FOOD STANDARDS Australia New Zealand
Te Mana Kounga Kai – Ahitereiria me Aotearoa

17 November 2023
270-23

Supporting document

Risk and technical assessment – Application A1254

Rosemary extract as a food additive – extension of use

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 extend the permission to use rosemary extract as an antioxidant (a food additive) to a number of different foods. The applicant also requested the maximum permitted levels (MPLs) of rosemary extract that each food could contain.

Rosemary extract is already permitted in the Code for use as a food additive in certain foods up to specified MPLs that may be present in each food. There are relevant identity and purity specifications for rosemary extract in the Code.

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.

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed rosemary extract at their 82nd 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, applying a date cut-off 18 months before the finalization of A1158, to determine if any new publications exist that would justify setting an ADI less than 0 – 0.3 mg/kg bw. It was concluded that there is a lack of recent evidence that would justify decreasing the ADI from the temporary ADI set by JECFA at its 82nd meeting.

Dietary exposure assessments were undertaken for a number of scenarios that included current permissions, requested permissions, MPLs and Usual Use Levels. Dietary exposures were estimated for both Australian and New Zealand population groups. The ADI was exceeded (110% and 150%) only in two scenarios in the New Zealand population aged 5-14 years, and only for the 90th 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 are 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 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.

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 categories and to the food categories the applicant suggested could include flavourings and colourings containing rosemary extract.

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1 Introduction

Kalsec Inc. (Kalsec) applied to Food Standards Australia New Zealand (FSANZ) to amend the Australia New Zealand Food Standards Code (the Code) to extend the use of rosemary extract as an antioxidant (a food additive) to a number of different foods. Kalsec also requested the maximum permitted levels (MPLs) of rosemary extract that each food could contain. See Table A1 in the Appendix for the foods and MPLs.

Rosemary extract is already permitted for use as a food additive in the Code in a variety of foods at specified MPLs (see Table A1 in the Appendix). These permissions were incorporated into the Code in 2019 following assessment by FSANZ of Application A1158 – Rosemary extract as a food additive[1].

The objectives of this risk and technical assessment were to:

- determine whether rosemary extract performs the technological purpose of an antioxidant in the amounts and foods proposed for its use
- evaluate potential public health and safety concerns that may arise from the use of rosemary extract in the proposed amounts and foods.

2 Food technology assessment

A technical assessment of rosemary extract and its use as a food additive/antioxidant was undertaken by FSANZ during the assessment of A1158. The identity, chemical properties, manufacturing process, product stability, specifications and analytical method for detection are provided in detail in section 2 of the supporting document for A1158[1]. That information is therefore not repeated here, however a summary of the key factors relevant to this application is provided below.

Rosemary extract is derived from the dried leaves of the *Rosemarinus officinalis L.* plant. The extract is a mixture of tannins, polyphenols, polysaccharides, triterpenic acids, volatiles, phenolic diterpenes, in particular carnosol and carnosic acid, as well as some protein matter and lipophilic substances (WHO 2017).

Rosemary extracts are isolated by ethanol or acetone extraction of the dried leaves of the rosemary plant. The resultant liquid is then processed to ultimately produce a dry powder which is diluted by adding excipients and carriers to standardise the active components carnosol and carnosic acid content at the appropriate concentration (WHO 2017).

Rosemary extract is insoluble in water but soluble in oil and can be sold as a liquid in vegetable oil or other compatible carriers.

INS[2] number 392 has been assigned for rosemary extract by the Codex Committee on Food Additives (CCFA).

Section 1.1.1—15 requires certain substances, when added to food in accordance with the Code or sold for use in food, including substances used as food additives, to comply with any relevant identity and purity specifications listed in Schedule 3. Subsection S3—2(1) of Schedule 3 incorporates by reference the specifications listed in the:

[1] A1158 – Rosemary extract as a food additive (foodstandards.gov.au)
[2] International Numbering System for food additives

- 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 (13th edition)
- Commission Regulation (EU) No 231/2012.

These all include specifications for rosemary extract.

Paragraph 1.3.1—4(6)(k) specifies that 'in this Standard' rosemary extract is calculated as the sum of carnosic acid and carnosol. The Food chemicals codex and the JECFA specifications provided for rosemary extract include a method of analysis for carnosic acid and carnosol.

2.1 Technological purpose

The applicant is seeking approval to amend Schedule 15 to extend the permissions for use of rosemary extract as a food additive to additional foods. The applicant states that rosemary extract would be used as an antioxidant. As defined in Schedule 14 of the Code, antioxidants retard or prevent the oxidative deterioration of a food.

The antioxidant properties of rosemary extract are well reported in the scientific literature (for example, Carrocho et al 2018, Koncsek et al 2019, Richheimer et al, 1996; Damodaran et al 2008). The main components of rosemary extract that impart the antioxidative properties are two phenolic diterpenes called carnosol and carnosic acid. These components were evaluated in the technical assessment for A1158 and details of their identities and structures were provided in Table 2.1 of the Supporting Document for A1158 – Rosemary extract as a food additive[3].

A range of studies and scientific literature provided by the applicant demonstrated the efficacy of rosemary extract as an antioxidant in a variety of foods (see Table 2 in the application). The studies covered most but not all of the individual foods requested in the application. For example, the evidence for colouring and flavouring preparations was limited to use of rosemary extract in paprika and paprika oleoresin.

A number of the studies reported the use of rosemary extract as a percentage, ppm or mg/kg but did not report the carnosol or carnosic acid content. As the MPL is required to be measured as the sum of carnosol and carnosic acid, the amounts used in the studies were not always directly comparable with the MPLs requested by the applicant for the use of rosemary extract as a food additive. In those instances the effectiveness of rosemary extract as an antioxidant up to the requested MPL in the foods in those studies was not able to be determined.

[3] Available at A1158 – Rosemary extract as a food additive (foodstandards.gov.au)

2.2 Conclusion

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 the addition of rosemary extract requested by the applicant were not comparable with the amounts used in the studies in all instances. In those instances the effectiveness of rosemary extract as an antioxidant up to the requested MPL in the foods in those studies was not able to be determined. 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 two phenolic diterpenes called carnosol and carnosic acid.

The use of rosemary extract containing carnosol and carnosic acid for use as a food additive in certain foods is already permitted in the Code.

There are relevant identity and purity specifications for rosemary extract in the Code.

3 Safety assessment

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) assessed rosemary extract at their 82nd meeting and published their conclusions in 2017 (WHO 2017). JECFA established a temporary acceptable daily intake (ADI) of 0 - 0.3 mg/kg bw for rosemary extract, expressed as the sum of carnosic acid and carnosol. FSANZ assessed the safety of rosemary extract as a food additive in A1158 in 2018 and found no new evidence to suggest that the temporary ADI set by JECFA was not protective of human health and safety.

As part of the current assessment, FSANZ has conducted a literature search of PubMed, using the search term 'rosemary extract' and applying a date cut-off eighteen months before the finalisation of A1158, to determine if any new publications exist that would justify setting an ADI less than 0 – 0.3 mg/kg bw. The following studies were identified based on their abstracts as being of possible relevance.

- Guo et al (2018) reported antidepressant and anti-inflammatory effects of rosemary extract in mice gavaged daily for 21 days with 100 mg rosemary extract/kg bw. The extract contained 60% carnosic acid, but the carnosol content was not specified. As a result, the dose administered cannot be accurately compared to the JECFA ADI.
- A review of the properties of rosemary extract by Nieto et al (2018) was not found to be relevant because it did not include review of adverse effects.
- Von Schonfeld et al (2018) found that rosemary extract had immunosuppressant effects *in vitro,* inhibiting proliferation of human lymphocytes and CD4+ T-cells in a dose-dependent manner through induction of apoptosis. Further experiments using components of rosemary extract including rosmanol, carnosolic acid, carnosol and trans-caffeic acid showed that the effect was attributable to trans-caffeic acid. FSANZ notes that immunosuppressant effects of rosemary extract have not been demonstrated in living mammals.
- In a review article, Ghasemzadeh Rahbardar and Hosseinzadeh (2020) cited evidence that rosemary, rosemary extract and some isolated components have beneficial effects including anti-inflammatory, analgesic and anxiolytic effects, as well as improvement of memory. When doses used in animal studies were stated, they were not expressed in terms of carnosic acid and carnosol and cannot be accurately compared to the temporary ADI.
- Araki et al (2020) reported positive effects on mood and sleep quality in men taking 1 g/day of a supplement containing 6% w/w rosemary extract for 4 weeks. No adverse effects were reported. The composition of the extract was likely to be different to that of rosemary extract that is the subject of this assessment, because the extraction was made using hot water rather than ethanol or acetone.
- A limited bacterial reverse mutation assay (Ames test) of rosemary extract, using only *Salmonella enterica* var. Typhimurium strains TA98 and TA100, was conducted by Christopoulou et al (2021), and produced negative results. The same authors found that rosemary extract had moderate to high antibacterial effects against *Escherichia coli*, *Staphylococcus aureus and Salmonella* spp, as well as inhibiting the growth of colonies of the fungus *Aspergillus niger.* The extract also had antiviral activity against Adenovirus 35 and exhibited antioxidant activity.
- A review of the properties of rosemary by Veenstra and Johnson (2021) included some brief details of rodent studies, all of which preceded either A1158, or the JECFA assessment.
- Veenstra et al (2021) reported the results of their investigations of the pharmacokinetics of carnosic acid and carnosol in mice, and the beneficial effects of rosemary extract on a murine model of colitis. The dose of rosemary extract administered to the mice was 100 mg/kg bw, but the levels of carnosic acid and carnosol were not specified. No adverse effects were reported.

- The use of rosemary extract in pigs was investigated by Yang et al (2021). The extract was added to feed at up to 400 mg/kg feed for 21 days. The supplementation resulted in positive effects on growth performance, nutrient digestibility, antioxidant capacity, intestinal morphology, and gastrointestinal microbiota. Supplementation with 400 mg/kg feed did not show any increased positive effect compared to supplementation with 200 mg/feed. Comparison of the doses used in this study to the JECFA ADI is confounded by the absence of an appropriate conversion factor for weanling piglets with a mean weight of 6.65 kg. JECFA specifies conversion factors for pigs weighing either 60 kg or 80 kg, but not for small piglets (WHO 2016).
- Elwardany et al 2022 reported a positive effect of growth rate in New Zealand White rabbits fed rosemary leaves at 0.5% of the diet for 49 days. It is not possible to quantify the dose in terms of carnosic acid and carnosol, in order to compare it to the ADI, because it is not clear whether the rosemary leaves were dry or fresh when added to the feed, or what effect pelleting the feed, which generally involves steaming, may have had on the carnosic acid or carnosol content.
- Gonçalves et al (2022) conducted a systematic review of *in vitro* and animal studies concerning the anti-inflammatory effects of rosemary and some of its constituents, including carnosic acid, rosmarinic acid, and carnosol. No adverse effects were reported.
- Dietary supplementation of dairy cows with 28 g/day rosemary extract for 74 days was associated with slight but statistically significant increases in milk production and milk lactose content in a study by Kong et al (2022). Alterations in ruminal microbiota were also observed. No adverse effects were reported. The extract was a methanolic extract, which would be expected to be similar to an ethanolic extract. The relevance of the findings to monogastric species, including humans, is uncertain.
- Yilmaz et al (2022) used a methanolic extract of rosemary in a seven-day study in normal female Wistar rats, and female Wistar rats in which ulcerative colitis had been induced by administration of trinitrobenzene sulfonic acid *per rectum*. The rosemary extract was administered by daily oral gavage at a dose of 120 mg. Rats weighed between 200 and 300 g, and the highest dose used was therefore approximately 600 mg/kg bw/day. Treatment with the extract had significant beneficial effects on ulcerative colitis but had adverse effects on the histopathology of liver and kidneys. Histopathological findings in the liver included congestion, sinusoidal dilation and minimal vacuolization, while kidney sections showed vacuolization, tubular degeneration, congestion, and glomerulosclerosis.
- Rosemary extract was associated with adverse effects on the thymus of chick embryos (Alzahri et al 2023). However, the solvent used to prepare the rosemary extract was water, rather than ethanol or acetone, and the relevance of adverse effects in avian embryos to mammals is uncertain.
- Yao et al (2023) supplemented the diets of meat ducks with ethanolic extracts of rosemary for up to 42 days and reported improved growth performance and meat quality. No adverse effects of supplementation were reported. As for the study by Alzahri et al (2023), the significance of findings in avian species are of uncertain relevance to mammalian species.

The only study in which adverse effects of concern were noted was that of Yilmaz et al (2022), in which adverse effects in liver and kidneys were observed in rats dosed with up to 600 mg/kg bw/day rosemary extract, for seven days. Interpretation of this study is confounded by the lack of characterisation of the rosemary extract, which is not described in terms of the carnosic acid content or carnosol content. FSANZ notes that adverse effects on liver or kidneys at similar doses of rosemary extract have not been reported in other rodent studies reviewed by FSANZ or by JECFA (WHO 2017), which include unpublished 90-day studies reviewed by JECFA. For this reason, the adverse effects observed by Yilmaz et al (2022) are not considered to be representative of rosemary extract.

Overall, there is a lack of recent evidence that would justify decreasing the ADI from the temporary ADI of 0 to 0.3 mg/kg bw (expressed as the sum of carnosic acid and carnosol) set by JECFA at its 82nd meeting.

4 Dietary exposure assessment

4.1 Approach to estimating dietary exposure

Dietary exposure assessments require data on the concentrations of the chemical of interest in the foods requested, including any naturally-occurring sources and any current permission for additions to food and consumption data for the foods that have been collected through a national nutrition survey. JECFA set a temporary ADI of 0–0.3 mg/kg body weight for rosemary extract, expressed as carnosic acid plus carnosol (FAO/WHO, 2016). FSANZ has already set MPLs for rosemary extract for a range of food classes and expressed as carnosic acid plus carnosol (Table A1 in the Appendix). Accordingly the dietary exposures to carnosic acid plus carnosol were estimated in this assessment using (1) the Maximum Permitted Levels in the Code, (2) proposed Maximum Permitted Levels for the requested food classes, (3) Usual Use Levels for the permitted food classes (4) Usual Use Levels for the requested food classes and (5) naturally occurring concentrations in rosemary leaves, combined with food consumption data from the most recent Australian and New Zealand national nutrition surveys.

The dietary exposure assessments were undertaken using FSANZ's dietary modelling computer program Harvest[4]. A summary of the general FSANZ approach to conducting dietary exposure assessments is on the FSANZ website. A detailed discussion of the FSANZ methodology and approach to conducting dietary intake assessments is set out in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ, 2009).

4.2 Food consumption data used and population groups assessed

The food consumption data used for the dietary exposure assessments were:

- **2011-12 Australian National Nutrition and Physical Activity Survey (2011-12 NNPAS)**, one 24-hour food recall survey of 12,153 Australians aged 2 years and above, with a second 24-hour recall undertaken for 64% of respondents (ABS, 2015).
- **2008–09 New Zealand Adult Nutrition Survey (2008 NZ ANS),** one 24-hour recall of 4,721 New Zealanders aged 15 years and above, with a second 24-hour recall undertaken for 25% of respondents (MoH 2011a; MoH 2011b).
- **2002 New Zealand National Children's Nutrition Survey (2002 NZ CNS)**, one 24-hour food recall of 3,275 New Zealand school children aged 5-14 years, with 25% of respondents also completing a second 24-hour recall (MoH 2005).

The design of these nutrition surveys and the key attributes, including survey limitations, are set out on the FSANZ website.

In this assessment, dietary exposures were estimated for 'consumers only' (e.g. consumers of foods containing rosemary or rosemary extract). Nutrition survey respondents who had no consumption of these foods were not included in the results presented. All results were weighted to make them representative of the respective populations.

[4] Harvest is FSANZ's custom-built dietary modelling program that replaced the previous program, DIAMOND, which does the same calculations just using a different software program.

As an ADI is the relevant health based guidance value for rosemary extract, a chronic dietary exposure assessment was undertaken. For the chronic dietary exposure assessment, one day of food consumption data from both of the New Zealand surveys were used, whereas the average of two days of data from the 2011-12 NNPAS was used for Australia. Two day average consumption better reflect longer term estimates of consumption and therefore are a better estimate of the chronic dietary exposure.

4.3 Concentration of carnosic acid plus carnosol in foods

4.3.1 Naturally-occurring concentration of carnosic acid plus carnosol in foods

The concentration of carnosic acid plus carnosol in dried and fresh rosemary leaves used in the dietary exposure assessments were 21,500 mg/kg and 7,525 mg/kg, respectively as calculated and used in the A1158 dietary exposure assessment (DEA). The applicant confirmed that there is no updated naturally occurring concentration data since the A1158 DEA.

4.3.2 Current permissions for the use of rosemary extract as a food additive in foods in Australian and New Zealand

The food classes already permitted in the Code to contain rosemary extract (carnosic acid plus carnosol) as a food additive and relevant food classifications in Harvest are provided in Table A2 in the Appendix. The applicant provided required data to estimate potential Usual Use Levels for rosemary extract as a food additive for these food classes: 80% MPL in fats and oils and foods with high fat content (e.g. processed meat) and 50% MPL in other food classes. These concentrations are also listed in Table A2 in the Appendix. Dietary exposure to carnosic acid plus carnosol was calculated using both the MPLs and the Usual Use Levels separately.

4.3.3 Proposed concentrations of carnosic acid plus carnosol as an antioxidant in foods

The additional food categories requested in this application to contain rosemary extract (carnosic acid plus carnosol) as an antioxidant and their proposed MPLs are listed in Table A3 in the Appendix. The applicant provided potential Usual Use Levels for rosemary extract for these food categories (Table A3 in the Appendix). These additional food categories include flavourings and colourings. The applicant initially provided a list of major food categories that flavourings and colourings containing rosemary extract would be added to and the list covered a wide range of final foods. Following a request from FSANZ, for the purpose of dietary exposure refinement, the applicant provided a list of food classes based on Schedule 15 where flavourings and colourings containing rosemary extract would more likely be included as an ingredient, along with the proposed MPLs in final food and potential use levels in final food from this use (which are the same) (Table A4 in the Appendix). Dietary exposure to carnosic acid plus carnosol was calculated using both the proposed MPLs and the Usual Use Levels separately.

The food classification codes in Harvest can vary from the classes in Schedule 15 and may also be split into sub-groups. To assess the populations' dietary exposures to carnosic acid plus carnosol, the food classes permitted to and requested to contain rosemary extract were assigned to the relevant Harvest food classification codes. The concentration data on naturally-occurring carnosic acid plus carnosol in rosemary leaves were also assigned to the relevant Harvest food classification codes. Hence, the Harvest classifications used reflect the description of the foods permitted to contain rosemary extract and requested to contain rosemary extract , not exactly the food class numbers used in Schedule 15.

4.4 Scenarios assessed

A dietary exposure assessment to carnosic acid plus carnosol was conducted for five scenarios under three situations as outlined below:

1. **Naturally occurring sources:**

1a. *'Naturally-occurring'*: includes only dietary exposure to naturally occurring carnosic acid plus carnosol (i.e. from dried and fresh rosemary leaves only).

2. **Current permissions:** includes dietary exposure to carnosic acid plus carnosol through the foods/food classes currently permitted in the Code. The following two scenarios are the baseline scenarios for this application. This situation does not include naturally occurring sources of carnosic acid or carnosol.

2a. *'Added extract at Permitted-MPL'*: includes only the MPLs currently permitted in the Code (Table A2 in the Appendix), at 100% market penetration into each food class listed in Schedule 15.

2b. *'Added extract at Usual Use Level for Permitted foods'*: includes only the Usual Use Levels for the currently permitted foods (Table A2 in the Appendix), at 100% market penetration into each food class listed in Schedule 15.

3. **Combined exposure:** includes dietary exposure to carnosic acid plus carnosol through the foods/food classes currently permitted in the Code plus requested extensions of use. This situation does not include naturally occurring sources of carnosic acid or carnosol.

3a. *'Added extract at Permitted-MPL plus Added extract at Proposed-MPL':* this is the combination of dietary exposure to carnosic acid plus carnosol through the MPLs currently permitted in the Code (*'Added extract at Permitted-MPL')* and proposed MPLs for requested foods *('Added extract at Proposed-MPL')* scenarios, at 100% market penetration into each food class listed in Schedule 15.

3b. *'Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods':* this is the combination of dietary exposure to carnosic acid plus carnosol through the permitted foods at Usual Use Level (*'Added extract at Usual Use Level for Permitted foods')* and the requested foods at Usual Use Level *('Added extract at Usual Use Levels for Requested foods')* scenarios, at 100% market penetration into each food class listed in Schedule 15.

The scenarios 2a and 3a, that are based on MPLs (permitted or proposed) represent the most conservative approach. The estimated dietary exposures to carnosic acid plus carnosol from these scenarios are likely to overestimate dietary exposures for the Australian and New Zealand populations over a period of time. The scenarios 2b and 3b are based on the Usual Use Levels. These two scenarios reflect a more likely dietary exposure to carnosic acid plus carnosol for the Australian and New Zealand populations over a period of time.

4.5 Method used for calculating the estimated dietary exposures

Carnosic acid plus carnosol dietary exposures were calculated for each individual respondent in the national nutrition surveys using their individual food consumption records.

The Harvest program multiplied the specified concentrations of carnosic acid plus carnosol for an individual food by the amount of the food that an individual consumed in order to estimate the exposure to carnosic acid plus carnosol from each food. Once this had been completed for all of the foods specified to contain carnosic acid plus carnosol, the total amount of carnosic acid plus carnosol consumed from all foods was summed for each individual. Where results are expressed on a body weight basis, each individual's body weight was used. Mean and 90th percentile (P90) exposures were then derived from the individuals' ranked exposures. Estimated dietary exposures for the population on a body weight basis were compared to the ADI for risk characterisation purposes.

4.6 Assumptions and limitations

The aim of the dietary exposure assessment was to make the most realistic estimation of dietary exposures to carnosic acid plus carnosol as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the estimated dietary exposure was not an underestimate of exposure.

Assumptions made in the dietary exposure assessment included:

- Unless otherwise specified, all foods within a class/classification contain carnosic acid plus carnosol at the concentrations listed in Tables A2, A3 and A4 in the Appendix.
- Where a food was not included in the dietary exposure assessment, it was assumed to contain a zero concentration of carnosic acid plus carnosol.
- 100% market penetration of the use of rosemary extract into the food category markets was considered for the scenarios assessed. Market data and product details provided by the applicant were used for risk characterisation purposes.
- Where a concentration was assigned to a food, this concentration is carried over to any mixed dishes where it has been used as an ingredient to capture exposure from all sources of the food in the diet.
- Although '8.3.1 Fermented, uncooked, processed, comminuted meat products' class has been requested in the current application with a 40 mg/kg MPL, a higher MPL (100 mg/kg) was used for that class as it was already included under '8.3.2 Sausage and sausage meat containing raw, unprocessed meat (only dried sausages)' with a 100 mg/kg MPL for the A1158 DEA to represent the worst-case scenario.
- For colourings and flavourings MPLs/Usual Use Levels proposed on a final food basis were only used in the DEA.
- As the food classes suggested to contain flavourings and colourings are the same, the combined proposed MPL/Usual Use Level in final food (10 mg/kg) was used assuming every suggested food contains both flavourings and colourings (the worst-case). If any food class is already permitted to contain rosemary extract (e.g. 7.2 Biscuits, cakes, and pastries products) or requested to be permitted to contain rosemary extract (e.g. 2.1 Edible oils essentially free of water) with an MPL higher than that of combined flavouring and colouring uses (>10 mg/kg) the colouring/flavouring use was not used for those foods in those relevant scenarios; the higher MPL was used.
- There is no contribution to carnosic acid plus carnosol exposures through the use of complementary or other medicines.

In addition to the specific assumptions made in relation to this dietary exposure assessment, there are a number of limitations associated with the nutrition surveys from which the food consumption data used for the assessment are based. A discussion of these limitations is included in Section 6 of the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

4.7 Estimated dietary exposure to carnosic acid plus carnosol for the population groups assessed

The estimated mean and P90 dietary exposures to carnosic acid plus carnosol for the different scenarios are provided in the Table 1 for the three population groups assessed, expressed as mg/kg bw/day and % ADI. The estimated mean and P90 dietary exposures for the *Naturally-occurring* scenario for all three population groups assessed were similar to the *Naturally-occurring* scenario assessed for the A1158 DEA. Hence, the naturally occurring results are not presented in this assessment.

Table 1. Estimated dietary exposures to carnosic acid plus carnosol for different scenarios assessed for the Australian and New Zealand populations

Country and Age group	Scenario	% cons to resp.[t]	Estimated dietary exposure			
			mg/kg bw/day		% ADI	
			Mean	P90	Mean	P90
Australia- 2 years and above[v]	*Added extract at Permitted-MPL*	99	0.094	0.20	30	65
	Added extract at Usual Use Level for Permitted foods	99	0.049	0.10	15	35
	Added extract at Permitted-MPL plus Added extract at Proposed-MPL	100	0.13	0.25	45	85
	Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods	100	0.082	0.15	25	50
New Zealand- 5 – 14 years[s]	*Added extract at Permitted-MPL*	99	0.17	0.34	60	110
	Added extract at Usual Use Level for Permitted foods	99	0.092	0.18	30	60
	Added extract at Permitted-MPL plus Added extract at Proposed-MPL	100	0.25	0.45	80	150
	Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods	100	0.16	0.29	55	95
New Zealand-15 years and above[s]	*Added extract at Permitted-MPL*	97	0.082	0.17	25	55
	Added extract at Usual Use Level for Permitted foods	97	0.044	0.091	15	30
	Added extract at Permitted-MPL plus Added extract at Proposed-MPL	100	0.12	0.22	40	75
	Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods	100	0.077	0.14	25	45

♦ Consumers as a % of total respondents. A consumer is a respondent in the national nutrition survey who consumes a food containing carnosic acid plus carnosol. A respondent is anyone in a national nutrition survey, irrespective of whether they consume a food that contains carnosic acid plus carnosol or not.

❖ Based on consumption data from Day 1 and 2; dietary exposures averaged over the two days.

▽ Based on consumption data from Day 1 respondents only.

Values ≥ 0.3 mg/kg bw/day or ≥ 100% are shaded.

4.7.1 Australians aged 2 years and above

Current permissions

The estimated mean and P90 dietary exposures for the Australian population are 0.094 mg/kg bw/day and 0.20 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL'* scenario. For the '*Added extract at Usual Use Level for Permitted foods'* scenario the estimated mean and P90 dietary exposures are 0.049 mg/kg bw/day and 0.10 mg/kg bw/day respectively.

Combined exposures

The estimated mean and P90 dietary exposures for the Australian population are 0.13 mg/kg bw/day and 0.25 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL plus Added extract at Proposed-MPL*' scenario. For the '*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods'* scenario the estimated mean and P90 dietary exposures are 0.082 mg/kg bw/day and 0.15 mg/kg bw/day respectively.

4.7.2 New Zealanders aged 5-14 years

Current permissions

The estimated mean and P90 dietary exposures for New Zealanders 5-14 years are 0.17 mg/kg bw/day and 0.34 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL'* scenario. For the '*Added extract at Usual Use Level for Permitted foods'* scenario the estimated mean and P90 dietary exposures are 0.092 mg/kg bw/day and 0.18 mg/kg bw/day respectively.

Combined exposures

The estimated mean and P90 dietary exposures for New Zealanders 5-14 years are 0.25 mg/kg bw/day and 0.45 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL plus Added extract at Proposed-MPL*' scenario. For the '*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods'* scenario the estimated mean and P90 dietary exposures are 0.16 mg/kg bw/day and 0.29 mg/kg bw/day respectively.

4.7.3 New Zealanders aged 15 years and above

Current permissions

The estimated mean and P90 dietary exposures for New Zealanders aged 15 years and over are 0.082 mg/kg bw/day and 0.17 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL'* scenario. For the '*Added extract at Usual Use Level for Permitted foods'* scenario the estimated mean and P90 dietary exposures are 0.044 mg/kg bw/day and 0.091 mg/kg bw/day respectively.

Combined exposures

The estimated mean and P90 dietary exposures for New Zealanders aged 15 years and over are 0.12 mg/kg bw/day and 0.22 mg/kg bw/day respectively for the '*Added extract at Permitted-MPL plus Added extract at Proposed-MPL*' scenario. For the '*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods'* scenario the estimated mean and P90 dietary exposures are 0.077 mg/kg bw/day and

0.14 mg/kg bw/day respectively.

4.8 Major food contributors

Contribution of different food classifications to carnosic acid plus carnosol dietary exposure for the combined exposure scenarios (‘*Added extract at Permitted-MPL plus Added extract at Proposed-MPL’* and *‘Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods’*) for the Australian and New Zealand population groups assessed are provided in Table 5 in the Appendix. The major contributors to dietary exposures are considered as those that contribute ≥5% of the estimated dietary exposure. There are four food classifications that are major contributors for both scenarios and all three population groups assessed: 1) Breads & bakery products 11%-22%; 2) Biscuits, crackers, cakes, pastries & scones 12%-20%; 3) Grains, cereals & cereal products 5%-8% and 4) Gravy, sauces & condiments 13%-23%. There are three food classifications that are major contributors for at least one scenario and two population groups assessed: 1) Edible oils essentially free of water-5%-7%; 2) Breakfast biscuits & flakes-5%-7%; and 3) Processed meat, poultry, game products in whole cuts or pieces, higher fat-5%-6%.

5 Discussion and risk characterisation

The applicant 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 the addition of rosemary extract 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 use of rosemary extract containing carnosol and carnosic acid for use as a food additive in certain foods is already permitted in the Code. Specifically, rosemary extract performs the technological purpose of an antioxidant in foods.

There are relevant identity and purity specifications for rosemary extract in the Code.

JECFA assessed rosemary extract at their 82nd meeting and published their conclusions in 2017 (WHO 2017). JECFA established a temporary ADI of 0 – 0.3 mg/kg bw for rosemary extract, expressed as the sum of carnosic acid and carnosol. FSANZ assessed the safety of rosemary extract as a food additive in A1158 in 2018 and found no new evidence to suggest that the temporary ADI set by JECFA was not protective of human health and safety.

As part of the current assessment FSANZ conducted a literature search of PubMed, using the search term ‘rosemary extract’ and applying a date cut-off eighteen months before the finalisation of A1158, to determine if any new publications exist that would justify setting an ADI less than 0 – 0.3 mg/kg bw. Fifteen papers were reviewed. Only one paper reported adverse effects in mammals (rats) however the test article in this paper was not characterised with regard to carnosic acid and carnosol. The findings of the study were not consistent with those in rat studies previously reviewed by JECFA and/or FSANZ. It was concluded that overall, there is a lack of recent evidence that would justify decreasing the ADI from the temporary ADI of 0 to 0.3 mg/kg bw (expressed as the sum of carnosic acid and carnosol) set by JECFA at its 82nd meeting.

The dietary exposure assessments results showed that the highest mean and P90 estimated dietary exposures were for the New Zealand population aged 5-14 years across all of the scenarios assessed. P90 dietary exposure exceeded the ADI only for Permitted/Proposed MPL scenarios, ‘*Added extract at Permitted-MPL’* -110% and *‘Added extract at Permitted-*

MPL plus Added extract at Proposed-MPL'-150% for this population group. This is due to a number of reasons including assuming concentrations at the MPL in every food in every relevant food class. In addition it is because only children are included in this set of results as a result of nutrition survey design, the results of which are therefore less reflective of dietary exposures over a lifetime (as shown by Australian results for 2 years and above). The lower body weights for that age group in comparison to the other two population groups assessed tend to result in higher estimates of exposure per kilogram of body weight as does the typically higher food consumption per kilogram of body weight for children based due to growth and development. It is also because only one day of food consumption data are used to estimate dietary exposures for the New Zealand populations. Where dietary exposures are able to be averaged using two days of food consumption data or more, the tails of the exposure distribution are narrowed resulting in lower P90 dietary exposure values, as demonstrated with the results for Australia.

The estimated dietary exposures were substantially lower for the Usual Use Level scenarios ('*Added extract at Usual Use Level for Permitted foods'* and *'Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods')* compared to the Permitted/Proposed MPL scenarios. The dietary exposure estimates based on MPLs are highly conservative and are not likely to occur in reality as it is assumed that all foods within a class contain rosemary extract at the MPL, that all of the foods within the food classes requested to contain rosemary extract will use rosemary extract, and that consumers always eat the products containing rosemary extract at these concentrations over a lifetime. The Usual Use Level scenarios represent a more likely estimate of dietary exposures. The P90 dietary exposures for Usual Use Level scenarios, '*Added extract at Usual Use Level for Permitted foods'* and *'Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods'* were 60% and 95% of the ADI respectively for the New Zealand population aged 5-14 years. For the Australian population 2 years and above and the New Zealand population aged 15 years and above, the highest P90 exposures were 85% and 75% of the ADI respectively for the '*Added extract at Permitted-MPL plus Added extract at Proposed-MPL' scenario.*

According to the data provided by the applicant, the proportion of food products labelled as including rosemary extract as an ingredient out of the total number of food products in respective food categories in the Mintel[5] database as a whole for each year from 2018 to 2022 was ≤ 4% and ≤ 8% for Australia and New Zealand, respectively. However, the 100% market penetration was assumed in this dietary exposure assessment as a conservative approach as is usual of FSANZ's tiered approach. If dietary exposure assessments based on such conservative assumptions do not present a public health and safety risk, further more refined dietary exposure assessments are not required. Dietary exposure estimates would be substantially reduced if actual market penetration information was applied.

Estimated dietary exposures to carnosic acid plus carnosol from the naturally occurring sources (exposure from dried and fresh rosemary leaves) have not changed for the three population groups assessed since the A1158 DEA. The contribution of naturally occurring sources to overall carnosic acid plus carnosol exposure was also estimated in A1158 and concluded to be very little (<4% for the Usual Use Level scenarios and <2% for the MPL scenarios) (FSANZ 2018). In estimating dietary exposure to carnosic acid plus carnosol from the use of rosemary extract as an antioxidant, JECFA did not include exposure to carnosic acid plus carnosol through use of rosemary leaves as a culinary herb, because JECFA considered that any exposure from rosemary leaves was not likely to significantly alter the overall exposure (WHO, 2017). Naturally occurring sources were not included in the combined scenario for this application and based on the above information, this is not

[5] Mintel - A Global Market Intelligence & Research Agency

expected to have an impact on the estimates of dietary exposures or conclusions for this assessment.

The estimated dietary exposures to carnosic acid plus carnosol indicated that extending the use of rosemary extract as a food additive at the proposed maximum limits to the newly requested food categories and food classes that could include flavourings and colourings containing rosemary extract, is unlikely to pose a public health and safety risk for the Australian and New Zealand population groups assessed.

6 Conclusion

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 an antioxidant at the requested maximum limits. This includes an extension of use to the requested foods/food categories and to the food classes the applicant suggested could include flavourings and colourings containing rosemary extract.

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Appendix : Additional results and information related to the Dietary Exposure Assessment

Table A1: Details of the food classes currently permitted to contain rosemary extract as a food additive and new food categories requested to extend the use

Schedule 15		Current permission		New foods/food categories requested in the application	
Class number	**Description**	**Conditions**	**MPL***	**Comments and examples**	**Proposed MPL***
0.2	Colourings	No permission		Not to exceed 5 mg/kg in the final food	1000
0.3	Flavourings			Not to exceed 5 mg/kg in the final food	1000
2.1	Edible oils essentially free of water	Only fish oils and algal oils	50	Fats and oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils.	50
2.2.1.3	Margarine and similar products	Nil	75	No amendments requested	
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	Only nut butters and nut spreads	50		
5.4	Icings and frostings	Nil	20		
6.3	Processed cereal and meal products	Only grain bars, breakfast bars and breakfast cereals	50		
6.4	Flour products (including noodles and pasta)	Only for flour based snacks e.g. pretzels, fritters, and crackers; Not for noodles and pasta	10	Addition of Noodles and pasta (only precooked or instant noodles with oil added, such as ramen, chow mein, wonton and other similar styles)	10
7	Bread and bakery products	See 7.2 below		Breadcrumbs[#]	40
				Tortillas (wheat or corn)	40
7.2	Biscuits, cakes and pastries	Nil	40	No amendments requested	
8.2	Processed meat, poultry and game products in whole cuts or pieces	(a) For meat with <10% fat; Not for dried sausages	15		

		(b) For meat with >10% fat; Not for dried sausages	37.5		
8.2.3	Dried meat	Nil	150		
8.1	Raw meat, poultry and game	Nil	N/A	Ground poultry[$]	40
8.3.1	Fermented, uncooked processed comminuted meat products	No permission		N/A	40
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	Only dried sausage	100	Raw meat sausages	40
12	Salts and condiments	Not for condiment sauces e.g. ketchup, Mayonnaise, mustard, and relishes	40	No amendments requested	
20.2	Food other than beverages	Only processed nuts	50		
20.2.0.4	Sauces and toppings (including mayonnaises and salad dressings)	Nil	50		
20.2.06	Starch based snacks (from root and tuber vegetables, legumes and pulses)	Nil	20		

*Maximum Permitted Level of Rosemary Extract, expressed as carnosic acid plus carnosol (mg/kg).
Nil-no conditions.
[#] The applicant originally requested both bread crumbs and bread coatings but later advised FSANZ to remove the request for bread coatings.
[$]The applicant originally requested ground poultry under class 8.3 Processed comminuted meat, poultry and game products, other than products listed in item 8.3.2, but later agreed it fitted better under 8.1 – raw meat, poultry and game.

Table A2: Concentrations of carnosic acid plus carnosol (mg/kg) used in the dietary exposure assessment for the permitted food classes in Schedule 15

Schedule 15				Harvest			
Class number	**Description**	**MPL[#]**	**Conditions**	**Classification code**	**Classification name**	**MPL used**	**Usual Use Level used**
2.1	Edible oils essentially free of water	50	Only fish oils and algal oils	50.1	Fish oils	50	40
2.2.1.3	Margarine and similar products	75		2.2.1.3	Margarine & similar products	75	60
4.3.4	Fruit and vegetable spreads including jams, chutneys and related products	50	Only nut butters and nut spreads	4.3.6.3	Nut butter	50	25
5.4	Icings and frostings	20		5.4	Icings & frostings	20	10
6.3	Processed cereal and meal products	50	Only grain bars, breakfast bars and breakfast cereals	6.3.1	Puffed &/or extruded cereals	50	25
				6.3.2	Breakfast biscuits & flakes	50	25
				6.3.4	Breakfast cereals, unspecified form	50	25
				20.2.2	Grains, cereals & cereal products	50	25
6.4	Flour products (including noodles and pasta)	10	Only for flour based snacks e.g. pretzels, fritters, and crackers; Not for noodles and pasta	20.2.4.2.2.2	Grain based snacks	10	5
				20.2.4.4.6.1	Snack food, savoury, pretzels, fritters	10	5
				20.2.4.4.4	Snack food, savoury, cracker-based	10	5
7.2	Biscuits, cakes and pastries	40		7.2	Biscuits, crackers, cakes, pastries & scones	40	20
8.2	Processed meat, poultry and game products in whole cuts or pieces	15	For meat with <10% fat; Not for dried sausages	8.2.0.1	Processed meat, poultry, game products in whole cuts or pieces, lower fat	15	7.5

		37.5	For meat with >10% fat; Not for dried sausages	8.2.0.2	Processed meat, poultry, game products in whole cuts or pieces, higher fat	37.5	30*
8.2.3	Dried meat	150		8.2.3	Dried meat	150	120*
				8.2.4	Slow dried cured meat	150	120*
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	100	Only dried sausages	8.3.1	Fermented, uncooked, processed, comminuted meat products	100	80*
12	Salts and condiments	40	Not for condiment sauces e.g. ketchup, Mayonnaise, mustard, and relishes.	12.1	Salt & salt substitutes	40	20
				12.3	Vinegars & related products	40	20
				12.5	Yeast & yeast products	40	20
20.2	Food other than beverages	50	Only processed nuts	4.1.1.2.1	Untreated fruits & vegies, nuts, salted/flavoured	50	25
				4.1.1.2.2.1	Processed nuts	50	25
				4.1.1.2.3	Untreated fruits and vegetables, nuts, unspecified as to unsalted/salted	50	25
20.2.0.4	Sauces and toppings (including mayonnaises and salad dressings)	50		20.2.6.1	Sauces & syrups, sweet	50	25
				20.2.6.2	Gravy, sauces & condiments	50	25
				20.2.7	Mayonnaise & salad dressings	50	25
				4.3.7.2	Soy sauce	50	25
20.2.06	Starch based snacks (from root and tuber vegetables, legumes and pulses)	20		20.2.4.4.1	Snack food, savoury, potato crisps	20	10
				20.2.4.4.6.2	Snack food, savoury, other, starch based	20	10

[#]Maximum Permitted Level of Rosemary Extract, expressed as carnosic acid plus carnosol (mg/kg).
*80% of MPL assuming high fat content (50% MPL was used in A1158 DEA).

Table A3: Concentrations of carnosic acid plus carnosol (mg/kg) proposed and used in the dietary exposure assessment for the requested food categories in the application

Category No.	Description	Proposed MPL	Proposed Usual Use Level	Comments/Examples	Harvest			
					Classification code	Classification name	MPL used	Usual Use Level used
0.2	Colouring[#]	1000	500	Not to exceed 5 mg/kg in the final food	Not applicable	Not applicable	Not applicable	Not applicable
0.3	Flavourings[#]	1000	500	Not to exceed 5 mg/kg in the final food	Not applicable	Not applicable	Not applicable	Not applicable
2.1	Edible oils essentially free of water	50	40	Fats and oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	2.1	Edible oils essentially free of water	50	40
6.4	Flour products (including noodles and pasta)	10	8[$]	Addition of noodles and pasta (only precooked or instant noodles with oil added, such as ramen, chow mein, wonton and other similar styles)	6.4.1.1.1	Noodles and pasta, precooked or instant	10	8[$]
7	Bread and bakery products	40	20	Breadcrumbs, tortillas (wheat or corn)	7.1.1.3.1	Breadcrumbs	40	20
					7.1.1.3.2	Tortillas, wheat or corn based	40	20
8.1	Raw meat, poultry and game	40	32*	Ground poultry	8.1.1.1.1	Poultry, ground or minced	40	32*
8.3.1	Fermented, uncooked processed comminuted meat products	40	32*		8.3.1	Fermented, uncooked, processed, comminuted meat products	100[^]	80*
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	40	30*	Add: raw meat sausages	8.3.2.1	Sausage containing raw, unprocessed meat	40	30*

[#]Concentration in the final food was used for DEA. See table A4 for details. [$]80% of MPL assuming rosemary extract is added to the oil used for cooking the noodles and pasta. *80% of MPL assuming high fat content. [^]The MPL used for the A1158 DEA was used to represent the worst-case scenario.

Table A4: Food classes that are suggested to contain flavouring and/or colourings and concentrations of carnosic acid plus carnosol used for the dietary exposure assessment (mg/kg in final food)

Food Groups (initially requested by the applicant)	Food classes as per Schedule 15 (provided later by the applicant)		Harvest			
	Class number	Description	Classification code	Classification name	MPL used	Usual Use Level used
Baked goods	7.2	Biscuits, cakes, and pastries products	7.2*	Biscuits, crackers, cakes, pastries & scones	10	10
Bread crumbs	7	Breads and bakery products	7	Breads & bakery products	10	10
Cereal and snacks	6.3	Processed cereal and meal products	6.3	Processed cereal & meal products	10	10
Meat alternatives	12.6	Vegetable protein products	12.6	Vegetable protein products	10	10
Fats & Oils	2.1	Edible oils essentially free of water	2.1**	Edible oils essentially free of water	10	10
Soup, sauces and dressings	20.2.0.5	Soup bases	20.2.8	Soups	10	10
	20.2.0.4	Sauces and toppings	20.2.6.1*	Sauces & syrups, sweet	10	10
			20.2.6.2*	Gravy, sauces & condiments	10	10
			20.2.7*	Mayonnaise & salad dressings	10	10
			4.3.7.2*	Soy sauce	10	10
Processed Cheese	1.6	Cheese and cheese products	1.6	Cheese & cheese products	10	10
Prepared meals	6.2	Flours, meals and starches	6.2	Flours, meals & starches	10	10
Processed meats	8.2	Processed meat, poultry and game products in whole cuts of pieces	8.2	Processed meat/poultry/game products in whole/cut pieces	10	10
	8.3	Processed comminuted meat, poultry and game products	8.3	Processed comminuted meat, poultry & game products	10	10
Pickles	4.3.7	Fermented fruit and vegetable products	4.3.7	Fermented fruit & vegetable products	10	10
Marinades/brine	20.2.0.4	Sauces and toppings	20.2.6.1*	Sauces & syrups, sweet	10	10
			20.2.6.2*	Gravy, sauces & condiments	10	10
			20.2.7*	Mayonnaise & salad dressings	10	10
			4.3.7.2*	Soy sauce	10	10

*Included in the food classes currently permitted with higher MPLs (>10 mg/kg in final food).
**Included in the food classes requested to extend the use with higher MPLs (>10 mg/kg in final food).
Note: MPL/Usual Use Level at 10 mg/kg in final food was used for all food classifications for the DEA as the food class list is the same for both flavourings and colourings.

Table A5: Major food contributors (≥ 5%) to estimated dietary exposures to Carnosic acid plus Carnosol, for the combined scenarios for the Australian and New Zealand population groups

Harvest classification code	Harvest classification name	Contribution %					
		Australia- 2 years and above[v]		New Zealand- 5 – 14 years[s]		New Zealand-15 years and above[s]	
		Added extract at Permitted-MPL plus Added extract at Proposed-MPL	*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods*	*Added extract at Permitted-MPL plus Added extract at Proposed-MPL*	*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods*	*Added extract at Permitted-MPL plus Added extract at Proposed-MPL*	*Added extract at Usual Use Level for Permitted foods plus Added extract at Usual Use Level for Requested foods*
1.6	Cheese & cheese products	3	4	2	3	2	3
2.1	Edible oils essentially free of water	5	7	3	4	5	6
2.2.1.3	Margarine & similar products	<1	<1	<1	<1	0	0
4.1.1.2.1	Untreated fruits & vegies, nuts, salted/flavoured	1	1	<1	<1	1	1
4.1.1.2.2.1	Processed nuts	0	0	<1	<1	<1	<1
4.1.1.2.3	Untreated fruits and vegetables, nuts, unspecified as to unsalted/salted	<1	<1	<1	<1	<1	<1
4.3.6.3	Nut butter	1	<1	1	1	1	<1
4.3.7	Fermented fruit & vegetable products	<1	<1	<1	<1	<1	<1
4.3.7.2	Soy sauce	1	1	<1	<1	<1	<1
5.4	Icings & frostings	<1	<1	1	<1	<1	<1
6.2	Flours, meals & starches	1	2	1	1	1	1
6.3.1	Puffed &/or extruded cereals	2	2	4	3	1	1
6.3.2	Breakfast biscuits & flakes	5	4	7	6	4	3
6.3.4	Breakfast cereals, unspecified form	<1	<1	<1	<1	<1	<1
6.4.1.1.1	Noodles and pasta, precooked or instant	2	2	2	3	3	4
7	Breads & bakery products	11	18	14	22	13	19

7.1.1.3.1	Breadcrumbs	3	3	2	2	2	2
7.1.1.3.2	Tortillas, wheat or corn based	1	1	<1	<1	1	<1
7.2	Biscuits, crackers, cakes, pastries & scones	15	12	20	15	15	12
8.1.1.1.1	Poultry, ground or minced	<1	1	1	1	1	1
8.2.0.1	Processed meat, poultry, game products in whole cuts or pieces, lower fat	1	1	1	1	1	1
8.2.0.2	Processed meat, poultry, game products in whole cuts or pieces, higher fat	4	5	3	4	5	6
8.2.3	Dried meat	<1	<1	<1	<1	<1	<1
8.2.4	Slow dried cured meat	<1	<1	2	2	2	3
8.3	Processed comminuted meat, poultry & game products	2	3	2	3	2	3
8.3.1	Fermented, uncooked, processed, comminuted meat products	2	2	1	1	1	1
8.3.2.1	Sausage containing raw, unprocessed meat	<1	<1	3	3	1	1
12.1	Salt & salt substitutes	<1	<1	1	<1	1	1
12.3	Vinegars & related products	1	<1	<1	<1	<1	<1
12.5	Yeast & yeast products	<1	<1	<1	<1	<1	<1
12.6	Vegetable protein products	<1	<1	<1	<1	<1	<1
20.2.2	Grains, cereals & cereal products	8	6	6	5	7	5
20.2.4.2.2.2	Grain based snacks	<1	<1	1	1	<1	<1
20.2.4.4.1	Snack food, savoury, potato crisps	1	1	2	1	1	1
20.2.4.4.6.1	Snack food, savoury, pretzels, fritters	<1	<1	<1	<1	<1	<1
20.2.4.4.6.2	Snack food, savoury, other, starch based	<1	<1	<1	<1	<1	<1
20.2.6.1	Sauces & syrups, sweet	1	1	1	1	1	1
20.2.6.2	Gravy, sauces & condiments	23	18	17	13	22	17
20.2.7	Mayonnaise & salad dressings	2	1	1	1	2	2
20.2.8	Soups	2	3	1	1	1	2
50.1	Fish oils	0	0	<1	<1	0	0

❖ Based on consumption data from Day 1 and 2.
▽ Based on consumption data from Day 1 respondents only.
Values ≥ 5% are shaded.