary extract)
- Antioxidant (392).

There are some exemptions to the requirement to display a statement of ingredients in section 1.2.1—6 of the Code for foods for retail sale that are not required to bear a label. These exemptions mean that food additives (including rosemary extract) are not required to be declared on foods that do not have to bear a label.

## **2.4.3 Risk management conclusion**

For the reasons stated in this report, FSANZ has decided to approve the draft variation to the Code, with amendments. That is, to extend the permission to use rosemary extract as a food additive to the following foods, in accordance with the Code:

- edible oils essentially free of water
- cooked or instant noodles or pasta
- breadcrumbs
- tortillas (wheat or corn based)
- sausages containing raw unprocessed meat, and
- fermented, uncooked processed comminuted meat products.

As described above, FSANZ decided to remove the proposed permission to use rosemary extract as a food additive in colouring or flavouring preparations from the draft variation. For further information about this amendment to the draft variation, see section 2.4.1.1 of this report.

The permission to use add rosemary extract to the foods listed above will be subject to specified MPLs of rosemary extract, calculated as the sum of carnosic acid and carnosol, that may be present in each food.

## **2.5 Risk communication**

### **2.5.1 Consultation**

Consultation is a key part of FSANZ's standards development process. FSANZ developed and applied a standard communication strategy to this application. The call for submissions was notified via the Food Standards Notification Circular, media release, FSANZ's social media channels and Food Standards News.

The process by which FSANZ considers standards development matters is open,

accountable, consultative and transparent. Public submissions were called to assist consideration of the draft variation to the Code. FSANZ acknowledges the time taken to make submissions on this application.

The draft variation was considered for approval by the FSANZ Board having regard to the submissions made during the call for submissions period.

## **2.6 FSANZ Act assessment requirements**

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

### **2.6.1 Section 29**

#### **2.6.1.1 Consideration of costs and benefits**

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>7</sup>. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes the OIA advised FSANZ that a Regulatory Impact Statement (RIS) was not required for the applications relating to food additives. This is because applications relating to permitting the use of food additives that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

FSANZ, however, gave 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 (paragraph 29 (2)(a)).

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 (where status quo is rejecting the application). This analysis considers the costs and benefits of permitting the use of rosemary extract as a food additive in additional foods.

The consideration of the costs and benefits in this section was 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 sought to highlight the potential positives and negatives of moving away from the status quo by permitting use of the food additive in additional foods.

FSANZ's conclusions regarding the costs and benefits of the proposed measure are set out below.

##### *2.6.1.1.1 Cost and benefits of extending the use of this food additive*

Industry may benefit from being able to use this food additive as an antioxidant in additional foods. Due to the voluntary nature of the permission, industry will only use the food additive where they believe a net benefit exists for them.

If industry were to experience cost savings as a result of using the food additive, industry

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<sup>7</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)



may pass on some of the cost savings onto consumers.

Permitting the use of this food additive may result in a small, inconsequential cost to government in terms of an addition to the current range of food additives that are already monitored for compliance. However, following concerns raised during the call for submissions period, FSANZ decided to remove the proposed permission to use rosemary extract as a food additive in colouring or flavouring preparations from the draft variation. This will minimise any additional cost to government that may have resulted from this proposed permission in terms of enforcement.

#### *2.6.1.1.2 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 in the additional foods listed above in section 2.4 most likely outweigh the associated costs. No further information was received during the consultation process that changed that assessment.

#### **2.6.1.2 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.

#### **2.6.1.3 Any relevant New Zealand standards**

The relevant standards apply in both Australia and New Zealand. There are no relevant New Zealand only standards.

#### **2.6.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.6.2 Subsection 18(1)**

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

#### **2.6.2.1 Protection of public health and safety**

FSANZ undertook a safety assessment (see section 2.2 above and the SD) and concluded there is no evidence of a public health and safety concern associated with extending the use of rosemary extract as an additive as proposed in this report.

#### **2.6.2.2 The provision of adequate information relating to food to enable consumers to make informed choices**

The labelling requirements relevant to this application are discussed in sections 1.3.3 and 2.4.2 of this report.

#### **2.6.2.3 The prevention of misleading or deceptive conduct**

The prevention of misleading or deceptive conduct in relation to the use of rosemary extract as a food additive in raw ground poultry is discussed in section 2.4.1.2 of this report. There were no other issues identified with this application relevant to this objective.

### 2.6.3 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 used the best available scientific evidence to conduct the risk analysis. The applicant submitted a dossier of information and scientific literature as part of its application. This dossier, together with other technical and scientific information, was considered by FSANZ in assessing the application. The risk assessment is provided in the SD.

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

As summarised in section 1.4.2 above, rosemary extract is permitted in some international jurisdictions. Approval for use in Australia and New Zealand would promote consistency with countries in which permissions exist.

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

Approval for use the different food classes would bring Australia and New Zealand into line with permissions for its use in other countries as outlined in section 1.4.2 above. In this way, Australia and New Zealand will remain competitive with other international markets. This will also help foster continued innovation and improvements in food manufacturing techniques and processes.

Ultimately, the food industries in Australia and New Zealand will make their own economic decisions, taking into account the costs and benefits of using rosemary extract, to determine if it is of benefit to their particular business.

- **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 Food Ministers' Meeting**

The Ministerial Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*<sup>8</sup> 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:

- (a) the purpose for adding the substance can be articulated clearly by the manufacturer as achieving a solely technological function (i.e. the 'stated purpose')
- (b) the addition of the substance to food is safe for human consumption
- (c) the amounts added are consistent with achieving the technological function
- (d) the substance is added in a quantity and a form which is consistent with delivering the stated purpose
- (e) no nutrition, health or related claims are to be made in regard to the substance.

Following assessment as outlined in this report and the SD, FSANZ has determined that permitting the extension of use of rosemary extract as a food additive as proposed in this

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<sup>8</sup> <https://foodregulation.gov.au/internet/fr/publishing.nsf/Content/publication-Policy-Guideline-on-the-Addition-of-Substances-other-than-Vitamins-and-Minerals>

report is consistent with the above principles (a), (b) and (e). Policy principles (c) and (d) are addressed in section 2.3.1 of this report.

All other relevant requirements of the policy guideline are met.

### 3 References

European Food Safety Authority (EFSA) (2008) [Use of rosemary extracts as a food additive](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/721.pdf). Scientific opinion of the panel on food additives, flavourings, processing aids and materials in contact with food. The EFSA Journal 721: 1-29  
[http://www.efsa.europa.eu/sites/default/files/scientific\\_output/files/main\\_documents/721.pdf](http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/721.pdf)

European Food Safety Authority (EFSA) (2015) Extension of use of extracts of rosemary (E392) in fat-based spreads. EFSA panel on food additives and nutrient sources added in food (ANS). The EFSA Journal 13(5): 4090 <https://www.efsa.europa.eu/en/efsajournal/pub/4090>

European Food Safety Authority (EFSA) (2018) Scientific Opinion on the refined exposure assessment of extracts of rosemary (E 392) from its use as food additive. EFSA Journal 2018;16(8):5373, 25 pp. <https://www.efsa.europa.eu/en/efsajournal/pub/5373>

WHO (2017) Safety evaluation of certain food additives: prepared by the Eighty-second meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA). (WHO Food Additives Series, No. 73). Geneva. <http://apps.who.int/iris/bitstream/handle/10665/258934/9789241660730-eng.pdf;jsessionid=A00597563B90160B44F104EB42259AF6?sequence=1>

### Attachments

- A. Approved draft variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement
- C. Draft variation to the *Australia New Zealand Food Standards Code* (call for submissions)

## Attachment A – Approved draft variation to the Australia New Zealand Food Standards Code



### Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation

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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 this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position]

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 clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation*.

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

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

## 3 Commencement

The variation commences on the date of gazettal.

### Schedule

#### Schedule 15 — Substances that may be used as food additives

**[1] Subsection S15—5 (table, numbered heading “2.1 Edible oils essentially free of water”, table item dealing with Rosemary extract)**

Repeal the item, substitute:

392	Rosemary extract	50
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**[2] Subsection S15—5 (table, numbered heading “6.4 Flour products (including noodles and pasta)”, table item dealing with Rosemary extract)**

Repeal the item, substitute:

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

**[3] Subsection S15—5 (table, numbered heading “7.1.1 Fancy Breads”, after the table item dealing with Steviol glycosides)**

Insert:

<b>7.1.2</b>	<b>Breadcrumbs</b>	
392	Rosemary extract	40

**[4] Subsection S15—5 (table, numbered heading “8.3.1 Fermented, uncooked processed comminuted meat products”, after the table item dealing with Nitrates (potassium and sodium salts))**

Insert:

392	Rosemary extract	40
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**[5] Subsection S15—5 (table, numbered heading “8.3.2 Sausage and sausage meat containing raw, unprocessed meat”, table item dealing with Rosemary extract)**

Repeal the item, substitute:

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

**[6] Subsection S15—5 (table, numbered heading “20.2.06 Starch based snacks (from root and tuber vegetables, legumes and pulses)”)**

Repeal the numbered heading, substitute:

<b>20.2.0.6</b>	<b>Starch based snacks (from root and tuber vegetables, legumes and pulses)</b>	
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## Attachment B – Explanatory Statement

### EXPLANATORY STATEMENT

*Food Standards Australia New Zealand Act 1991*

#### ***Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation***

##### **1. Authority**

Section 13 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that the functions of Food Standards Australia New Zealand (the Authority) include the development of standards and variations of standards for inclusion in the *Australia New Zealand Food Standards Code* (the Code).

Division 1 of Part 3 of the FSANZ Act specifies that the Authority may accept applications for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering an application for the development or variation of food regulatory measures.

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

Following consideration by the Food Ministers' Meeting (FMM), section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the approved draft variation.

##### **2. Variation is a legislative instrument**

The approved draft variation is a legislative instrument for the purposes of the *Legislation Act 2003* (see section 94 of the FSANZ Act) and is publicly available on the Federal Register of Legislation ([www.legislation.gov.au](http://www.legislation.gov.au)).

This instrument is not subject to the disallowance or sunset provisions of the *Legislation Act 2003*. Subsections 44(1) and 54(1) of that Act provide that a legislative instrument is not disallowable or subject to sunset if the enabling legislation for the instrument (in this case, the FSANZ Act): (a) facilitates the establishment or operation of an intergovernmental scheme involving the Commonwealth and one or more States; and (b) authorises the instrument to be made for the purposes of the scheme. Regulation 11 of the *Legislation (Exemptions and other Matters) Regulation 2015* also exempts from sunset legislative instruments a primary purpose of which is to give effect to an international obligation of Australia.

The FSANZ Act gives effect to an intergovernmental agreement (the Food Regulation Agreement) and facilitates the establishment or operation of an intergovernmental scheme (national uniform food regulation). That Act also gives effect to Australia's obligations under an international agreement between Australia and New Zealand. For these purposes, the Act establishes the Authority to develop food standards for consideration and endorsement by the FMM. The FMM is established under the Food Regulation Agreement and the international agreement between Australia and New Zealand, and consists of New Zealand, Commonwealth and State/Territory members. If endorsed by the FMM, the food standards

on gazettal and registration are incorporated into and become part of Commonwealth, State and Territory and New Zealand food laws. These standards or instruments are then administered, applied and enforced by these jurisdictions' regulators as part of those food laws.

### **3. Purpose**

The Authority has approved a draft variation amending Schedule 15 of the Code to extend the permitted use of rosemary extract as a food additive to additional foods, subject to maximum permitted levels.

### **4. Documents incorporated by reference**

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

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

### **5. Consultation**

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1254 included one round of public consultation following an assessment and the preparation of a draft variation and associated assessment summary. Submissions were called for on 17 November 2023 for a 4-week consultation period.

Changes have been made to the Impact Analysis requirements by the Office of Impact Analysis (OIA)<sup>9</sup>. Impact analysis is no longer required to be finalised with the OIA. Prior to these changes, the OIA advised the Authority that a Regulatory Impact Statement (RIS) was not required for the applications relating to food additives. This is because applications relating to permitting the use of food additives that have been determined to be safe are considered to be minor and deregulatory in nature as their use will be voluntary if the draft variation concerned is approved. Under the new approach, the Authority's assessment is that a RIS is not required for this application.

### **6. Statement of compatibility with human rights**

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 44 of the *Legislation Act 2003*.

### **7. Variation**

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

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<sup>9</sup> [Regulatory Impact Analysis Guide for Ministers' Meetings and National Standard Setting Bodies | The Office of Impact Analysis \(pmc.gov.au\)](https://www.pmc.gov.au/regulatory-impact-analysis-guide-for-ministers-meetings-and-national-standard-setting-bodies)

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

Clause 3 of the variation provides that the variation will commence on the date of gazettal of the instrument.

## 7.1 Item [1] – [5]

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

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

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

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

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

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

The effects of this amendment are to:

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

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

‘7.1.2	<b>Breadcrumbs</b>	
392	Rosemary extract	40’



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

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

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

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

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

The effects of this amendment is to:

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

## 7.2 Item [6]

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

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



### Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation

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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 this variation.

Dated [To be completed by the Delegate]

[Insert Delegate's name and position 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 clause 3 of the variation.

## 1 Name

This instrument is the *Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation*.

## 2 Variation to Standards 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

#### Standard 1.3.1 – Food additives

##### [1] At the end of the Standard

Insert:

##### 1.3.1—7 Maximum permitted level of rosemary extract in certain foods

Despite subsection 1.3.1—3(2), rosemary extract that has been \*used as a food additive in accordance with this Standard must not be present in a food for sale within a class of food listed in Column 1 of the table to section S15—6 at a level greater than the maximum permitted level listed in Column 2 of that table for that food.

##### 1.3.1—8 Restriction on use of colourings or flavourings containing rosemary extract as a food additive

- (1) This section applies to:
  - (a) a colouring in which rosemary extract has been \*used as a food additive in accordance with this Standard and item 0.2 of the table to section S15—5; and
  - (b) a flavouring in which rosemary extract has been \*used as a food additive in accordance with this Standard and item 0.3 of the table to section S15—5.
- (2) Despite sections 1.3.1—3 and 1.3.1—4, the colouring or flavouring must not be \*used as a food additive in a food unless:
  - (a) the food is within a class of food listed in Column 1 of the table to section S15—6; and
  - (b) any conditions of use specified in the corresponding row of Column 3 of that table are complied with.

#### Schedule 15 — Substances that may be used as food additives

##### [2] Subsection S15—5 (table, numbered heading “0.2 Colourings”, after the table item dealing with Ethanol)

Insert:

392	Rosemary extract	1 000	See section 1.3.1—8
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##### [3] Subsection S15—5 (table, numbered heading “0.3 Flavourings”, after the table item dealing with Butylated hydroxyanisole)

Insert:

392	Rosemary extract	1 000	See section 1.3.1—8
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##### [4] Subsection S15—5 (table, numbered heading “2.1 Edible oils essentially free of water”, table item dealing with Rosemary extract)

Repeat the item, substitute:

392	Rosemary extract	50	
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**[5] Subsection S15—5 (table, numbered heading “6.4 Flour products (including noodles and pasta)”, table item dealing with Rosemary extract)**

Repeal the item, substitute:

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

**[6] Subsection S15—5 (table, numbered heading “7.1.1 Fancy Breads”, after the table item dealing with Steviol glycosides)**

Insert:

<b>7.1.2</b>	<b>Breadcrumbs</b>	
392	Rosemary extract	40

**[7] Subsection S15—5 (table, numbered heading “8.3.1 Fermented, uncooked processed comminuted meat products”, after the table item dealing with Nitrates (potassium and sodium salts))**

Insert:

392	Rosemary extract	40
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**[8] Subsection S15—5 (table, numbered heading “8.3.2 Sausage and sausage meat containing raw, unprocessed meat”, table item dealing with Rosemary extract)**

Repeal the item, substitute:

392	Rosemary extract	(c) 40	Only sausage containing raw, unprocessed meat
		(d) 100	Only dried sausages

**[9] Subsection S15—5 (table, numbered heading “20.2.06 Starch based snacks (from root and tuber vegetables, legumes and pulses)”)**

Repeal the numbered heading, substitute:

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

**[10] At the end of the Schedule**

Insert:

**S15—6                      Rosemary extract used as food additive – maximum permitted level in final foods**

- (1) A class of food listed in the table to this section has the same meaning as in the table to section S15—5.
- (2) For section 1.3.1—7 and section 1.3.1—8, the table to this section is:

**Rosemary extract used as a food additive – maximum permitted levels**

<i>Class of food</i>	<i>MPL (mg/kg)</i>	<i>Conditions</i>
Breads and bakery products	10	Not for Biscuits cakes and pastries. Not for Breadcrumbs
Biscuits cakes and pastries	40	

<b>Class of food</b>	<b>MPL (mg/kg)</b>	<b>Conditions</b>
Breadcrumbs	40	
Cheese and cheese products	10	
Edible oils essentially free of water	50	Use of the colouring is not permitted in olive oil. See Note
Fermented fruit and vegetable products	10	
Fermented, uncooked processed comminuted meat products	40	
Grain bars, breakfast bars and breakfast cereals	50	
Processed cereal and meal products	10	Not for Grain bars, breakfast bars and breakfast cereals
Processed comminuted meat, poultry and game products (other than products listed in item 8.3.2)	10	Not for Fermented, uncooked processed comminuted meat products
Processed meat, poultry and game products in whole cuts or pieces	15	For meat with <10% fat. Not for dried sausages
	37.5	For meat with >10% fat. Not for dried sausages
Sauces and toppings (including mayonnaises and salad dressings)	50	
Sausage and sausage meat containing raw, unprocessed meat)	40	Only raw sausage. Use of the colouring is not permitted. See Note
	100	Only dried sausage. Use of the colouring is not permitted. See Note
Soup bases (the maximum permitted levels apply to soup made up as directed)	10	
Vegetable protein products	40	Use of the colouring is not permitted. See Note

**Note** A reference to 'the colouring' is a reference to a colouring in which rosemary extract has been \*used as a food additive in accordance with Standard 1.3.1 and item 0.2 of the table to section S15—5. See section 1.3.1—8