Application to Extend the Uses of Rosemary Extract (E392) under the Australia and New Zealand Food Standard Code as a Food Additive

Contents

Executive Summary

In 2018, Rosemary extract (INS 392) was approved by FSANZ s a food additive (antioxidant) for a range of food classes (A1158). The purpose of this application is to extend the uses of rosemary extract as an antioxidant to additional food categories and thus proposes amendments to the following Schedule:

- Schedule 15: Substances that may be used as food additives

Rosemary extracts are derived from Rosmarinus officinalis L. and contain several compounds which have been shown to exert antioxidative functions. Although the entire rosemary (*Rosmarinus officinalis* L.) plant, excluding the woody portions, may be used, it is normally only the leaves, that are commonly used as a culinary herb, flavouring agent and naturally occurring antioxidant. Rosemary extracts are increasingly employed not only to provide flavour but also as natural alternatives to synthetic antioxidants for the stabilisation of oxygen-sensitive foods. The antioxidative function is due to several components in the rosemary extracts, which belong mainly to the classes of phenolic acids, flavonoid diterpenoids and triterpenes

The antioxidative function of rosemary extracts helps to stabilise product formulations thus providing longer shelf-life. Rosemary extracts are naturally derived extracts and thus provide a benefit to consumers seeking more ‘natural’ ingredients in their food products.

Rosemary extract is approved as a food additive in several regions / countries including the EU, Japan, China, Vietnam, Brazil, and Singapore.

The application includes information and data that is new or been updated since the original application A1158 was approved in 2018 including updated safety information

3.1.1 General Requirements

B Applicant Details

(a) Applicant:

KALSEC®, INC.,

(b) Name of Contact Person:

[redacted]

(c) Address:

[redacted]

(d) Telephone Number

[redacted]

(e) Email Address

[redacted]

(f) Nature of Applicants Business

Kalsec® is a supplier of a full line of natural, innovative products and solutions to meet the challenges faced by food and beverage manufacturers throughout the industry and around the world. Their products derived from natural herbs, spices, vegetables, and hops.

(g) Details of other Individuals, Companies or Organisations associated with the Application

The following Scientific and Regulatory Consultant is involved in the preparation, submission, and stewardship of this application:

[redacted]

C Purpose of the Application

The applicant applies to FSANZ to extend the uses of Rosemary Extract (E392) as a food additive (antioxidant) in the FSANZ Food Standards Code. Amendments to the following Schedules of the Food Standards Code are sought:

- Schedule 15: Substances that may be used as food additives

D Justification for the Application

Rosemary extracts are derived from Rosmarinus officinalis L. and contain several compounds which have been shown to exert antioxidative functions. Although the entire rosemary (*Rosmarinus officinalis* L.) plant, excluding the woody portions, may be used, it is normally only the leaves, that are commonly used as a culinary herb, flavouring agent, and naturally occurring antioxidant. Rosemary extracts are increasingly employed not only to provide flavour but also as natural alternatives to synthetic antioxidants for the stabilisation of oxidatively-sensitive foods. The antioxidative function is due to several components in the rosemary extracts, which belong mainly to the classes of phenolic acids, flavonoid diterpenoids and triterpenes

The antioxidative function of Rosemary extracts helps to stabilise product formulations thus providing longer shelf-life. Rosemary extracts are naturally derived extracts and thus provide a benefit to consumers seeking more ‘natural’ ingredients in their food products.

Rosemary extract is currently approved as an antioxidant for use in a selected group of food categories. However, the antioxidant effect of rosemary extract can also benefit other food categories. Thus, the purpose of this application to extend the uses of rosemary extract currently approved.

D.1 Regulatory Impact Information

D.1.1 Costs and Benefits of the Application

(a) Cost and Benefits to the Consumer

Rosemary extracts are derived from Rosmarinus officinalis L. and contain several compounds which have been proven to exert antioxidative functions. Rosemary extracts are naturally derived extracts and thus provide a benefit to consumers seeking more ‘natural’ ingredients in their food products. It is anticipated that rosemary extracts would replace other currently used antioxidants and thus is not anticipated to have any cost impact on the consumer.

(b) Costs and Benefits to Industry

Rosemary extracts are derived from Rosmarinus officinalis L. and contain several compounds which have been proven to exert antioxidative functions. Rosemary extracts are naturally derived extracts and thus offer an alternative to industry who wish to provide g more ‘natural’ ingredients in their food products. Industry would only use rosemary extract where it provides a net benefit to them. It is anticipated that rosemary extracts would replace other currently used antioxidants and thus is not anticipated to have any cost impact on the industry.

(c) Cost and Benefits to Government

It is not anticipated that the availability of rosemary extract would have any cost impact on Government.

D.1.2 Impact on International Trade

Rosemary extracts are currently approved in a number of countries for the addition to food products. Allowing the use of rosemary extract in a broader range of food categories in Australia and New Zealand would enhance international trade by allowing import and export of products containing rosemary extract. Expanding the uses of rosemary extract would enhance international trade with countries / regions that allow rosemary extract in broader range of products.

E Information to Support the Application

E.1 Data Requirements

Please note, rosemary extract was thoroughly evaluated by FSANZ in 2018 under application A1158. Only data relevant to the new uses or new safety data is presented in this dossier.

E.1.1 Data related to safety Studies

Safety of rosemary extract has been previously evaluated by FSANZ under application A1158. Since rosemary extract was approved in 2018 there have been some additional safety studies reported in the literature. These additional studies are presented section 3.11 **B Information related to the safety of the food additive**

E.1.2 Data related to surveys on chemicals and other substances in food

Please refer to section 3.11 **A. Technical Information on the Food Additive**

E.1.3 Data related to epidemiological / intervention studies in human

Please refer to section 3.11 **C Information Related to the Dietary Exposure of the Food Additive**

F Assessment Procedure

The applicant considers the most appropriate assessment procedure for the application herein relating to the extension of use of a food additive to be General Procedure, Level 2.

G Confidential Commercial Information (CCI)

Not applicable

H Other Confidential Information

Not applicable

I Exclusive Capturable Commercial Benefit (ECCB)

There is no exclusive capturable commercial benefit to the applicant.

J International and Other National Standards

J.1 International Standards

Following the Twenty-third Session of the Codex Committee on Fats and Oils (CCFO) in 2013 (FAO/WHO, 2013a), CCFO decided to refer to Codex Committee on Food Additives (CCFA) its intention to include “rosemary extract” as an antioxidant in the standard for fish oils, noting that it had not yet been included in the General Standard for Food Additives (GSFA). At the Forty-fifth Session of CCFA in 2013 (FAO/WHO, 2013b), it was concluded that although rosemary extract had been assigned an INS number (392), it had not yet been evaluated by Joint FAO/WHO Expert Committee on Food Additives (JECFA). The Committee evaluated rosemary extract at the 82nd meeting at the request of CCFA.

The Committee concluded that there are sufficient data to establish an acceptable daily intake (ADI) for rosemary extract prepared according to the specifications established at this meeting. The Committee established a temporary ADI of 0–0.3 mg/kg bw for rosemary extract, expressed as carnosic acid plus carnosol, on the basis of a NOAEL of 64 mg/kg bw per day, expressed as carnosic acid plus carnosol, the highest dose tested in a short-term toxicity study in rats, with application of a 200-fold uncertainty factor. The overall uncertainty factor of 200 incorporates a factor of 2 to account for the temporary designation of the ADI. The Committee made the ADI temporary pending the submission of studies to elucidate the potential developmental and reproductive toxicity of the rosemary extract under consideration. An additional uncertainty factor to account for the lack of a chronic toxicity study was not considered necessary based on the absence of adverse effects in the short-term toxicity studies at doses up to and including the highest dose tested. The temporary ADI applies to rosemary extract that meets the specifications prepared at the present meeting. The temporary ADI will be withdrawn if the required data are not provided by the end of 2018.

The Committee noted that the dietary exposure estimates for rosemary extract for high consumers in the European and USA populations of 0.09–0.81 mg/kg bw per day (expressed as carnosic acid plus carnosol) may exceed the upper bound of the temporary ADI by up to 2.7-fold (for young children at the top end of the range of estimated dietary exposures). Based on the conservative nature of the dietary exposure assessments, in which it was assumed that all foods contained rosemary extracts at the maximum use level, the Committee concluded that this exceedance of the temporary ADI does not necessarily represent a safety concern. The Committee requested that data on typical use levels in foods be provided by the end of 2018 in order to refine the dietary exposure estimates.

The data from these studies were submitted to FSANZ during the evaluation of A1158. These studies were also submitted to JECFA in 2018. JECFA then requested additional studies on developmental toxicity to complete the evaluation. JECFA requested a deadline of data submission by December 2021 for the additional data, or its ADI will be withdrawn.

In response to JECFA’s request for additional information for the evaluation of rosemary extract, the manufacturers of rosemary extract and data providers are in the process of addressing the identified data gaps. The requested studies were expected to be available at the end of 2021 or beginning of 2022. However, because of additional delays, based on current timelines, the studies are scheduled to be completed in the first quarter of 2022, with the audited draft reports expected by June 2022. It was therefore requested for an extension to submit the requested data to JECFA be end 2022 and that the temporary ADI as established at the 87th meeting be extended until the evaluation of rosemary extract following provision of the requested data to the Committee.

The applicant, however, does not believe that waiting for these additional studies should hold up the progression of this application on consideration of the OECD 421 study (Phipps et al., 2021a) results and additional analysis discussed above in section B.1 Additional Safety Studies Published in the Literature. The applicant is willing to provide the data for the additional studies to FSANZ to review when available.

J.2 Other National Standards or Regulations

Rosemary extract is permitted in a number of regions / countries internationally. These include the EU, Brazil, Central America, China, Eurasian Union, Indonesia, Mexico, Singapore, Taiwan, Vietnam and Japan. **Table 1** provides a list of international permissions / uses for rosemary extract and maximum permitted use levels.

Table 1: Rosemary Extract - International Permissions

Food Category	Food Name	Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
		FSANZ	**EU**	**Brazil**	**Central America**	**China**	**Eurasian Union**	**Indonesia**	**Mexico**	**Singapore**	**Taiwan**	**Vietnam**	**Japan****
0	Preparations of Food Additives (flavourings)		1000 (5mg/kg in final product										
0.2	Colourings		1000 (5mg/kg in final product										
1.5	Dried milk for manufacturing of ice cream		30				30				30*		
1.5	Milk powder for vending machines		200*										
2	Vegetable oils and fats					700			50*				
2.1	Vegetable oils (except for the olive oil) designated for frying)						50*						
2.1	Vegetable oils (excluding virgin oils and olive oils) and fat where content of polyunsaturated fatty acids is higher than 15% w/w of the total fatty acid, for the use in non-heat-treated foods products.		30*	300			30*			50	50*		
2.1	Only fish oil and algal oil	50	50*	500						50			
2.1	Lard, beef, poultry, sheep and porcine fat		50*			300	50*			50			
2.1	Frying oils for the professional manufacture of heat-treated foods		50*				50*						

Food Category	Food Name	Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
		FSANZ	EU	Brazil	Central America	China	Eurasian Union	Indonesia	Mexico	Singapore	Taiwan	Vietnam	Japan**
2.1.2	Vegetable oils and fats							50					
2.21	Emulsions containing 80% or more fat					700							
2.2.1.3	Margarine and similar products Other fat and oil emulsions including spreads - only spreadable fats with a fat content less than 80%	75	100*						75*		100*	100	
2.3	Vegetable oil pan spray - only fats and oils for the professional manufacture of heat-treated foods		50*								50*		
4.2.2.2	Fruit and vegetable preparations excluding compote - only seaweed-based fish roe analogues		200								200		
4.2.5.4	Nut butters and nut spreads	50	200*							200*	200*		
4.2.6	Dehydrated potato products		200				200				200		
4.3.4	Jellies, jams and purees								100				
5.3	Chewing gum		200				200				200		
5.4	Only sauces	50	100*										
5.4	Icing and frostings	20							20*				
6.3	Processed cereal and meal products - only grain bars, breakfast bars, breakfast cereals	50					50*		50*				

		Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
Food Category	**Food Name**	**FSANZ**	**EU**	**Brazil**	**Central America**	**China**	**Eurasian Union**	**Indonesia**	**Mexico**	**Singapore**	**Taiwan**	**Vietnam**	**Japan****
6.4	Flour products - only flour-based snacks e.g. pretzels, fritters and crackers; not for noodles	10											
6.4	Fried flour products					300							
6.4.5	Fillings stuffed dry pasta (ravioli and similar)		250*								250*		
7.1.2	Crackers, excluding sweet crackers												
7.2	Fine bakery wares (e.g. biscuits, cakes, pastries)	40	200*		200		200*		50*		200*		
8	Meat products with a fat content not greater than 10% excluding salami								15*				
8	Salami								100*				
8.2	Processed meat products					300							
8.2	Processed meat, poultry and game products, fat content <10%	15						100					
8.2	Processed meat, poultry and game products, fat content >10%	37.5						100					
8.2.3	Dried meat	150					150						
8.3.1	Non-heat-treated meat products - only dried sausages		100				100			100	100*		

		Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
Food Category	**Food Name**	**FSANZ**	**EU**	**Brazil**	**Central America**	**China**	**Eurasian Union**	**Indonesia**	**Mexico**	**Singapore**	**Taiwan**	**Vietnam**	**Japan****
8.3.1	Non-heat-treated meat products - only meat with fat content <10%, excluding dried sausages		15							15*	15*		
8.3.1	Non-heat-treated meat products - only meat with fat content >10%, excluding dried sausages	37.5	150*							150*	150*		
8.3.1	Non-heat-treated meat products - only dehydrated meat	150	150							150			
8.3.1	Fermented meat product					300							
8.3.2	Heat treated meat products					300							
8.3.2	Heat treated meat products - only meat with fat content <10%, excluding dried sausages		15							15*	15*		
8.3.2	Heat treated meat products - only meat with fat content >10%, excluding dried sausages	37.5	150*							150*	150*		
8.3.2	Heat treated meat products - only dried sausages	100	100			300	100			100	100*		
8.3.2	Heat treated meat products - only dehydrated meat	150	150							150			
	Meat and fish products (except for dried meat and dried sausage)						150*						

		Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
Food Category	Food Name	FSANZ	EU	Brazil	Central America	China	Eurasian Union	Indonesia	Mexico	Singapore	Taiwan	Vietnam	Japan**
9.2	Processed fish and fishery products including molluscs and crustaceans - only fish and fishery products including molluscs and crustaceans with a fat content <10%		15								15*		
9.2	Processed fish and fishery products including molluscs and crustaceans - only fish and fishery products including molluscs and crustaceans with a fat content >10%		150*								150*		
10.2	Processed eggs and egg products		200				200				200*		
12.0	Salts and condiments (not for sauces)	40							75*				
12.2.2	Seasoning and condiments		200*		200	300	200*				200*		
12.4	Mustard		100*										
12.5	Soups and broths		50		50		50				50		
12.6	Sauces	50	100*		100					100*	200*	100	
13.4.2	Liquid formulated supplementary sports foods - plant protein RTD beverages					150							
15.1	Potato, cereal, flour or starch-based snacks	20	50*		50		50*		120*	50*	50*		
15.2	Processed nuts	50	200*		200	300	200*			200*	200*		
15.3	Fish-based snacks												

		Maximum Permitted Level of Rosemary Extract (expressed as carnosic acid plus carnosol) (mg/kg)											
Food Category	**Food Name**	**FSANZ**	**EU**	**Brazil**	**Central America**	**China**	**Eurasian Union**	**Indonesia**	**Mexico**	**Singapore**	**Taiwan**	**Vietnam**	**Japan****
16.06	Puffed food					300							
17.1	Food supplements supplied in a solid form, excluding food supplements for infants and young children		400								400		
17.2	Food supplements supplied in a liquid form, excluding food supplements for infants and young children		400								400		
20.2.04	Sauces and toppings (including mayonnaises and salad dressings)					300	100*		75*				

*Expressed on fat basis

**Rosemary extract permitted in all foods at GMP in Japan

K Statutory Declaration

See Appendix 1.

L Checklist

See Appendix 2.

3.3.1 Food Additives

A. Technical Information on the Food Additive

A.1 Nature and Technological Purpose of the Additive:

Rosemary extract is intended for use as an antioxidant in various food and beverage applications. Extracts of the rosemary plant can have both flavouring and antioxidative properties, but of late are becoming popular as antioxidant alternatives for the stabilisation of oxygen-sensitive foods. In many cases both functions are utilised within a food; however, extracts can be optimised and marketed primarily for their antioxidant properties.

Efficacy as an Antioxidant:

Rosemary extract has significant antioxidative activity, mainly contributed from two key antioxidant components belonging to the classes of phenolic acids, flavonoids, diterpenoids and triterpenes, namely, carnosol and carnosic acid. Carnosol and carnosic acid, are phenolic diterpenes, that are responsible for the main antioxidant activity of rosemary extract (Addis & Warner, 1991); (Richheimer, et al., 1996).

There have been several reviews of antioxidants and in particular of rosemary extract regarding their efficacy. A recent review (Carocho, et al., 2018) of food antioxidants looked at the different antioxidant groups, describing their properties, function and applicability, as well as indexing the relevant legislation in order to be a guide for academia and industry. This review concludes rosemary extract is a useful natural antioxidant. Another short overview of the use and effectiveness of rosemary extract is also present by Robbins et. al. (Robbins & Sewalt, 2005).

The efficacy of rosemary extract as an antioxidant was reviewed under application A1158. A1158 provided a number of studies elucidating the efficacy of rosemary extract as antioxidant for a number of different foods groups. **Table 2** below provides a summary of additional studies on the efficacy of rosemary extract in additional food groups. These studies show that rosemary extract is an effective antioxidant when added to a variety of different foods.

Table 2: Efficacy Studies

Author / Reference	Food Category	Dose	Conclusion
Permana et al 2021 (Review paper)	Fats and Oils for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Review paper – usage levels of rosemary extract range from 400 to 500mg/kg	Rosemary extract has the potential to improve oxidative stability in edible oils used for frying (>160°C),
Diaz-Sanchez et al 2019	Fats and Oils for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Rosemary extract 1000ppm Tetrabutylhydroquinone (TBHQ) 200ppm	The use of RE in palm olein for frying of wheat pellet snacks in an industrial continuous fryer showed slightly higher oxidative degradation, and similar hydrolytic degradation than TBHQ. The use of either antioxidant did not result in an increase in the shelf life of the fried product
Trujillo Agudelo et al 2019	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	0-2% rosemary extract	Rosemary extract incorporated into whey protein based-coating applied to potato chips before frying reduces acrylamide formation in the fried potato chips.
Saini et al 2019	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Rosemary extract 3%	Rosemary extract incorporation into fried chicken snacks improved physicochemical (TBARs, free fatty acid content and Tyrosine value), microbiological (Total plate count, Staphylococcus count and yeast and mould count) and sensory parameter (flavour, texture and overall acceptability) of the chicken snacks during 60 days storage
Li et al 2021	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	TBHQ, Carnosic acid, Rosmanic acid, and Rosemary extract at 0.2 g/kg	The quality and stability of frying oils with rosemary-based antioxidants showed higher efficiency than TBHQ regarding oxidation parameters (i.e., chemical indices, sensory, etc.), where rosmarinic acid (RA) was the most effective, followed by rosemary extracts (RE) and carnosic acid (CA
Wong et al 2019	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Rosemary extract 200ppm, compared with BHA, BHT, TBHQ and sage extract (all at 200ppm)	TBHQ and oleoresin rosemary showed significantly lower levels of 3-MCPD esters and GE. The order of effectiveness of the selected antioxidants in the frying oil and fried potato chips was BHT < BHA < sage extract < oleoresin rosemary < TBHQ.
Gashi et al 2020	Fats and Oils used for the professional manufacture	Rosemary extract 1000ppm	The addition of rosemary extract in sunflower oil effectively protect its triglyceride structure and level of unsaturation during thermal heating and

Author / Reference	Food Category	Dose	Conclusion
	of heat-treated foods or more specifically, industrial frying oils		increase its thermal stability. Performed FTIR spectroscopy has indicated the role of rosemary extract as a natural protective agent. Samples of sunflower oil with rosemary extract have shown improved thermal stability compared with pure sunflower oil.
Escobar de Carvalho et al 2019	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Four treatment groupss: lard (control), lard + 100 mg/kg TBHQ (L + TBHQ), lard + 100 mg kg-1rosemary extract (L + RE) and lard + 100 mg kg-1rosemary essential oil (L + REO	The treatments were submitted to thermoxidation at 180°C, where samples were taken off at intervals of 0, 5, 10, 15 and 20 hours. During the analysis of the thermoxidated lard, the rosemary essential oil showed results as favorable as those obtained by the antioxidant TBHQ, showing that the antioxidants from natural source can be a good alternative to synthetics ones
Yuan et al 2019	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils	Rosmarinic acid	In potato crisps, response surface methodology showed that frying temperature of 140.11 °C, frying time of 6.02 min and rosmarinic acid (RosA) concentration of 0.012 μm had the lowest acrylamide (AA) formation. In conclusion, RosA inhibited AA formation in both the model systems and potato crisps, and its application in food industry is well expected
Xu et al 2022	Fats and Oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils. Fried foods.	Rosemary extract at 0.2 g/kg	Compared with the control group, the optimum stage of soybean oil added with rosemary was prolonged by 25%.,
Rajeev et al 2017	Colouring and flavouring preparations	Rosemary extract containing 3%, 6% or 10% carnosic acid Rosemary extract was dosed at 3% (w/w) in paprika oleoresin	Rosemary extract improved the colour stability of paprika oleoresin (100,000 CU) plated on dry salt and in paprika-coloured raw meat relative to BHA.
Koncsek et al 2019	Colouring and flavouring preparations	Rosemary extract up to 0.25%	Rosemary extract supplementation (up to 0.25%) reduced the colour loss of dry paprika powder from 23%–36% to 14%–27% after a 12-month storage period.
De Guevara at al 2002	Colouring and flavouring preparations	Rosemary extract 1%	Rosemary extract and tocopherols had a clear protective effect on the colour stability of paprika stored at different temperatures and relative

Author / Reference	Food Category	Dose	Conclusion
			humidity.
De Guevara et al 2005	Colouring and flavouring preparations	Rosemary extract 1%	Rosemary extract at 1% added to heat-treated paprika increased colour stability significantly.
Deora et al 2016	Noodles and pasta	Commercial preparation of Rosemary extract = PRESOL PRESOL added to oil at 200 ppm. PRESOL contains1.7% carnosic acid	Rosemary extract added to palmolein oil used for deep fat frying of noodles inhibited palmolein oil degradation (as measured by total polar compounds and free fatty acids) to a greater extent than TBHQ and reduced oil consumption and colour development.
Whalin et al 2021	Fermented meat products and raw meat sausage.	Rosemary extract 200ppm (R) Rosemary extract 200ppm and phospholipase 400ppm mixture (R + P)	Rosemary extract and phospholipase offer an effective natural antioxidant in pork sausage and the antioxidant mechanism may be related to the suppression of neutral lipid hydroperoxides.
Zhou et al 2020	Fermented meat products and raw meat sausage	Rosemary extract concentration ranged from 0% to 0.5%	The effects of rosemary extract, grape seed extract (GSE) and green tea polyphenol (GTP) on the physicochemical properties and N-nitrosamines content of western style smoked sausage were investigated. Among the additives, GTP had the highest total phenol content (109.82 mg GAE/g DW) and the best scavenging capacity on ABTS (IC50 = 0.16 g/ml). Rosemary extract and GTP reduced the hardness of sausage ($p < .05$). Rosemary extract, GSE and GTP reduced the gumminess and chewiness of sausage ($p < .05$), but had little effects on the cohesiveness and springiness ($p > .05$). Rosemary extract increased the a* and b* values of sausage significantly ($p < .05$), GSE and GTP had little effects on color ($p > .05$). The additives all decreased the pH values, TBARs values of sausage ($p < .05$) and increased the moisture content in sausage ($p < .05$). The additives can significantly reduce the residual nitrite and N-nitrosamines content of western-style smoked sausage. GTP showed the best effect on TBARs (48.29%), residual nitrite (68.87%) and N-nitrosamines (61.29%). Above all, the additives had good antioxidant ability and could inhibit the formation of N-nitrosamines. Compared with other additives, GTP had the best effect.
Naveena et al 2013	Ground poultry	Carsonic acid 22.5ppm and 130ppm	Rosemary extracts added at 22.5 ppm carnosic acid phenols in ground buffalo and chicken patties significantly reduced oxidation in storage at 4oC for up to 9 days (raw) or 28 days (cooked).

Author / Reference	Food Category	Dose	Conclusion
Gao et al 2019	Ground poultry	Rosemary extract 1%,	Adding rosemary extract resulted in reduced microbial growth, lipid oxidation (LPO), and L* values and increased pH, a*, and b* values in both cold plasma (CP) treated and non-CP treated patties. Rosemary is a promising additive for maintaining microbial quality and controlling LPO in CP-processed meat

A.2 Information to Enable Identification of the Additive:

Information to enable the identification of rosemary extract, including the chemical structure, the chemical name, the molecular weight and formula, and the common name, was presented in A1158. No new information is available since A1158 was approved.

A.3 Information on the Chemical and Physical Properties of the Additive:

Information on the chemical and physical properties of rosemary extract was present in A1158. No new information is available since A1158 was approved.

A.4 Information on the Impurity Profile:

Information on the impurity profile of rosemary extract was presented in A1158. No new information is available since A1158 was approved.

A.5 Manufacturing Process:

Information on the manufacturing process of rosemary extract was presented in A1158. There have been no changes to the manufacturing process since A1158 was approved.

A.6 Specification for Identity and Purity:

Rosemary extract complies with specifications from the United States Pharmacopeial Convention (2017) Food Chemicals Codex (FCC), (FCC 2016). No changes to the specifications for rosemary extract have been made since A1158 was approved.

A.7 Information for Labelling:

Rosemary extracts are considered to be antioxidants as well as having flavour and odour properties enhancers when added to various food products. Rosemary extracts have been assigned the INS number of 392. Rosemary extracts will be labelled under its functional class, antioxidant, either as antioxidant (392) or antioxidant (rosemary extract).

A.8 Analytical Method for Detection

Information on the analytical methods for rosemary extract was presented in A1158. No changes to analytical methods have been made since A1158 was approved.

A.9 Potential Additional Purposes of the Food Additive when Added to Food

Rosemary is a common herb used commonly in cooking. Extracts of the rosemary plant, in addition to their antioxidative properties, can also be used for flavouring.

B Information related to the safety of the food additive

FSANZ undertook a comprehensive evaluation of the safety of rosemary extract in 2018 under application A1158 and concluded that rosemary extract was a safe food additive. The information presented in this section is a summary of new information / studies relating to rosemary extract since approval of A1158 in 2018.

B.1 Additional Safety Studies Published in the Literature

Presented below are studies on the safety of rosemary extract published since the approval of A1158 in 2018.

Reproductive and developmental toxicity screening study of an acetone extract of rosemary
Kirt R. Phipps , Barbara Danielewska-Nikiel, Jessica Mushonganono , Nigel Baldwin
Regulatory Toxicology and Pharmacology 120 (2021) 104840

In 2017, JECFA requested reproductive and developmental toxicity studies to finalize an acceptable daily intake for solvent rosemary extracts.

In response to JECFA's request for additional data to elucidate the potential developmental and reproductive toxicity of rosemary extracts (JECFA, 2017), a consortium of manufacturers of rosemary extract co-sponsored a study on the potential effects of an acetone extract of rosemary on male and female reproductive performance and offspring development in rats following OECD Test Guideline No. 421 (OECD, 2016) and the U.S. Environmental Protection Agency (EPA) Pesticides and Toxic Substances Health Effects Test Guideline No. 870.3550 (U.S. EPA, 2000; OECD, 2016) (Phipps et al., 2021a[1]). This was a screening study designed to provide initial information on potential effects on reproduction and development. Groups of rats (10 males and 10 females) were fed diets containing acetone extract of rosemary (4.2% w/w carnosol + 43% carnosic acid content) at concentrations of 2100, 3600, or 5000 ppm (equal to 130, 219, or 316 mg/kg bw/day [61, 103, or 149 mg/kg bw/day carnosol and carnosic acid] for males, and 167, 276, or 401 mg/kg bw/day [79, 130, or 189 mg/kg bw/day carnosol and carnosic acid] for females); for females, the dietary concentrations were halved (1050, 1800, or 2500 ppm for low-, mid-, and high-concentration groups, respectively) during the lactation period, to account for the increased food consumption of lactating female rats. An identically comprised control group received basal diet. Test article or basal diets were provided for 14 days before mating, during mating and thereafter until necropsy (in Week 5 for males and on Lactation Day [LD] 13 for females). The low dietary concentration was selected to provide a mean total carnosic acid and carnosol content of at least 64 mg/kg bw/day, equivalent to the no-observed- adverse-effect level (NOAEL) 90-day study conducted with a supercritical carbon dioxide extract of rosemary described (Phipps et al., 2021b), on which the temporary ADI for rosemary extract is based (JECFA, 2017). Ascending approximately 1.5-fold intervals were selected for the mid and high concentrations. Dams with litters were euthanized and subjected to full necropsy on LD 13. Parental males were also euthanized and subjected to a full necropsy in Week 5 of the study). F1 animals were euthanized on Day 4 or 13 of age and examined externally for gross abnormalities. One female in the low concentration group was euthanized on LD 2, as no pups were present after parturition was considered to be complete; this was considered to be incidental.

[1] This study is the published results of data submitted to and evaluated by FSANZ as part of A1158 in 2018

There were no treatment-related effects on clinical observations, mean body weights for parental and F1 males and females, and food consumption for parental animals. All parameters of fertility, pregnancy, mating, and littering were comparable between controls and rosemary extract groups including the length and number of estrous cycles, gestation length, mean number of live pups born, pup sex ratio, pup survival, pup mean body weights, and anogenital distance. A statistically significantly lower pre-coital interval for test article groups was in the opposite direction for biological relevance and was caused by delayed mating in the control group. Except for one female in the low concentration group, all females gave birth to live pups.

Total serum T4 concentrations in parental males and Day 4 pups were similar between the control and rosemary extract groups. However, Day 13 pups showed statistically significant reductions in T4 at 2100 ppm for females and 3600 or 5000 ppm for both sexes compared with controls. Despite this difference, T4 concentrations for all test groups on Day 13 of age were higher than those measured on Day 4, confirming that T4 concentrations increased with age. With the exception of the high-dose group males and females, group mean T4 values were within or similar to the range of the laboratory’s historical control data for PND 13 pups (see **Table 3** below), as well as the range of published historical control values for T4 levels in PND 14 pups (see **Table 3** below), indicating that the statistically significant differences in the treated groups were not biologically relevant. High-dose group mean T4 values, i.e., 3.50 / 3.58 pg/mL for M / F, respectively, were only slightly below the lower end of the historical control data ranges for Wistar rats on PND 13 and 14 (i.e., 3.76 / 3.84 pg/mL for M / F, respectively, [Sequani, unpublished data, 2017] and 4.28 / 4.04 pg/mL for M / F, respectively, [Beekhuijzen et al., 2019]). Histopathological examination revealed no test article-related effects on male reproductive organ weights (i.e. testes, epididymides, prostate, and seminal vesicles) relative to body weights and no macroscopic or microscopic findings (including microscopic analysis of thyroids from Day 13 pups and examinations of the female in the low concentration group that did not give birth to live pups).

Due to the lower T4 levels for Day 13 pups, samples from these animals were subsequently analysed for T3 and TSH (Phipps et al., 2021a [*Table 2*]). There was a high degree of individual variation in TSH values. Mean TSH concentration was lower for male pups in the mid- and high concentrations compared to controls; the decrease was dose-dependent and only the high dose group was statistically significant. Mean TSH concentration was similarly lower for female pups in the mid- and high concentrations compared to controls, but there was no dose-response and the change was not statistically significant. Conversely, T3 values were only slightly higher in test article groups compared with controls, but there was no evidence of a dose response or statistical significance.

Table 3: Summary of T4 Thyroid Hormone Data from Rosemary Extract OECD 421 Study

Dose Sex	Group 1 (Vehicle Control) 0 ppm M Mean ± SD	 F Mean ± SD	Rosemary Extract Group 2 2100/1050ppm[d] M Mean ± SD	 F Mean ± SD	Rosemary Extract Group 3 3600/1800ppm[d] M Mean ± SD	 F Mean ± SD	Rosemary Extract Group 4 5000/2500ppm[d] M Mean ± SD	 F Mean ± SD
	Total T4 (pg/mL)							
PND 13 Data (Study IZI0006 [Phipps et al., 2021a])[a]	4.821±0.600 (n=10)	4.786±0 343 (n=10)	4.563±0.363 (n=9)	4.480*±0.364 (n=9)	3.971***±0.521 (n=10)	4.046***±0.235 (n=10)	3.505***±0.474 (n=10)	3.579***±0.533 (n=10)
Testing Facility Historical Control Data for PND 13 Pups Mean ± SD [*Min/Max*][b]	5.14±0.68 [*3.76 / 6.84*] (n=48)	5.34±0.72 [*3.84 / 7.00*] (n=45)						
Published Historical Control Data for PND 14 Pups Mean ± SD [*P5 /P95 percentile*][c]	5.93±1.118 [*4.28 / 8.03*] (n=499)	5.57±1.030 [*4.04 / 7.50*] (n=499)						

M = Males; F = Females; PND = Postnatal Day

[a] Mouse/Rat Total T4 ELISA kits (Batch Nos. T4G4967 and T4G5519).

[b] Sequani historical control database for 5 studies in Crl:WI(Han) rats aged 13 days (unpublished data, 2017). Mouse/Rat Total T4 ELISA kits (Batch Nos. T4G4967 and T4G5223).

[c] Published historical control data from Charles River Den Bosch, The Netherlands (years 2017–2018; 56 studies) for Wistar Han rats aged 14 days (Beekhuijzen et al., 2019)

[d] Parental rats were provided diets containing rosemary extract at concentrations of 0 (basal diet), 2100, 3600 or 5000 ppm; for the females, the dietary concentrations were reduced to 1050, 1800 or 2500 ppm, respectively from Day 20 of gestation and during lactation.

*Underlined values indicate the mean value was statistically significantly different (Williams, Anova & Dunnett) from vehicle controls at p ≤ 0.05.

***Bolded values indicate the mean value was statistically significantly different (Williams, Anova & Dunnett) from vehicle controls at p ≤ 0.001.

As noted in OECD Guideline 421 for the reproduction/developmental toxicity screening test, a number of factors are known to influence the variability and absolute concentration of hormone determinations, including time of sacrifice because of diurnal variation of hormone concentrations, and method of sacrifice to avoid undue stress to the animals that may affect hormone concentrations (OECD, 2016). In the study reported in Phipps et al., 2021a, blood samples for thyroid hormone analysis were taken from all animals between 0800 and 1200 hours and the time of sample collection for the groups was randomized, where possible, to minimize the impact of sampling time on T4 concentrations. However, it is worth noting that on Day 13, the time point at which significant differences between groups in T4 levels were seen, blood collection from the pups was performed following decapitation. Thus, it is likely that the stress from decapitation of the pups before blood collection could have affected hormone levels (Everds et al., 2013). In the paper by Beekhuijzen et al. (2019) which reported the Charles River Laboratories historical control values for PND 14 pup T4 levels (**Table 3** above), the blood sampling method for PND 14 pups was by aorta puncture under anesthesia using isoflurane.

Beekhuijzen et al. (2019) performed a robust evaluation on 124 repro screening studies (27 OECD 421 and 97 OECD 422 studies) with Wistar Han rats (Crl:WI (Han), outbred, SPF-Quality from Charles River Deutschland, Sulzfeld, Germany) performed at Charles River Den Bosch, The Netherlands, from 2015 to 2018. All studies were conducted with industrial chemicals for REACH registration purposes and followed Good Laboratory Practice (GLP). Historical control data (individual data) of total T4 and TSH for rats were reported for 56 studies. The historical control data of T4 showed a coefficient of variation (CV) of 24–26% for F0 animals and 18–19% for postnatal day (PND) 14 pups. Evaluation of the frequency of a statistically significant change ($p < 5\%$) in T4 levels for all treated groups compared to the concurrent control group for F0 males and PND 14 pups revealed that a statistically significant finding for T4 was very frequent; 38% and 19% of the studies showed a statistically significant change for F0 males and PND 14 pups T4 levels, respectively in at least one treatment group. This high incidence of statistically significant changes was considered to be due to the high variability in the control group means, since it was observed that most T4 levels of treatment groups, although statistically significant, fell within the range (i.e., 3.43–6.06 µg/dL; min-max) of the control group means. Therefore, these results show that a possible treatment-related effect should not be based on statistics alone, but that it is extremely important to take the historical control range into account. Integral changes in hormonal levels include a transient fluctuation due to an adaptive or compensatory response, circadian rhythm, or through some feedback mechanism. The level of circulating T4 is impacted by a feedback mechanism associated with the production of T4 initiated through thyroid stimulating hormone (TSH). T3, the effector type of thyroid hormone, is produced from T4 through a metabolic cascade. As levels of T3 become lower, the production of TSH is induced leading to the production of T4. In addition to the production of T3, T4 can be transformed into reverse T3 (rT3), an inactive form of T3. The production of T3 versus rT3 from T4 can be associated with the needs for T3 versus the level of T4. In addition, excess T4 can be acted on by Phase II hepatic metabolic enzymes such as sulfotransferases and UDP-glucuronosyl transferases. Thus, circulating levels of T4 are impacted by a number of factors including the need for the T3 effector form, the production of TSH, the production of rT3, and direct metabolic clearance activity associated with hepatic sulfonation and glucuronidation. A disturbance in the production of TSH is an important aspect of T4 production and thus T3 production. Because effects were not observed on levels of TSH and T3, the thyroid hormone cascade was not adversely affected. The drop in T4 levels is likely associated with the normal functioning of the thyroid hormonal cascade with the removal of excess T4 through the production of rT3 or hepatic enzyme metabolic activity.

Altered circulating levels of thyroid hormone should not be seen as the only markers for thyroid disruption. This should be supplemented by data on down-stream effects of an adverse nature, such as effects on the developing brain, or on other thyroid hormone target organs. These data also showed that there is no clear relationship between T4 level and liver weight, thyroid weight or thyroid histopathological findings (Beekhuijzen et al., 2019).

In addition, Wistar rats are one of a number of mice and rat strains that have been associated with observed decreases in circulating T4 without effect on T3 or TSH levels and without downstream or hormonal feedback mechanisms (Berry et al., 1993; Herwig et al., 2014; Knight et al., 1998; Macchia et al., 2001; Stocia et al., 2007; van Raaij et al., 1993; Walker et al., 1980; Zaitune et al., 2019; Zabka, 2011; Noyes et al., 2019; Kato et al., 2004). It is possible that such responses are observed following exposure to exogenous compounds which may induce either or both CYP and UDP-glucuronosyl-transferases involved with the metabolic clearance of T4 and/or deiodinase enzymes. A current Adverse Outcome Pathway associated with compounds potentially acting on thyroid hormonal pathways as defined by the EPA (EDSP, 2017) is associated with not only hormonally controlled pathways of T4 production, but also with hormonal and nonhormonal pathways for T4 metabolism/catabolism that help regulate levels of T4. Because carnosol and carnosic acid are known to be associated with the induction of phase I and II hepatic metabolic enzymes (Johnson, 2011; Vaquero et al., 2013; Curran and DeGroot, 1991; Casula and Bianco, 2012; Habza-Kowalska et al., 2019), a reduction in serum T4 could also be viewed as an adaptive effect associated in response to such enzyme induction. As observed in the recovery phase of Phipps et al. (2021a), serum T4 levels returned to levels not different than the control animals. Carnosol was observed to inhibit selected CYP450 enzymes and modulate metabolic enzymes and transporters in in vitro assays; however, the authors concluded that carnosol exhibited low potential for drug interactions (Vemu et al., 2021).

It is also worth noting again that in the 90-day dietary toxicity study with D74 rosemary extract (supercritical CO2) at doses up to 2400 ppm (59-66 mg/kg bw/day carnosol and carnosic acid) or F62 rosemary extract (acetone) at 3800 ppm (30-34 mg/kg body weight/day carnosol and carnosic acid), there were no treatment-related effects on body weights, thyroid or pituitary organ weights, or thyroid or pituitary histopathological changes in the test article treated weanling (4-week-old) rats (Phipps et al., 2021b).

In consideration of the OECD 421 study (Phipps et al., 2021a) results and additional analysis discussed above, the NOAEL for general toxicity and reproduction from this study was 5000 ppm, the highest tested dietary concentration (equivalent to an average daily dose of 316 or 401 mg/kg bw/day for males and females). This dietary concentration was equivalent to a combined carnosic acid and carnosol intake of 149 mg/kg bw/day for males and 189 mg/kg bw/day for females. The reductions in T4 for Day 13 pups were not associated with any adverse effects on offspring development (there were no histopathological thyroid findings, thyroid weight changes or differences in anogenital distance). Notably, these reproductive toxicity NOAELs are higher than the subchronic systemic toxicity NOAEL of 64 mg/kg bw/day (expressed as carnosic acid and carnosol) determined from the 90-day studies summarized above (Covance Laboratories Ltd, 2000b; Phipps et al., 2021b) and referenced in the derivation of the ADI for rosemary extract.

Genotoxicity and subchronic toxicity studies of supercritical carbon dioxide and acetone extracts of rosemary

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Toxicology studies conducted with oil-soluble rosemary extracts to support authorization as a food additive (antioxidant) in the EU include an Ames test using a supercritical carbon dioxide extract (D74), a full 90-day study using D74 and an acetone extract (F62), and an investigative 90-day study with a 28-day recovery period (using D74 only). D74 was non-mutagenic in the Ames test. In the full

90-day study, where rats (20/sex/ group) were either provided control diet or diets containing D74 (300, 600, or 2400 mg/kg) or F62 (3800 mg/ kg), liver enlargement and hepatocellular hypertrophy were observed. To determine a mode of action and assess the reversibility of the hepatic effects, an investigative 90-day study was conducted using female rats (10/group receiving control diet or diet containing 2400 mg/kg D74). Liver enlargement was fully reversible after 28 days and microsomal enzyme analysis revealed reversible induction of cytochrome P450 enzymes (CYP2A1, CYP2A2, CYP2C11, CYP2E1, and CYP4A), demonstrating that the hepatic effects were adaptive and of no toxicological concern. Therefore, the highest dietary concentrations were established as the NOAELs. The investigative 90-day study NOAEL (providing 64 mg/kg bw/day carnosol and carnosic acid [the primary antioxidant components]) was used to establish a temporary ADI for rosemary extracts (Phipps et al 2021b).

Embryotoxicity estimation of commonly used compounds with embryonic stem cell test
Hui Liu, Caiping Ren, Weidong Liu, Xingjun Jiang, Lei Wang, Bin Zhu, Wei Jia, Jianxing Lin1, Jun Tan And Xiuying Liu
Molecular Medicine Reports 16: 263-271, 2017

The embryonic stem cell test (EST), an alternative model to animal studies, is a reliable and scientifically validated *in vitro* system for testing embryotoxicity. In contrast to most *in vivo* animal tests, two permanent cell lines, murine fibroblasts (BALB/c-3T3 cells) and murine embryonic stem cells (mES-D3 cells), are used in EST instead of animals in standard tests of toxicity. The embryotoxic potential of compounds (non, weak or strong embryotoxicity) may be obtained with a biostatistics-based prediction model and calculated from three different experimental endpoint values: The potency to inhibit growth of i) BALB/c-3T3 cells and ii) mES-D3 cells (IC503T3 and IC50ES) as presented using a cell cytotoxicity assay, and iii) the potency to inhibit differentiation of mES-D3 cells into contracting cardiomyocytes (ID50 D3) as demonstrated in a mES-D3 cell differentiation assay. In the present study, a model of EST with mES-D3 cells and BALB/c-3T3 cells was established, according to the standard EST system of the EU Center for the Validation of Alternative Methods, and verified it with 5-fluorouracil (strong embryotoxicity) as a positive control and penicillin G (non-embryotoxic) as a negative control. In addition, the authors further assessed the embryotoxicity of four compounds (eugenol, carnosic acid, procyanidin and dioctyl phthalate) with this model. The embryotoxic potentials of the four compounds were successfully classified by the EST system. Eugenol exhibited strong embryotoxicity, carnosic acid and dioctyl phthalate exhibited weak embryotoxicity, while procyanidin exhibited non-embryotoxicity

Biological activities of Rosmarinus officinalis L. (rosemary) extract as analyzed in microorganisms and cells
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Experimental Biology and Medicine 2017; 242: 625–634. DOI: 10.1177/1535370216688571

Biological activities of rosemary extract were evaluated in this study, as antimicrobial effect on mono- and polymicrobial biofilms, cytotoxicity, anti-inflammatory capacity, and genotoxicity. Monomicrobial biofilms of Candida albicans, Staphylococcus aureus, Enterococcus faecalis, Streptococcus mutans and Pseudomonas aeruginosa and polymicrobial biofilms composed of C. albicans with each bacterium were formed in microplates during 48 h and exposed for 5 min to R. officinalis L. extract (200 mg/mL). Its cytotoxic effect was examined on murine macrophages (RAW 264.7), human gingival fibroblasts (FMM-1), human breast carcinoma cells (MCF-7), and cervical carcinoma cells (HeLa) after exposure to different concentrations of the extract, analyzed by MTT, neutral red (NR), and crystal violet (CV) assays. The anti-inflammatory activity was evaluated on RAW 264.7 non-stimulated or stimulated by lipopolysaccharide (LPS) from Escherichia coli and treated with different concentrations of the extract for 24 h. Interleukin-1 beta (IL-1b) and tumor necrosis factor alpha (TNF-a) were quantified by ELISA. Genotoxicity was verified by the frequency of micronuclei (MN) at 1000 cells after exposure to concentrations of the extract for 24 h. Data were analyzed by T-Test or ANOVA and Tukey Test (P_0.05). Thus, significant reductions in colony forming units per milliliter (CFU/mL) were observed in all biofilms. Regarding the cells, it was observed that concentrations_50 mg/mL provided cell viability of above 50%. Production of proinflammatory cytokines in the treated groups was similar or lower compared to the control group. The MNfrequency in the groups exposed to extract was similar or less than the untreated group. It was shown that R. officinalis L. extract was effective on mono- and polymicrobial biofilms; it also provided cell viability of above 50% (at_50 mg/mL), showed anti-inflammatory effect, and was not genotoxic.

B.2 Safety assessment reports prepared by international agencies or other national government agencies, if available

Rosemary extract has been reviewed by both the European Food Safety Authority (EFSA) and Joint FAO/WHO Expert Committee on Food Additives (JECFA). A summary of their safety assessments was presented as part of A1158. JECFA undertook a further evaluation in 2018 and a summary is presented below.

JECFA

The Joint FAO/WHO Expert Committee on Food Additives (JECFA) previously evaluated rosemary extract at its eighty-second meeting. At that meeting, the Committee established a temporary acceptable daily intake (ADI) of 0–0.3 mg/kg body weight (bw) for rosemary extract, expressed as carnosic acid plus carnosol. This ADI was based on a no observed-adverse-effect level (NOAEL) of 64 mg/kg bw per day, the highest dose tested in a short-term toxicity study in rats. An uncertainty factor of 200 was used, which includes an uncertainty factor of 100 and an additional uncertainty factor of 2 to account for the temporary designation of the ADI, pending the submission of studies to elucidate the potential developmental and reproductive toxicity of the rosemary extract under consideration. An additional uncertainty factor to account for the lack of a chronic toxicity study was not considered necessary, based on the absence of adverse effects in the short-term toxicity studies at doses up to and including the highest dose tested.

JECFA undertook a further assessment of rosemary extract at the request of the Fiftieth Session of the Codex Committee on Food Additives (CCFA) for an assessment of its safety, including studies to elucidate its potential developmental and reproductive toxicity, A study on the reproductive and developmental toxicity of an acetone-based rosemary extract was submitted by the sponsors. A summary of JECFA’s evaluation is presented below. (JECFA/WHO 2020).

A new OECD-compliant (Test Guideline 421) reproductive/developmental toxicity screening study in rats using an acetone extract of rosemary with a high content of carnosic acid was submitted to

JECFA in 2018[2]. Rats were administered rosemary extract in the diet at initial concentrations of 0, 2100, 3600 and 5000 mg/kg feed, which were later reduced in females from GD 20 to 0, 1050, 1800 and 2500 mg/kg feed (equal to 0, 130, 219 and 316 mg/kg bw per day for males and 0, 167, 276 and 401 mg/kg bw per day for females, respectively). No adverse effects were observed in parental males or females or in reproductive parameters. Gestation duration, litter size and pup body weight on PND 1 and pup survival and body weight gain until PND 13 (termination) were not affected by treatment. A clear dose-related reduction in total-T4 serum levels in male and female pups was observed on PND 13. Histopathological examination of the thyroid gland (one male and one female pup per litter) showed no abnormality (Blunt, 2018). The Committee noted the high variability in the thyroid hormone measurements in the pups.

A NOAEL of 5000 mg/kg feed (equal to 316 mg/kg bw per day), the highest dose tested, was identified for reproductive and parental toxicity. The Committee noted that it was unclear whether the treatment-related effects on thyroid hormone levels in pups were adverse, and therefore a NOAEL for offspring toxicity could not be identified. The study also did not provide adequate evidence for the absence of developmental toxicity, given that no fetuses were examined.

One toxicological study on carnosic acid was identified in the literature search. Liu et al. (2017) tested carnosic acid in an in vitro screening assay for embryotoxic potential using mouse embryonic stem cells. The embryonic stem cell test is an extensively used screening assay for developmental toxicity that has been validated by the European Union Reference Laboratory for alternatives to animal testing. Studies on the predictivity of the embryonic stem cell assay indicated a significant false-positive rate (approximately 40%), but a very low false-negative rate (approximately 7%). According to the results from this in vitro assay, carnosic acid is weakly embryotoxic (Liu et al., 2017).

The Committee concluded that the new studies provided evidence for the absence of reproductive toxicity, but not for the absence of developmental toxicity. The Committee retained the temporary ADI of 0–0.3 mg/kg bw, pending the submission of studies on the developmental toxicity of rosemary extract and studies to elucidate whether the effects noted on rodent pup thyroid hormone levels can be replicated.

In response to JECFA's request for additional information for the evaluation of rosemary extract, the manufacturers of rosemary extract and data providers are in the process of addressing the identified data gaps. The requested studies were expected to be available at the end of 2021 or beginning of 2022. However, because of additional delays, based on current timelines, the studies are scheduled to be completed in the first quarter of 2022, with the audited draft reports expected by June 2022. It was therefore requested for an extension to submit the requested data to JECFA be end 2022 and that the temporary ADI as established at the 87th meeting be extended until the evaluation of rosemary extract following provision of the requested data to the Committee.

The applicant, however, does not believe that waiting for these additional studies should hold up the progression of this application on consideration of the OECD 421 study (Phipps et al., 2021a) results and additional analysis discussed above in section B.1 Additional Safety Studies Published in the Literature. The NOAEL for general toxicity and reproduction from this study was 5000 ppm, the highest tested dietary concentration (equivalent to an average daily dose of 316 or 401 mg/kg bw/day for males and females). This dietary concentration was equivalent to a combined carnosic acid and carnosol intake of 149 mg/kg bw/day for males and 189 mg/kg bw/day for females. The reductions in T4 for Day 13 pups were not associated with any adverse effects on offspring development (there were no histopathological thyroid findings, thyroid weight changes or differences in anogenital distance). Notably, these reproductive toxicity NOAELs are higher than the

[2] Note: Summary and raw data from this study was submitted to FSANZ during the evaluation of A1158. This study has been published as Phipps et al 2021a and 2021b,

subchronic systemic toxicity NOAEL of 64 mg/kg bw/day (expressed as carnosic acid and carnosol) determined from the 90-day studies summarized above (Covance Laboratories Ltd, 2000b; Phipps et al., 2021b) and referenced in the derivation of the ADI for rosemary extract. The applicant is willing to provide the data for the additional studies to FSANZ to review when available.

C Information Related to the Dietary Exposure of the Food Additive

C.1 A list of the food groups or foods proposed to contain the food additive, or changes to currently permitted foods

Please refer to Table 4Table 4: Proposed Food Uses and Maximum Permitted Levels below for proposed additional uses and maximum proposed levels for rosemary extract as a food additive.

C.2 The maximum proposed level or the concentration range of the food additive for each food group or food, or the proposed changes to the currently permitted levels

Please refer to Table 4 below for proposed additional uses and maximum proposed levels for rosemary extract as a food additive.

Table 4: Proposed Food Uses and Maximum Permitted Levels

Category No.	Description	Proposed MPL (mg/kg)*	Comments / Examples
0.2	Colouring	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
2.1	Edible oils essentially free of water	50	Fats and oils used for the professional manufacture of heat-treated foods or more specifically, industrial frying oils.
6.4	Flour products (including 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)
7	Bread and bakery products	40	Breadcrumbs and bread coatings
7?		40	Tortillas (wheat or corn)
8.3	Processed comminuted meat, poultry and game products, other than products listed in item 8.3.2	40	Ground poultry
8.3.1	Fermented, uncooked processed comminuted meat products	40	
8.3.2	Sausage and sausage meat containing raw, unprocessed meat	40	Add: Raw meat sausages

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

C.3 For foods or food groups not currently listed in the most recent Australian or New Zealand National Nutrition Surveys (NNSs), information on the likely level of consumption

Not applicable.

C.4 The percentage of the food group in which the food additive is proposed to be used or the percentage of the market likely to use the food additive

Since rosemary extract was approved as a food additive by FSANZ in 2018 typical use levels of rosemary extract are between 0.05 – 0.2% across most applications. This corresponds to 10-100 ppm CA+CN, however majority fall within the range of 20 – 50ppm. This is based on feedback received by the applicant from its customers in Australia and New Zealand since its approval by FSANZ in 2018.

Based the experience in the EU, it is estimated that typical us levels is about 50% of the MPL except in the categories of fats and oils, where the use level is probably around 75-80%.

Appendix 3 provides data extracted from the Mintel GNP database on new products introduced from to 2018 to 2021. The data is broken as follows:

1. Total new products introduced by year
2. Total new products introduced by category
3. New products introduced containing rosemary extract by category
4. Percentage new products introduced containing rosemary extract by category
5. Total new products introduced by country
6. New products introduced by country containing rosemary extract
7. Percentage new products introduced containing rosemary extract by country
8. New products introduced by category in Australia
9. Percentage new products introduced by category in Australia
10. New products introduced by category in New Zealand
11. Percentage new products introduced by category in Zealand

C.5 Information relating to the use of the food additive in other countries, if applicable

Appendix 3 provides data extracted from the Mintel GNP database on new products introduced for the 2018 to 2021. The data includes the number and percentage of new products new products introduced containing rosemary extract by country.

EFSA undertook a refined assessment of extracts of rosemary from its use as a food additive (EFSA 2018). In 2018 the EFSA Panel on Food Additives and Nutrient Sources added to Food (ANS) provided a scientific opinion on the refined exposure assessment of extracts of rosemary (E392) when used as a food additive. Extracts of rosemary (E392) was evaluated by the AFC Panel in 2008. Following this EFSA evaluation, extracts of rosemary (E392) was authorised for use as a food additive in the EU in several food categories with maximum levels. In 2015, the ANS Panel provided a scientific opinion on the safety of the proposed extensions of use for extracts of rosemary (E 392) in fat-based spreads. Based on the data provided by food industry, the Panel was able to refine the exposure estimates of extracts of rosemary (E 392). The highest mean refined exposure estimate (non-brand loyal scenario) was 0.09 mg/kg bw per day in children (3–9 years) and the highest 95th percentile of exposure was 0.20 mg/kg bw per day in children. Taking uncertainties into account, the Panel concluded that these exposure estimates very likely overestimate the real exposure to extracts of rosemary (E 392) from its use as a food additive according to Annex II. Margins of safety were estimated for children and adults using the refined exposure estimate; these are higher than the ones calculated in 2015. Intake of carnosic acid and carnosol from natural diet (herbs) was estimated. It was maximally 1.66 mg/kg bw per day.

An assessment of the dietary exposure of rosemary extract was undertaken as part of the review of rosemary extract by the eighty-seventh meeting of the Joint FAO/WHO Expert Committee on Food Additives (JECFA) (WHO 2020). Estimates of dietary exposure was based on data from Europe, USA and Australia & New Zealand.

Estimated mean and high-percentile dietary exposures to carnosic acid plus carnosol from use of rosemary extract as a food additive for all countries assessed based on typical use levels did not exceed the upper end of the temporary ADI of 0–0.3 mg/kg bw. The Committee noted that when dietary exposures from naturally occurring sources are combined with dietary exposures from added sources at typical use levels, the estimated dietary exposures for children were up to 0.42 mg/kg bw per day, which exceeds the ADI. The Committee, however, noted that the temporary ADI is based on the highest dose tested in a short-term toxicity study in rats and that in the newly submitted reproductive/developmental toxicity screening study, no effects on reproductive toxicity or on parental animals were observed at 316 mg/kg bw per day, the highest dose tested. Therefore, the Committee does not consider the slight exceedance of the ADI to be a safety concern.

C.6 For foods where consumption has changed in recent years, information on likely current food consumption

Not applicable.

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Appendices

Appendix 1: Statutory Declaration

STATUTORY DECLARATION

Statutory Declarations Act 1959

I, Jim Moshovelis, Director, Scientific & Regulatory Solutions of Killarney Heights NSW Australia,

make the following declaration under the *Statutory Declarations Act 1959*:

1. the information provided in this application fully sets out the matters required
2. the information provided in this application is true to the best of my knowledge and belief
3. no information has been withheld that might prejudice this application, to the best of my knowledge and belief

I understand that a person who intentionally makes a false statement in a statutory declaration is guilty of an offence under section 11 of the *Statutory Declarations Act 1959*, and I believe that the statements in this declaration are true in every particular.

Signature

Declared at FORESTVILLE NSW. on 6 May 2022.

Before me,

Signature:

Full Name: Celina Anne Jabbour

Qualification: Pharmacist (PHA0002461985)

Address: 2 Starkey St Forestville NSW 2087

Appendix 2: Checklists

Checklist for General requirements

This Checklist will assist you in determining if you have met the mandatory format and information requirements as detailed in Guideline 3.1.1 – General requirements. All applications **must** include this Checklist.

General requirements (3.1.1)		
Check	**Page No.**	**Mandatory requirements**
☑		A Form of application ☐ *Application in English* ☐ *Executive Summary (separated from main application electronically)* ☐ *Relevant sections of Part 3 clearly identified* ☐ *Pages sequentially numbered* ☐ *Electronic copy (searchable)* ☐ *All references provided*
☑	5	B Applicant details
☑	5	C Purpose of the application
☑	6	D Justification for the application ☐ *Regulatory impact information* ☐ *Impact on international trade*
☑	7	E Information to support the application ☐ *Data requirements*
☑	7	F Assessment procedure ☑ *General* ☐ *Major* ☐ *Minor* ☐ *High level health claim variation*
☑	7	G Confidential commercial information ☐ *CCI material separated from other application material* ☐ *Formal request including reasons* ☐ *Non-confidential summary provided*
☑	7	H Other confidential information ☐ *Confidential material separated from other application material* ☐ *Formal request including reasons*
☑	7	I Exclusive Capturable Commercial Benefit ☐ *Justification provided*
☑	8	J International and other national standards ☐ *International standards* ☐ *Other national standards*
☑	39	K Statutory Declaration
☑	41	L Checklist/s provided with application ☐ *3.1.1 Checklist* ☐ *All page number references from application included* ☐ *Any other relevant checklists for Chapters 3.2–3.7*

Checklist for applications for substances added to food

This Checklist is in addition to the Checklist for Guideline 3.1.1 and will assist you in determining if you have met the information requirements as specified in Guidelines 3.3.1–3.3.3.

Food additives (3.3.1)		
Check	**Page No.**	**Mandatory requirements**
☑	17	A.1 Nature and technological purpose information
☑	22	A.2 Identification information
☑	22	A.3 Chemical and physical properties
☑	22	A.4 Impurity profile
☑	22	A.5 Manufacturing process
☑	22	A.6 Specifications
☑	22	A.7 Food labelling
☑	22	A.8 Analytical detection method
☑	22	A.9 Additional functions
☑	N/A	B.1 Toxicokinetics and metabolism information
☑	23	B.2 Toxicity information
☑	29	B.3 Safety assessments from international agencies
☑	32	C.1 List of foods likely to contain the food additive
☑	32	C.2 Proposed levels in foods
☑	33	C.3 Likely level of consumption
☑	33	C.4 Percentage of food group to contain the food additive
☑	33	C.5 Use in other countries (if applicable)
☑	34	C.6 Where consumption has changed, information on likely consumption

Appendix 3: Mintel GNP Database – Data on Rosemary Extract 2018 – 2021

Search Criteria

All product by year

All product by Category

All Products with Rosemary Extract by Category

Percent of Products with Rosemary Extract by Category

All products by Country

All Products with Rosemary Extract by Country

Percent of Products with Rosemary Extract by Country

All Products with Rosemary Extract by Category – Australia

Percent of Products with Rosemary Extract by Category – Australia

All Products with Rosemary Extract by Category – New Zealand

Percent of Products with Rosemary Extract by Category – New Zealand

		All product search
	Search Criteria	
	Market	Bakery(Cakes - Pastries & Sweet Goods, Savory Biscuits/Crackers, Sweet Biscuits/Cookies); All Cereals; Confectionery(Other Sugar Confectionery); Dairy(Fats & Spreads); Meat, Fish & Eggs(Fish & Seafood, Meat Products, Poultry); Sauces & Seasonings(Cooking Sauces, Mayonnaise - Dressings & Vinegar, Oils, Pickled Condiments/Chutney, Table Sauces); Snacks(Meat Snacks, Savory/Salty Snacks, Snack Nuts & Seeds); All Spreads
	Country	All East Europe; All West Europe; Australia; New Zealand; Other Countries
	Positioning	All Positionings
	Flavours	All Flavors
	Ingredients	All Ingredients
	Date	Jan 2018 - Dec 2021
		Products with rosemary extract on ingredient list
	Search Criteria	
	Market	Bakery(Cakes - Pastries & Sweet Goods, Savory Biscuits/Crackers, Sweet Biscuits/Cookies); All Cereals; Confectionery(Other Sugar Confectionery); Dairy(Fats & Spreads); Meat, Fish & Eggs(Fish & Seafood, Meat Products, Poultry); Sauces & Seasonings(Cooking Sauces, Mayonnaise - Dressings & Vinegar, Oils, Pickled Condiments/Chutney, Table Sauces); Snacks(Meat Snacks, Savory/Salty Snacks, Snack Nuts & Seeds); All Spreads
	Country	All East Europe; All West Europe; Australia; New Zealand; Other Countries
	Positioning	All Positionings
	Flavours	All Flavors
	Ingredients	Rosemary extract
	Date	Jan 2018 - Dec 2021

By Year		
All products		
Total	**Product Launches**	**Total**
2018	26,500	26,500
2019	27,650	27,650
2020	26,651	26,651
2021	24,541	24,541
Total	**105,342**	**105,342**
All products with rosemary extract		
Time – Annually	**Product Launches**	**Total**
2018	392	392
2019	369	369
2020	322	322
2021	269	269
Total	**1,352**	**1,352**

By Category All

Market Sub-Category	2018	2019	2020	2021	Total
Breakfast Cereals	1,630	1,647	1,453	1,246	5,976
Cakes - Pastries & Sweet Goods	2,067	2,323	2,098	2,005	8,493
Cooking Sauces	726	749	805	859	3,139
Dressings & Vinegar	507	472	472	482	1,933
Fish & Seafood	2,264	2,186	2,308	1,993	8,751
Mayonnaise	181	202	219	191	793
Meat Products	3,797	3,823	3,674	3,223	14,517
Meat Snacks	259	300	248	192	999
Oils	991	960	1,150	1,401	4,502
Other Sugar Confectionery	225	195	167	155	742
Pickled Condiments/Chutney	1,027	1,076	1,184	1,162	4,449
Poultry	1,568	1,510	1,630	1,361	6,069
Savory Biscuits/Crackers	876	913	762	613	3,164
Savory Spreads	1,274	1,277	1,247	1,152	4,950
Snack Mixes	419	406	368	327	1,520
Snack/Cereal/Energy Bars	1,726	2,137	1,363	918	6,144
Snack Nuts & Seeds	993	1,152	1,204	1,139	4,488
Sweet Biscuits/Cookies	2,720	2,954	2,523	2,336	10,533
Sweet Spreads	2,039	2,063	2,477	2,388	8,967
Table Sauces	893	963	997	1,130	3,983
Total	**26,182**	**27,308**	**26,349**	**24,273**	**104,112**

By Category Rosemary Extract

Market Sub-Category	2018	2019	2020	2021	Total
Breakfast Cereals	33	21	27	18	99
Cakes - Pastries & Sweet Goods	2	5	7	6	20
Cooking Sauces	1	2	7	3	13
Dressings & Vinegar	6	11	5	4	26
Fish & Seafood	9	15	5	5	34
Mayonnaise	14	12	9	11	46
Meat Products	73	68	45	49	235
Meat Snacks	11	11	7	10	39
Oils	2	2	3	1	8
Other Sugar Confectionery	0	1	0	0	1
Pickled Condiments/Chutney	1	0	0	0	1
Poultry	55	49	41	31	176
Savory Biscuits/Crackers	47	35	44	34	160
Savory Spreads	14	10	15	14	53
Snack Mixes	3	7	6	9	25
Snack/Cereal/Energy Bars	50	55	26	23	154
Snack Nuts & Seeds	4	9	9	11	33
Sweet Biscuits/Cookies	47	42	47	25	161
Sweet Spreads	1	5	1	7	14
Table Sauces	19	7	18	8	52
Total	**392**	**367**	**322**	**269**	**1,350**

By Category Rosemary Extract %

Market Sub-Category	2018	2019	2020	2021
Breakfast Cereals	2.0%	1.3%	1.9%	1.4%
Cakes - Pastries & Sweet Goo	0.1%	0.2%	0.3%	0.3%
Cereal & Energy Bars	0.1%	0.3%	0.9%	0.3%
Cooking Sauces	1.2%	2.3%	1.1%	0.8%
Fats & Spreads	0.4%	0.7%	0.2%	0.3%
Fish & Seafood	7.7%	5.9%	4.1%	5.8%
Mayonnaise - Dressings & Vi	1.9%	1.8%	1.2%	1.5%
Meat Products	4.2%	3.7%	2.8%	5.2%
Meat Snacks	0.2%	0.2%	0.3%	0.1%
Oils	0.0%	0.5%	0.0%	0.0%
Other Sugar Confectionery	0.1%	0.0%	0.0%	0.0%
Pickled Condiments/Chutney	3.5%	3.2%	2.5%	2.3%
Poultry	5.4%	3.8%	5.8%	5.5%
Savory Biscuits/Crackers	1.1%	0.8%	1.2%	1.2%
Savory Spreads	0.7%	1.7%	1.6%	2.8%
Savory/Salty Snacks	2.9%	2.6%	1.9%	2.5%
Snack Nuts & Seeds	0.4%	0.8%	0.7%	1.0%
Sweet Biscuits/Cookies	1.7%	1.4%	1.9%	1.1%
Sweet Spreads	0.0%	0.2%	0.0%	0.3%
Table Sauces	2.1%	0.7%	1.8%	0.7%
Total	1.5%	1.3%	1.2%	1.1%

By Country - All

Country	2018	2019	2020	2021	Total
Australia	1,882	1,992	1,761	1,726	7,361
Austria	668	661	727	629	2,685
Belarus	0	150	211	214	575
Belgium	443	469	466	489	1,867
Bulgaria	0	227	204	230	661
Croatia	388	410	387	297	1,482
Czech Republic	645	578	686	482	2,391
Denmark	616	566	518	503	2,203
Estonia	0	239	289	244	772
Finland	464	439	568	546	2,017
France	3,633	3,293	2,930	3,091	12,947
Germany	3,013	3,173	3,126	2,182	11,494
Greece	512	543	441	329	1,825
Hungary	348	374	349	284	1,355
Ireland	274	306	343	342	1,265
Italy	1,784	1,796	1,853	1,702	7,135
Latvia	0	181	244	282	707
Lithuania	0	136	226	208	570
Netherlands	1,109	1,026	1,166	1,025	4,326
New Zealand	465	493	576	445	1,979
Norway	650	684	670	590	2,594
Poland	1,345	1,397	1,350	1,345	5,437
Portugal	288	362	334	246	1,230
Romania	461	454	384	286	1,585
Russia	1,085	988	961	902	3,936
Serbia	0	125	145	187	457
Slovakia	283	320	214	265	1,082
Slovenia	0	154	128	160	442
Spain	1,673	1,709	1,248	1,324	5,954
Sweden	655	648	677	637	2,617
Switzerland	569	553	549	436	2,107
Turkey	472	377	360	398	1,607
UK	2,506	2,538	2,254	2,247	9,545
Ukraine	269	289	306	268	1,132
Total	**26,500**	**27,650**	**26,651**	**24,541**	**105,342**

By Country - Rosemary Extract

Country	2018	2019	2020	2021	Total
Australia	62	78	52	34	226
Austria	8	6	5	2	21
Belarus	0	0	1	1	2
Belgium	21	9	15	10	55
Bulgaria	0	1	1	1	3
Croatia	5	2	8	2	17
Czech Republic	14	5	6	0	25
Denmark	5	11	7	5	28
Estonia	0	3	0	2	5
Finland	2	1	2	2	7
France	62	54	39	39	194
Germany	31	18	22	14	85
Greece	3	10	6	6	25
Hungary	12	6	7	2	27
Ireland	1	4	6	2	13
Italy	38	30	29	32	129
Latvia	0	5	2	0	7
Lithuania	0	7	5	5	17
Netherlands	20	9	17	11	57
New Zealand	6	2	7	8	23
Norway	7	13	6	9	35
Poland	17	4	9	7	37
Portugal	10	8	0	1	19
Romania	2	4	5	2	13
Russia	5	8	5	11	29
Serbia	0	4	2	5	11
Slovakia	8	3	3	2	16
Slovenia	0	1	3	3	7
Spain	14	12	13	13	52
Sweden	8	11	9	12	40
Switzerland	5	5	4	1	15
Turkey	0	0	0	0	0
UK	24	35	25	23	107
Ukraine	2	0	1	2	5
Total	**392**	**369**	**322**	**269**	**1,352**

By Country - Rosemary Extract - %

Country	2018	2019	2020	2021
Australia	3.3%	3.9%	3.0%	2.0%
Austria	1.2%	0.9%	0.7%	0.3%
Belarus	0.0%	0.0%	0.5%	0.5%
Belgium	4.7%	1.9%	3.2%	2.0%
Bulgaria	0.0%	0.4%	0.5%	0.4%
Croatia	1.3%	0.5%	2.1%	0.7%
Czech Republic	2.2%	0.9%	0.9%	0.0%
Denmark	0.8%	1.9%	1.4%	1.0%
Estonia	0.0%	1.3%	0.0%	0.8%
Finland	0.4%	0.2%	0.4%	0.4%
France	1.7%	1.6%	1.3%	1.3%
Germany	1.0%	0.6%	0.7%	0.6%
Greece	0.6%	1.8%	1.4%	1.8%
Hungary	3.4%	1.6%	2.0%	0.7%
Ireland	0.4%	1.3%	1.7%	0.6%
Italy	2.1%	1.7%	1.6%	1.9%
Latvia	0.0%	2.8%	0.8%	0.0%
Lithuania	0.0%	5.1%	2.2%	2.4%
Netherlands	1.8%	0.9%	1.5%	1.1%
New Zealand	1.3%	0.4%	1.2%	1.8%
Norway	1.1%	1.9%	0.9%	1.5%
Poland	1.3%	0.3%	0.7%	0.5%
Portugal	3.5%	2.2%	0.0%	0.4%
Romania	0.4%	0.9%	1.3%	0.7%
Russia	0.5%	0.8%	0.5%	1.2%
Serbia	0.0%	3.2%	1.4%	2.7%
Slovakia	2.8%	0.9%	1.4%	0.8%
Slovenia	0.0%	0.6%	2.3%	1.9%
Spain	0.8%	0.7%	1.0%	1.0%
Sweden	1.2%	1.7%	1.3%	1.9%
Switzerland	0.9%	0.9%	0.7%	0.2%
Turkey	0.0%	0.0%	0.0%	0.0%
UK	1.0%	1.4%	1.1%	1.0%
Ukraine	0.7%	0.0%	0.3%	0.7%
Total	**1.5%**	**1.3%**	**1.2%**	**1.1%**

By Category - Australia - Rosemary Extract

Market Sub-Category	2018	2019	2020	2021	Total
Breakfast Cereals	12	3	4	8	27
Cakes - Pastries & Sweet Goods	0	0	0	1	1
Cooking Sauces	0	2	2	1	5
Dressings & Vinegar	0	6	2	0	8
Mayonnaise	6	1	0	0	7
Meat Products	23	21	12	8	64
Oils	0	1	0	0	1
Poultry	12	16	13	8	49
Savory Biscuits/Crackers	7	4	9	8	28
Savory Spreads	3	3	2	4	12
Snack Mixes	0	0	3	0	3
Sweet Biscuits/Cookies	0	2	2	0	4
Table Sauces	4	0	1	1	6
Total	**67**	**59**	**50**	**39**	**215**

By Category - Australia - Rosemary Extract - %

Market Sub-Category	2018	2019	2020	2021
Breakfast Cereals	44.4%	11.1%	14.8%	29.6%
Cakes - Pastries & Sweet Goo	0.0%	0.0%	0.0%	100.0%
Cooking Sauces	0.0%	40.0%	40.0%	20.0%
Dressings & Vinegar	0.0%	75.0%	25.0%	0.0%
Mayonnaise	85.7%	14.3%	0.0%	0.0%
Meat Products	35.9%	32.8%	18.8%	12.5%
Oils	0.0%	100.0%	0.0%	0.0%
Poultry	24.5%	32.7%	26.5%	16.3%
Savory Biscuits/Crackers	25.0%	14.3%	32.1%	28.6%
Savory Spreads	25.0%	25.0%	16.7%	33.3%
Snack Mixes	0.0%	0.0%	100.0%	0.0%
Sweet Biscuits/Cookies	0.0%	50.0%	50.0%	0.0%
Table Sauces	66.7%	0.0%	16.7%	16.7%
Total	**31.2%**	**27.4%**	**23.3%**	**18.1%**

By Category - New Zealand - Rosemary Extract					
Market Sub-Category	**2018**	**2019**	**2020**	**2021**	**Total**
Breakfast Cereals	5	0	2	3	10
Cooking Sauces	0	0	1	0	1
Mayonnaise	0	0	0	1	1
Meat Products	0	1	0	1	2
Poultry	0	0	1	1	2
Savory Biscuits/Crackers	3	0	0	3	6
Sweet Biscuits/Cookies	1	0	0	0	1
Table Sauces	0	0	4	1	5
Total	**9**	**1**	**8**	**10**	**28**

By Category - New Zealand - Rosemary Extract - %

Market Sub-Category	2018	2019	2020	2021
Breakfast Cereals	50.0%	0.0%	20.0%	30.0%
Cooking Sauces	0.0%	0.0%	100.0%	0.0%
Mayonnaise	0.0%	0.0%	0.0%	100.0%
Meat Products	0.0%	50.0%	0.0%	50.0%
Poultry	0.0%	0.0%	50.0%	50.0%
Savory Biscuits/Crackers	50.0%	0.0%	0.0%	50.0%
Sweet Biscuits/Cookies	100.0%	0.0%	0.0%	0.0%
Table Sauces	0.0%	0.0%	80.0%	20.0%
Total	**32.1%**	**3.6%**	**28.6%**	**35.7%**