

1 October 2013
[18-13]

Approval Report – Application A1075

Quillaia Extract¹ (Quillaja Extract) as a Food Additive (Emulsifier)

Food Standards Australia New Zealand (FSANZ) has assessed an application made by Ingredient Pty Ltd to permit quillaia extract as a food additive (emulsifier) in a range of beverages to emulsify oil soluble substances.

On 26 July 2013, FSANZ sought submissions on a draft variation and published an associated report. FSANZ received six submissions.

FSANZ approved the draft variation on 19 September 2013. The COAG Legislative and Governance Forum on Food Regulation² (Forum) was notified of FSANZ's decision on 27 September 2013

This Report is provided pursuant to paragraph 33(1)(b) of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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.

² Previously known as the Australia and New Zealand Food Regulation Ministerial Council

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Supporting document

The following document used to prepare this Report is available on the FSANZ website at <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1075quilt5602.aspx>

SD1 Risk and Technical Assessment Report

1. Executive summary

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

The Application sought 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 *Quillaja 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 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).

The Application requested maximum permitted levels (MPLs) of 50 mg quillaia saponins/kg for various types of beverages. In order to ensure that the ADI was not exceeded for any population group, these MPLs were subsequently set lower with a range between 30 to 40 mg quillaia saponins/kg. The types of beverages permitted to contain quillaia extract were also reduced. Estimates of dietary exposure to quillaia saponins resulting from the use of quillaia extract as an emulsifier in beverages under these conditions indicated no exceedances of the ADI for all population groups assessed, including children. Therefore, there were no public health and safety concerns associated with adding quillaia extract to the food categories requested.

The food technology assessment concluded that quillaia extract fulfilled the stated technological function as an emulsifier at these proposed levels of use.

There is an analytical method available to determine the presence of, and quantify, quillaia saponins in beverages containing added quillaia extract. This method had 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 of specifications in the *Australia New Zealand Food Standards Code*, which the Applicant's product meets.

The variations for quillaia extract provide a MPL related to quillaia saponins for each of the beverage categories.

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. The Application sought 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 mixed into the aqueous phase.

Quillaia is sometimes written as quillaja; 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 the term is quoted.

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

2.3 The current Standard

Food additive permissions are listed in Standard 1.3.1 – Food Additives in the *Australia New Zealand Food Standards Code* (the Code). There is currently no permission in the Code to use quillaia extract as an emulsifier food additive. There is permission for its use as a generally permitted flavouring, due to it being an approved Flavour and Extract Manufacturers' Association (FEMA) of the United States flavouring with FEMA number 2973, due to subclause 11(a) of Standard 1.3.1.

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 extracts type 1 (INS 999 i) and type 2 (INS 999ii)³ 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 a 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.

³ 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 (USA)

The US Code of Federal Regulations (CFR) has permissions for use of quillaia 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 flavoring 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 good manufacturing practice (GMP).

The Applicant also has self-affirmed quillaia extract as GRAS (generally recognised as safe) in the USA, 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 as 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) as detailed in the Application. The permissions are for its use with flavours, as an emulsifier or stabiliser, or as a foaming agent for a range of beverages at a wide range of levels from 50 mg/kg saponins to 1,500 mg/kg to no use restriction for some 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 was assessed under the General Procedure.

2.6 Decision

The draft variation, as proposed following assessment, was approved without change. This permits the use of quillaia extract as a food additive for a variety of beverages with specific maximum permitted levels (MPLs).

The draft variation is at Attachment A.

3. Summary of the findings

3.1 Risk assessment

Quillaia extract is obtained by aqueous extraction of the bark, stems and branches of the *Quillaja 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 combination of a hydrophobic component such as quillaic acid and hydrophilic oligosaccharides makes saponins amphipathic substances.

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 1 (unpurified) or Type 2 (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.

The Application requested MPLs of 50 mg quillaia saponins/kg for various types of beverages. To ensure that the ADI was not exceeded for any population group, these MPLs were subsequently set at a lower MPL with a range between 30 to 40 mg quillaia saponins/kg. The types of beverages permitted to contain quillaia extract were also reduced.

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

The food technology assessment concluded that quillaia extract fulfilled the stated technological function as an emulsifier at the proposed levels of use.

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 MPLs as allowed for in the variation to Standard 1.3.1. The main risk management option undertaken was to limit the food categories and MPLs for the categories as noted in section 3.2.1. An additional risk management consideration relates to labelling of this food additive in order for consumers to be fully informed of its presence in foods (refer to 3.2.4 below).

3.2.1 *Limit food categories and maximum permitted levels*

The Dietary Exposure Assessment in SD1 concludes that there are no public health and safety issues for any Australian or New Zealand population group at the levels of use allowed for in the variation.

The Dietary Exposure Assessment relied on food categories and MPLs for quillaia saponins different to those sought in the Application. The relevant food categories and MPLs were amended with the Applicant's agreement following acceptance of the Application.

The revised MPLs relating to the permission to use quillaia extract in specific foods are as follows, using the food categories in Schedule 1 of Standard 1.3.1:

Food Category	Name	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 quillaia saponins

3.2.2 Analytical methods

The Applicant provided an analytical method for determining quillaia saponins from beverages where quillaia extract had been added as a food additive. This analytical method uses C-18 UHPC (Ultra High Pressure Chromatography). FSANZ considered the method is sufficient for purposes of monitoring the level of quillaia saponins in beverages.

The method of analysis had 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 needed 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 contain quillaia extract will be required to declare the food additive in the ingredients list. Therefore, consequential amendments were 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.

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 additive that is permitted to be added to beer and spirits that is not allergenic or genetically modified, quillaia extract will not be required to be declared on the label of these beverages.

As the risk assessment concluded that the use of quillaia extract at the levels in the variation to Standard 1.3.1 posed no risk to public health and safety, FSANZ considered that the current food additive declaration requirements in Standard 1.2.4 are appropriate for all foods permitted to use quillaia extract.

3.3 Summary of submissions

Consultation is a key part of FSANZ's standards development process. FSANZ acknowledges the time taken by individuals and organisations to make submissions.

Every submission on an application or proposal is reviewed by FSANZ staff, who examine the issues identified and prepare a response to those issues. All submissions are valued and all contribute to the rigour of our assessment.

FSANZ called for public comment between 26 July 2013 and 6 September 2013 following assessment of the Application.

Six submissions were received: three from enforcement jurisdictions, two from industry associations and one from a food technology association. All submissions supported the draft variation to approve quillaia extract as an emulsifier food additive for specific beverages, although a number of issues were raised.

The summary of issues raised in submissions and FSANZ's response to them is provided in Table 1. The Report has been amended, as necessary, following these submissions.

The issues raised in submissions can be summarised as:

- Permissions should be consistent with Codex MPLs, which are higher than proposed in the draft variations.
- The food categories to which quillaia extract is permitted to be added should be expanded.
- The name and INS number of the food additive for labelling purposes are more detailed than deemed appropriate and usually found in Standard 1.2.4.
- The requirement for the Applicant to supply an analytical method to check for compliance with the Code when enforcement agencies in other countries have not done likewise is questioned. This could be a potential barrier for local applicants and industries.
- The suitability of the Applicant's analytical method for determining quillaia saponins at low levels in beverages was questioned, since little information is provided explaining how the sensitivity has been improved and how the method addresses potential swamping of the saponin peak due to interfering substances.
- No evidence or discussion has occurred addressing whether quillaia extract can cause allergic or adverse reactions in some individuals. This issue should be addressed when assessing all new substances or foods.

Table 1: Summary of issues raised in submissions

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>The MPLs should be consistent with Codex, which is 50 mg/kg (L), higher than the MPLs in the Application.</p>	<p>Food Technology Association of Australia</p>	<p>The MPLs as well as the food categories to which quillaia extract was proposed to be permitted were reduced from that requested in the Application. They are also lower than those set in Codex. This was done with the Applicant's agreement and to ensure no population group exceeded the ADI, noting there are more permitted product categories than permitted by Codex. (See section 3.2.1 of the Report and section 4 of SD1, Dietary Exposure Assessment for more detail)</p>
<p>Incorrect statement that quillaia extract is currently not permitted in the Code as a food additive. It is an approved FEMA flavouring, number 2973, permitted as a flavouring due to subclause 11(a) of Standard 1.3.1.</p>	<p>Food Technology Association of Australia</p>	<p>Noted. The Report has been amended to reflect this information.</p>
<p>Quillaia extract has been used for many years as a foaming agent in beverages.</p>	<p>Food Technology Association of Australia</p>	<p>Noted. See section 2.3 of the Report.</p>
<p>Expand the food categories to which quillaia extract can be added, to ensure consistency across food categories and avoid the need for future applications to extend permissions.</p>	<p>Ministry for Primary Industries, New Zealand</p>	<p>The food categories for which quillaia extract were proposed to be added were reduced from those requested in the Application. This was done with the Applicant's agreement and to ensure no population group exceeded the ADI. Expanding the food categories from those agreed and modelled in the Dietary Exposure Assessment exceeds the ADI for high consumers in some population groups. (See section 3.2.1 of the Report and section 4 of SD1, Dietary Exposure Assessment for more detail)</p>
<p>Questioned why both the food additive INS number and food additive name for labelling purposes in Standard 1.2.4 are proposed to be more detailed than necessary or that is standard in the Code. It was suggested the INS numbers do not need the additional Roman numerals, i.e. 999i and 999ii need only be referred to as 999. Also no need to state type 1 or type 2 in parenthesis after the name quillaia extract.</p>	<p>Ministry for Primary Industries, New Zealand</p>	<p>FSANZ aims to be as consistent as possible with Codex food additive nomenclature and INS numbering. Therefore, the variations for both the food additive name and number for labelling purposes are consistent with Codex.</p> <p>This differs from some of the INS numbering currently in Standard 1.2.4.</p>

Issue	Raised by	FSANZ Response (including any amendments to drafting)
<p>Questioned why the Applicant needed to develop an analytical method for determination of the substance in beverages, when it seems other international regulatory agencies have not required the same. Suggests FSANZ reconsiders this requirement in the future as it could provide a significant barrier for international applicants.</p>	<p>New Zealand Food & Grocery Council</p>	<p>The requirement for applicants to provide an analytical method (literature reference or their own in-house method if a robust method does not exist in the literature) has been required so that regulatory enforcement agencies are able to check for compliance with the permissions added into the Code permissions. It is inappropriate to permit a new substance to be added to food via the Code if its presence cannot be analysed and quantified, as required, for food safety or enforcement purposes. This issue led to the development of an Implementation Sub Committee⁴ (ISC, renamed as Implementation Subcommittee for Food Regulation, ISFR) Expert Advisory Group on Analytical Methods consisting of members from jurisdictions with expertise in analytical methods to provide FSANZ with expert advice, as required, on analytical methods relating to applications.</p>
<p>Concern expressed that no details are provided on how the analytical method proposed will be able to analyse for the quite low levels of quillaia saponins permitted in beverages. It is believed there will be analytical difficulties due to the saponin peaks being swamped by other interfering substances.</p>	<p>Department of Health, Queensland</p>	<p>As noted above, FSANZ provided the Applicant's improved sensitivity analytical method for determining quillaia saponins in beverages to the ISC analytical methods EAG for their expert opinion. The response from the expert group was:</p> <p>"The consensus is that the method provided is suitable for the determination of quillaia saponins in the food categories specified in the application i.e. a range of beverages."</p>
<p>There is no discussion in the reports about whether quillaia extract at the proposed MPLs could cause allergic or other adverse reactions in some individuals. It is suggested that FSANZ should include in their normal assessment processes for new substances or foods possible allergic or other adverse reactions in some individuals.</p>	<p>Department of Health, Queensland</p>	<p>FSANZ currently requires that applicants address whether major allergens are present that require mandatory declaration due to the requirements of clause 4 of Standard 1.2.3 in their commercial products. This is not the case for this product based on its source and its known manufacturing process.</p> <p>There has been no discussion in the scientific literature over the use of quillaia extract in food having allergenic or adverse properties such that FSANZ would need to investigate it as a possible food allergen. Quillaia extract also does not contain protein, so will not be a possible allergen. The mandatory declaration of substances on labels is only required when there is evidence the substance is a food allergen of public health significance. This is not the case here. As noted above, quillaia extract is already permitted as a flavouring substance in the Code and FSANZ is not aware of reports of adverse effects for consumers from this use.</p>
<p>Noted that use of quillaia extract as a FEMA flavouring for non-alcoholic beverages may be used as a level of 90 mg/kg, which is higher than requested levels as an emulsifier in the Application.</p>	<p>Victorian Department of Health</p>	<p>The FEMA flavouring use levels do not refer to quillaia saponins, while the Application does and this is reflected in the MPLs. The FEMA use level was listed in early FEMA approvals where the form of quillaia extract is the crude form containing about one fifth saponins. So the actual figure for quillaia saponins is less than 20 mg/kg.</p>

⁴ <http://www.health.gov.au/internet/main/publishing.nsf/Content/foodsecretariat-isc.htm>

3.4 Risk communication

FSANZ 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 website⁵.

The draft variations were considered and approved by the FSANZ Board taking into account public comments received from the call for submissions.

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

The draft variations to the Code approved by the FSANZ Board have been notified to the COAG Legislative and Governance Forum on Food Regulation (the Forum). If the Forum does not request a review of the Board's decision, 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.

4. Reasons for decision

The draft variations to Standards 1.2.4 and 1.3.1, as proposed following assessment, were approved without change.

The approval was based on the best available evidence that quillaia extract, used at the MPLs proposed in various beverages, is safe and suitable as a food additive.

The MPLs are expressed as 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).

⁵ <http://www.foodstandards.gov.au/code/applications/Pages/applicationa1075quil5602.aspx>.

4.1 Section 29 of the FSANZ Act matters

FSANZ had regard to the following matters under 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. The Office of Best Practice Regulation, in a letter dated 24 November 2010 (reference 12065), provided a standing exemption from the need to assess whether 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 performed a summary cost benefit analysis. FSANZ concluded permitting quillaia extract as a food additive for a variety of beverages provides benefits to the food industry which were not outweighed by possible costs to enforcement agencies relating to developing analytical methods for checking Code compliance.
- 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. Standards 1.2.4 and 1.3.1 apply to New Zealand and there are no relevant New Zealand only standards.
- Any other relevant matters. None were identified. Section 18 matters are considered in section 4.2.

4.2 Addressing FSANZ's objectives for standards-setting

FSANZ has considered the three objectives in subsection 18(1) of the FSANZ Act during the assessment of this Application as follows.

4.2.1 Protection of public health and safety

FSANZ performed a safety assessment (SD1) of the use of quillaia extract as a food additive, and concluded there are no public health and safety concerns with its proposed use.

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

The existing labelling requirements in Standard 1.2.4 – Labelling of Ingredients 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).

4.2.3 The prevention of misleading or deceptive conduct

No issues were identified.

4.2.4 Subsection 18(2) considerations

FSANZ 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 variations are consistent with various international food standards.

- the desirability of an efficient and internationally competitive food industry

The variations are 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 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 Council⁶.

The Policy Guideline *Addition to Food of Substances other than Vitamins and Minerals*⁷ 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'.

4.3 Implementation

The variations will take effect on gazettal.

⁶ Now known as the COAG Legislative and Governance Forum on Food Regulation

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

5. References

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<http://www.fao.org/fileadmin/teimpactates/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. Approved variation to the *Australia New Zealand Food Standards Code*
- B. Explanatory Statement

Attachment A – Approved variation to the *Australia New Zealand Food Standards Code*



Food Standards (Application A1075 – Quillaia Extract (Quillaja 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.

“
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 – 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.

Following consideration by the COAG Legislative and Governance Forum on Food Regulation⁸, section 92 of the FSANZ Act stipulates that the Authority must publish a notice about the standard or draft variation of a standard.

Section 94 of the FSANZ Act specifies that a standard, or a variation of a standard, in relation to which a notice is published under section 92 is a legislative instrument, but is not subject to parliamentary disallowance or sunseting under the *Legislative Instruments Act 2003*.

2. Purpose

The Authority has approved 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 approved in various beverage categories in Schedule 1 of Standard 1.3.1. Consequential amendments are also approved in both Part 1 and 2 of 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 included one round of public consultation following an assessment and the preparation of a draft Standard and associated report. Submissions were called for on 26 July 2013 for a six-week consultation period.

⁸ Previously known as the Australia and New Zealand Food Regulation Ministerial Council

A Regulation Impact Statement was not required because the 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 (type 1) 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 have been expressed as the active ingredients, quillaia saponins, from the quillaia extract, either from type 1 or type 2.