

26 July 2013
[26-13]

Call for submissions – Application A1075

Quillaia¹ Extract (Quillaja extract) as a Food Additive (Emulsifier)

FSANZ has assessed an Application made by Ingredion ANZ Pty Ltd (formerly known as National Starch Pty Ltd) to permit quillaia extract as a food additive (emulsifier) in a range of beverages to emulsify oil soluble substances and has prepared a draft food regulatory measure. Pursuant to section 31 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [information for submitters](#).

All submissions on applications and proposals will be published on our website. We will not publish material that is provided in-confidence, but will record that such information is held. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1991*. Submissions will be published as soon as possible after the end of the public comment period. Where large numbers of documents are involved, FSANZ will make these available on CD, rather than on the website.

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

Submissions should be made in writing; be marked clearly with the word 'Submission' and quote the correct project number and name. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website via the link on [documents for public comment](#). You can also email your submission directly to submissions@foodstandards.gov.au.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 6 September 2013.

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

Questions about making submissions or the application process can be sent to standards.management@foodstandards.gov.au.

¹ Quillaja extract is the term used by the Applicant when the application was submitted to FSANZ. However, the more appropriate scientific term is quillaia extract, as all the safety studies and the specifications are based on the term quillaia extract. Therefore, for consistency FSANZ has used quillaia in the draft variation and associated reports.

Hard copy submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
CANBERRA BC ACT 2610
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6143
NEW ZEALAND
Tel +64 4 978 5630

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Supporting documents

The following documents which informed the assessment of this Application are available on the FSANZ website at

<http://www.foodstandards.gov.au/code/applications/Pages/applicationa1075quil5602.aspx>

SD1 Risk and Technical Assessment Report

1. Executive summary

FSANZ received an Application from Ingredion ANZ Pty Ltd (formerly National Starch Pty Ltd) on 8 June 2012.

The Applicant seeks permission to use quillaia extract as a food additive (emulsifier) for adding oil-soluble substances to various beverages. These oil-soluble substances include flavours and colours.

Quillaia extract is obtained by aqueous extraction of the milled inner bark, stems and branches of the *Quillaia saponaria* Molina tree. Quillaia extract is a Codex Alimentarius permitted food additive with INS numbers 999i and 999ii for type 1 and type 2, respectively. The differences between type 1 and 2 relate to purity and more specifically the concentration of the active ingredients which are quillaia saponins. Type 2 is purer with a greater concentration of saponins.

Quillaia extract is permitted to be added to various beverages in Europe, the USA, Canada and a number of Asian countries.

The Applicant requested maximum permitted levels (MPLs) ranging from 30–40 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.

The current hazard assessment established an acceptable daily intake (ADI) of 0–1 mg quillaia saponins/kg bodyweight, which is the same as that established by the Joint FAO/WHO Expert Committee on Food Additives (JECFA).

Estimates 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.

There is an analytical method available to determine the presence of, and quantify, quillaia saponins in beverages containing added quillaia extract. This method has been modified, to improve the sensitivity, from a method for determining the purity and levels of saponins in quillaia extract. There is a specification for quillaia extract (both type 1 and 2) in the JECFA specifications which is a primary reference for specifications in the Code, which the Applicant's product meets.

The draft variations proposed for quillaia extract for each of the beverage categories provides a maximum permitted level related to quillaia saponins.

2. Introduction

2.1 The Applicant

The Application was received from Ingredion ANZ Pty Ltd, formerly National Starch Pty Ltd.

2.2 The Application

The Application was received by FSANZ on 8 June 2012, while work commenced on 31 October 2012. The Applicant seeks permission to use quillaia extract as a food additive (emulsifier) for adding oil-soluble substances to various beverages. The relevant substances include flavours and colours that are soluble in oil but poorly soluble in water based (aqueous) beverages. Emulsifiers assist in allowing water insoluble substances to be miscible in the aqueous phase.

Quillaia is sometimes written as quillaia; although, the two terms are synonymous. This report uses the term quillaia unless the other term is used in a reference or in any official regulation where that term is specifically quoted.

Quillaia extract is obtained by aqueous extraction of the milled inner bark, stems and branches of the *Quillaia saponaria* Molina tree.

2.3 The current Standard

Food additive permissions are listed in Standard 1.3.1 – Food Additives of the *Australia New Zealand Food Standards Code* (the Code). There is currently no permission in the Code to use quillaia extract as a food additive.

2.3.1 Overseas situation

The international and national permissions for quillaia extract relevant to this Application are provided below.

2.3.1.1 Codex Alimentarius

Quillaia (Codex spelling) extracts type 1 (INS 999 i) and type 2 (INS 999ii)² are listed in the Codex Alimentarius General Standard for Food Additives. The permissions are for addition to specific types of water-based flavoured drinks, including “sport”, “energy”, or “electrolyte” drinks and particulated drinks. The maximum level of addition is 50 mg/kg expressed on saponins basis, but only for quillaia extract type 1. The functional class is listed as emulsifier and foaming agent.

2.3.1.2 European Union

Quillaia extract (E999) is permitted for use in non-alcoholic flavoured beverages and cider (excluding cidre bouché) to a maximum level of 200 mg/L as an anhydrous extract. The technological function of the food additive is as an emulsifier, stabiliser, foam stabiliser and encapsulent for these products.

² Both extracts differ in their purity and the concentrations of the active ingredients, saponins (see the Risk and Technical Assessment, SD1 for further information)

2.3.1.3 United States of America

The United States Code of Federal Regulations (CFR) has permissions for use of quillaia for use as a flavouring adjuvant, with technological function as emulsifier, stabiliser or foam stabiliser for both natural and synthetic flavours. These permissions are listed in 21 CFR §172.510 (Natural flavouring substances and natural substances used in conjunction with flavors) and §172.515 (Synthetic flavoring substances and adjuvants). The permissions are for the extract to be used at a minimum quantity to achieve the intended physical or technical effect and in accordance with GMP (good manufacturing practice).

The Applicant also has obtained self-affirmed quillaia extract as GRAS (generally recognised as safe) in the United States, for its use as an emulsifier or encapsulating agent in beverage products, to deliver fats, nutrients, vitamins, colours and clouding agents to a similar range of beverages to the current Application. This GRAS notification builds on an earlier GRAS notice, GRN 165, where quillaia extract was considered GRAS when used as a foaming agent for semi-frozen carbonated and non-carbonated beverages.

2.3.1.4 Canada

Quillaia extract is approved in Canada as a miscellaneous food additive in beverage bases, beverage mixes and soft drinks as a foaming agent at GMP.

2.3.1.5 Other country permissions

Quillaia extract is permitted in a number of other countries (China, Japan, India, Singapore, Thailand, Taiwan and Vietnam). The uses are to be used with flavours, as an emulsifier or stabiliser, or as a foaming agent for a range of beverages.

2.4 Reasons for accepting the Application

The Application was accepted for assessment because:

- it complied with the procedural requirements under subsection 22(2) of the FSANZ Act
- it related to a matter that might be developed as a food regulatory measure.

2.5 Procedure for assessment

The Application is being assessed under the General Procedure.

3. Summary of the assessment

3.1 Risk assessment

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 30–40 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 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.

Estimates 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.

3.2 Risk management

The risk assessment conclusions are that quillaia extract is a safe and suitable food additive to be added to the various beverage categories with maximum permitted levels as requested by the Applicant. Therefore, there are minimal risk management considerations, other than the labelling of this food additive in order that consumers are fully informed of its presence in foods (refer to 3.2.4 below).

3.2.1 *Limit food categories and maximum permitted levels*

The food categories and maximum permitted levels (MPLs) for quillaia saponins modelled for in the Dietary Exposure Assessment of SD1 were different to what was originally requested in the Application. With the agreement of the Applicant to reductions in both the food categories and maximum permitted levels for quillaia saponins, a revised dietary exposure assessment concluded that there are no public health and safety issues at the proposed levels of use in a range of beverages for any Australian or New Zealand population group.

In summary, the revised MPLs requested by the Applicant relating to permission to use quillaia extract in specific foods in Schedule 1 of Standard 1.3.1 are as follows:

| 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

3.2.2 Analytical methods

The Applicant cited the reversed phase High Pressure Liquid Chromatography (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.

The method of analysis has been modified from the method detailed in the JECFA specification for purity of quillaia extract (type 1 and 2). These JECFA specifications are those referred to in the Code, noted below. The JECFA specification analytical method is used to determine the purity of the quillaia extract product itself. Therefore, the method needed to be modified to ensure greater sensitivity to determine low concentrations of saponins in beverages containing added quillaia extract. The greater sensitivity was achieved by concentrating the sample, enhancing the detection limits of the detector device and altering the solvents used for the UHPC.

The Applicant noted that no other national regulatory agencies have requested the details for the analytical method to determine either the presence or concentration of quillaia saponins where quillaia extract is permitted as a food additive.

3.2.3 Specification

As noted above JECFA has specifications for quillaia extract (type 1 and 2). JECFA specifications are listed as a primary source of specifications in clause 2 of Standard 1.3.4 – Identity and Purity. The quillaia extract of the Application meets these specifications; therefore no new specification needs to be added to Standard 1.3.4.

3.2.4 Labelling Requirements

In accordance with existing labelling provisions in Standard 1.2.4 – Labelling of Ingredients, the label on most beverages permitted to add quillaia extract will be required to declare the food additive in the ingredients list.

Under clause 2 of Standard 1.2.4, some foods are exempt from ingredient labelling including the declaration of food additives. This includes beer and spirits standardised in Standards 2.7.2 and 2.7.5 respectively. Therefore, as with any other food additives that are permitted to be added to beer and spirits that are not allergenic or genetically modified, quillaia extract will not be required to be declared on the label of these beverages.

As the risk assessment concludes that the use of quillaia extract poses no risk to public health and safety, FSANZ considers the current food additive declaration requirements in Standard 1.2.4 are appropriate for all foods permitted to use quillaia extract.

3.3 Regulatory options and impacts

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

- Whether costs that would arise from a food regulatory measure developed or varied as a result of the application outweigh the direct and indirect benefits to the community, Government or industry that would arise from the development or variation of the food regulatory measure. This is considered below.
- Whether other measures (whether available to FSANZ or not) would be more cost-effective than a food regulatory measure developed or varied as a result of the

Application. There are no other measures which could achieve the same result other than amendments to the Code.

- Any relevant New Zealand standards. Standard 1.3.1 applies to New Zealand and there are no relevant New Zealand only standards.
- Any other relevant matters. None were identified. Section 18 matters are considered below.

3.3.1 Cost/benefit analysis

Two regulatory options were considered:

- (1) prepare a draft variation to Standard 1.3.1 to permit the use of quillaia extract as a food additive (emulsifier) for various beverages
- (2) reject the Application.

FSANZ is required to consider the impact of various regulatory and non-regulatory options on all sectors of the community, especially relevant stakeholders who may be affected by this Application. The costs and benefits associated with the proposed amendments to the Code have been analysed using regulatory impact principles. The level of analysis is commensurate to the nature of the Application and significance of the impacts.

The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess if a Regulation Impact Statement is required for applications relating to food additives as they are machinery in nature and the permission if granted is voluntary. However, FSANZ has undertaken a limited impact analysis.

A consideration of the costs and benefits of the regulatory options is not intended to be an exhaustive, quantitative economic analysis of the options and, in fact, most of the effects that are considered cannot be assigned a dollar value.

Rather, the assessment seeks to highlight the qualitative effects of criteria that are relevant to each option. These criteria are deliberately limited to those involving broad areas such as trade, consumer information and compliance.

Option 1 – Prepare draft variations to Standard 1.3.1

| Sector | Costs or benefits to sector |
|-------------|---|
| Consumers | There maybe advantages in product functionality and appearance arising from use of quillaia extract. Apart from this are unlikely to be any further direct benefits or costs for consumers from this option. |
| Industry | There are specific benefits to the various beverage industries for this option, through improving the emulsification of oil-soluble substances such as colours and flavours in production of aqueous based beverages. Australian and New Zealand beverage manufacturers will now be able to use the food additive to improve the emulsification of oil-soluble substances in aqueous beverages compared to international competitors. |
| Governments | Enforcement costs and how they are dealt with by jurisdictions will vary. However, there are likely to be added costs to governments associated with this option if they are required to determine whether beverages have had quillaia extract added to them as a food additive. There is an analytical method available to test for the presence and determine the concentration of added saponins from using quillaia extract as a food additive. |

Option 2 – Reject the Application

| Sector | Costs or benefits to sector |
|---------------|--|
| Consumers | There are no benefits or costs to consumers of this option. |
| Industry | There are no benefits to industry with this option. However, there are likely to be opportunity costs through not allowing industry the option to use a food additive to improve the appearance of their products by forming more miscible products or innovating by developing new products utilising the emulsifier like their international competitors are able to do. |
| Governments | There are no benefits or costs to governments for this option. |

From an assessment of the costs and benefits of the two options, FSANZ concluded that the preferred option is option 1 to prepare draft variations to permit quillaia extract as a food additive for a variety of beverages. The reason for this is this option provides benefits to the food industry which are not outweighed by possible costs to enforcement agencies relating to developing analytical methods for checking Code compliance.

3.3.2. Addressing FSANZ’s objectives for standards-setting

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

3.2.1.1 Protection of public health and safety

FSANZ has conducted a safety assessment (SD1) of using quillaia extract as a food additive, and the conclusions indicate there are no public health and safety concerns with its proposed use (see section 3.1).

3.2.1.2 The provision of adequate information relating to food to enable consumers to make informed choices

The existing labelling requirements in Standard 1.2.4 for declaring food additives will apply. These requirements are considered to be appropriate for all foods permitted to use quillaia extract (see section 3.2.4).

3.2.1.3 The prevention of misleading or deceptive conduct

No issues were identified.

3.2.1.4 Subsection 18(2) considerations

FSANZ has also had regard to the matters listed in subsection 18(2) of the FSANZ Act:

- the need for standards to be based on risk analysis using the best available scientific evidence

This Application was assessed using the best available scientific evidence. The Applicant submitted a dossier of scientific studies in support of their Application. Other resource material including published scientific literature and general technical information was also used in assessing this Application.

- the promotion of consistency between domestic and international food standards

The proposed variations are consistent with various international food standards.

- the desirability of an efficient and internationally competitive food industry

The proposed variation is expected to have a positive impact on competitiveness of the various beverage industries, where Australian and New Zealand companies will be able to use the same food additive as their international competitors.

- the promotion of fair trading in food

The proposed variations will assist in promoting fair trading in food by allowing Australian and New Zealand beverage manufacturers the same access to quillaia extract that other international competitors currently have. Conversely overseas products that already use the food additive will be permitted to be sold in both Australia and New Zealand.

- any written policy guidelines formulated by the Ministerial Council³.

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁴ includes specific order policy principles for substances added to achieve a solely technological function, such as food additives. These specific order policy principles state that permission should be granted where:

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

FSANZ has determined that permitting the use of quillaia extract as a food additive in various beverages is consistent with the specific order policy principles for ‘Technological Function’.

3.4. Risk communication

FSANZ has developed and applied a basic communication strategy to this Application. All calls for submissions are notified via the FSANZ Notification Circular, media release and through FSANZ’s social media tools and *Food Standards News*.

Subscribers and interested parties are also notified via email about the availability of reports for public comment.

The process by which FSANZ considers standard development matters is open, accountable, consultative and transparent. Public submissions are called to obtain the views of interested parties on issues raised by the Application and the impacts of regulatory options. Documents relating to A1075 are available on the website at www.foodstandards.gov.au/code/applications/Pages/applicationa1075quil5602.aspx

³ Now known as the COAG Legislative and Governance Forum on Food Regulation

⁴ <http://www.foodstandards.gov.au/code/fofr/fofrpolicy/documents/Addition%20to%20Food%20of%20Substances%20other%20than%20Vitamins%20and%20Minerals%20May%202008.pdf>

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

The Applicant, individuals and organisations that make submissions on this Application will be notified at each stage of the assessment.

If the draft variations to the Code are approved by the FSANZ Board, that decision will be notified to the COAG Legislative and Governance Forum on Food Regulation (the Forum). If the decision is not subject to a request for a review, the Applicant and stakeholders including the public will be notified of the gazettal of the variation to the Code in the national press and on the FSANZ website.

3.4.1 World Trade Organization (WTO)

As members of the World Trade Organization (WTO), Australia and New Zealand are obliged to notify WTO member nations where proposed mandatory regulatory measures are inconsistent with any existing or imminent international standards and the proposed measure may have a significant effect on trade.

There are relevant international standards and amending the Code to permit the use of quillaia extract as a food additive will not have any negative effect on international trade as this is a permission rather than a restriction. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Sanitary and Phytosanitary Measures Agreement was not considered necessary.

4. Draft variation

The conclusion of the assessment was that permitting quillaia extract at the maximum permitted levels proposed by the Applicant (see below) in the various beverages was both safe and suitable as a food additive.

The draft variations in Schedule 1 of Standard 1.3.1 and the maximum permitted levels are expressed, for the active ingredients, being the quillaia saponins, from the quillaia extracts. They can be derived from either the quillaia extract type 1 (INS 999i) or quillaia extract type 2 (INS 999ii).

Consequential amendments are also required to Standard 1.2.4 to include the new food additive in the list of food additive names and numbers for labelling purposes.

The draft variations to Standards 1.2.4 and 1.3.1 are at Attachment A.

A draft Explanatory Statement is at Attachment B.

4.1 Implementation

The variations will take effect on gazettal.

5. References

Güçlü-Ustündağ, O and Mazza, G. (2007). Saponins: Properties, Applications and Processing. *Critical Reviews in Food Science and Nutrition*, **47**:231–258.

JECFA (2005). Quillaia Extracts Type 1 and Type 2. Chemical and Technical Assessment 65th JECFA. Prepared by P.M. Kuznesof and L.M.V. Soares.
<http://www.fao.org/fileadmin/templates/agns/pdf/jecfa/cta/65/quillaia.pdf>

JECFA specifications (2005) Combined Compendium of Food Additive Specifications, FAO JECFA Monograph 1 (2005), specifications for Quillaia Extract (Type 1) and (Type 2), Food and Agriculture Organization of the United Nations, Rome
<http://www.fao.org/ag/agn/jecfa-additives/details.html?id=909>
<http://www.fao.org/ag/agn/jecfa-additives/details.html?id=908>

The Commission of European Communities (2011) Commission Regulation (EU) No 1129/2011 of 11 November 2011 amending Annex II to Regulation (EC) No 1333/2008 of the European Parliament and of the Council by establishing a Union list of food additives <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2011:295:0001:0177:EN:PDF>

The Commission of European Communities (2012) Commission Regulation (EU) No 231/2012 of 9 March 2012 laying down specifications for food additives listed in Annexes II and III to Regulation (EC) No 1333/2008. http://eur-lex.europa.eu/JOIndex.do?year=2012&serie=L&textfield2=83&Submit=Search&_submit=Search&ihtmlang=en

Attachments

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

Attachment A – Draft variations to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1075 – *Quillaia Extract as a Food Additive (Emulsifier)*) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The Standard commences on the date specified in clause 3 of this variation.

Dated [To be completed by Standards Management Officer]

Standards Management Officer
Delegate of the Board of Food Standards Australia New Zealand

Note:

This variation will be published in the Commonwealth of Australia Gazette No. FSC **XX on XX Month 20XX**. This means that this date is the gazettal date for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Application A1075 – Quillaia Extract as a Food Additive (Emulsifier)) Variation*.

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

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

3 Commencement

The variations commence on the date of gazettal.

SCHEDULE

[1] **Standard 1.2.4** is varied by inserting in Part 1 and in Part 2 of Schedule 2

“

| | | | |
|---------------------------|---------|--|--|
| Quillaia extract (type 1) | 999(i) | | |
| Quillaia extract (type 2) | 999(ii) | | |

”

[2] **Standard 1.3.1** is varied by inserting in Schedule 1

[2.1] under item 14.1.1.2 Carbonated, mineralised and soda waters

“

| | | | |
|-----------------|---|----|-------|
| 999(i) and (ii) | Quillaia saponins (from Quillaia extract type 1 and type 2) | 40 | mg/kg |
|-----------------|---|----|-------|

”

[2.2] under item 14.1.2.2 Fruit and vegetable juice products

“

| | | | |
|-----------------|---|----|-------|
| 999(i) and (ii) | Quillaia saponins (from Quillaia extract type 1 and type 2) | 40 | mg/kg |
|-----------------|---|----|-------|

”

[2.3] under item 14.1.3 Water based flavoured drinks

“

| | | | |
|-----------------|---|----|-------|
| 999(i) and (ii) | Quillaia saponins (from Quillaia extract type 1 and type 2) | 40 | mg/kg |
|-----------------|---|----|-------|

”

[2.4] under item 14.1.4 Formulated beverages

“

| | | | |
|-----------------|---|----|-------|
| 999(i) and (ii) | Quillaia saponins (from Quillaia extract type 1 and type 2) | 40 | mg/kg |
|-----------------|---|----|-------|

”

[2.5] under item 14.1.5 Coffee, coffee substitutes, tea, herbal infusions and similar products –

“

| | | | |
|-----------------|---|----|-------|
| 999(i) and (ii) | Quillaia saponins (from Quillaia extract type 1 and type 2) | 30 | mg/kg |
|-----------------|---|----|-------|

”

[2.6] under item 14.2.1 Beer and related products

“
999(i) and (ii) Quillaia saponins (from Quillaia extract type 1 and type 2) 40 mg/kg
”

[2.7] under item 14.2.5 Spirits and liqueurs

“
999(i) and (ii) Quillaia saponins (from Quillaia extract type 1 and type 2) 40 mg/kg
”

[2.8] under item 14.3 Alcoholic beverages not included in item 14.2

“
999(i) and (ii) Quillaia saponins (from Quillaia extract type 1 and type 2) 40 mg/kg
”

Attachment B – Draft Explanatory Statement

1. Authority

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

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

FSANZ accepted Application A1075 which seeks to permit quillaia extract as a food additive (emulsifier) in a range of beverages to emulsify oil soluble substances. The Authority considered the Application in accordance with Division 1 of Part 3 and has prepared draft variations to Standards 1.2.4 and 1.3.1.

2. Purpose

The Authority has proposed permission to use quillaia extract as a food additive emulsifier to various beverages.

Quillaia extract functions as a food additive emulsifier to assist in incorporating oil-soluble substances such as colours and flavours into water based beverages where these substances are poorly soluble. Permissions are proposed in various beverage categories in Schedule 1 of Standard 1.3.1. Consequential amendments are also proposed in Schedule 2 of Standard 1.2.4 to include the name and number of quillaia extract for labelling purposes.

3. Documents incorporated by reference

The variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 1 of Part 3 of the FSANZ Act, the Authority's consideration of Application A1075 will include one round of public consultation following an assessment and the preparation of draft variations and associated reports.

A Regulation Impact Statement was not required because the proposed variations to Standards 1.2.4 and 1.3.1 are likely to have a minor impact on business and individuals.

5. Statement of compatibility with human rights

This instrument is exempt from the requirements for a statement of compatibility with human rights as it is a non-disallowable instrument under section 94 of the FSANZ Act.

6. Variation

Item [1] amends Schedule 2 of Standard 1.2.4 to insert references to Quillaia extract (type1) and Quillaia extract (type 2) in the numerical and alphabetical lists of food additives for labelling purposes.

Item [2] amends Schedule 1 of Standard 1.3.1 to insert permissions for quillaia extract to be added as a food additive to a range of beverage categories. The maximum permitted levels for the food additive has been expressed as the active ingredients, quillaia saponins, from the quillaia extract, either from type 1 or type 2.