

**17 November 2023**  
**270-23**

## **Call for submissions – Application A1254**

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

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

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made by emailing your submission to [submissions@foodstandards.gov.au](mailto:submissions@foodstandards.gov.au). FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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

### **DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 15 December 2023**

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

Questions about making a submission or application and proposal processes can be sent to [standards.management@foodstandards.gov.au](mailto:standards.management@foodstandards.gov.au).

Submissions in hard copy may be sent to the following addresses:

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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

## 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 an antioxidant (a food additive) in a number of different foods. The applicant also requested maximum permitted levels (MPLs) in relation to rosemary extract for each food. 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 in general 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.

Based on the safety and dietary exposure assessments conducted by FSANZ, 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 use to the requested foods/food classes and to the food classes the applicant suggested could contain added flavourings and colourings that use rosemary extract as an antioxidant.

FSANZ has therefore prepared a draft variation to the Code. The draft variation, if approved, would extend the permission to use rosemary extract as a food additive to the following foods:

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

FSANZ seeks submissions on the draft variation (Attachment A).

# 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 application is to amend the Australia New Zealand Food Standards Code (the Code) to extend permissions to use rosemary extract as an antioxidant (food additive) to the following additional foods:

- colourings
- flavourings
- 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) in relation to rosemary extract that each food could contain<sup>1</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 various foods up to specific MPLs, but not the foods requested for permission in 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.

Schedule 14 lists the permitted technological purposes of food additives. The table in section

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<sup>1</sup>Paragraph 1.3.1—4(6)(k) of the Code specifies that rosemary extract is calculated as the sum of carnosic acid and carnosol. References to MPLs of rosemary extract in this report therefore mean the sum of carnosic acid and carnosol.

S14—2 provides that use as an antioxidant is a permitted 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 food additives to be declared in the statement of ingredients by 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); otherwise, by referring to the name of the food additive as indicated in Schedule 8.

## **1.4 International requirements**

### **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>2</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>3</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 (see table 1 in the application): European Union, Brazil, Central America, China, Eurasian Union, Indonesia, Mexico, Singapore, Taiwan, Vietnam and Japan.

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).

In Japan, rosemary extract is listed in the Japanese Existing Additives List<sup>4</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 is being assessed under the General Procedure in the FSANZ Act.

## **2 Summary of the assessment**

### **2.1 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 in general 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.

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<sup>2</sup> Codex Alimentarius General Standards for Food Additives. [Food Additives DB \(GSFA Online\) | CODEXALIMENTARIUS FAO-WHO](#)

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

<sup>4</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)

## 2.2 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 acceptable daily intake (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. There is a lack of 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, requested permissions, MPLs and Usual Use Levels. 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 mainly due to 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 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 assessment as part of a tiered 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>5</sup> database as a whole for each year from 2018 to 2022 was ≤ 4% and ≤ 8% for Australia and New Zealand, respectively.

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 use to the requested foods/food classes and to the food classes the applicant suggested could include flavourings and colourings containing rosemary.

## 2.3 Risk management

The risk management options available to FSANZ after assessment were to either:

- reject the application, or
- prepare a draft variation of the Code.

For the reasons listed in this report, FSANZ decided to prepare a draft variation to the Code (Attachment A) extending 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

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<sup>5</sup> [Mintel - A Global Market Intelligence & Research Agency](#)

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.

If approved, the additional permissions would be subject to MPLs for rosemary extract, calculated as the sum of carnosic acid and carnosol, that may be present in the foods.

The specific risk management considerations for this application are discussed below.

### 2.3.1 Regulatory approval

The conclusions from the risk and technical assessment were that rosemary extract functions as an antioxidant in food and there were no safety concerns associated with its proposed use up to the requested MPLs, apart from the exceptions described below.

Although the amounts of rosemary extract used to achieve a technological function in the experimental studies provided were not always able to be compared with the proposed MPLs, FSANZ considers that the food industry would only use rosemary extract where they believe it will be of benefit. On that basis and because no safety concerns were identified, FSANZ is proposing to permit the extension of use of rosemary extract as a food additive as requested, with exceptions to the applicant's request as outlined in sections 2.3.1.1 and 2.3.1.2.

#### 2.3.1.1 Preparations of food additives that are colourings and flavourings

The applicant requested permission for rosemary extract to be used as a food additive in colourings and flavourings as outlined in Table 1. Colourings and flavourings are themselves used as food additives. Such food additive preparations sometimes require the use of food additives for technological reasons.

**Table 1: Request for permission to use rosemary extract in colourings and flavourings**

Class number and description (Schedule 15)	Proposed MPL mg/kg*	Comments
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 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).

Based on the risk assessment, FSANZ is proposing to permit rosemary extract to be used as a food additive in colourings and flavourings up to an MPL of 1000 mg per kg. Additionally, FSANZ is proposing to provide a permission to use colourings and/or flavouring in which rosemary extract has been used as a food additive in the following food classes (noting that the draft variation would not permit the use of a colouring containing rosemary extract as a food additive in a class of food<sup>6</sup> that does not otherwise have a permission to add colourings):

<sup>6</sup> the class names are consistent with the terminology used in Schedule 15

- Biscuits, cakes, and pastries products
- Breads and bakery products
- Processed cereal and meal products
- Vegetable protein products
- Edible oils
- Soup bases
- Sauces and toppings
- Cheese and cheese products
- Processed meat, poultry and game products in whole cuts of pieces
- Processed comminuted meat, poultry and game products
- Fermented fruit and vegetable products

In addition, FSANZ is proposing that a food for sale that falls within one of above food classes must not contain more than a set maximum amount of rosemary extract that has been \*used as a food additive in accordance with Standard 1.3.1 and Schedule S15. That is, rosemary extract that has been used as a permitted food additive in any food.

For this purpose, the proposed table to section S15—6 lists the MPL for each food class. For example, that table lists a MPL of 10 mg rosemary extract per kg of a food for sale that falls within the food class *breads and bakery products* (excluding breadcrumbs, biscuits, cakes and pastries). On the other hand, the table lists a MPL of 40 mg rosemary extract per kg of a food for sale that falls within the food class of *biscuits, cakes and pastries*. This will mean that a cake may contain up to 40 mg per kg of rosemary extract that has been used as a permitted food additive in the ingredients or components of that food (e.g., rosemary extract used as a food additive to manufacture a flavouring, a colouring, margarine, icing or frosting, a nut butter or spread, salt, processed nuts etc that was in turn used to manufacture that cake), whereas a bread may contain up to 10 mg per kg of rosemary extract that has been used as a permitted food additive in the manufacture of any of the foods that were used to make that bread.

### **2.3.1.2 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 has decided not to permit the use of rosemary extract as a food additive in raw ground poultry (unprocessed). This will 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.

### **2.3.1.3 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 they fitted under class 7 – Bread and bakery products in Schedule 15.

FSANZ is proposing to 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 is proposing to list permission to use rosemary extract as a food additive in tortillas under that class number and description.

#### **2.3.1.4 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, as proposed, would need to comply with (refer to Section 1.2.2 above).

#### **2.3.2 Labelling requirements**

The labelling requirements that apply to the existing permitted uses of rosemary extract, as outlined below, will also apply to the proposed 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). Note that '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 for display of 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 Risk communication**

### **2.4.1 Consultation**

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

The process by which FSANZ approaches standards development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on the draft variation.

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

### **2.4.2 World Trade Organization (WTO)**

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO Members where proposed mandatory regulatory measures are not substantially the same as existing international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards (see Section 1.4 above), however amending the Code to extend current permissions in Australia and New Zealand for the use of rosemary extract as a food additive to additional foods is unlikely to have a significant effect on international trade as use of rosemary extract is voluntary; the proposed amendment is a minor amendment to extend existing permissions; and permissions to use rosemary extract vary across different countries. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

## **2.5 FSANZ Act assessment requirements**

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

### **2.5.1 Section 29**

#### **2.5.1.1 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 application is approved. Under the new approach, FSANZ's assessment is that a RIS is not required for this application.

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 (paragraph 29 (2)(a)).

The purpose of this consideration is to determine if the community, government and industry as a whole is likely to benefit, on balance, from a move from the status quo (where status quo is rejecting the application). This analysis considers permitting the use of rosemary extract as a food additive in additional foods.

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 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. However, information received from the call for submissions may result in FSANZ arriving at a different outcome.

##### *2.5.1.1.1 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.

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

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

#### **2.5.1.1.2 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 additional foods most likely outweigh the associated costs.

#### **2.5.1.2 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.

#### **2.5.1.3 Any relevant New Zealand standards**

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

#### **2.5.1.4 Any other relevant matters**

Other relevant matters are considered below.

### **2.5.2. Subsection 18(1)**

FSANZ has also 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 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 antioxidant as proposed in this report.

#### **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 are discussed in Sections 1.3.3 and 2.3.2 of this report.

#### **2.5.2.3 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 2.3.1.2 of this report. There were no other issues identified with this application relevant to this objective.

### **2.5.3 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**

There are relevant international specifications with which rosemary extract would have to comply with if added to foods as proposed in this report, as referenced in Section 1.3.2 above.

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

If the draft variation is approved, it 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 would remain competitive with other international markets. This would also help foster continued innovation and improvements in food manufacturing techniques and processes.

Ultimately, the domestic food industry 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 Forum on Food Regulation**

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 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.

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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>

### **3 Draft variation**

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

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

### **4 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

### **Attachments**

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

## Attachment A – 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 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
-----	------------------	-------	---------------------

##### [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
-----	------------------	-------	---------------------

##### [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	
-----	------------------	----	--

##### [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 | (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  |

**[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 |
|-----|------------------|----|

**[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 | (a) 40  | Only sausage containing raw, unprocessed meat |
|     |                  | (b) 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	
Breadcrumbs	40	

<b><i>Class of food</i></b>	<b><i>MPL (mg/kg)</i></b>	<b><i>Conditions</i></b>
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

# Attachment B Draft Explanatory Statement

## DRAFT 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 sought 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 prepared a draft variation - the *Food Standards (Application A1254 – Rosemary Extract as a Food Additive – extension of use) Variation*.

#### **2. Variation will be a legislative instrument**

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

If approved, this instrument would not be 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 Food Ministers Meeting (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 prepared a draft variation amending Standard 1.3.1 and Schedule 15 of the Code to extend the permitted use of rosemary extract as a food additive.

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

The 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 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 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 be open for a 5-week 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 FSANZ that a Regulatory Impact Statement 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 application is approved. Under the new approach, FSANZ's assessment is that a regulatory impact statement is not required for this application.

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

If approved, this instrument would be exempt from the requirements for a statement of compatibility with human rights as it would be 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*.

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.

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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)

## 7.1 Item [1]

**Item [1]** of the Schedule to the draft variation would amend Standard 1.3.1 – Food additives by inserting the following two new sections at the end of the Standard:

### *New section 1.3.1—7*

New section 1.3.1—7 provides that 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 that is within a class of food listed in the new table to section S15—6 at a level greater than the maximum permitted level (MPL) indicated in that table for that food. “In accordance with this Standard” means in accordance with any provision of Standard 1.3.1, and covers any use of rosemary extract as a food additive permitted by Standard 1.3.1 (including the use as a food additive directly, as well as the use of a colouring or flavouring food additive preparation containing rosemary extract).

Section 1.3.1—7 itself would not provide the permission to use rosemary extract as a food additive. Rather, the section would place a restriction on the permitted use of rosemary extract by setting a maximum permitted level. The rosemary extract used as a food additive in accordance with the permissions provided in the Standard could not be present in a food within a class listed in Column 1 of the table to section S15—6, in an amount that exceeds the stated MPL in column 2 of the table.

### *New section 1.3.1—8*

New section 1.3.1—8 would provide permission for the following substances to be used as a food additive:

- 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; and
- a flavouring in which rosemary extract has been used as a food additive in accordance with Standard 1.3.1 and item 0.3 of the table to section S15—5.

The section would provide two criteria for the relevant flavouring or the relevant colouring’s use as a food additive:

- (i) the colouring or flavouring may only be used in a food within a food class listed in column 1 of the table to section S15—6; and
- (ii) the colouring or flavouring must comply with any conditions listed in column 3 of the table to section S15—6.

Subsection 1.3.1—8(2) would make it clear that the above two criteria apply “despite sections 1.3.1—3 and 1.3.1—4”. That is, even where sections 1.3.1—3 or 1.3.1—4 would otherwise permit the use of a colouring or flavouring as a food additive, if that colouring or flavouring is covered by subsection 1.3.1—8(1), the criteria provided in 1.3.1—8(2) will apply to restrict its use.

## 7.2 Items [2] – [8]

**Items [2] to [8]** of the Schedule to the draft variation would make the following amendments in the table to section S15—5 in Schedule 15 – Substances that may be used as food additives. In each item, the relevant MPL for rosemary extract is calculated as the sum of carnosic acid and carnosol (expressed in mg/kg) (see paragraph 1.3.1—4(6)(k)).

**Item [2]** would insert a new item into the table to subsection S15—5, after the table item dealing with Ethanol under the heading ‘0.2 Colourings’. The new table item consists of:

‘392	Rosemary extract	1 000	See section 1.3.1—8’
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The effect of this amendment would be to permit rosemary extract (INS number 392) to be used as a food additive in colourings up to an MPL of 1000 mg/kg and in accordance with proposed new section 1.3.1—8 (see item [1] above).

**Item [3]** would insert a new item into the table to subsection S15—5, after the table item dealing with Butylated hydroxyanisole under the heading ‘0.3 Flavourings’. The new table item consists of:

‘392	Rosemary extract	1 000	See section 1.3.1—8’
------	------------------	-------	----------------------

The effect of this amendment would be to permit rosemary extract (INS number 392) to be used as a food additive in flavourings up to an MPL of 1000 mg/kg and in accordance with proposed new section 1.3.1—8 (see item [1] above).

**Item [4]** would repeal 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 substitute 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 would be 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.

Currently, in this class of food—rosemary extract is permitted to be used as a food additive only in fish oils and algal oils, up to an MPL of 50 mg/kg.

**Item [5]** would repeal 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 substitute 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 would be to:

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

**Item [6]** would insert 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:

'7.1.2 392	<b>Breadcrumbs</b> Rosemary extract	40'
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The effect of this amendment would be to permit rosemary extract (INS number 392) to be used as a food additive in a class of food identified as 'Breadcrumbs' at an MPL of 40 mg/kg.

**Item [7]** would insert 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'
------	------------------	-----

The effect of this amendment would be 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 [8]** would repeal 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 substitute 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 would be 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.

**7.3 Item [9]**

Item [9] would remove the numbered heading for class '20.2.06 *Starch based snacks (from root and tuber vegetables, legumes and pulses)*' and replace it with a new numbered heading. The effect of the amendment would be to correct an error in the subheading by changing the heading number from 20.2.06 to 20.2.0.6 and italicising '*Starch based snacks (from root and tuber vegetables, legumes and pulses)*'.

**7.4 Item [10]**

Item [10] would insert a new section S15—6 at the end of Schedule 15 for the purposes of new sections 1.3.1—7 and 1.3.1—8 (see item [1] above).

Subsection S15—6(1) provides that a class of food listed in the table to this section has the same meaning as in the table to section S15—5.

Subsection S15—6(2) sets out the table to this section.

The table to section S15—6 is headed ‘Rosemary extract used as a food additive – maximum permitted levels’ and has three columns:

Column 1 lists the classes of food in which a colouring or flavouring for which rosemary extract has been used as a food additive (in accordance with subsection 1.3.1—8(1)) may be used as a food additive.

Column 2 provides the corresponding MPLs (mg/kg) for each class or subclass of food for the purpose of section 1.3.1—7. The MPL would be the *total* amount of rosemary extract permitted to be present in the food for sale, irrespective of how the rosemary extract was added to the food i.e. its use in the food as a food additive in its own right; and/or its use as a food additive in colourings or flavourings, which have then been added to the food.

Column 3 sets out any associated conditions of use for particular classes of food for the purpose of paragraph 1.3.1—8(2)(b). These conditions provide further restrictions on the use of a relevant colouring or flavouring as a food additive in the corresponding food class.

A Note would be provided below the table for clarity. It would state that a reference in the table 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. It would also point the reader to section 1.3.1—8 (which provides the permission for the relevant colouring to be used as a food additive in particular classes of food and subject to particular conditions of use).

There are 9 conditions of use specified in column 3 of the table:

The first condition would apply to the food class 7 ‘Breads and bakery products’. This condition states “Not for Biscuits cakes and pastries. Not for breadcrumbs”. This condition would make it clear that the prescribed MPL for food class 7 would not apply to the food subclasses 7.2 Biscuits, cakes and pastries; and 7.1.2 Breadcrumbs. This is because the listed food subclasses have been assigned a different MPL in the table rows below.

The second condition would apply to the food class ‘Edible oils essentially free of water’. This condition states that use of the colouring is not permitted in olive oil. See Note. This condition would make it clear that 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 would not be not permitted to be used in olive oil.

The third condition would apply to the food class 6.3 ‘Processed cereal and meal products’, This condition states “Not for Grain bars, breakfast bars and breakfast cereals”. This condition would make it clear that the prescribed MPL for food class 6.3 would not apply to grain bars, breakfast bars and breakfast cereals. This is because the foods listed have been assigned a different MPL as per the table row above.

The fourth condition would apply to the food class 8.3 ‘Processed comminuted meat, poultry and game products (other than products listed in item 8.3.2)’. This condition states “Not for Fermented, uncooked processed comminuted meat products”. This condition would make it clear that the prescribed MPL for food class 8.3 would not apply to the food subclass 8.3.1 Fermented, uncooked processed comminuted meat products. This is because the food subclass has been assigned a different MPL in the table.

The fifth and sixth conditions would apply to the food class 8.2 ‘Processed meat, poultry and game products in whole cuts or pieces’. The fifth condition states “For meat with <10% fat. Not for dried sausages.” The sixth condition states “For meat with >10% fat. Not for dried

sausages.” These conditions would have the effect of assigning one MPL to foods within the food class 8.2 that have less than 10% fat; and a different MPL to foods within 8.2 that have more than 10% fat. The conditions also make it clear that these MPLs do not apply to dried sausages. A separate MPL would be assigned to dried sausage in a subsequent row of the table.

The seventh and eighth conditions would apply to the food class 8.3.2 ‘Sausage and sausage meat containing raw, unprocessed meat’. The seventh condition states “Only raw sausage. Use of the colouring is not permitted. See Note.” The eighth condition states “Only dried sausage. Use of the colouring is not permitted. See Note.” These conditions have the effect of assigning one MPL to raw sausage and a different MPL to dried sausage. They also make it clear that raw sausage and dried sausage are the only foods within class 8.3.2 that are permitted to contain a substance described in subsection 1.3.1—8(1). Additionally, 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 would not be permitted to be used food class 8.3.2.

The ninth condition would apply to the food class 12.6 ‘Vegetable protein products’. This condition states “Use of the colouring is not permitted. See Note”. This condition would make it clear that 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 would not be permitted to be used in vegetable protein products.