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

Supporting document 1

RISK AND TECHNICAL ASSESSMENT REPORT

Quillaia[1] Extract (Quillaja extract) as a Food Additive (Emulsifier)

Executive Summary

FSANZ received an Application from National Starch Pty Ltd seeking to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to permit the addition of quillaia extract as an emulsifier in several beverage categories.

Quillaia extract is obtained by aqueous extraction of the bark, stems and branches of the *Quillaia saponaria* tree (soap bark tree) which is native to China and South America. The extract contains a mixture of over 100 tri-terpenoid saponins. The saponins consist mainly of quillaic acid as the hydrophobic moiety with various attached oligosaccharides. Quillaia extract functions as an emulsifier due to the amphipathic nature of the saponins.

The Application requested maximum permitted levels (MPLs) ranging from 30 to 40 mg quillaia saponins/kg depending on the type of beverage. The food technology assessment concluded that quillaia extract fulfils the stated technological function as an emulsifier at the proposed levels of use.

Quillaia extract has a history of safe use as a food additive in a number of countries. The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated the toxicological hazard of quillaia extract on several occasions, most recently in 2005, when a group acceptable daily intake (ADI) was established at 0-1 mg quillaia saponins/kg bodyweight (bw). This group ADI specified an amount of pure quillaia saponins to enable the use of use either type I (unpurified) or type II (saponin enriched) extract to be used. The toxicological studies that had been considered by JECFA, and more recently published studies, were evaluated in this hazard assessment. A group ADI of 0-1 mg quillaia saponins/kg bw has been established.

Predictions of dietary exposure to quillaia saponins resulting from the use of quillaia extract as an emulsifier in beverages indicate no exceedances of the ADI for all population groups assessed, including children. Thus, there are no public health and safety concerns associated with the proposed addition of quillaia extract to the food categories requested.

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[1] Quillaja extract is the term used by the Applicant when the application was submitted to FSANZ. However, the technically correct term is Quillaia, as all the safety studies and JECFA specifications are based on the term quillaia extract. Therefore, for consistency FSANZ has used the term quillaia in all reports.

Abbreviations

Time		**Weight**	
sec	Second	bw	Bodyweight
min	Minute	wt	Weight
d	Day	ng	Nanogram
wk	Week	µg	Microgram
mo	Month	mg	Milligram
yr	Year	kg	Kilogram
Length		**Dosing**	
nm	Nanometre	iv	Intravenous
µm	Micrometre	po	Oral
mm	Millimetre	mg/kg bw/day	mg/kg bodyweight/day
cm	Centimetre		
m	Metre		
Volume		**Concentration**	
µL	Microlitre	M	Molar
mL	Millilitre	ppb	Parts per billion
L	Litre	ppm	Parts per million
		w/v	Weight per volume
		w/w	Weight per weight

Clinical chemistry & haematology	
ALT	Alanine aminotransferase
AST	Aspartate aminotransferase
CRP	C-reactive protein
Hb	Haemoglobin
Hct	Haematocrit
LDH	Lactate dehydrogenase
RBC	Red Blood Cells (erythrocyte) (count)
WBC	White Blood Cells (leucocyte) (count)
Terminology	
ADFI	Average Daily Feed Intake
ADI	Acceptable Daily Intake
ANCNPAS	Australian National Children's Nutrition and Physical Activity Survey
AusNNS	Australian National Nutrition Survey
DEA	Dietary Exposure Assessment
FAO	Food and Agriculture Organization of the United Nations
FSANZ	Food Standards Australia New Zealand
G:F	Growth to Feed intake ratio
GMP	Good Manufacturing Practice
GRAS	Generally Recognised As Safe
HPLC	High Performance Liquid Chromatography
JECFA	Joint FAO/WHO Expert Committee on Food Additives
MPL	Maximum Permitted Level
NOAEL	No Observed Adverse Effect Level
NZCNS	New Zealand National Children's Nutrition Survey
NZNNS	New Zealand National Nutrition Survey
WBFD	Water Based Flavoured Drinks
WHO	World Health Organization

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1. INTRODUCTION

On the 8 June 2012, Food Standards Australia New Zealand (FSANZ) received an Application from National Starch Pty Ltd seeking to amend Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code) to permit the addition of quillaia extract to food as an emulsifier being an alternative to such food additives as gum arabic and modified food starch.

1.1 Risk assessment context

For the purpose of this risk assessment, the proposed addition of quillaia extract to food in Australia and New Zealand will be considered in the context of the following:

- The main family of functionally-relevant compounds present in quillaia extract, the saponins, are a normal component of the human diet by virtue of their presence in a range of edible plant materials.

- Quillaia extract is already a permitted food additive and/or food ingredient in the European Union, the US, Canada, China, Japan, India, Singapore, Thailand, Taiwan and Vietnam.

- The Joint FAO/WHO Expert Committee on Food Additives (JECFA) has evaluated quillaia extract, establishing product specifications and a group acceptable daily intake (ADI).

1.2 Risk Assessment questions

For this Application, the risk assessment questions were developed in the context of the Section 18 Objectives of the *Food Standards Australia New Zealand Act 1991*.

The following risk assessment questions are addressed in this report:

1. Does quillaia extract achieve its technological function in the form and quantity used as an emulsifier?

2. Are there any public health and safety issues associated with the use of quillaia extract as an emulsifier?

2. FOOD TECHNOLOGY ASSESSMENT

2.1 Characterisation of quillaia extract

2.1.1 Identity

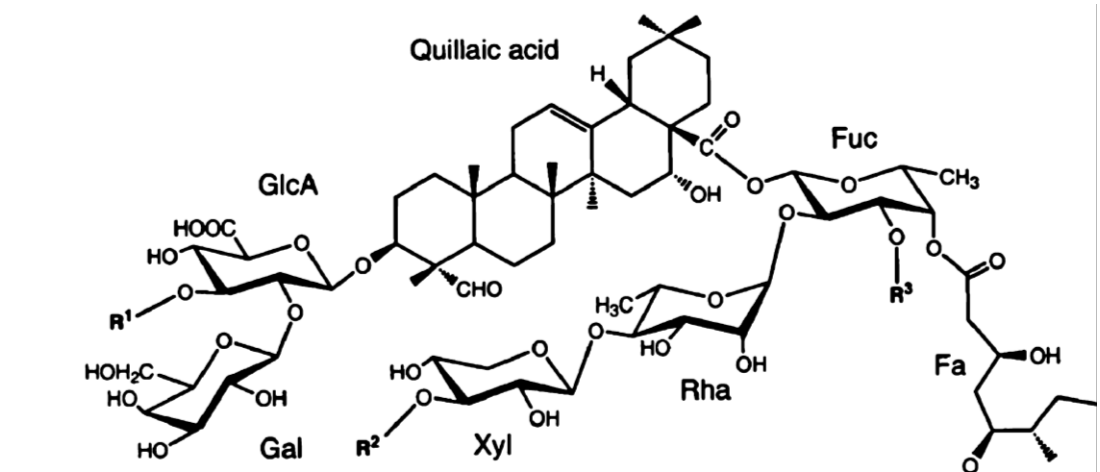
Common name:	Quillaia extract
Other names:	Quillaja extract, Soapbark extract, Quillay bark extract, Panama bark extract, Quillai extract, Murillo bark extract, China bark extract
C.A.S. registry number:	68990-67-0
INS number:	999(i) [type 1 extract] and 999(ii) [type 2 extract]
Structural formula:	Not applicable (Mixture of substances)
Molecular weight:	Not applicable (Mixture of substances)
Marketing names:	Q-Naturale® 100, Q-Naturale® 200 and Q-Naturale® 300.

2.1.2 Chemical and physical properties

Quillaia extract is obtained by aqueous extraction of the milled inner bark, stems and branches of the *Quillaia saponaria* Molina tree. The tree is native to China and South America. The extract is a heterogeneous mixture of over 100 tri-terpenoid saponins. The saponins consist mainly of quillaic acid as the hydrophobic moiety with various attached oligosaccharides (JECFA 2005). The oligosaccharides consist of various combinations of sugars such as glucose, galactose, arabinose, xylose and rhamnose. Other components that may be present include polyphenols, tannins and calcium oxalate (JECFA 2005; The Commission of the European Communities 2012).

The combination of a hydrophobic component such as quillaic acid and hydrophilic oligosaccharides makes saponins amphipathic substances. They are surface-active substances that form micelles in an aqueous solution, and this gives quillaia extracts emulsifying and foaming properties (Güçlü-Ustündağ and Mazza 2007).

The general structure of quillaia saponins is as shown in Figure 1.



	R¹	R²	R³
S1	α-L-Rha*p*	H	H
S2	β-D-Xyl*p*	H	H
S3	α-L-Rha*p*	β-D-Xyl*p*	H
S4	β-D-Xyl*p*	β-D-Xyl*p*	H
S5	α-L-Rha*p*	β-D-Api*f*	H
S6	β-D-Xyl*p*	β-D-Api*f*	H
S7	α-L-Rha*p*	H	Acetyl
S8	β-D-Xyl*p*	H	Acetyl
S9	α-L-Rha*p*	β-D-Xyl*p*	Acetyl
S10	β-D-Xyl*p*	β-D-Xyl*p*	Acetyl
S11	α-L-Rha*p*	β-D-Api*f*	Acetyl
S12	β-D-Xyl*p*	β-D-Api*f*	Acetyl

Figure 1: General structure of quillaia saponins. In this example, the aglycone component is quillaic acid (Güçlü-Ustündağ and Mazza 2007).

There are two types of quillaia extract. Type 1 is obtained by aqueous extraction and type 2 by further purification (chromatographic separation or ultrafiltration) of the type 1 extract. Type 1 extract contains 10-30% saponins, while type 2 contains 65-90% saponins on a dry basis. Quillaia extract is highly water-soluble but insoluble in ethanol, acetone and butanol.

Commercial extracts can be in the form of a reddish-brown powder or light reddish-brown liquid. Some extracts are bleached to lighten the colour. Highly purified extracts, which have had polyphenols and other constituents removed, are used as adjuvants in the production of human and animal vaccines (JECFA 2005).

It is also possible that high levels of quillaia extracts added to beverages may have detrimental effects on the taste and appearance of the products. Quillaia saponins are bitter.

2.1.3 Production of quillaia extract

The traditional method of obtaining quillaia extract involves removing the outer part of the bark of the *Quillaia saponaria* Molina tree, then treating the remaining bark with hot water. This yields an extract with about 20% saponins (JECFA 2005).

Commercial manufacture of quillaia extract now usually involves milling the wood with its bark to yield an extract of similar quality to that obtained from bark alone. Following aqueous extraction, the crude extract is clarified and its pH adjusted. It is then filtered to give the type

1 extract. Type 2 extract is then obtained by chromatographic separation or ultrafiltration of the type 1 extract. The final product is then pasteurised and packaged.

JECFA (2005) notes that quillaia extract is often standardised with carriers such as lactose, maltodextrin or maltitol.

2.1.4 Specifications

The Applicant's quillaia extract product meets the JECFA specification for quillaia extract (JECFA 2005). JECFA specifications are listed as a primary source in the Code in clause 2 of Standard 1.3.4 – Identity and Purity, so no separate specifications for quillaia extracts is required in the Code. The specification for quillaia extract type 2 requires the quillaia saponins content to be between 65 and 90% on a dry basis, whereas for type 1 extract the specified range is 20 to 26 %.

2.1.5 Methods of analysis in foods

The Applicant cited the reversed phase HPLC method as detailed in the JECFA specification as a suitable method for detecting and quantifying the amount of quillaia saponins in food, with amendments to improve sensitivity. FSANZ considers the updated method is sufficient for purposes of monitoring the level of quillaia saponins in beverages.

Furthermore, FSANZ notes that the quantity of saponins required to achieve the intended technological purpose (emulsification of oil-soluble substances) is in the range 2.6 to 39 mg/L, which is in the range of proposed maximum permitted levels (MPLs) of 30 to 40 mg/L in various beverages.

2.2 Technological function of quillaia extract

The Applicant seeks approval to use quillaia extract type 2 as an emulsifier in a range of beverages. The Applicant intends to market the type 2 extract in Australia and New Zealand and has provided a study investigating the ability of this extract to form high oil load emulsions, see Appendix A of the Application.

In their study, the Applicant prepared 50% oil emulsions with different emulsifiers, namely gum arabic (20%), modified starch (20%) or quillaia extract type 2 (10%). Part of the emulsion was stored to check for stability, and the other was used in a beverage. The study reported that emulsions prepared with gum arabic or modified starch were paste-like and did not flow, and had an oil layer at the top after six months in storage. The beverages prepared using these emulsifiers developed a "ring" after 1 month in storage. The quillaia extract emulsion flowed and was stable after six months in storage. The beverage prepared using the quillaia emulsion did not form any rings and remained stable after six months in storage. The Applicant also reports that beverages prepared using quillaia extract as an emulsifier were clear compared with those using modified starch.

FSANZ considers the observations reported in the studies are consistent with the known properties of quillaia saponins.

Food categories in which quillaia extract is proposed for use

The Applicant has requested permission to use quillaia extract in the following food types as categorised in Schedule 1 of Standard 1.3.1:

Food Category		Proposed MPL (mg/kg)^
14.1.1.2	Carbonated, mineralised and soda waters	40
14.1.2.2	Fruit and vegetable juice products	40
14.1.3	Water based flavoured drinks	40
14.1.4	Formulated beverages	40
14.1.5	Coffee, coffee substitutes, tea, herbal infusions and similar products	30
14.2.1	Beer and related products	40
14.2.5	Spirits and liqueurs	40
14.3	Alcoholic beverages not included in item 14.2	40

^ MPL - Maximum Permitted Level, expressed as saponins

FSANZ considers quillaia extracts (both type 1 and type 2) fulfil a legitimate technological function when used in all of the food categories listed in the Table above.

FSANZ notes that quillaia extracts are currently used as foaming agents and emulsifiers in food in a number of countries (JECFA 2005). The Codex General Standard for Food Additives (GSFA) lists quillaia extracts (types 1 and 2) under the functional class “Emulsifier, Foaming agent” for water-based flavoured drinks, including “sport”, “energy” or “electrolyte” drinks and particulated drinks. The MPL for the type 1 extract is set in the GSFA at 50 mg/kg on a saponins basis, except in semi-frozen beverages where the limit is 130 mg/kg (dried basis).

In the European Union, quillaia extracts are permitted to be used in water-based flavoured non-alcoholic drinks and cider (excluding cidre bouché) at a maximum level of 200 mg/L calculated as anhydrous extract. The EU provisions do not distinguish between type 1 and type 2 extracts.

In Canada, quillaia extract is permitted as a foaming agent in beverage bases, beverage mixes and soft drinks at Good Manufacturing Practice (GMP) levels. No distinction is made between type 1 and type 2 extracts.

In the United States, quillaia extract is listed in *Section 172.510 Natural flavoring substances and natural substances used in conjunction with flavors* under Title 21 of the US Code of Federal Regulations. The extract is permitted at GMP levels, and no distinction is made between type 1 and type 2. There is also a Generally Recognised as Safe (GRAS) notice (GRN 000165) for the type 1 extract as a foaming agent in semi-frozen carbonated and non-carbonated beverages. The extract is to be used at a maximum permitted level of 500 mg/kg (dried basis) in beverage concentrate prior to the incorporation of water and carbon dioxide or air in retail establishments. The Food and Drug Administration has raised no objection to GRN 000165.

The Applicant has also completed a self-affirmed GRAS determination for the type 2 extract when used as an emulsifier or encapsulation agent in alcoholic beverages, coffee, tea, processed fruit and vegetable juices and other beverages.

2.3 Conclusion

The Applicant has clearly articulated the technological function of quillaia extract when used as an emulsifier for adding oil soluble ingredients to various beverages. Based on its known physico-chemical properties and evidence provided by the Applicant, quillaia extract fulfils the stated technological function at the proposed levels of use i.e. it is effective as an emulsifier in various beverages. Furthermore, quillaia extract has a history of safe use as a food additive in a number of countries. The Applicant has provided a suitable method of analysis for detecting and quantifying quillaia saponins in various foods.

3. HAZARD ASSESSMENT

3.1 Introduction

JECFA has evaluated the toxicological hazard of quillaia extracts on several occasions, most recently in 2005, when a group ADI of 0-1 mg quillaia saponins/kg bw was established for type I (unpurified) and type II (saponin enriched) extracts (see Section 2 for more details about the type I and II extracts). Type I and type II quillaia extracts have separate specifications but because the acute toxicity was similar it was concluded that a group ADI which specified the quillaia saponin content could be used for both extract types.

The Applicant submitted published laboratory animal studies conducted on type I quillaia extract, which have previously been evaluated by JECFA and used as the basis for a group ADI for quillaia saponins. These studies are reported and evaluated in the following sections.

An additional literature search was conducted by FSANZ to identify any relevant published supplementary data on the toxicity of quillaia extract. Searches were conducted in PubMed (http://www.ncbi.nlm.nih.gov/pubmed), TOXNET (http://toxnet.nlm.nih.gov/), Google Scholar (http://scholar.google.com.au/) and SCIRUS (http://www.scirus.com/) using the keywords "quillaia" or "quillaia" *and* "toxicity" or "safety" or "growth". A tolerance study in weaned piglets (Ilsley et al 2005) was identified for inclusion in this hazard assessment. However, other studies in piglets by Turner et al (2002) and Václavková & Beèková (2008) were excluded on the grounds that there was insufficient detail surrounding the composition of the quillaia extract used.

3.2 Evaluation

3.2.1 Biochemical aspects

Chemically saponins (Latin: sapo → soap) are characterised as being amphiphilic, the triterpene or steroid (eg quillaic acid in the saponins from quillaia extract) part being hydrophobic and the sugar part (eg glucose, galactose, arabinose, xylose and rhamnose) hydrophilic, giving saponins their characteristic surfactant activity from which the name is derived. As a result of their chemistry, many ingested saponins have been shown to form large mixed micelles with bile acids and cholesterol leading to decreased intestinal cholesterol absorption. Similarly, many ingested saponins have been shown to affect the enterohepatic circulation of bile acids by forming mixed micelles (Francis et al 2002).

Saponins from soapbark trees and administered orally to rabbits with experimental atherosclerosis resulted in an increased ratio of plasma lecithin to cholesterol, normalized blood cholesterol levels, and decreased elevated blood pressure[2]. Subcutaneous injection of the saponin extract did not affect the atherosclerotic symptoms (Efimova et al 1966).

The effect of a range of saponins, including crude quillaia saponin extract on gut permeability was assessed by monitoring the steady-state glucose transfer potential *in vitro* in sections of jejunal mucosa from male Wistar rats. The individual saponins elicited widely different responses in the small gut and these were significantly affected by pH,

[2] The term 'decreased elevated blood pressure' was a direct reference from the abstract of the Efimova et al 1966 study, obtained from the JECFA Report (2005)

concentration, chemical formula, and the presence of other materials in the solution. Quillaia extract caused a reduction in transmural potential difference comparable to that observed with the basic glycoalkaloids in potato and tomato and the complex bisdesmosides from Gypsophilia and alfalfa. These saponins were all more potent than the saponins from soya, which showed only weak activity.

The reduction in transmural potential difference has been associated with increased uptake of both passively permeable sugars and large compounds and with a loss of the ability of the mucosa to accumulate actively transported organic species (Gee et al 1989).

The effect of the quillaia saponin fractions QH-A, QH-B, and QH-C and a crude quillaia saponin extract (Spikoside) on haemolytic activity, cytotoxicity, and macromolecular synthesis was studied in vitro. A concentration of 5 µg/mL of QH-B or QH-C caused haemolysis of chicken erythrocytes after 1 h of incubation at 37^{o} C. QH-A was haemolytic at an approximately 10-fold higher concentration, 50 µg/mL. The crude extract caused haemolysis at a concentration of 20 µg/mL. No haemolytic activity was observed at concentrations <100 µg/mL when these preparations were incorporated into an immunostimulating complex matrix. Cytotoxicity was assessed by measuring intracellular dehydrogenase activity by a colorimetric method. Seeded WEHI 164 cells (clone 139) were incubated with various concentrations of the extracts for 2 h before analysis. QH-B and QH-C inhibited enzyme activity at 10 µg/mL and the crude extract at a concentration of approximately 20 µg/mL. QH-A was tolerated at concentrations <100 µg/mL. When QH-A, QH-B, QH-C, and the crude extract were incorporated into the immunostimulating complex matrix, the cells tolerated approximately 10-fold higher concentrations. Macromolecular synthesis was assessed by measuring incorporation of [^{3}H]leucine and [^{3}H]uridine into protein and RNA, respectively, in WEHI 164 cultured cells. Treatment with QH-B or QH-C at concentrations <10 µg/mL for 30 min had no effect on protein or RNA synthesis (Rönnberg et al 1995).

3.2.2 Absorption, distribution, metabolism and excretion

No studies were submitted on the absorption, distribution, metabolism and excretion of quillaia extract.

3.2.3 Acute toxicity

No acute studies were submitted by the Applicant. However, in previous JECFA monographs the following studies have been cited.

In mice, saponins extracted from the soapbark tree were less acutely toxic when administered orally (LD50, 1600 mg/kg bw) than when administered intravenously (280 mg/kg bw) (Efimova et al 1966).

Groups of five Sprague-Dawley rats of each sex were gavaged once with doses ranging from 3000 to 20 000 mg/kg bw and were observed for clinical signs of toxicity for 14 days. The LD50 for the type II extract when expressed in relation to the saponin content was calculated to be 900 mg/kg bw. The LD50 for the type I extract expressed in relation to the saponin content was 1000 mg/kg bw. On the basis of the saponin content, the LD50s for the two extracts were the same: about 900 mg/kg bw (JECFA 2006).

3.2.4 Repeat-dose toxicity studies

Gaunt IF, Grasso P & Gangolli SD (1974) Short-term toxicity of quillaia extract in rats. Fd Cosmet. Toxicol. 12: 641-650.

An aqueous type I quillaia extract (Food Industries Ltd, Birkenhead, Cheshire, UK) was admixed in the diet at concentrations of 0, 0.6, 2 or 4% (w/w) and fed *ad libitum* to Carworth Farms Elias (CFE) strain rats (15/sex/group; males bw range 130-175 g; females bw range 105-135 g) for 13 weeks. Separate groups of 5/rats/sex were fed diets containing 0, 2 or 4% (w/w) quillaia extract for 2 or 6 weeks. The test material was described as a spray dried aqueous extract, with 100 parts by weight of quillaia bark yielding ~15 parts of the extract. The test material contained 5% (w/w) lactose added to the extract before drying. The dried extract was stated to contain <10% (w/w) moisture and <10% (w/w) ash. Bodyweight and food consumption were recorded prior to the commencement of dosing and weekly thereafter. An *in vitro* haemolysis assay was performed using blood collected during week 6 (5 rats/sex from the control and high-dose group) and 13 (5 females from the control and high-dose group). During weeks 6 and 13, urine was collected at 0-2 and 16-20 h following a water load of 25 mL/kg bw and the following parameters analysed: microscopic constituents, blood, bile and ketones. Also during week 13, urine volume and specific gravity were analysed following a 6 h period without water. At the end of the treatment period, rats were sacrificed, necropsied and the following organs weighed: brain, pituitary, thyroid, heart, liver, spleen, stomach, small intestine, caecum, kidneys, adrenals and gonads. Samples of these organs and of oesophagus, colon, rectum, lung, lymph nodes, skeletal muscle, trachea, uterus, urinary bladder and pancreas were examined histopathologically. During autopsy blood was collected for the analysis of haematology [haemoglobin (Hb), haematocrit (Hct), erythrocyte counts (RBC), reticulocytes, leucocytes (WBC) and differential leucocyte count] and clinical chemistry parameters [urea, glucose, total protein, albumin, alanine aminotransferase (ALT), aspartate aminotransferase (AST) and lactate dehydrogenase (LDH)]. The intake of the test material was calculated by the authors to be 0.36, 1.18 and 2.47 g/kg bw per day in males and 0.44, 1.37 and 3.03 g/kg bw per day in females at dietary concentrations of 0.6, 2 or 4% (w/w), respectively.

There were no deaths or clinical signs. Bodyweight and food consumption findings are summarised in Table 3.1.

Table 3.1. Bodyweight and food consumption in rats exposed to quillaia extract for up to 13 weeks

Parameter	Dietary concentration (% w/w)							
	0		0.6		2.0		4.0	
	Male	***Female***	***Male***	***Female***	***Male***	***Female***	***Male***	***Female***
Bodyweight (g)								
d 29	333	214	319	215	321	207	**306*** **	206
d 57	428	263	407	264	419	251	**409***	254
d 92	496	272	466	293	478	277	457	281
Bodyweight gain (g)								
d 0-92	346	149	316	172	328	154	307	159
Feed consumption (g/rat/day)								
d 1	19.4	15.6	18.2	15.6	14.7	13.3	9.4	6.4
d 29	24.0	22.7	26.4	19.2	22.9	16.8	22.3	15.5
d 57	22.0	17.5	19.4	17.2	20.4	11.3	20.4	15.1
d 92	21.3	17.2	21.5	17.6	20.2	12.4	20.2	16.6
Overall mean	21.9	17.8	20.5	17.4	20.3	**14.0****	20.0	**15.3****

Results expressed as means; *p<0.05; **p<0.01; ***p<0.001

The mean absolute bodyweight of high-dose males was significantly lower than the control on d 29 (p<0.001) and 57 (p<0.01), with overall bodyweight gain ~11% lower than the control. The reduced bodyweight gain in high-dose males over ninety-two days are not

matched by a corresponding significant reduction in food consumption. An overall reduction in food consumption was observed in mid- and high-dose females but this was not associated with a corresponding reduction in bodyweight gain. Overall mean water consumption was significantly lower than the control in mid- and high-dose male rats ($p<0.05$ and 0.001, respectively) and was also reduced in high-dose females, but not significantly. The magnitude of these decreases was ~10%, 18% and 7%, respectively.

There was no treatment-related effect on any haematology, clinical chemistry or urinalysis parameter. There were a number of significant differences in absolute and/or relative organ weights between treated and control rats (Table 3.2).

Table 3.2. Selected organ weights of rats exposed to quillaia extract for 13 weeks

Organ	**Dietary concentration (% w/w)**							
	0		**0.6**		**2.0**		**4.0**	
	Male	***Female***	***Male***	***Female***	***Male***	***Female***	***Male***	***Female***
Absolute weight (g)								
Liver	12.39	6.51	**11.21***	6.32	**10.86****	6.29	**10.57*****	6.68
Kidney	2.86	1.69	2.67	1.65	**2.28***	1.59	**2.55***	1.55
Stomach	1.65	1.29	1.65	1.27	1.76	1.30	1.75	1.39
Relative organ weight (%)								
Liver	2.64	2.32	2.53	2.24	**2.40*****	2.32	**2.41*****	2.45
Kidney	0.61	0.60	0.60	0.59	**0.57***	0.58	0.58	**0.57***
Stomach	0.35	0.46	0.37	0.45	**0.39****	0.48	**0.40****	**0.51****

Results expressed as means; *p<0.05; **p<0.01; ***p<0.001

In males, absolute liver weights were significantly lower ($p<0.01$ or 0.05) than the control across all doses; when corrected for bodyweight, significant differences ($p<0.001$) were evident at the mid- and high-doses. The lower relative liver weights were not associated with any histopathological abnormalities or clinical chemistry findings. The absolute kidney weight of mid- and high-dose males was significantly lower ($p<0.05$) than control, while only the relative kidney weight of mid-dose males was significantly lower ($p<0.05$); in the absence of a dose-response relationship, kidney histopathology, effects on clinical chemistry or urinary parameters or the same findings in females, these differences in kidney weights are considered to be incidental. Relative stomach weight was significantly higher ($p<0.01$) than the control in mid-dose males and high-dose males and females. While the authors suggested that these higher stomach weights may reflect a local irritant effect, the absence of any actual signs of irritation by way of macroscopic examination, histopathology or clinical signs would not seem to support this interpretation.

The No Observed Adverse Effect Level (NOAEL) of the type I quillaia extract was 0.6% (w/w), equivalent to 400 mg/kg bw per day based on reduced bodyweight gain, reduced food consumption, reduced liver weight, and increased stomach weights.

Phillips JC, Butterworth KR, Gaunt IF, Evans JG & Grasso P (1979) Long-term toxicity study of quillaia extract in mice. Fd Cosmet. Toxicol. 17: 23-27.

An aqueous type I quillaia extract (sourced from Food Industries Ltd, Birkenhead, Cheshire, UK) was admixed in the diet at concentrations of 0, 0.1, 0.5 or 1.5% (w/w) and fed *ad libitum* to TO strain mice (48/sex/group) for 84 weeks (equivalent to 0, 1000, 5000 and 15000 ppm, respectively). The estimated doses were 0, 150, 750 and 2250 mg/kg bw per day using a dietary conversion factor of 0.15. Based on the description given in the paper, the extract appears to be consistent with that used in the preceding study by Gaunt et al (1974). Mice were observed regularly for clinical signs. Sixteen male mice per group were weighed at weeks 1, 4, 10, 14, 28, 40, 57 and 84. Food consumption was not recorded. Blood was

sampled from 10 mice/sex/group at week 26 and 54, and all surviving mice at week 84, for the analysis of Hb, Hct, reticulocytes, RBC and WBC. At the end of the exposure period, survivors were sacrificed, necropsied and the following organs weighed: brain, heart, liver, kidneys, spleen, stomach, small intestine, caecum and testes. These along with the following organs/tissues were histopathologically examined: salivary gland, thyroid, adrenal glands, lymph nodes, aorta, pancreas, pituitary, prostate, seminal vesicles, ovaries, uterus, urinary bladder, lungs, colon, rectum, spinal cord, skeletal muscle, eye, Harderian gland and any gross lesions.

There were no intergroup differences in survival; cumulative mortality to week 80 was 16, 18, 12 and 9% in males and 9, 11, 10 and 12% in females at dietary concentrations of 0, 0.1, 0.5 and 1.5% (w/w), respectively. There were no treatment-related clinical signs. The only significant effect on absolute bodyweight was in high-dose males where the terminal bodyweight (47 g) was significantly lower ($p<0.05$) than the control (53 g). The significantly higher ($p<0.05$) relative brain and stomach weights in high-dose males is attributable to the lower terminal bodyweight. At week 26, RBC was significantly lower ($p<0.05$) than the control in mid-dose males and high-dose males and females ($p<0.01$), while at week 84, RBC was significantly lower ($p<0.01$) than the control only in mid-dose males. In the absence of a dose-response relationship, a consistent effect between the sexes or any corroborative perturbations in other haematology parameters (e.g. Hb, Hct or reticulocytes), these significant differences in RBC between treated and control groups are considered to be incidental findings. There were no treatment-related macroscopic or histopathological abnormalities.

The NOAEL of the type I quillaia extract was 0.5% (750 mg/kg bw per day), based on reduced terminal bodyweight in males at 1.5% (2250 mg/kg bw per day).

Drake JJ-P, Butterworth KR, Gaunt IF, Hooson J, Evans JG & Gangolli SD (1974) Long-term toxicity of quillaia extract in rats. Fd Cosmet. Toxicol. 20: 15-23.

Prior to the main study, two short-term palatability studies were conducted in groups of two male Wistar rats that had access to a control diet and a diet supplemented with 0.3, 1.0 or 3.0% (w/w) type I quillaia extract. The test material appears to be consistent with that used in the two preceding studies undertaken by the same group. In the first study, the amount of each diet consumed was recorded for 21 days. In the second study, rats were fed diets containing 0.3, 1.0 or 3.0 % (w/w) quillaia extract for 7 days: bodyweight and food consumption were recorded daily. In the first study, when there was a choice between a control and test diet, rats (bw range 255-275 g) consumed 18, 12 and 34 times less of the diet containing 0.3, 1.0 or 3.0% (w/w) type I quillaia extract, respectively, relative to the control diet. In the second study, the mean daily food consumption in rats (bw range 358-395 g) over 7 days was 25, 29, 26 and 21 g/day, with the corresponding bodyweight gains of 26, 29, 30 and 11 g. These findings suggest that ingestion of quillaia extract reduces bodyweight gain in the absence of a proportional reduction in feed consumption.

In the main study, type I quillaia extract was admixed in the diet at concentrations of 0, 0.3, 1.0 or 3.0% (w/w) and fed *ad libitum* to Wistar rats (48/sex/group) for 2 years. Observations for clinical signs and deaths were made “regularly”. Bodyweight and food consumption were measured approximately every 2 months. Blood was taken from 10 rats/sex in the control, mid- and high-dose groups at week 15, 25 and 52, with blood collected from all surviving rats after 108 weeks. The following haematology and clinical chemistry parameters were analysed: Hb, Hct, RBC, WBC, differential WBC, urea, glucose, total protein, albumin, ALT, AST and LDH. Urine was collected from 10 control and 10 high-dose rats/sex at weeks 13, 24 and 78 for the analysis of volume, specific gravity, microscopic constituents, protein, glucose, blood, bile and ketones. Decedents and those sacrificed at the end of the study were necropsied and their organs/tissues examined macroscopically and histopathologically.

Cumulative mortality to 103 weeks was 33, 27, 42 and 19% in males and 27, 27, 21 and 29% in females in the control, low-, mid- and high-dose, respectively. There were no clinical signs reported. For males the mean food consumption measured at weeks 4, 25, 54, 71, 89 and 106 was 20.2, 19.3, 18.9, and 18.5 g/rat/day for the control, 0.3%, 1% and 3% groups respectively. In females the food consumption for the same treatment groups was 15.9, 15.3, 15.2 and 14.9 g/rat/day respectively. Water consumption was unaffected by treatment. The mean absolute bodyweight of high-dose males was significantly lower ($p<0.05$ or 0.01) than the control at week 4, 42, 48, 54, 63, 71, 80 and 89 (3-9% lower than the control), with the overall bodyweight gain to week 106 being ~9% lower than the control.

In high-dose males, mean urine specific gravity was significantly higher ($p<0.01$) than the control at week 78 but not at weeks 13 or 24. However, as the week 78 value (1.075) was identical to that determined at week 24, the significant difference is attributed to the reduction in specific gravity of the control from week 24 to week 78 concomitant with an increase in urine volume. There was no treatment-related effect on any haematology or clinical chemistry parameter. It was noted that WBC were significantly higher than the control in treated males at week 15 [13.8, 19.5 ($p<0.05$) and 23.0 $10^3/mm^3$ ($p<0.01$) at 0, 1 and 3% quillaia extract, respectively] and 25 [13.8, 12.2 and 18.5 ($p<0.01$) at 0, 1 and 3% quillaia extract, respectively]. No differences were determined at week 52, with both sexes having significantly *lower* ($p<0.05$) WBC at week 108. In the differential WBC, significantly higher ($p<0.01$) neutrophils and lower ($p<0.01$) lymphocytes were determined in high-dose males at week 15 only. Due to the inconsistent nature of these findings (over time and between doses and sexes), these significant differences in males are not considered treatment-related. Some significant differences in absolute or relative organ weights were noted but were considered to be incidental findings due to their inconsistent occurrence and the lack of corroboration with any clinical chemistry or histopathological findings. There were no treatment-related non-neoplastic or neoplastic lesions.

The NOAEL of the type I quillaia extract was 1% (500 mg/kg bw per day) based on reduced bodyweight gain in males at 3% (1174 mg/kg bw per day). There was no evidence that quillaia extract was carcinogenic up to a maximum dose of 1500 mg/kg bw per day.

3.2.5 Growth performance study

Ilsley SE, Miller HM & Kamel C (2005) Effects of dietary quillaia saponin and curcumin on the performance and immune status of weaned piglets. J. Anim. Sci. 83:82-88

The objective of this study was to determine whether dietary quillaia saponin and curcumin (an extract of turmeric) would modulate weaned piglet growth characteristics and their immune status, as measured by changes in serum immunoglobulins G and A, C-reactive protein, and interferon-γ concentrations immediately after weaning. As investigations into the effects of curcumin are not the focus of this review no results from this aspect of the study are reported here. Quillaia extract (type I; Acros Organics, Geel, Belgium) was admixed in the diet at 0 or 750 mg/kg for one week then 300 mg/kg from day 8 to 20. Water and the respective diets were available ad libitum to groups (48/group; matched by weight, litter, and gender) of weaned 29-day old piglets (62.5% Large White, 25% Landrace, 12.5% Duroc). Feed intake was measured daily and the piglets were weighed on day 7, 14, and 20 after weaning. On day 6 and 20 after weaning, eight pigs per treatment were sacrificed for blood and small intestine collection. Villus and crypt lengths of the small intestine were measured.

Feed supplementation with quillaia saponin had no effect on piglet growth (Control v treatment group on day 0; 7.7 kg v 7.7 kg; day 7, 9.1 kg v 9.2 kg; day 14, 11.7 kg v11.9 kg; day 20, 14.6 kg v 14.7 kg). Table 3.3 shows that the average daily feed intake (ADFI) and

growth to feed intake ratio (G:F) were similar between days 0 and 14 of the trial. However, between days 15 and 20, ADFI and G:F were lower in quillaia saponin-supplemented piglets (ADFI = 621 vs. 572 g/d; P < 0.05; G:F = 0.75 vs. 0.85). Serum immunoglobulin IgG, IgA, interferon-γ, and C-reactive protein (CRP) did not differ on day 6 after weaning. On day 20, IgG and CRP concentrations were greater (IgG = 18.2 vs. 12.1 mg/mL; CRP = 26.7 vs. 12.3 mg/ mL; P < 0.05).
Small intestine villus and crypt measurements did not differ on either day 6 or 20.

Table 3.3. Bodyweight and food consumption in weaned piglets exposed to quillaia saponin for 3 weeks

	Dietary quillaia saponin concentration		
	0	750 mg/kg week1 300 mg/kg thereafter	p-value*
Average Daily Feed Consumption (g/day)			
d 0-7	200	212	0.565
d 8-14	429	456	0.366
d 15-20	572	621	0.044
d 0-20	388	420	0.098
Bodyweight gain:Feed ratio			
d 0-7	1.00	1.04	0.521
d 8-14	0.87	0.85	0.309
d 15-20	0.85	0.75	0.072
d 0-20	0.89	0.84	0.056

*Piglet weaning weight and age used as covariates in the statistical analysis.

3.3 Discussion

In general saponins, as a consequence of their chemistry, have poor membrane permeability capacity because of their large molecular mass, high hydrogen-bonding capacity and molecular flexibility (Yu et al 2012). While no pharmacokinetic data were available for the saponins from quillaia it is likely that intestinal absorption of unchanged saponins will be poor. Since many saponins are enzymatically cleaved by microflora in the gastrointestinal tract to form deglycosylated aglycones it is less certain such metabolites will not be absorbed.

Quillaia saponins administered orally to rabbits with experimental atherosclerosis have resulted in an increased ratio of plasma lecithin to cholesterol, normalized blood cholesterol levels, and decreased elevated blood pressure. It is unclear whether quillaia extract would also affect cholesterol levels in normal animals. The data from repeat dose oral administration in mice and rats showed no evidence any change in plasma cholesterol levels. A consistent toxicological finding in all animal studies (mice. rats and weaned piglets) was an appreciable reduction in the food:bodyweight conversion ratio that was especially apparent during the fast growing stages in juvenile animals. In some cases a reduction in bodyweight gain correlated with a slightly reduced feed intake but this relationship became less consistent as the duration of dosing increased. For example weaned piglets needed to consume more feed over twenty days to maintain their bodyweight when their diet was admixed with 300 mg/kg of quillaia derived saponins (effect level is equivalent to 126 mg/kg bw/day). Similarly, in young male rats fed 2% or 4% quillaia extract there was a marked reduction in bodyweight at days 29 and 57 that was not accompanied by a corresponding reduction in feed intake. However, by day 92 the reduction in bodyweight was no longer as

marked but nevertheless by week 106 the bodyweight of male rats fed 3% quillaia extract was still significantly less than control. There are no data available to consider a possible mode of action for the reduction in the food:bodyweight conversion ratio in juvenile animals although impaired uptake of essential nutrients cannot be excluded.

Following a re-evaluation of the repeat-dose dietary studies considered previously by JECFA and a recent published study in piglets, FSANZ considers that the NOAELs established in rodent studies (750 mg/kg bw per day in mice and 500 mg/kg bw per day in rats) are suitable to derive a group ADI. Since the amount of quillaia saponins in type I extract is around 20%, the NOAEL can be calculated to be 100 mg quillaia saponins/kg bw per day in rats, leading to a group ADI of 0-1 mg quillaia saponins/kg bw. A group ADI is established to permit the use of type I (unpurified) and type II (saponin enriched) extracts.

3.4 Conclusion

Data relevant to the hazard assessment of quillaia extract have been evaluated. A group ADI of 0-1 mg quillaia saponins/kg bw has been established.

4. DIETARY EXPOSURE ASSESSMENT

4.1 Approach to predicting dietary exposure to quillaia saponins

Dietary exposure assessments (DEAs) require data on concentrations of the chemical of interest in the foods requested, and consumption data for the foods that have been collected through a national nutrition survey.

Information was provided by the Applicant on the proposed food categories to which quillaia saponins would be added, the proposed MPLs and the proportion of the food product categories listed that were likely to include quillaia saponins. The dietary exposure was predicted using a calculated proxy MPL value for the concentration of quillaia saponins in the food categories requested. The proxy MPL value (*proxy concentration*) used for the modelling was calculated by multiplying the MPL provided for each food category by 0.2 to account for a 20% market uptake after 10 years, as predicted by the Applicant. Market share data were used in order to obtain a more refined predicted of likely population exposures over time.

The proxy concentration data together with food consumption data from the available Australian and New Zealand national nutrition surveys were then used to predict the populations' exposure to quillaia saponins. The dietary exposure assessment was undertaken using FSANZ's dietary modelling computer program, DIAMOND.

A summary of the general FSANZ approach to conducting the dietary exposure assessment for this Application is at Appendix 1. A detailed discussion of the FSANZ methodology and approach to conducting dietary exposure assessments is set out in the *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

4.1.1 Consumption data used

The food additive permissions contained in the Code apply to foods produced or sold in both Australia and New Zealand. Therefore the dietary exposure assessment was undertaken for both countries.

The food consumption data used for the exposure assessment were:

- 1995 Australian National Nutrition Survey (1995 AusNNS), one 24 hour food recall covering 13,858 Australians aged 2 years and above, however, only the data for respondents aged 17 years and above were used for this assessment (n=11,129).
- 1997 New Zealand National Nutrition Survey (1997 NZNNS), one 24 hour food recall covering 4,636 New Zealanders aged 15 years and above.
- 2002 New Zealand National Children's Nutrition Survey (2002 NZCNS), one 24-hour food recall covering 3,275 New Zealand school children aged 5-14 years.
- 2007 Australian National Children's Nutrition and Physical Activity Survey (also known as 'Kids Eat Kids Play') (2007 ANCNPAS), two non-consecutive 24 hour food recalls covering 4,487 Australian children aged 2-16 years.

The design of these nutrition surveys vary and the key attributes of each, including survey limitations, are set out in Appendix 1.

The hazard identification and characterisation (Section 3) did not identify any population sub-

groups for which there were specific safety considerations in relation to exposure to quillaia saponins. In addition, the food categories requested in the application for addition of quillaia saponins, are consumed by all sectors of the Australian and New Zealand populations. Therefore, for the DEA, the available food consumption data were matched with the proxy concentration values for the requested food categories for the following population groups:

- Australians aged 2-16 years
- Australians aged 17 years and above
- New Zealanders aged 5-14 years, and
- New Zealanders aged 15 years and above.

4.1.2 Proposed food categories and concentrations of quillaia saponins used

The Applicant provided the list of food categories within which the quillaia saponins are proposed to be used, the proposed MPLs in Australia and New Zealand, and the proportion of the product category likely to include quillaia saponins. The food category codes used by the Applicant were based on the Australia New Zealand Food Classification System (ANZFCS) in Standard 1.3.1 – Food Additives in the Code and its related Schedules. However, the food classification codes in DIAMOND do vary slightly depending on the date of collection of the nutrition survey data, and may also be split into sub-groups. To assess the populations' dietary exposure to quillaia saponins, the food categories proposed by the Applicant were assigned to the relevant DIAMOND food classification codes.

Where a specific food category had been listed by the Applicant and no sub-groups of foods within the category had been specified as excluded, the calculated proxy concentration of quillaia saponins was applied to all the sub-groups within the food category. For example, permission to add quillaia saponins to *fruit and vegetable juice products* was requested, therefore all foods under this main category were included in the DEA. Overall, this results in a conservative prediction of dietary exposure to quillaia saponins, in line with the tiered approach to DEAs usually used by FSANZ.

The food categories for which permission to add quillaia saponins was requested, the corresponding ANZFCS food groups used in the DEA, the maximum proposed concentrations of quillaia saponins and the proportion of the product likely to include quillaia saponins, as specified by the Applicant, are set out in Table 4.1. The Table also shows the calculated proxy concentrations used in the dietary exposure assessment for the relevant DIAMOND food categories.

4.1.3 Dietary modelling approach used for assessing exposure to quillaia saponins

The dietary modelling approach used for this assessment is summarised in Figure 4.1. Where the nutrition surveys had captured foods from all the food categories listed by the Applicant, the population approach was used with no modifications. For these foods, the calculated proxy MPL concentration was directly determined from the provided MPL and the proportion of each food category likely to contain quillaia saponins. The proxy concentrations were then used in the dietary modelling to predict the Australian and New Zealand populations' dietary exposure to quillaia saponins.

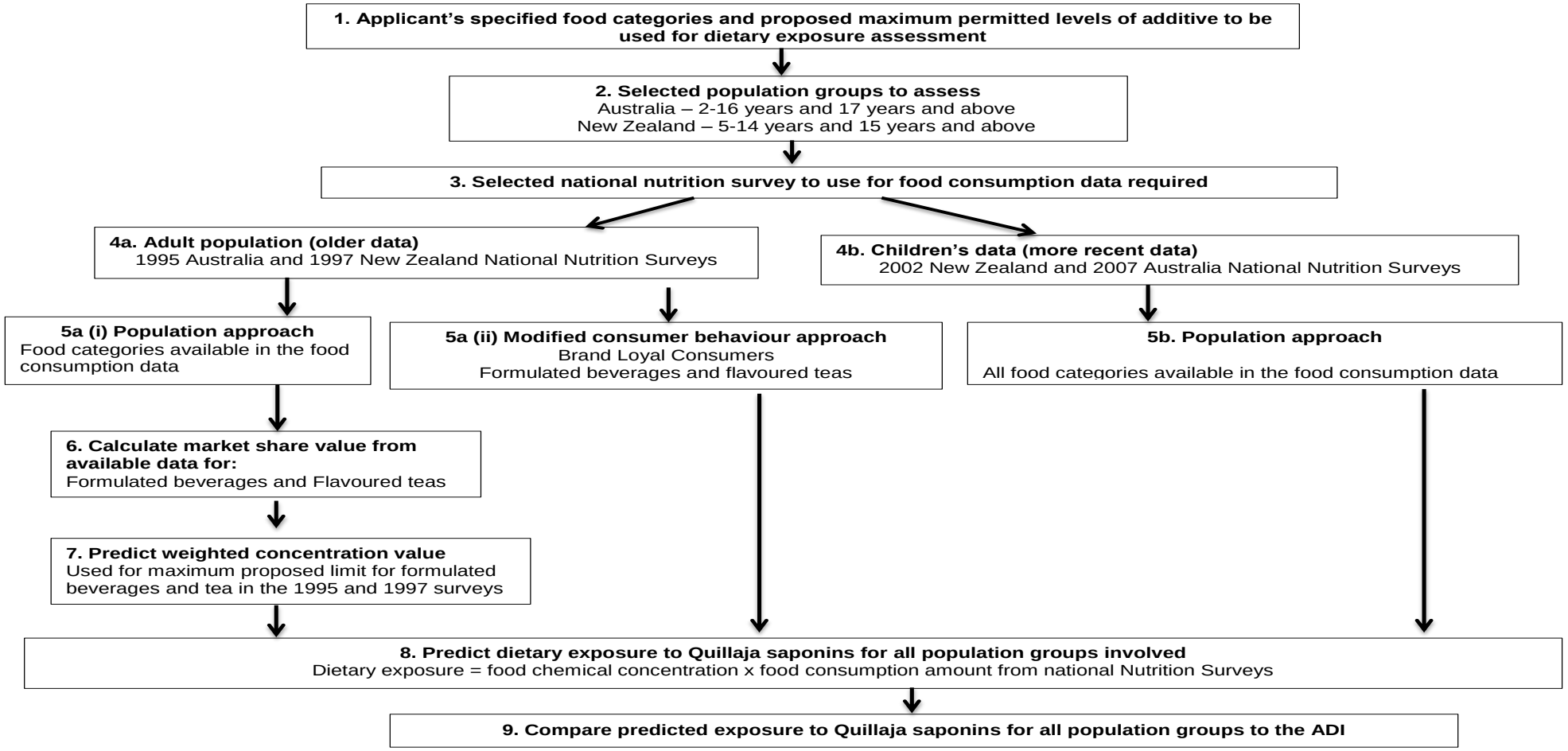


Figure 4.1 Dietary modelling approach used for assessing exposure to quillaia saponins for Australia and New Zealand

Table 4.1: Requested food categories, corresponding DIAMOND food classification codes, proposed MPLs of quillaia saponins, the proportion of the food category likely to contain quillaia saponins; and the levels used for the DEA

Requested food categories to contain quillaia extract	DIAMOND Food Code	DIAMOND main food groups and sub-group names	Applicant's proposed MPL of quillaia saponins – dry basis (ppm)	Uptake after 10 years - % of food category likely to include quillaia saponins	Calculated proxy values of quillaia saponins used for DEA			
					Population approach (concentration in mg/kg x market uptake percentage)		Modified consumer behaviour approach 1995 and 1997 NNS**	
					2002 and 2007 NNS	1995 and 1997 NNS	Maximum MPL	Zero MPL
Carbonated, mineralised and soda waters	14.1.1.2	Carbonated, mineralised and soda waters	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2
Fruit and vegetable juice products	14.1.2.2	Fruit and vegetable juice products	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2
Water based flavoured drinks	14.1.3	Water based flavoured drinks	40	20	40 x 0.2	40* x 0.2	40	0
Formulated beverages	14.1.4	Formulated beverages	40	20	40 x 0.2	N/A[#]	N/A[#]	N/A[#]
Coffee (or substitute), tea, herbal infusion and similar products (**include only flavoured coffee and tea**)	14.1.5	**Coffee substitute beverages, coffee-based mixes and instant coffee powders/granules including decaffeinated**	**30**	**20**				
		Coffee beverage, caffeine, instant powder/granules (includes flavoured coffee)	30	20	30 x 0.2	30 x 0.2	30 x 0.2	30 x 0.2

Requested food categories to contain quillaia extract	DIAMOND Food Code	DIAMOND main food groups and sub-group names	Applicant's proposed MPL of quillaia saponins – dry basis (ppm)	Uptake after 10 years - % of food category likely to include quillaia saponins	Calculated proxy values of quillaia saponins used for DEA			
					Population approach (concentration in mg/kg x market uptake percentage)		Modified consumer behaviour approach 1995 and 1997 NNS**	
					2002 and 2007 NNS	1995 and 1997 NNS	Maximum MPL	Zero MPL
		Coffee beverage, decaffeinated, instant powder/granules (includes flavoured coffee)	30	20	30 x 0.2	30 x 0.2	30 x 0.2	30 x 0.2
		Coffee substitutes beverage	30	20	30 x 0.2	30 x 0.2	30 x 0.2	30 x 0.2
		Coffee-based mixes beverage	30	20	30 x 0.2	30 x 0.2	30 x 0.2	30 x 0.2
		Teas (including flavoured tea)	30	20	30 x 0.2	11.3* x 0.2	30	0
		Herbal tea	30	20	30 x 0.2	30 x 0.2	30 x 0.2	30 x 0.2
Alcoholic beverages (including no and low alcohol)	14.2	**Alcoholic beverages (including no and low alcohol)**	**40**	**20**				
		Beer and related products	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2
		Wine based drinks and reduced alcohol wines[@]	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2
		Spirits and Liqueurs	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2
Alcoholic beverages not included in item 14.2 (Include blend of a cider with other drinks	14.3	Alcoholic beverages not included in item 14.2	40	20	40 x 0.2	40 x 0.2	40 x 0.2	40 x 0.2

* Calculated MPL value based on market share of the beverage type in the food category using the proposed maximum permitted levels given by the Applicant.
[#] Food group was not categorised or consumed in the 1995 and 1997 nutrition surveys.
[@] This food category not listed by Applicant but was included in modelling because of request to include a blend of cider with other drinks.
** Modified consumer behaviour model in that only water based flavoured beverages and teas were assumed to contain quillaia extract at either the MPL or zero concentration levels, proxy concentration used for all other beverages.

4.1.3.1 Inclusion of foods foods not available at time of nutrition survey in the predicted dietary exposures

The Applicant had requested the use of quillaia saponins in formulated beverages and flavoured teas in addition to other food categories. Although now available for purchase, these two foods were not commonly available on the markets in either Australia or New Zealand in 1995 and 1997 when these two nutrition surveys were conducted, therefore, consumption of these foods were not reported.

To take account of this, market weighted concentrations were calculated for the food categories of which they are components, based on current market share data obtained from the *RetailWorld Annual Report, December 2011*. The calculated values were then used together with the proportion of the products likely to include quillaia saponins, to provide the proxy MPL concentration of quillaia saponins in these foods. The details of how the calculations were done and the values obtained for use in the exposure assessments are shown in section A1.4 of Appendix 1 with the final values summarised in Table 4.1.

Because weighted concentrations were used in the calculations, the predicted dietary exposures can only infer the long term dietary exposures for the populations as a whole.

4.1.3.2 Modified consumer behaviour model

The use of market weighted concentrations in the exposure assessment for Australians aged 17 years and above (1995 NNS) and for the New Zealand population aged 15 years and above (1997 NNS), does not give an indication of potential dietary exposure for specific consumers in these populations who may be brand or product loyal. These consumers may choose to always, or never, consume the specific type of food. Therefore, for these population groups, a modified 'consumer behaviour' dietary exposure assessment was also conducted for the 1995 and 1997 NNSs only. As food consumption records were available for beverages other than formulated beverages and flavoured teas in these two surveys, the consumer behaviour model was modified to include these two categories only, rather than all foods.

The assessment used two models to determine the two possible extremes of consumer behaviour in such a situation. In Model 1 (40-30) all the food groups in the *Water based flavoured drinks* category *(*WBFD) were assigned the Applicant's proposed MPL of 40 mg/kg for formulated beverages. All teas in this model were assigned an MPL of 30 mg/kg. This model assumes a brand or product loyal consumer always selects formulated beverages which contain quillaia saponins whenever they have water based flavoured drink, and always selects flavoured teas which contain quillaia saponins when having tea. In Model 2 (0-0) all WBFDs and all teas were each assigned an MPL of 0 mg/kg. This assumes a brand or product loyal consumer selects a formulated beverages which does not contain quillaia saponins whenever they have water based flavoured drink or selects flavoured teas that do not contain quillaia saponins when having tea.

There are other possible combinations of the modified consumer behaviour exposures, such as a consumer choosing a WBFD with quillaia saponins and a tea with no quillaia saponins, or vice versa. However, it was assumed that all other combinations of consumer behaviour would fall somewhere between the results for the two models used for the modified consumer behaviour exposure assessment.

All other food groups were also included in these models and were assigned the proxy market weighted concentrations as per the population based DEAs.

4.1.4 Naturally occurring saponins

There are many different kinds of saponins depending on the type of plant. Some occur naturally in foods such as legumes, onions, tea, ginger beet, oats, capsicum, eggplant and asparagus, which are consumed by humans. However, the ones used as a food additive are not the same as those consumed in the diet through their natural occurrence in foods.

The ADI for quillaia saponins is specific to the ones used as a food additive. Therefore, background dietary exposure to naturally occurring sources was not included in the DEA.

4.1.5 Assumptions and limitations of the Dietary Exposure Assessment

The aim of the DEA was to make a realistic prediction of dietary exposure to quillaia saponins as possible. However, where significant uncertainties in the data existed, conservative assumptions were generally used to ensure that the predicted dietary exposure was not an underestimate of exposure.

Assumptions made in the dietary exposure assessment included:

- unless otherwise specified by the Applicant, all the foods within the category contained quillaia saponins at the calculated proxy concentration as specified in Table 4.1
- where a food was not included in the exposure assessment, it was assumed to contain a zero concentration of quillaia saponins
- where a food was assigned a calculated proxy concentration for quillaia saponins, this concentration was carried over to mixed foods where the food had been used as an ingredient
- there was no contribution to quillaia saponins exposure through the use of complementary medicines or through natural occurrence of other saponins.

In addition to the specific assumptions made in relation to this DEA, there are a number of limitations associated with the nutrition surveys from which the food consumption data used for the DEA 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).

4.2 Predicted population dietary exposure to quillaia saponins

The predicted dietary exposures to quillaia saponins were calculated for ‘consumers’ only and were reported in three ways:

- predicted mean and 90th percentile dietary exposures in milligrams of quillaia saponins per day, derived from each individual’s ranked daily exposures
- predicted dietary exposures derived on a per kilogram body weight basis using each individual’s body weight
- predicted exposures to quillaia saponins as a percentage of the ADI.

The major food contributors to the predicted total dietary exposure to quillaia saponins were also calculated for each population group assessed. Major food contributors were calculated from consumers’ total exposures from foods consumed that are proposed to contain the additive. In interpreting the results of major food contributors, the fact that the dietary exposure assessment used broader categories of some food groups compared to others, and some foods had weighted concentrations (Australians 17 years and above and New Zealanders 15 years and above only) while others did not, needs to be taken into account.

4.2.1 Predicted dietary exposures for each population group assessed

The predicted mean and 90th percentile dietary exposure to quillaia saponins for consumers were at or below 15 mg/day for all the population groups assessed. The predicted daily means ranged from 3 to 7 mg, and the 90th percentile daily means ranged from 6 to 15 mg.

Australia and New Zealand consumers aged below 17 and 15 years respectively, were assessed to be likely to have lower mean and 90th percentile daily dietary exposures (3 mg/day and 6-7 mg/day respectively) compared to those in the older age groups (mean and 90th percentile dietary exposures ranged from 5-7 mg and 11-15 mg respectively).

The predicted mean and 90th percentile population exposures for the four population groups assessed for the application are summarised in Figure 4.2. The detailed results are set out in Tables A2.1 and A2.2 in Appendix 2.

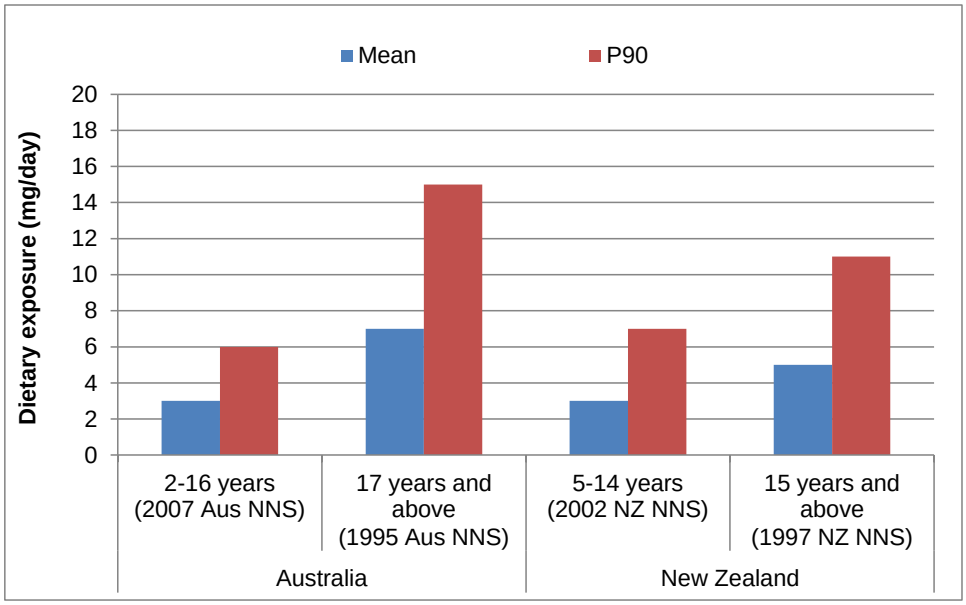


Figure 4.2: Predicted mean and 90th percentile population daily dietary exposures (mg/day) to quillaia saponins for all population groups assessed

4.2.2 Major foods contributing to quillaia saponins exposure

The foods that were major contributors to predicted quillaia saponins exposure (providing ≥5%) were calculated from consumers' mean intake from all foods consumed that were proposed to contain the additive.

For Australians aged 2-16 years, water based flavoured drinks (79%), fruit and vegetable juice products (12%) and tea (5%) were major contributors. Coffee beverage, caffeinated, instant powder/ granules (including flavoured coffee) (30%), water based flavoured drinks (26%), beer and related products (22%) and tea (13%) were the major contributors for Australians aged 17 years and above. These results are shown in Figures 4.3 and 4.4 respectively for the two Australian population groups.

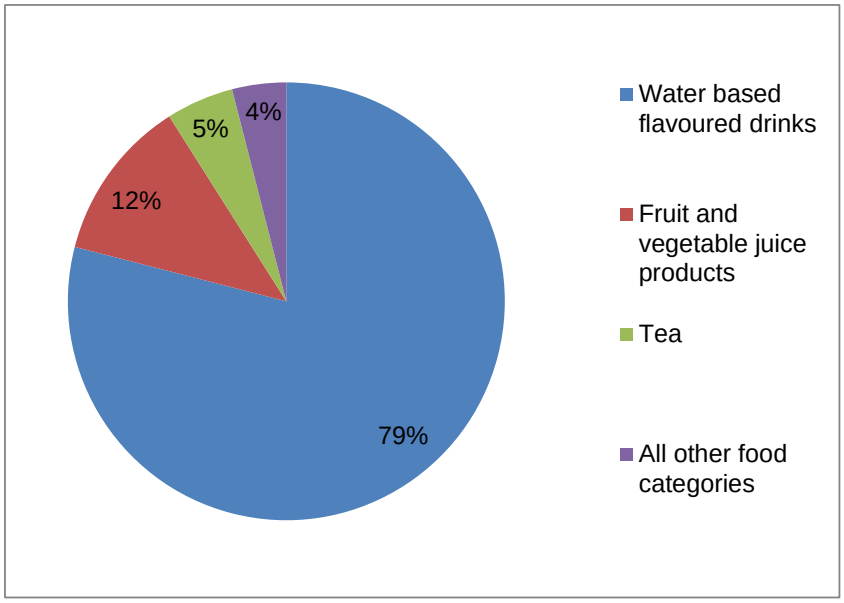


Figure 4.3: Contributors to predicted population quillaia saponins dietary exposure for Australian aged 2-16 years

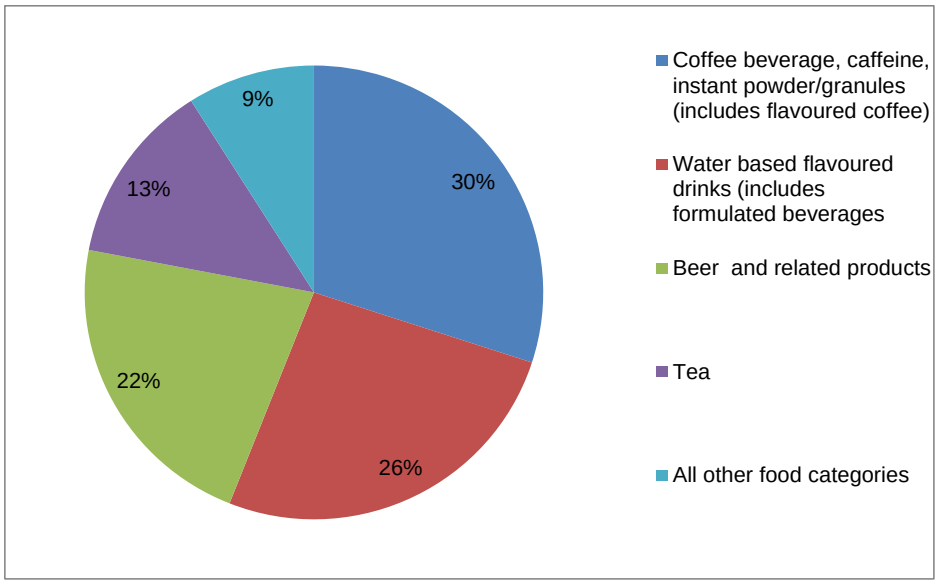


Figure 4.4: Contributors to predicted population quillaia saponins dietary exposure for Australians aged 17 years and above

The major food contributors to the New Zealand populations' predicted dietary exposure to quillaia saponins are shown in Figures 4.5 and 4.6. For those aged 5 to 14 years, water based flavoured drinks (82%), fruit and vegetable juice products (7%) and tea (5%) were major contributors. However, for the population aged 15 years and above, the major contributors were water based flavoured drinks (29%), beer and related products (26%), instant coffee powders and granules (including flavoured coffee) (19%) and tea (including flavoured tea) (19%).

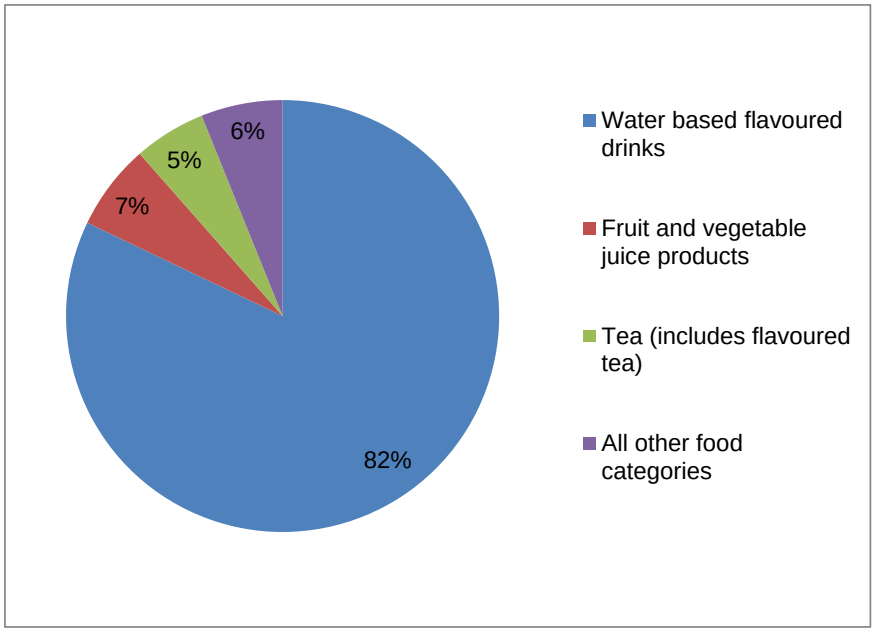


Figure 4.5: Contributors to predicted population quillaia saponins dietary exposure for New Zealanders 5 -14 years

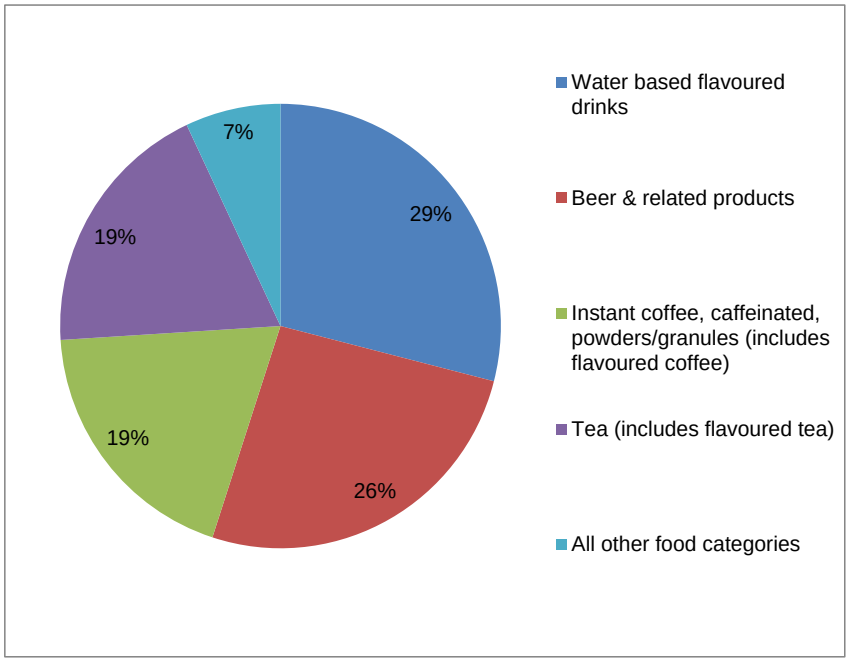


Figure 4.6: Contributors to predicted population quillaia saponins dietary exposure for New Zealanders 15+ years

The percentage contributions to quillaia saponins exposure from all the food categories for each population group are shown in Table A2.5 in Appendix 2.

4.3 Modified consumer behaviour dietary exposure assessment results

4.3.1 Predicted dietary exposures to quillaia saponins

A modified consumer behaviour assessment was undertaken as part of the DEA as

described in section 4.1.3.3. This situation applied only to two population groups, Australians 17 years and older and the New Zealand population aged 15 years and above as consumption of formulated beverages and flavoured teas were not reported in the 1995 and 1997 NNSs. This assessment helped to determine how the predicted dietary exposure for these groups would be affected by consumers who are brand loyal.

The result of this assessment is shown in Figure 4.7. Model 1 predictions are labelled Maximum MPL and refer to where water based flavoured drinks were assigned a value of 40 mg/kg and teas 30 mg/kg. Model 2 is Zero MPL representing where both of these food categories were each assigned values of 0 mg/kg.

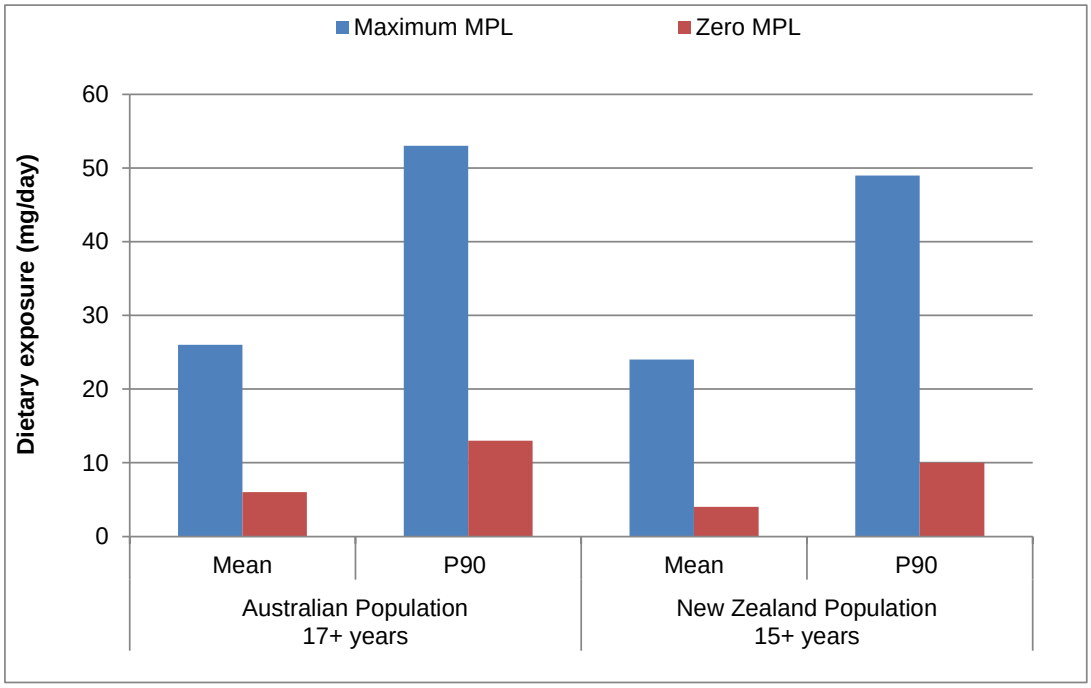


Figure 4.7: Predicted mean and P90 consumer behaviour dietary exposure for water based flavoured drinks and teas at MPL and zero concentration

The modified consumer behaviour assessment showed that for the two population groups, the predicted mean dietary exposures ranged from 4-6 mg/day (formulated beverages and flavoured teas at zero concentration) to below 30 mg/day (formulated beverages and flavoured teas at MPL); the 90th percentile exposures ranged from 10-13 mg/day (formulated beverages and flavoured teas at zero concentration) to 53 mg/day (formulated beverages and flavoured teas at MPL). The detailed results are set out in Tables A2.3 and A2.4 in Appendix 2.

4.4 Conclusion

4.4.1 Predicted daily population exposures and major food contributors

The approaches used for assessing the Australian and New Zealand populations' exposure to quillaia saponins, showed that all the population groups had predicted daily dietary exposures that were below 16 mg with minor differences between the age groups.

The younger populations in both countries, Australia (2-16 years) and New Zealand (5-14 years) had predicted 90th percentile exposures that were below 8 mg/day.

The older population groups Australia 17 + years) and New Zealand (15 + years) had predicted 90th percentile exposures that ranged between 11-15 mg/day.

The food category assessed as the main contributor to quillaia saponins exposure for the younger population groups in Australia and New Zealand was *water based flavoured drinks,* and tending to contribute between 79-82% of the total exposure to quillaia saponins.

The groups of beverages that were major contributors to quillaia saponins among the adult Australia and New Zealand populations were identical. There were some differences in the beverages that made the highest percentage contributions to the predicted quillaia exposure for the older populations in the two countries. Coffee beverages (including flavoured coffee) (31%) was the main food contributor to predicted quillaia saponins exposure for Australians aged 17 years and above, and water based flavoured drinks (30%) was the main contributor for New Zealanders aged 15 years and above. The differences could reflect differences in food preferences.

4.4.2 Predicted modified consumer behaviour daily exposures

Where formulated beverages and flavoured teas contain quillaia at MPLs, the older population groups in Australia and New Zealand who were brand loyal consumers of these beverages were predicted to have 90th percentile dietary exposures to quillaia saponins that ranged from 49 to 53 mg/day. At the zero MPL level for these two products, the daily exposure to quillaia saponins ranged from 10-13 mg/day for the two population groups.

5. RISK CHARACTERISATION

The predicted dietary exposures on a body weight basis were compared to the ADI of 1 mg/kg bw.

5.1 Predicted population dietary exposure

The predicted mean and 90th percentile dietary exposures expressed as a percentage of the ADI for all the population groups were all well below the ADI at between 7%-10% and between 15%-20% respectively (Figure 5.1).

The mean daily dietary exposures as a percentage of the ADI for younger Australian and New Zealand populations ranged between 7-9 mg, and for the older populations ranged between 7-10 mg.

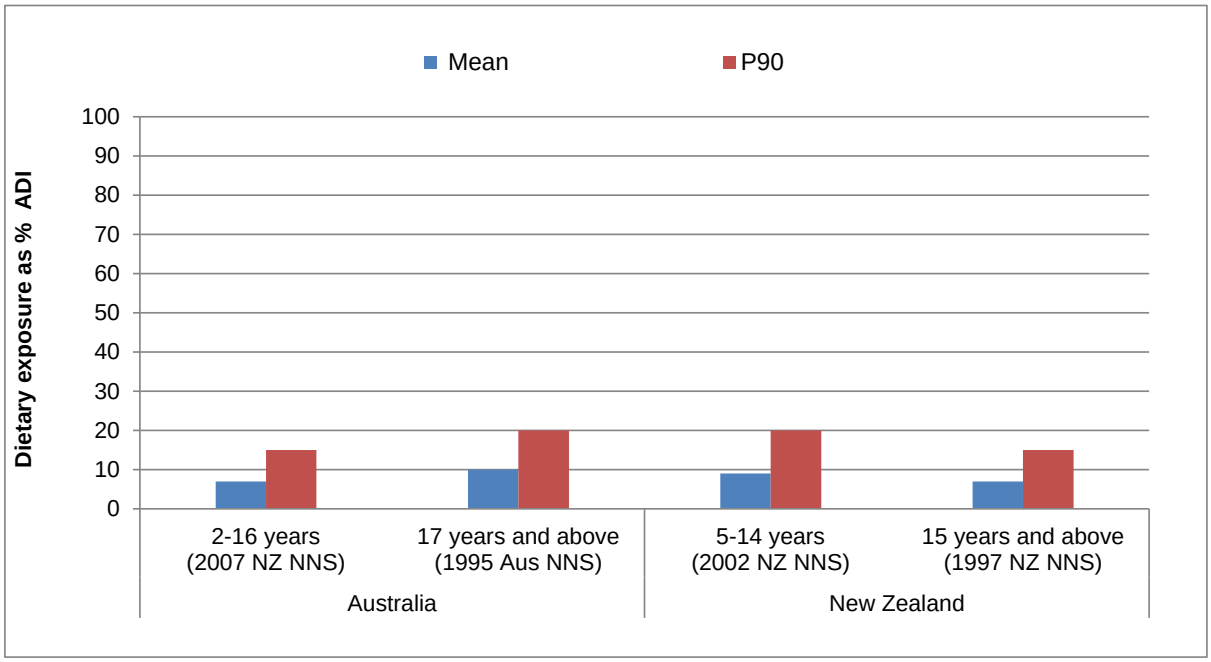


Figure 5.1: Predicted mean and 90th percentile population dietary exposure to quillaia saponins as a percentage of the ADI (1 mg/kg bw) for all population groups assessed

5.2 Modified consumer behaviour dietary exposure

The consumer behaviour predictions of dietary exposure expressed as a percentage of the ADI were predicted only for Australians aged 17 years and above, and New Zealand population aged 15 years and above. The results showed the predicted mean exposures for the brand loyal consumers who selected flavoured teas and formulated beverages with quillaia saponins at maximum MPL value were below 40% of the ADI; and the predicted 90th percentile exposures for all the populations groups were below 75% of the ADI (Figure 5.2).

It is noted that although the DEA predicts for the modified consumer behaviour assumes that these brand or product loyal consumers would choose formulated beverages and flavoured teas containing quillaia saponins over their lifetime, in reality it is unlikely, hence the DEA is considered a conservative prediction.

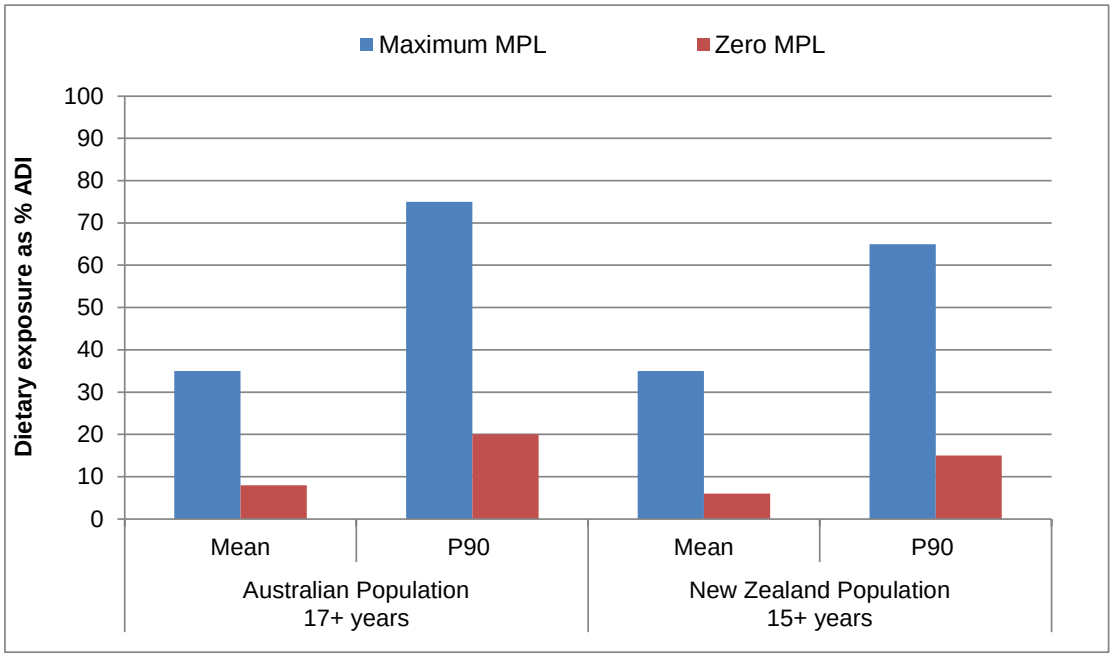


Figure 5.2: Predicted mean and P90th dietary exposure as percentage of the ADI (1 mg/kg bw/day) for formulated beverages and flavoured teas at maximum and zero MPLs

5.3 Conclusion

Using the population approach, the predicted dietary exposure for all the population groups does not exceed 20% of the ADI. The modified consumer behaviour approach resulted in predicted dietary exposures below 75% of the ADI for the worst case scenario.

Based on these predictions, there are no identifiable public health and safety issues associated with the proposed addition of quillaia saponins to the food categories requested by the Applicant at the listed MPLs and the anticipated market uptake of the foods in Australia and New Zealand.

6. RISK AND TECHNICAL ASSESSMENT CONCLUSIONS

This risk and technical assessment evaluated the technological suitability and safety of the proposed addition of quillaia extract to food.

6.1 Responses to risk assessment questions

1. Does quillaia extract achieve its technological function in the form and quantity used as an emulsifier?

Section of report	*Summary response/conclusion*
Section 2	Evidence submitted in support of this Application provides adequate assurance that quillaia extract fulfils the stated technological function as an emulsifier in the requested food categories.

2. Are there any public health and safety issues associated with the use of quillaia extract as an emulsifier?

Section of report	*Summary response/conclusion*
Section 5	There are no identifiable public health and safety issues associated with the proposed addition of quillaia extract to the food categories requested.

6.2 Consolidated conclusion

On the basis of these responses, it is concluded that the use of quillaia extract as a food additive in the requested food categories is technologically justified and presents no identifiable public health and safety issues.

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APPENDICES

Appendix 1: Dietary Exposure Assessments at FSANZ

A dietary exposure assessment is the process of predicting how much of a food chemical a population, or population sub group, consumes. Dietary exposure to (or intake of) food chemicals is predicted by combining food consumption data with food chemical concentration data. The process of doing this is called 'dietary modelling'.

Dietary exposure = food chemical concentration x food consumption

FSANZ's approach to dietary modelling is based on internationally accepted procedures for estimating dietary exposure to food chemicals. Different dietary modelling approaches may be used depending on the assessment, the type of food chemical, the data available and the risk assessment questions to be answered. In the majority of assessments FSANZ uses the food consumption data from each person in the national nutrition surveys to predict their individual dietary exposure. Population summary statistics such as the mean exposure or a high percentile exposure are derived from each individual person's exposure.

An overview of how dietary exposure assessments are conducted and their place in the FSANZ Risk Analysis Process is provided on the FSANZ website at:

http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/dietaryexposureandin4438.cfm

FSANZ has developed a custom built computer program 'DIAMOND' to calculate dietary exposures. More information on DIAMOND is available on the FSANZ website at:

http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/fsanzdietaryexposure4439.cfm

Further detailed information on conducting dietary exposure assessments at FSANZ is provided in *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009), available at:

http://www.foodstandards.gov.au/_srcfiles/Principles%20&%20practices%20exposure%20assessment%202009.pdf

A1.1 Food consumption data used

The most recent food consumption data available were used to predict exposures to quillaia saponins for the Australian and New Zealand populations. The national nutrition survey (NNS) data used for these assessments were:

- The 2007 Australian National Children's Nutrition and Physical Activity Survey (also known as '*Kids Eat Kids Play*') (2007 AusNNS)
- The 1995 Australian National Nutrition Survey (1995 AusNNS)
- The 2002 New Zealand National Children's Nutrition Survey (2002 NZNNS)
- The 1997 New Zealand National Nutrition Survey (1997 NZNNS).

The results for Australian children aged 2-16 years were reported using the 2007 AusNNS and for the population 17 years and above used the 1995 AusNNS. The design of each of these surveys varies somewhat and key attributes of each are set out below.

A1.1.1 2007 Australian Children's Nutrition & Physical Activity Survey (2007 AusNNS)

The 2007 AusNNS collected data on nutrition and physical activity for 4,487 children aged 2-16 years across Australia. The survey was conducted over a seven month time period, from February to August 2007.

In contrast to other national nutrition surveys used by FSANZ (the 1995 Australian, 1997 and 2002 New Zealand surveys), in the 2007 AusNNS each respondent completed two 24-hour recalls on non-consecutive days. The availability of two days of food consumption data provides a more realistic prediction of long term consumption of infrequently consumed foods, because it takes account of those who may eat a food on one day of the survey but not on the other. Using one 24-hour recall may capture an unusual eating occasion for an individual that does not describe how they normally eat.

In this assessment, exposure to quillaia saponins was predicted from each consumer's average exposures from foods containing quillaia saponins across Day 1 and Day 2. The results of the 2007 AusNNS were weighted to represent the overall population of Australian children because stratified sampling with non-proportional samples was used.

A1.1.2 1995 Australian National Nutrition Survey (1995 AusNNS)

The 1995 AusNNS provides comprehensive information on dietary patterns of a sample of 13,858 Australians aged from 2 years and above (McLennan & Podger 1998). It is the most recent NNS for Australians aged 17 years and above. The survey used a 24-hour recall method for all respondents, with 10% of respondents also completing a second 24-hour recall on a second, non-consecutive day. Food frequency data are available for a subset of the national sample (respondents aged 12 years and above) as are responses to a series of short dietary questions about food habits. Only the day 1 24-hour recall data for all respondents aged 17 years and over were used for this assessment. These data are used unweighted in DIAMOND as the survey sample was generally representative of the population.

A1.1.3 2002 New Zealand National Children's Nutrition Survey (2002 NZNNS)

The 2002 NZNNS was a cross-sectional and nationally representative survey of 3,275 New Zealand children aged 5-14 years. The data was collected during the school year from February to December 2002. The survey used a 24-hour food recall and provided information on food and nutrient intakes, eating patterns, frequently eaten foods, physical activity patterns, dental health, anthropometric measures and nutrition-related clinical measures. It was also the first children's nutrition survey in New Zealand to include a second day diet recall data for about 15% of the respondents, and dietary intake from both foods (including beverages) and dietary supplements. Only the day 1 24-hour recall data for all respondents (excluding supplements) were used for this assessment. These data are used weighted in DIAMOND.

A1.1.4 1997 New Zealand National Nutrition Survey (1997 NZNNS)

The 1997 NZNNS provides comprehensive information on the dietary patterns of a sample of 4,636 respondents aged from 15 years and above. The survey was conducted on a stratified sample over a 12 month period. The survey used a 24-hour recall methodology with 15% of respondents also completing a second 24-hour recall with an additional food frequency questionnaire and questions on food consumption patterns. Only the day 1 24-hour recall data for all respondents were used for this assessment. These data are used unweighted in DIAMOND.

Further information on the National Nutrition Surveys used to conduct dietary exposure assessments is available on the FSANZ website at:

http://www.foodstandards.gov.au/scienceandeducation/scienceinfsanz/dietaryexposureassessmentsatfsanz/foodconsumptiondatau4440.cfm

A1.2 Change in approach for 'high consumers'

Because of the exaggeration of extremes of consumption that arise where predictions of dietary exposure are based on food consumption data from one or two days of single 24-hour recall from NNSs, FSANZ has adopted a policy that a high consumer's chronic dietary exposure is best represented by the 90th percentile of exposure. This replaces the previous standard use of the 95th percentile and is in line with international best practice. For further information on the use of the 90th percentile for dietary exposure assessments, refer to the information paper on the FSANZ website: Protecting 'high consumers' (FSANZ 2009b).

For more information on FSANZ dietary exposure assessment principles, methodology, assumptions and limitations and uncertainties of the concentration and food consumption data, see the FSANZ document, *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

A1.3 Limitations of dietary exposure assessments

Dietary exposure assessments based on 2007 AusNNS, 1995 AusNNS, 2002 NZNNS and 1997 NZNNS food consumption data provide the best prediction of actual consumption of a food and the resulting predicted dietary exposure assessment for the Australian population 2-16 years and 17 years and above, as well as the New Zealand populations aged 5-14 years and 15 years and above, respectively. However, it should be noted that NNS data do have limitations. Further details of the limitations relating to dietary exposure assessments undertaken by FSANZ are set out in the FSANZ document, *Principles and Practices of Dietary Exposure Assessment for Food Regulatory Purposes* (FSANZ 2009).

A1.4 Calculation of market weighted concentrations for food categories not captured in 1995 and 1997 nutrition surveys

To account for the change in consumption patterns over time of some foods that were not consumed in the 1995 and 1997 nutrition surveys, market weighted concentrations of quillaia saponins were calculated for the exposure assessment to adjust for this. The foods involved were formulated beverages and flavoured tea.

Formulated beverages are water based flavoured drinks which are represented in the cold beverage segment of the market share data in *RetailWorld*. Therefore, data on the percentage shares by volume for the cold beverage segment were used. The sub-groups of the segment and their market shares are soft drinks at 58.2%, energy drinks at 2.1% and sports drinks including formulated beverages at 2.0%.

- Total market share volume (%) of cold beverage category that contains formulated beverages = 58.2 + 2.1 + 2.0 = 62.3
- Market share of formulated beverages = 2.0/62.3 = 0.032 (3.2%)
- Market share of other cold beverages (excluding formulated beverage) = (58.2 + 2.1)/62.3 = 0.968 (96.8%)

The applicant had proposed an MPL of 40 mg/kg for formulated beverages and 40 mg/kg for other water based flavoured drinks. To capture current consumption of formulated

beverages in the dietary exposure assessment, food category 14.1.3 was used in the modelling and a weighted concentration applied to the whole category.

The weighted concentration value used for the MPL for water based flavoured drinks for the 1995 and 1997 surveys was calculated as follows:
(40 mg/kg x 0.032) + (40 mg/kg x 0.968) = 1.28 + 38.72 = 40 mg/kg

A similar approach was used to calculate the weighted concentration value for teas. Flavoured teas belong to the Tea segment which comprises mainstream and non-mainstream teas. Their percentage shares by volume are mainstream tea (e.g. black tea, tea bags and leaves) at 53.6% and non-mainstream tea (e.g. flavoured tea, green tea) at 46.4%.

Non-mainstream tea consists of:

- Premium tea (40.4%)
- Flavoured/Health tea (59.6%)

Flavoured/Health Tea is made up of 51.2% herbal or health teas. Herbal teas have specific consumption data, therefore do not need to be included in the weighted concentration.

The percentage of flavoured teas in non-mainstream teas was calculated as:

- Flavoured/Health teas minus herbal teas = 59.6 – {(51.2/100)*59.6} = 29.1
- Premium tea (40.4) + Flavoured minus herbal tea (29.1) = 69.5%
- Non-mainstream tea - herbal teas = 46.4 x 0.695 = 32.25%

Total volume of mainstream and non-mainstream (minus herbal) =53.6 + 32.25 = 85.85%

Calculated market share for mainstream tea = 62.4% (i.e. 53.6/85.85) and for flavoured tea = 37.6% (i.e. 32.25/85.85).

Mainstream teas (e.g. black, tea bags and leaves) are not permitted to contain quillaia saponins, therefore a zero concentration applies to these types of teas. The proposed concentration to be added to flavoured teas is 30 mg/kg. The weighted MPL value assigned to tea category for the 1995 and 1997 consumption data is therefore = {(0.624*0) + (0.376*30)} = 11.3 mg/kg.

Appendix 2: Dietary Exposure Assessment Results

Table A2.1: Predicted dietary exposures for consumers of quillaia saponins – Population approach

Survey	Age group	Number of consumers	Number of respondents	Consumers as % of respondents	Dietary exposure (mg/day)	
					Mean	P90
2007 AusNNS[3]	2-16 years	3,144	4,487	70	3	6
1995 AusNNS[4]	17+ years	10,562	11,129	95	7	15
2002 NZNNS[2]	5-14 years	2,103	3,275	64	3	7
1997 NZNNS[2]	15+ years	4,346	4,636	94	5	11

Table A2.2: Predicted dietary exposures for consumers of quillaia saponins as per kilogram of body weight and percentage of the ADI – Population approach

Survey	Age group	Dietary exposure (mg/kg bw/day)		Dietary exposure as % ADI (ADI = 1 mg/kg bw/day)	
		Mean	P90	Mean	P90
2007 AusNNS	2-16 years	0.07	0.15	7	15
1995 AusNNS	17+ years	0.10	0.20	10	20
2002 NZNNS	5-14 years	0.09	0.18	9	20
1997 NZNNS	15+ years	0.07	0.15	7	15

[3] The 2007NNS data used was weighted and the average of 2-days of 24-hour food records (Tables A2.1 to A2.4)

[4] The data used for the other three surveys were single day 24-hour food records (Tables A2.1 to A2.4)

Table A2.3: Predicted dietary exposures for consumers of quillaia saponins – Modified consumer behaviour approach

Survey	Age group	Number of consumers		Number of respondents	Consumers as % of respondents		Dietary exposure (mg/day)			
							Mean		P90	
		Maximum MPL	Zero MPL		Maximum MPL	Zero MPL	Maximum MPL	Zero MPL	Maximum MPL	Zero MPL
1995 AusNNS	17+ years	10,562	7,482	11,129	95	67	26	6	53	13
1997 NZNNS	15+ years	4,346	2,867	4,636	94	62	24	4	49	10

Table A2.4: Predicted dietary exposures for consumers of quillaia saponins per kilogram of body weight and as a percentage of the ADI – Modified consumer behaviour approach

Survey	Age group	Dietary exposure (mg/kg bw/day)				Dietary exposure % ADI (ADI = 1 mg/kg bw)			
		Mean		P90		Mean		P90	
		Maximum MPL	Zero MPL	Maximum MPL	Zero MPL	Maximum MPL	Zero MPL	Maximum MPL	Zero MPL
1995 AusNNS	17+ years	0.36	0.08	0.73	0.18	36	8	73	18
1997 NZNNS	15+ years	0.33	0.06	0.67	0.13	33	56	67	13

Table A2.5: Food contributors to predicted quillaia saponins exposure – Population approach

Food group name	% contribution to quillaia saponins exposure			
	Australia		New Zealand	
	2-16 years	17 years and above	5-14 years	15 years and above
Water based flavoured drinks	79	26	82	29
Fruit & vegetable juice products	12	3	6	2
Tea (includes flavoured tea)	5	13	5	19
Coffee beverage, caffeinated, instant powder/granules (includes flavoured coffee)	2	30	<1	19
Carbonated, mineralised & soda waters	<1	1	2	<1
Herbal infusions	<1	2	<1	2
Coffee beverage, decaffeinated, instant powder/granules (includes flavoured coffee)	<1	2	<1	<1
Formulated beverages	<1	N/A	3	N/A
Beer & related products	<1	22	0	26
Coffee substitutes beverage	0	<1	0	<1
Wine based drinks & reduced alcohol wines	<1	<1	<1	<1
Spirits & liqueurs	<1	<1	<1	<1
Other alcoholic beverages not already specified (i.e. not included in item 14.2)	0	<1	0	<1

N/A = not applicable to the assessments based on 1995 and 1997 nutrition survey data.