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Final consideration report – Proposal P1057

Review of the kava standard

Food Standards Australia New Zealand (FSANZ) has approved a draft food regulatory measure after considering an urgent proposal to review the Australia New Zealand Food Standards Code (the Code). The proposal was to clarify the existing permission for kava to ensure it continues to protect public health and safety following the Australian Government’s decision to allow the commercial importation of kava from 1 December 2021 under Phase 2 of the Pacific Step-up Kava Pilot.

On Friday 10 December 2021, FSANZ prepared and sought submissions on a draft variation and published an associated initial consideration report. FSANZ received 38 submissions, including one confidential submission.

FSANZ approved the variation on 7 March 2022.

The variation took effect on public notice.

This Report is provided pursuant to section 97 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

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Supporting document

The following document¹ which informed the assessment of this proposal is available on the FSANZ website:

SD1 Risk and technical assessment report (at Approval)

¹ [Proposal P1057 - Review of the kava standard \(foodstandards.gov.au\)](http://www.foodstandards.gov.au)

Executive summary

Proposal P1057 was prepared by Food Standards Australia New Zealand (FSANZ) to consider whether the kava provisions of the Australia New Zealand Food Standards Code (the Code) needed to be amended following the Australian Government's decision to allow the commercial importation of kava from 1 December 2021 under Phase 2 of the Pacific Step-up Kava Pilot. FSANZ declared the proposal urgent.

At present, the Code prohibits the sale of food that consists of, or has as an ingredient or a component, kava or any substance derived from kava unless the food is:

- a beverage obtained by the aqueous suspension of kava root using cold water only, and not using any organic solvent, or
- dried or raw kava root.

The policy underpinning this partial prohibition is that the wholesale and retail sale of kava in Australia and New Zealand should only allow sales of kava in line with its historically safe preparation and use. This policy recognises that kava beverage has significant cultural importance for communities throughout Micronesia, Melanesia and Polynesia, and has been consumed for more than 1000 years. Kava beverage is an integral part of the dynamic and evolving cultural practices of many Pacific peoples, and is often regarded as an icon of national and/or ethno-cultural identity. It further recognises the history of kava preparation and consumption associated with these traditional cultural practices, as well as the public health and safety risks associated with excessive kava consumption.

As part of its commitment to the Pacific, the Australian Government recently amended Australia's customs laws to allow the commercial importation of kava as food into Australia under a two year trial program. The effects of the trial importation of kava will be monitored and evaluated over a two-year period, after which the Australian Government will decide whether the program should continue.

The prospect of increased consumption of kava as food in Australia prompted this proposal and the request by the Chair of the Food Ministers' Meeting to consider whether current Code provisions relating to kava remain appropriate in both Australia and New Zealand.

For the purposes of this proposal, FSANZ conducted a detailed risk assessment in relation to kava's use as food. That assessment acknowledged the long history of kava beverage consumption in the Pacific and its important and ongoing role in maintaining cultural continuity and identity. This significant history of use demonstrates that it is possible to safely consume kava beverage in moderation when prepared and consumed in line with historically safe practices.

However, kava beverage has a demonstrated potential to become a substance of abuse in certain contexts, and high consumption can result in intakes of kavalactones (the active ingredient of kava) that adversely impact health and well-being. Evidence of negative health outcomes have been observed in communities with established patterns of ongoing high-level consumption of kava beverage. Such ongoing high-level consumption has been associated with a scaly skin rash, altered liver function and other general reductions in overall health.

FSANZ's Initial Consideration of the urgent proposal was released for public comment from 10 December 2021 to 23 December 2021. That report proposed draft variations to Standard 2.6.3 intended to provide clarity and tighten permissions to better reflect historically safe kava preparation and consumption. The proposed amendments were to:

- require that permitted kava beverages be produced 'for immediate consumption at the place of preparation'
- prohibit the addition and use of food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages.

A total of 38 submissions were received, incorporating 26 from consumers (with one confidential), 8 from government agencies and 4 from the kava industry and businesses. Many of the consumer and industry submissions were received from New Zealand.

A large number of submitters expressed strong opposition to the proposed amendment that kava be produced for immediate consumption at the place of preparation. A main reason for their opposition was that it would in effect prohibit the current practice for many kava beverage consumers to purchase a kava beverage from a business and take it away for consumption at a different venue. Submitters also noted this is not inconsistent with historical practices, as had previously been suggested by FSANZ. Evidence was provided that takeaway kava beverage is very common in some Pacific countries and so considered historically safe preparation and use and so consistent with the regulatory policy. There was also no evidence of any additional public health and safety issues with this practice compared to consumers purchasing kava powder and preparing a kava beverage themselves. It is noted that the takeaway kava beverage that is the untreated beverage produced in compliance with the Standard has only a limited shelf life as it is not treated to be shelf stable. For these reasons FSANZ has decided to amend the draft variation to remove the requirement that kava beverages be produced for immediate consumption at the place of preparation.

The prohibition on adding and using food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages proposed in the Initial Consideration has been maintained. The justification is that this measure is to ensure consistency with historically safe kava preparation and consumption as is the original policy intent of the current standard. FSANZ notes that the *Codex Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) does not permit the use of food additives in kava products. FSANZ had concerns about the broadening of the market of kava beverage by the addition of food additives and processing aids to make them more palatable and appealing to consumers. FSANZ's assessment found evidence that kava products (pre-packaged kava beverages or kava root powders) that contain food additives or may be produced using processing aids, are available on the market in Australia and New Zealand. FSANZ's assessment identified some ambiguity in the Code about the use of food additives and processing aids in relation to kava so it has sought to ensure regulatory clarity consistent with the original policy intent of the kava standard.

There was support from a number of government enforcement agencies for the prohibition of food additives and processing aids as it provides regulatory clarity. There was some support in submissions from business and consumers for enzyme processing aids to be allowed as this assists in treating prepared kava beverage for further processing to produce shelf stable kava beverage. The regulatory intent and policy has been to limit kava beverages to historically safe preparation and use and this does not permit food additives or processing aids. Persons wishing to use food additives or processing aids in kava products had and will continue to have the option of applying to FSANZ to vary the Code to provide the required permission. This proposal is not the vehicle to assess and provide a general permission for kava products.

There was support from a number of government enforcement agencies and some kava exporting countries to require only Noble kava cultivars, being the safe varieties for food use, to be mandated in the Code. After considering the supportive submissions, FSANZ amended the draft variation to require that permitted kava products be obtained from a Noble kava

cultivar named in the Codex Regional Standard for Kava. This amendment was considered warranted given the potential public health and safety risk posed by other varieties of kava cultivars. As explained in submissions it is understood that there are methods to differentiate between kava varieties. Making the change also provides greater certainty for industry and jurisdictions in compliance and enforcement, and the measure would be consistent with international standards such as the Codex Regional Standard for Kava.

The summary of issues from submissions and FSANZ's response including the amendments to draft variations is provided in Table 1 of the report. Some submissions referred to the need for FSANZ to consider labelling requirements. FSANZ will give consideration to labelling requirements for permitted kava foods separately to this urgent part of the proposal as part of further assessment of the approved variation, including future public consultation.

Based on the findings of the risk assessment, and for the reasons stated in this report, FSANZ identified a need to amend the Code's kava provisions so they better reflect the regulatory policy intent of only permitting the sale of historically safe kava. FSANZ therefore approved the amended draft variation to vary the Code's kava provisions for this purpose. The variation will take effect on public notice.

The *Food Standards Australia New Zealand Act 1991* provides that FSANZ must, within 12 months of notification of the approved draft variation, undertake a full assessment of that variation, call for public comment and either reaffirm its approval of the variation or prepare a proposal to amend, replace or revoke that variation. The variation remains until such time as it may be changed via the above process.

1 Introduction

1.1 The proposal

The proposal was prepared following a request from the Chair of the Food Ministers' Meeting, Senator the Hon Richard Colbeck, to the Chair of the FSANZ Board. The request was for FSANZ to consider preparing and then declaring urgent a proposal to review the provisions of the Australia New Zealand Food Standards Code (the Code) relating to kava. The reason for the request and review was to ensure the Code's kava provisions can continue to protect public health and safety following the commencement of commercial importation of kava into Australia from 1 December 2021 under Phase 2 of the Pacific Step-up Kava Pilot².

As explained below, the Code's kava provisions generally restrict the sale of kava as a food in line with historically safe preparation and use. FSANZ prepared the proposal to consider whether these provisions needed to be amended to better reflect that regulatory policy objective and to ensure that, consistent with that policy and with historically safe preparation and use, food additives and processing aids may not be added to dried or raw kava root or kava beverages.

Declaration of Urgency

On 12 November 2021, FSANZ declared the proposal to be an urgent proposal for the purposes of Division 4 of Part 3 of *the Food Standards Australia New Zealand Act 1991* (FSANZ Act). FSANZ considered that the declaration of urgency was needed in order to protect public health and safety for the following reasons.

- The possible expansion of permitted kava products and increased consumption of kava products is considered a health and safety risk to the populations of Australia and New Zealand in terms of the acute effect (intoxication) as well as the potential for misuse by consumers. Past importation of kava led to well documented severe adverse health, safety, social and economic problems in some Australian First Nations communities, which could be exacerbated with the potential increased availability.
- The public health and safety risks posed by undue kava consumption are well documented. High levels of kava consumption can result in a scaly skin rash, nausea, loss of appetite, weight loss, indigestion, sore red eyes, lethargy, loss of libido and elevated liver enzymes. This is not the situation for the occasional consumption of kava beverage prepared according to historically safe practices by communities familiar with its consumption.
- Excessive kava consumption is also associated with adverse social and economic impacts, including apathy, excess absence from paid work, child neglect, loss of connection to family and community and diversion of financial resources from essentials.

FSANZ will give consideration to labelling requirements for permitted kava foods separately to this urgent part of the proposal as part of further assessment of the approved variation, including future public consultation.

FSANZ notes a recent definition of kava (beverage) which provides additional context to the proposal. It is: 'Kava is kava; it is the traditional beverage prepared by cold water extraction of the ground organs of the plant *Piper Methysticum*, and it is nothing else' (Aporosa SA 2019).

² <https://www.dfat.gov.au/geo/pacific/economic-prosperity-in-the-pacific/australia-kava-pilot>

1.2 The current standards

1.2.1 The Code

Standard 1.1.1 of the Code provides that the sale of kava as a food and the sale of foods that contain kava as an ingredient or component is prohibited unless expressly permitted by the Code.

Paragraph 1.1.1—10(5)(e) states that, unless expressly permitted by this Code, food for sale must not be kava or any substance derived from kava.

Paragraph 1.1.1—10(6)(i) states that, unless expressly permitted by this Code, a food for sale must not consist of, or have as an ingredient or a component, kava or any substance derived from kava.

Standard 2.6.3 of the Code provides permissions for the purposes of the above prohibitions. Section 2.6.3—3 of that Standard provides that the prohibitions do not apply to a food that is:

- (a) a beverage obtained by the aqueous suspension of kava root using cold water only, and not using any organic solvent; or
- (b) dried or raw kava root.

This means both the above foods may be sold.

Standard 1.1.2 of the Code provides a definition of kava and kava root for the purposes of the above prohibitions and permissions. Subsection 1.1.2—3(2) of that Standard defines 'kava' to mean 'plants of the species *Piper methysticum*' and 'kava root' to mean 'the peeled root or peeled rootstock of kava'.

Food additives

Paragraph 1.1.1—10(6)(a) provides that, unless expressly permitted by the Code, a food for sale must not have, as an ingredient or component, a substance that is used as a food additive.

Section 1.1.2—11 defines the expression 'used as a food additive'. Subsection 1.1.2—11(1) provides that a substance is 'used as a food additive' in relation to a food if both of the following conditions are met: the substance is added to the food to perform one or more technological functions listed in Schedule 14; and the substance is identified in subsection 1.1.2—11(2) – this includes a substance identified in the table to section S15—5 as a permitted food additive or a permitted substance (food additive) listed in sections S16—2, S16—3 or S16—4 of the Code.

Section 1.3.1—3 details when substances are permitted to be used as food additives in food.

Schedule 14 lists the permitted technological purposes of food additives.

Schedule 15 lists the specific food additive permissions for different classes of foods in the table to section S15—5.

Processing aids

Paragraph 1.1.1—10(6)(c) provides that food for sale cannot contain, as an ingredient or component, a substance 'used as a processing aid' unless that substance's use as a processing aid is expressly permitted by the Code.

Section 1.1.2—13 provides that a substance ‘used as a processing aid’ in relation to a food is a substance used during the course of processing that meets all of the following conditions: it is used to perform a technological purpose during the course of processing; it does not perform a technological purpose in the food for sale; and it is a substance listed in Schedule 18 or identified in section S16—2 as an additive permitted at Good Manufacturing Practice (GMP).

Enzymes used in processing and manufacturing food are considered processing aids.

Existing labelling requirements

The following relates to the two types of kava foods that the Code permits to be sold (see (a) and (b) above).

Food for retail sale

The Code requires food for retail sale in a package to bear a label with the information set out in subsection 1.2.1—8(1), with some exemptions.

This means the label on permitted kava foods must contain the warning statements set out in section 2.6.3—4 of the Code (i.e. *Use in moderation; May cause drowsiness*).

The Code provides that foods for retail sale are not required to bear a label with the information requirements referred to in subsection 1.2.1—8(1) if the food for sale is:

- not in a package³ (e.g. kava root may be sold unpackaged)
- made and packaged on the premises from which it is sold (e.g. a beverage in a bowl or glass)
- packaged in the presence of the purchaser (e.g. a beverage in a bowl or glass).

The labelling information requirements for food for retail sale that is not required to bear a label, are set out in section 1.2.1—9. Paragraph 1.2.1—9(3)(f) states that, for food for retail sale that consists of kava root not in a package, the following information must accompany the food or be displayed with the food:

- the warning statements in section 2.6.3—4; and
- the name and address of the supplier.

In addition, for food for retail sale that is not required to bear a label, sections 1.2.1—9(6) and 1.2.1—9(7) state the requirements for information that must be displayed with the food or provided to the purchaser on request. The provision of the name of the food is relevant for kava.

Food sold to caterers

Food sold to caterers in a package must bear a label with certain information (e.g. name of the food, lot identification) (section 1.2.1—15). Other information such as the name and address of the supplier and the two warning statements about kava must be provided on the label (if any) or in documentation (subsection 1.2.1—16(1)). If the name and address of the supplier is provided in documentation, the documentation must accompany the food for sale

³ ‘Package’ is defined in subsection 1.1.2—2(3) of the Code and includes:

any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged.

(subsection 1.2.1—16(2)).

Nutrition content and health claims

Nutrition content and health claims about kava are prohibited (subsection 1.2.7—4(a)).

1.2.2 Code's interaction with other kava related laws

As stated in Standard 2.6.3⁴, that Standard needs to be considered in conjunction with Australian customs laws and certain State and Territory restrictions on the supply of kava which seek to minimise the detrimental effects associated with kava abuse. Standard 2.6.3 is intended to complement the measures imposed by these other laws.

Australian customs laws have generally prohibited the importation of kava into Australia.

However, on 11 October 2019, the Australian Government launched a kava pilot program as part of its commitment to the Pacific. The pilot consists of two phases:

- Phase 1 – Australian customs laws were amended to increase the amount of kava that incoming passengers (18 years or over) are allowed to bring into Australia in their accompanied baggage from 2 kg to 4 kg. Phase 1 commenced in December 2019.
- Phase 2 - Australian customs laws were amended to allow the commercial importation of kava into Australia for use as a food subject to the issue of an import permit (Imported Food Control Legislation Amendment (Risk Foods) Order 2021⁵). This phase commenced on 1 December 2021. This legislation specifically states '**kava products** means a food mentioned in section 2.6.3—3 of the Australia New Zealand Food Standards Code, as in force at the commencement of this definition'.

State and Territory laws also regulate the sale and supply of kava. FSANZ understands, for example, that *Northern Territory Kava Management Act 1998* (NT) prohibits the importation into and sale of kava in the Northern Territory.

1.2.3 Codex standard

The relevant international standard for kava is the *Codex Regional Standard for Kava Products for use as a Beverage when Mixed with Water* CXS 336R-2020 (Codex Regional Standard for Kava) (Codex Alimentarius Commission 2020). This is an international regional standard for kava, which is used to prepare a kava beverage when mixed with water for human consumption. It is noted that the Codex Regional Standard for Kava does not apply to the final kava beverage as such. Kava products are derived from selected parts of the Noble⁶ cultivar of the kava plant, *Piper methysticum* G Forst in the Family *Piperaceae*. The relevant parts of the kava plant used to produce kava products include:

- peeled, fresh and/or dried rhizomes, basal stems (up to the first node of each kava branch)
- fresh and/or dried roots.

The Codex Regional Standard for Kava also does not apply to kava products used for

⁴ Standard 2.6.3 – Kava [Australia New Zealand Food Standards Code – Standard 2.6.3 – Kava \(legislation.gov.au\)](https://www.legislation.gov.au/Details/F2021L01659)

⁵ <https://www.legislation.gov.au/Details/F2021L01659> commenced on 1 December 2021

⁶ A non-exhaustive list of various Noble varieties from different regions are listed in the Codex Regional Standard for Kava. These are the safe kava varieties used to produce kava and kava products for food use.

medicinal purposes, or as ingredients in foods or other tradeable products, or for any other purposes.

No food additives are permitted in products covered by the Codex Regional Standard for Kava. It allows that potable water can be used to prepare kava beverage from dried kava powder, or if prepared from fresh kava, that the ground or macerated kava is again mixed with potable water. Both methods of production may be filtered prior to consumption.

The Codex Regional Standard for Kava also includes other parameters such as more requirements on composition and quality factors, contaminants, hygiene, labelling and methods of analysis and sampling. A number of these parameters are not comparable to Code requirements as many relate to quality considerations, not specifically addressing public health and safety concerns. Contaminant and hygiene requirements are captured by relevant Code requirements, being Standard 1.4.4 and 1.6.1 respectively, as well as the generic requirement of the Food Acts that food is safe for human consumption. The labelling and methods of analysis and sampling requirements are not directly relevant to Code standards.

1.3 Reasons for preparing the proposal

The proposal was prepared to review the kava provisions of the Code to ensure they continue to protect public health and safety with the lifting on the ban on importation into Australia of kava as a food from 1 December 2021.

1.4 Procedure for assessment

The proposal was considered as an urgent proposal. For the reasons explained in section 1.1, the proposal was declared an urgent proposal for the purposes of Division 4 of Part 3 of the FSANZ Act.

1.5 Decision

The draft variation as proposed following initial consideration was approved with three amendments in order to :

- add a requirement that kava food products must only be obtained from the Noble varieties of the species of *Piper methysticum* that are named in the Codex Regional Standard for Kava; and.
- remove the proposed requirement that a permitted kava beverage must be for immediate consumption at the place of preparation.

The approved variation, as varied after consideration of submissions, is at Attachment A. The related explanatory statement is at Attachment B. An explanatory statement is required to accompany an instrument if it is lodged on the Federal Register of Legislation. The draft variation on which submissions were sought is at Attachment C.

The variation will take effect on public notice. Subsection 97(5) of the FSANZ Act provides that the commencement date of the variation is the date that public notice of the variation's approval was given in accordance with subsection 97(4) of that Act.

The FSANZ Act provides that FSANZ must, within 12 months of public notice of the approval of the variation, undertake a full assessment of that variation, call for public comment and either reaffirm its approval of the variation or prepare a proposal to amend, replace or revoke

that variation.

2 Summary of the findings

A total of 38 submissions were received, incorporating 26 from consumers and kava consumer groups (mostly from New Zealand), 8 from government agencies and 4 from kava industry organisations or companies. One late submission was received from the Republic of Vanuatu. The issues and comments raised in this submission were similar to other submissions so they had been already summarised and addressed within Table 1.

2.1 Summary of issues raised in submissions

The summary of issues raised in submissions and the FSANZ response to them are provided in Table 1. High level overviews of the main issues identified from the submissions are provided below, in the same order as provided in the Table.

General support

Four Australian and New Zealand government agencies provided general support to the intent and proposed draft variations of the Initial Consideration, noting they each had additional issues and comments. No support was noted in the other submissions which in the main opposed various aspects of the proposal and proposed draft variations. It is also noted that one Australian government agency expressed its continued opposition to the Australian Government's pilot program to allow the commercial importation of kava into Australia.

Intent not to broaden consumption

A number of kava business groups and advocacy groups expressed disappointment that the intent of the proposal was not to broaden the consumption of kava to the wider community which they took to be part of the Australian Government's principles of the Pacific Step-up. They considered the proposed amendments restrictive and also not necessary. FSANZ notes that some of the matters discussed are outside its remit. The request to prepare the proposal included the specific consideration of amending the Code to more explicitly limit the preparation and consumption of kava beverages to practices in line with historical safe use.

Warning labelling statements

A number of Government agencies requested FSANZ consider mandating specific additional labelling statements as part of the proposal. They suggested additional warning statements, including some similar to those required on therapeutic goods containing kava. FSANZ will consider the need for additional warning statements as part of the assessment undertaken within 12 months of the approved draft variation. Other additional labelling matters will also be considered at this time.

Noble varieties of kava

FSANZ's initial position to not mandate Noble cultivars was due to concern that the Codex Regional Standard for Kava list was non-exhaustive and that differentiating Noble cultivars appeared not readily achievable for enforcement purposes. However, after receiving feedback via a number of government and kava industry submissions FSANZ decided to amend the Code to require that the permitted forms of kava must be only from a Noble kava cultivar named in the Codex Regional Standard for Kava. This amendment was considered warranted given the potential public health and safety risk posed by other varieties of kava cultivars which are not suitable for making kava beverage. As explained in submissions, it is

understood that there are methods to differentiate between kava varieties. Making the change also provides greater certainty for industry and jurisdictions in compliance and enforcement, and the measure would be consistent with international standards such as the Codex Regional Standard for Kava.

Other specification suggestions

Two Government agencies suggested additional specification requirements be added to Standard 2.6.3 for safety reasons. They were to limit the maximum moisture content of the dried kava to reduce the risk of aflatoxin poisoning, and to apply a maximum limit of kavalactones to kava powder. FSANZ considered both specification suggestions but did not support them. As explained further in the Table, FSANZ considers moisture content is not an appropriate risk management measure. The imposition of a kavalactone limit is also not considered to be an appropriate risk management measure and would impose costs on compliance and enforcement that have limited justification or benefit.

Disagreement with prohibition of takeaway kava

Kava industry representatives, advocacy groups and individuals strongly disagreed with FSANZ's proposed draft variation that kava beverages should be prepared for immediate consumption at the place of preparation. Submitters expressed concern that the measure would prohibit takeaway of kava beverages. Submitters noted that takeaway kava beverage is commonplace in different kava consuming countries including New Zealand. This arrangement serves people who are not experienced in preparing kava beverage but want to consume it at home or in an alternative place. Submitters stated that what was proposed by FSANZ in the initial consideration is not considered by them as representing traditional safe practices, which evolves over time. Submitters noted that what is important is the safety of takeaway kava beverage. FSANZ has reconsidered its position due to the information and issues raised in the submissions. It has concluded that the takeaway of kava beverage from the place of preparation is indeed consistent with historically safe preparation and is therefore not considered to pose additional public health and safety concerns compared to consumers purchasing kava powder and preparing a kava beverage themselves or be inconsistent with the policy intent of the kava standard. Therefore, FSANZ has removed the proposed amendment limiting consumption to the place of preparation. This will enable consumers to take away kava beverage that has been prepared consistent with the requirements of Standard 2.6.3.

Kava is important for Pasifika communities and Australia should not dictate New Zealand regulations

A number of kava industry advocacy groups and individuals noted that kava is important for Pasifika communities in both New Zealand and Australia. They appreciate the benefits kava consumption has for them and stated the kava culture is different in New Zealand to Australia. Submitters perceived Australia was dictating kava use regulations to New Zealand and considered the proposed changes to show a lack of understanding of kava use in the Pacific. FSANZ notes that the kava standard has applied to both Australia and New Zealand under the joint Code for more than 20 years. The aim of the current proposal is to continue to allow the sale of kava in both New Zealand and Australia for traditional use, while minimising potential adverse health and social impacts. It seeks to do this by limiting its use to historically safe preparation and consumption practices.

Prohibition of use of food additives and processing aids

How the Code regulates food additives and processing aids is described in Section 1.2.1. FSANZ notes the Code does not explicitly permit the use of any food additives or processing

aids (including enzymes) for the preparation of kava beverage and their use is inconsistent with historical safe preparation on which the risk assessment was conducted. It is apparent there are kava products available on the market that contain food additives and have been produced using processing aids. Therefore, FSANZ proposed the prohibition to provide regulatory certainty in relation to the original policy intent of the kava standard. A number of government agencies supported the prohibition. Including express prohibition in Standard 2.6.3 is consistent with kava being a distinct commodity with specific and unique issues associated with its use, and that as previously agreed a separate commodity standard - Standard 2.6.3 - was an appropriate means to regulate kava. One government agency questioned whether the prohibition approach was appropriate or required, which FSANZ has addressed in Table 1. Comments from some kava businesses and individuals questioned why such a prohibition was required, especially the prohibition on enzymes as they have been used in New Zealand for many years to assist in producing pasteurised takeaway kava products.

Inconsistency with FSANZ Act requirements

An individual submission claimed the proposal assessment document was not consistent with the requirements of the FSANZ Act. For the reasons stated in this report, FSANZ remains satisfied that both its assessment and decision are in accordance with the FSANZ Act.

Disputed risk assessment conclusions

A number of individuals raised specific questions related to various aspects of FSANZ's risk assessment. FSANZ's responses to these issues are provided in Table 1. It is noted that FSANZ made some amendments to SD1 as appropriate after considering comments made in submissions, however the risk assessment conclusions have not changed.

Fewer negative impacts compared to alcohol, over the counter drugs and some foods

A kava industry association and some individuals noted that kava has fewer individual and social harms compared to alcohol and other drugs and foods. FSANZ has not considered the public health policies for other foods as part of this proposal. Specifically submissions noted that kava extracts are a better alternative to conventional medicines such as anti-anxiety and sleep medications. FSANZ has only considered kava beverages, not kava extracts, as they are not foods and are therefore out of scope of the proposal.

FSANZ further noted that some of the issues are out of scope of the proposal or do not require a specific response as they expressed general comments. These have been noted for completeness in Table 1.

Table 1: Summary of issues in submissions to the initial consideration and FSANZ response

Issue	Raised by	FSANZ response (including any amendments to drafting)
General support for the proposal		
Generally supportive of the proposed amendments to Standard 2.6.3 to enhance the policy intent of the 20-year old standard. Supports for the continued, responsible use of kava as it has an important traditional and ceremonial role for the cultures of South Pacific communities. However, careful management is required as kava misuse has been associated with significant health and social harms in Australia when last commercially available, particularly in Indigenous communities.	New South Wales Food Authority	Noted
Supportive of the draft variation as it will enable consistent and appropriate compliance activities through the Imported Food Inspection Scheme at the Australian border. The draft variations are consistent with the intent of the current standard.	Department of Agriculture, Water and the Environment	
Supports the proposed draft variations to the Code, which are easy to interpret and appear enforceable. It notes that the proposed amendments should allow kava to be used for traditional Pacific communities' ceremonial use. It should also legally prevent the sale of pre-packaged kava beverages and some types of 'instant' kava beverage powders to help limit its availability and uptake by the broader community.	Queensland Department of Health	
Largely supportive of the approach proposed to clarify ambiguities in the standard, noting it is consistent with existing policies to support the use of kava for traditional purposes in both New Zealand and Australia.	New Zealand Food Safety	
Issues out of scope		
Some issues are noted that cannot be resolved by the food regulatory system. These are concerns from the NSW Police Force relating to: <ul style="list-style-type: none"> • The increased availability of kava in the community may impact road safety due to possible driver impairment • Concern that with the current permit system organised crime syndicates could infiltrate the importation of kava. As well there is concern that importers could bring in illicit substances alongside kava. 	New South Wales Food Authority	As the submitter notes, these comments are outside the scope of this proposal and FSANZ's remit.
Since the deletion of the National Code of Kava Management it is no longer possible to regulate marketing and advertising of kava. There may be merit in seeking guidance from the Australian Association of National Advertising on appropriate non-regulatory management of marketing strategies for consumed psychoactive substances (e.g. alcohol) that could be replicated for kava.	New South Wales Food Authority	These comments are outside the scope of this proposal and FSANZ's remit.
Notes reports that kava use had impacted the social and emotional wellbeing of individuals and families, particularly in First Nation communities in the Northern	West Australian Department of Health	Some of these issues are outside the remit of FSANZ and as noted in the submission are related to the broader Commonwealth

Issue	Raised by	FSANZ response (including any amendments to drafting)
Territory. Concern expressed that similar problems could occur in remote First Nation communities in WA (including dry communities) with earlier reports identifying conflict and tension within family units (including economic impacts) and negative impacts on employment, community and cultural activities. Concern is also expressed that people in these communities may be able to purchase kava via their cashless welfare cards, where these concerns have not been responded to via the Commonwealth Government kava pilot project team.		Government oversight of the kava pilot program. The general comments and concerns are noted and, where relevant, have been considered as part of FSANZ's consideration of the proposal.
Potential issues raised are the consumption of kava with alcohol, sale to minors, sale to intoxicated consumers and the operation of vehicles under the influence of kava. A number of these issues are noted to be outside the remit of FSANZ and are the responsibility of state and territory governments but still there are some controls that FSANZ has.	Queensland Department of Health	The comment and issue is noted, along with the understanding that these matters are outside FSANZ's remit.
The two submissions relate to kava extracts, not traditional forms of kava beverages, which are classed as dietary supplements or natural medicines. The submitter hoped the proposed changes will not impact their members who produce such products.	New Zealand Association of Medical Herbalists, Natural Health Products New Zealand	The proposal and proposed amendments to Standard 2.6.3 are not directly related to kava extracts used as dietary supplements or natural medicines and as such the comments and information provided in the submissions are considered out of scope.
Suggests that in future the prohibition on using kava (or any substance derived from kava) as an ingredient or component in other foods should be reconsidered as such an initiative will help Pacific kava stakeholders grow their market. It notes this prohibition is consistent with the Codex Regional Standard for Kava.	Pacific Horticultural and Agricultural Market Access Program (PHAMA Plus)	As the submitter notes, what it is suggesting (i.e. using kava or components of kava in other foods) in the future is also not consistent with the Codex Regional Standard for Kava and would be a major change to the regulation of kava. As such it is out of scope of this proposal. Any change along the lines outlined would require a future application to change the Code.
General issues for response		
Suggests that FSANZ should publish guidance material related to the Code requirements for kava to be applicable for industry, consumers and government agencies. The information for consumers should include the risks associated with kava and its safe use.	Queensland Department of Health	The issue of guidance can be considered in conjunction with jurisdictions through the Implementation Subcommittee for Food Regulation ⁷ during the subsequent 12 month review period of the proposal after approval of the urgent variation.
Questions what is intended by the addition of the proposed draft variation 'for immediate consumption at the place of preparation' and how it will operate, especially at kava bars that produce kava beverage at a large scale like a microbrewery. Such businesses have on-site processing, sale to the public [for takeaway] and consumption on premises.	South Australia Health	Noted. For the reasons stated in this report, FSANZ has amended the draft variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation.
Suggested that the draft Explanatory Statement (ES) at Attachment B to the report is updated to include the effect of repealing and substituting paragraph 2.6.3—3(a) to include a requirement that a kava beverage permitted by the Code be prepared for	Department of Agriculture, Water and the Environment	Noted. FSANZ is satisfied that the original proposed Explanatory Statement was consistent with section 2.2.2 of the report. For the reasons stated in this report, FSANZ has also amended the draft

⁷ [Food Regulation - Implementation Subcommittee for Food Regulation \(ISFR\)](#)

Issue	Raised by	FSANZ response (including any amendments to drafting)
immediate consumption at the place of preparation. The effect is captured in section 2.2.2 of the report but is not reflected in the draft Explanatory Statement.		variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation. The Explanatory Statement has been amended accordingly.
Expressed concern about which food businesses can sell kava beverages 'for immediate consumption at the place of preparation'. Kava beverages cannot be mixed with alcohol but there is nothing preventing a business selling kava beverages from also selling alcohol from the same premises, which was considered concerning. The submission suggested the Code should be more specific about the food businesses and persons selling the kava products in a similar manner to that of Standard 2.9.5 – Food for Special Medical Purposes.	West Australian Department of Health	Noted. FSANZ is not aware of or been provided with any evidence of such a problem. Nor has any other jurisdiction raised this as an issue. The food categories of 'Food for special medical purposes' and 'kava' are not similar and neither are the public health and safety risks relating to each.
It notes the regulation to permit the commercial trade of kava as a food does not have a sunset date; it is not like the phase 2 pilot which is for two years. The issue of warning statements should not be restricted to the 2 year time period to ensure consumer safety and awareness.	New South Wales Food Authority	Noted. The amendments made to the Code by the approved variation are not subject to a sunset date or provision. The issue of labelling will be considered during the 12 month review that follows approval of the variation.
A submission was received which contained track changes to FSANZ's Imported Food Risk Statement (Kava).	Individual	Noted. FSANZ will review the Imported Food Risks Statement to ensure it is in line with the outcomes of this proposal.
The World Health Organization (WHO) makes no reference to where kava is consumed (traditional or non-traditional) as having any impact on causing adverse health effects, nor does it stipulate the necessity of consuming kava where it is prepared.	Individual	Noted. For the reasons stated in this report, FSANZ has amended the draft variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation.
Claimed there is no evidence of causation between kava consumption and the suggested social and economic effects FSANZ reported in the Initial Consideration report.	Individual	Noted. FSANZ does not agree. These conclusions were from documented reports of kava consumption in First Nations communities in the Northern Territory.
Concerned that the Code does not prevent a food business from selling a kava beverage, as well as a syrup or sweetener (e.g. sugar sachets, alternative sweeteners, honey, maple syrup) separately, for immediate consumption. The syrup or sweetener would likely make the kava beverage more palatable.	West Australian Department of Health	Noted. FSANZ is not aware of or been provided with any evidence of such a problem. Nor has any other jurisdiction raised this as an issue, including New Zealand where kava beverages have been sold from businesses for many years.
General comments not needing a response but noting concerns		
Concern expressed that although there is a long tradition of use of kava in Pacific communities, past importation led to excessive consumption in some First Nations communities resulting in well documented severe adverse health, safety, social and economic impacts.	Queensland Department of Health	The comments are noted.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Concern expressed and notes that it does not support the Commonwealth Government's pilot to allow the commercial importation of kava into Australia. It is concerned about the potential harms and implications of the establishment of a kava market and the misuse of kava products in WA communities, including the accessibility of kava products to people of any age under the pilot. It further noted that the importation of kava ceased in 2007 due to concerns that the abuse of kava was contributing to negative health and social outcomes, including in some remote First Nation communities. Additional specific concerns were detailed, including those provided in FSANZ's Imported Food Risk Statement for kava and within SD1.</p>	<p>West Australian Department of Health</p>	
<p>Disagreement about the intent to limit and not broaden the consumption of kava</p>		
<p>The submission argues the Australian Government recently amended Australia's customs law to allow the commercial importation of kava not because of 'its commitment to the Pacific', but to simply normalise the trade that was stopped in 2007. It further argues that the normalisation of the kava trade was a pre-condition of Vanuatu ratifying the <i>Pacerplus Agreement</i>. Kava constitutes more than 63% of Vanuatu exports to Australia so it is very disappointing if it is excluded in a free-trade agreement between the countries. This is especially so when the product is considered safe by the WHO and Codex.</p>	<p>Vanuatu Kava Industry Association</p>	<p>Noted. Some of these matters are beyond the FSANZ remit and outside the scope of this proposal. For the reasons stated in this report, FSANZ has approved a draft variation that confirms the regulatory intent of the Code's kava provisions and generally preserves the regulatory status quo in relation to kava. Anyone can make an application at any time to amend these provisions and the Code's requirements in relation to kava.</p>
<p>The kava pilot program is not about limiting kava consumption to traditional use, but it is about the normalisation of trade in kava. Traditional preparation consistent with the Codex Regional Standard for Kava makes sense, but not to limit consumption to 'traditional use amongst sub-populations familiar with its occasional and ceremonial use'. Vanuatu understands the pilot program is to not only to supply kava to existing kava consumers in Australia but also to promote it as a healthy, relaxing and social drink that is healthier than alcohol. The focus should be on trade, on public health and safety of kava including the benefits of kava verses alternative beverages consumers are using for relaxation and socialising.</p>	<p>Vanuatu Kava Industry Association</p>	
<p>Concern expressed about the proposed changes and the ramifications they will have on kava use in both Australia and New Zealand. The submitter organisation is a kava advocacy group. The reasoning related to the proposed changes of the proposal are void of the values of inclusion, community engagement and kava expertise. The submission notes that those in the kava community and kava academia know the dangers that making significant changes in kava regulation in the absence of informed or true community engagement has.</p>	<p>Fair Canberra Inc. Pacific Island Showcase Association</p>	
<p>The intent of the proposal to limit the use of kava beverage and not to promote</p>	<p>Pacific Horticultural</p>	

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>broader consumption is not appropriate under the principles of the Australian Government's Pacific Step-up, with the proposed amendments restrictive and also not necessary. Given that kava is recognised as a food by Codex and the Code, with appropriate warning labels, and there are quality requirements to ensure safe consumption, kava should be open to other communities outside the Pacific Island diaspora.</p>	<p>and Agricultural Market Access Program (PHAMA Plus)</p>	
<p>Warning labelling statements</p>		
<p>Concerned about potential impacts on at-risk sub-populations, such as children, adolescents and pregnant or lactating women. Also concerned that kava consumption may impair the ability of individuals to safely operate a motor vehicle and other machinery, which may be exacerbated by alcohol consumption. Requests FSANZ review current warning statements and suggests additional statements be introduced as part of the urgent proposal including that kava should not be consumed: by pregnant and breastfeeding women; by adolescents and children; when driving a motor vehicle; when operating heavy machinery; and not in conjunction with alcohol. The review should consider both packaged kava products and the role and applicability of warnings to kava beverages sold for immediate consumption e.g. at kava bars. Suggests it is appropriate to consider labelling now as it would apply lower costs for manufacturers rather than later once products are on the market.</p>	<p>New South Wales Food Authority, Queensland Department of Health, Victorian Department of Health, and the Victorian Department of Jobs, Precincts and Regions, West Australian Department of Health</p>	<p>Noted. FSANZ must undertake a full assessment of the approved draft variation, including public consultation, within 12 months of the commencement of the approved variation and will during this time consider the current warning labelling statements and the need for any additional warning statements as appropriate risk management options. This will include considering the costs and benefits of any labelling changes.</p>
<p>Concerned the consumption of the active components of kava, being kavalactones, can be higher by consuming kava beverages compared to kava containing therapeutic goods and that the Therapeutic Goods Administration (TGA) requires warning statements on kava containing therapeutic goods additional to those in the Code.</p>	<p>New South Wales Food Authority, Victorian Department of Health, and the Victorian Department of Jobs, Precincts and Regions</p>	<p>Consistent with the 2016 FAO/WHO technical report, the 2004 FSANZ risk assessment and the P1057 SD1, FSANZ has differentiated between kava beverage preparations with a history of safe use (cold water extraction from kava root) and kava extracts (organic solvent extraction and standardisation). This recognises that kava beverage has a different risk profile to kava extracts used as complementary medicines or therapeutic products. Therefore, risk management approaches including labelling of complementary medicines cannot be directly applied to kava beverage. However, as noted above FSANZ will consider the need for additional warning statements as appropriate risk management options as part of the full assessment to be undertaken within 12 months of the notification and commencement of the approved variation.</p>
<p>Concerned about the sale of kava beverages for immediate consumption at places such as kava bars which have become popular in other countries, and can be expected to open in Australia. Suggests FSANZ should consider amending the Code to extend (or explicitly clarify) labelling warning statements to sale of kava beverages</p>	<p>Queensland Department of Health</p>	<p>As noted at Initial Consideration, FSANZ will consider labelling requirements for permitted kava foods, including provision of warning statements for the sale of kava not required to bear a label (e.g. from kava bars) as part of the further assessment of the</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
for immediate consumption e.g. signage.		approved variation.
Noble varieties of kava		
Suggests that the Code should limit the varieties of kava that may be legally sold as food to those of Noble origin. This is considered necessary due to the concern FSANZ has raised regarding safety risks of using <i>Tu-dei</i> (two day) varieties and wild kavas (<i>Piper wichannii</i>). Suggests that the list of Noble varieties in the Codex Regional Standard for Kava be adopted as a new Schedule in the Code as an exclusive and exhaustive list so it can be enforceable.	New South Wales Food Authority	Noted. After considering submissions FSANZ decided to amend the Code to require that the permitted forms of kava must be only from a Noble kava cultivar named in the Codex Regional Standard for Kava. This amendment was considered warranted given the potential public health and safety risk posed by other varieties of kava cultivars which are not suitable for making kava beverage. The safe varieties of kava for food are required to be what are called the Noble cultivars (see sections 3.1 (risk assessment) and 3.2.4 (risk management)) for discussion on Noble cultivars. It is understood that there are methods to differentiate between kava varieties. Making the change also provides greater certainty for industry and jurisdictions in compliance and enforcement, and the measure promote consistency with an international regional standard; the Codex Regional Standard for Kava.
Notes that general adoption of the Codex Regional Standard for Kava, explicitly the list of Noble kava varieties, would permit enforcement action at the border or market if this should be necessary.	Victorian Department of Health, and the Victorian Department of Jobs, Precincts and Regions	
States that there are a few published methods to clearly differentiate Noble and other cultivars. There are various scientific published documents on the colorimetric test and on kava DNA testing and differentiation. Vanuatu Kava has been systematically tested before being exported for nobility for several years.	Vanuatu Kava Industry Association	
Notes there is scientific literature that explains the characteristics of known Noble kava cultivars and their associated morphological, chemical and genetic evidence.	Pacific Horticultural and Agricultural Market Access Program (PHAMA Plus)	
Additional specification suggestions		
Suggests that FSANZ should consider regulating a maximum moisture content for dried imported kava to be consistent with the limit of the Codex Regional Standard for Kava. The justification for suggesting adding this moisture limit is to reduce the risk of aflatoxin poisoning should the drying or storage conditions for harvested kava not be appropriate. The limit provides a simple enforceable check at the border for incoming shipments of kava.	New South Wales Food Authority	FSANZ does not consider moisture content (MC) to be an appropriate risk management measure in this context. The scientific evidence base for the effects of moisture on growth and aflatoxin production by certain fungi in foods, particularly <i>Aspergillus</i> species, is based on water activity (a_w). While MC is used as a proxy measure for a_w , it is not possible to readily convert between the two. FSANZ further notes that the lower limits of water activity for growth and aflatoxin production are not clearly defined, and there is no published literature on growth and aflatoxin production on kava. Similar risks from fungal growth and mycotoxin production could apply to many low moisture content foods such as spices, grains etc. However, limits on moisture content of these foods have not been set in the Code.

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Notes that SD1 states that 'total kavalactone content in kava varies from 3% to 20% of dry weight'. Proposes the Code incorporates a maximum limit for kavalactone content of 20% of the kava powder as dried weight. Suggests this limit would prevent any potential future health impacts of higher kavalactone concentrations due to possible changes in cultivation or other factors in the future.</p>	<p>Victorian Department of Health, and the Victorian Department of Jobs, Precincts and Regions</p>	<p>The suggestion is not supported by FSANZ. Each kavalactone has unique chemical properties leading to variations in their physiological effects, while each kava variety (both Noble and tu-dei) produces a unique mix of kavalactones.</p> <p>Total kavalactone content is a poor indicator of kava variety and/or potency. FSANZ considers the imposition of a maximum limit would impose costs (from analytical testing) for enforcement and compliance with limited justification or benefit.</p>
<p>Disagreement with prohibition of takeaway kava beverage</p>		

<p>A submitter considered the new amended draft variation 'For immediate consumption at the place of preparation' is wrong and inconsistent with the kava pilot program statement that 'Australia's commercial kava pilot will initially only allow kava powder and kava beverages to be imported into Australia'.</p> <p>Bottled kava beverage in takeaway bottles is now quite common in Vanuatu, as it allows kava drinkers to have their cup of kava at home, and is considered a traditional consumption nowadays. bottled takeaway kava beverages also have been sold and distributed for years in New Zealand without any issue.</p> <p>Many people consume kava beverages as takeaway bottled beverage. Kava is commonly prepared for commercial consumption for social drinking and it does not reflect traditional consumption. As kava consumption has become more commercialised, some consumers prefer to take their kava beverage away to consume in a quieter and more comfortable place. The consumption of kava has increased in New Zealand and businesses have opened to cater for kava consumption (including takeaway). Traditions relating to the preparation and consumption of kava beverages must be allowed to adapt and change with the circumstances, including due to the COVID pandemic, as per the preferences of the relevant communities.</p> <p>Many people who wish to consume kava do not know how to prepare kava themselves or have access to kava cafes so takeaway kava (ordered online and delivered) is an alternative, especially for people with a disability. Some submitters have not been able to prepare their own kava beverage at home to a comparable quality to purchasing a prepared takeaway bottle from a commercial premise and consuming at home.</p> <p>A suggestion was made that only registered food businesses be allowed to produce and sell takeaway kava beverage, to ensure controls over potency, ratio and water quality. Such bottled takeaway kava beverages should be required to contain current labels or additional ones to ensure consumers understand sensible use and maximum daily dosage recommendations.</p> <p>The proposed amendment (consumption of kava beverage where it is prepared) is considered restrictive and unnecessary since the comparative risks associated with kava are not higher than for other processed foods such as spices. The point is made to consider traditional use verses safe use.</p>	<p>Vanuatu Kava Industry Association, a number of individuals, Pacific Horticultural and Agricultural Market Access Program (PHAMA Plus), The Kava Society</p>	<p>Noted. For the reasons stated in this report, FSANZ has amended the draft variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation. It has concluded that the takeaway of kava beverage from the place of preparation is indeed consistent with historically safe preparation and is therefore not considered to pose additional public health and safety concerns compared to consumers purchasing kava powder and preparing a kava beverage themselves or be inconsistent with the policy intent of the kava standard.</p> <p>The legality of selling takeaway bottles of kava beverages in New Zealand is an issue for New Zealand enforcement agencies.</p> <p>The licensing and/or registration of kava businesses is outside FSANZ's remit and the scope of this proposal. It is for other government agencies to consider in the first instance.</p> <p>FSANZ has not explicitly determined a maximum daily dosage recommendation for kava beverages and therefore is not proposing requiring such information on a takeaway kava beverage label. As noted above, FSANZ will consider labelling requirements for permitted kava foods, including the need for additional labelling as appropriate risk management options as part of the full assessment to be undertaken within 12 months of public notification of the approved draft variation.</p>
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Issue	Raised by	FSANZ response (including any amendments to drafting)
Australia should not be dictating kava use in New Zealand		
<p>The submissions do not believe the proposal should apply in New Zealand. Legislation designed for Australia should not be applied to New Zealand, as they are different nations that currently share different laws surrounding the consumption of kava. The kava culture in New Zealand is different to that in Australia, and Australia should not be dictating what occurs in New Zealand. The requirements for kava in Standard 2.6.3 have operated well for nearly twenty years in New Zealand. They do not understand why there is a need for any change, especially in New Zealand, when no evidence pointing at any concerns associated with the current situation of kava consumption in New Zealand was provided in the proposal documents. The proposed changes are considered paternalistic and demonstrate a lack of understanding of how kava is used throughout the Pacific.</p> <p>The proposed two changes to the Code due to the proposal are in breach of the two country's governments' commitment to the United Nations Declaration on the Rights of Indigenous Peoples (UNDRIP). Efforts to unilaterally dictate what is the traditional way of kava consumption is not only a flawed thinking in trying to homogenise diverse Pacific peoples' different cultures, but also repeating colonial history of the Pacific. Any restrictions on the use of kava by Māori in New Zealand would counter Māori cultural rights under the Treaty of Waitangi. Restriction on kava use counters the New Zealand Bill of Rights Act, which endorses cultural engagement and expression, of which kava is critical for Pacific peoples.</p> <p>With the impending national roll-out by the NZ Government of the Enabling Good Lives pilot (https://www.enablinggoodlives.co.nz/about-egl/), FSANZ should be wary of creating social barriers for disabled people to participate in cultural activities on their own terms.</p> <p>The proposal targets kava differently to other food products (e.g. coffee) that exist in the market without regulation (about how the food can be prepared and consumed, noting these foods also have traditions and are culturally important but are not restricted in a similar way to that proposed for kava).</p> <p>The amendments due to the proposal should preferably be put on hold entirely or explicitly stated to be applicable to Australia only, and the current status quo maintained for New Zealand.</p>	<p>A number of individuals, Kava Society Ltd (NZ)</p>	<p>FSANZ notes that the current kava standard in the Code (Standard 2.6.3) applies to both Australia and New Zealand, as do most standards, as part of the joint food regulatory system that has been operating for the last 20 years and since the joint Code came into being. The context of this urgent proposal is the Australian Government's kava pilot program (Phase 2) allowing unlimited commercial imports of kava into Australia.</p> <p>The aim of the current proposal is to allow the sale of kava in both Australia and New Zealand for historically safe preparation and use, while minimising potential health and social impacts. It seeks to do this by limiting its use to historically safe preparation and consumption practices. FSANZ recognises that kava is an integral part of the dynamic and evolving cultural practices of many Pacific peoples, and that its traditional use can vary over time and according to custom. To this end, FSANZ has reconsidered its position regarding the takeaway of prepared kava beverage according to its traditional usage within Pacific communities and beyond.</p> <p>For the reasons stated in this report, FSANZ has amended the draft variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation</p> <p>The draft variation approved by FSANZ confirms the regulatory purpose and intent of the Code's kava provisions and preserves the status quo in relation to kava, including in relation to the prohibition on the use of processing aid and food additives in kava beverages.</p> <p>Anyone can make an application at any time to amend these provisions and the Code's requirements in relation to kava.</p>
Kava very important to Pasifika communities		
<p>Kava is a necessary part of Pasifika communities. Submitters appreciate the benefits kava consumption has for them, their family and friends including in Australia, by</p>	<p>A number of individuals, Friends of</p>	<p>FSANZ recognises that kava is an integral part of the dynamic and evolving cultural practices of many Pacific peoples, and that its</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>having a huge impact on mental health and wellbeing. Submitters have noted it has allowed them to re-engage with their Pasifika community heritage. It has allowed submitters to use kava and the connections made as an alternative to the disruptive effects of alcohol. Kava is scientifically proven to be a natural and healthy relaxant being the opposite to alcohol which is a toxin and makes consumers dangerous and violent.</p> <p>A submitter has first-hand experience that kava culture has cultivated international relationships for decades between Pasifika and western communities. For the vast majority of these events the kava was prepared and served by third parties and delivered to kava consumers. The proposal would prevent that, under the guise that it will better serve the Pasifika communities. This is incorrect and insulting. Traditional practices should be allowed to evolve in different times and spaces.</p>	Tonga, Inc.	<p>traditional use can vary over time and according to custom. The aim of the current proposal is to allow the sale of kava in both Australia and New Zealand for traditional cultural use, while minimising potential health and social impacts. It seeks to do this by limiting its use to historically safe preparation and consumption practices.</p> <p>For the reasons stated in this report, FSANZ has amended the draft variation to remove the proposed requirement that a permitted kava beverage be prepared for immediate consumption at the place of preparation</p> <p>The draft variation approved by FSANZ confirms the regulatory purpose and intent of the Code's kava provisions and preserves the status quo in relation to kava, including in relation to the prohibition on the use of processing aid and food additives in kava beverages.</p> <p>Anyone can make an application at any time to amend these provisions and the Code's requirements in relation to kava.</p>
Prohibition of use of food additives and processing aids		
<p>No evidence is provided why using processing aids (e.g. enzymes that could consistently facilitate thermal treatment) is seen as a risk factor. It is noted that shelf-stable kava beverage is produced using pasteurisation to produce takeaway bottled product.</p> <p>Using processing aids with kava has been legal in New Zealand for decades. FSANZ should consult with local kava businesses and allow for food additives and processing aids sufficient to enable the provision of unflavoured kava retaining traditional characteristics prepared professionally and in controlled doses but in a shelf stable form. This is before it considers prohibiting their use.</p>	Kava Society Ltd (NZ), Inasi Inc., individual	<p>Noted.</p> <p>The interpretation and application of the Code as applied in New Zealand by and as a part of New Zealand food laws is a matter for the New Zealand Government and regulatory agencies.</p> <p>That said, FSANZ's understanding is that the intent of the Code was not to permit the use of processing aid (including enzymes), as well as food additives, in kava beverages. This is based on the fact that the Code stated and states that a food for sale (such as a kava beverage) cannot contain, as an ingredient or component, a substance that was used as a processing aid unless that substance's use as a processing aid is itself expressly permitted by the Code (see section 1.2.1 of the report). There is no express permission in the Code. In addition, section 2.6.3—3 imposes a requirement that the sole permitted beverage must be one that is 'obtained' or produced 'by the aqueous suspension of kava root using cold water only'. The requirement 'by the aqueous suspension of kava root using cold water only' limits the beverage's production itself to this means or method of production or processing only and,</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
		<p>as such, the addition, use or presence of substances other than water or kava root is not permitted. A similar argument is made related to food additives.</p> <p>The above is consistent with the regulatory policy or intent to permit the sale of kava as a food in line with its historically safe preparation and use.</p> <p>For the reasons stated in this report, FSANZ has approved an amendment to Standard 2.6.3 to remove any doubt that food additives and processing aids cannot be used in kava food products permitted by the Code.</p> <p>Anyone wishing to use substances in kava food products as processing aids or as food additives may apply at any time to vary the Code to permit that use.</p>
<p>It supports the express prohibition of the use of food additives and processing aids in the preparation of kava beverage or for use on dried or raw kava root to provide legal clarity. This is important since commercial ready to consume shelf stable forms of kava beverages are available in some countries. Such forms could promote increased kava consumption by populations unfamiliar with its occasional and appropriate use which is against the policy intent of the kava standard.</p>	<p>New South Wales Food Authority</p>	<p>The general support and comments are noted.</p>
<p>Noting its opposition to the kava pilot and therefore the proposal, the submission does support the proposal to prohibit the use of food additives and processing aids in kava beverage preparation or use on dried/raw kava root. It notes that this prohibition is part of ensuring preparation and consumption of kava beverages is for traditional and/or cultural purposes. But the purposes of kava consumption are changing and evolving with kava beverages now becoming a fully commercial food for sale, which will impact on Australian populations. FSANZ needs to factor this into its consideration of the proposal, since there is not an explicit requirement for kava to be consumed for traditional purposes.</p>	<p>West Australian Department of Health</p>	<p>The comments are noted.</p>
<p>It agrees with the prohibition of food additives which it states the Code currently allows and could be used to flavour, sweeten, clarify and colour kava beverages. Likewise, it is now possible to preserve kava beverages to make them shelf stable.</p>	<p>Queensland Department of Health</p>	<p>Noted.</p> <p>The interpretation and application of the Code as applied in Queensland by and as a part of Queensland food laws is a matter for the Queensland Government and regulatory agencies. That said, FSANZ notes its comments above.</p>
<p>It welcomes clarity relating to the prohibition of the use of food additives and processing aids in prepared and packaged kava for sale as it was aware of recent questions on this matter. This is consistent with traditional use that involves immediate</p>	<p>New Zealand Food Safety</p>	<p>The comments are noted.</p> <p>FSANZ does not consider adding specific cross reference notes to</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>consumption of kava without the need for processing [aids] or food additives. It questions whether specific notes are required to be added to the food additive and processing aid standards cross referencing to the prohibition of their use in kava under Standard 2.6.3.</p>		<p>the relevant standards for food additives and processing aids (assuming that would be Schedule 15 and 18 respectively as they deal with specific permissions) as stakeholders interested in the regulations for kava should be ensuring they comply with all the requirements of Standard 2.6.3. These prohibitions are proposed to be added into Standard 2.6.3.</p>
<p><i>Amendment not required</i></p> <p>The proposed draft variations prohibiting food additives and processing aids to be added to kava and kava products is not required due to the current operation of the Code, in particular the requirements of subsection 1.1.1—10(6). It understands that Standard 1.3.1 – Food Additives expressly prohibits food additives unless expressly permitted in the Schedules [15 and 16].</p> <p><i>Amendment inconsistent</i></p> <p>Adding express prohibitions for a specific standard (i.e. 2.6.3 – Kava) is inconsistent with the rest of the Code and makes the Code confusing i.e. will this example need to be followed for all other food standards.</p> <p><i>Alternative amendment</i></p> <p>A better alternative is to make it clear within the food additive schedule [within Schedule 15] that the food class ‘fruits and vegetables’ does not include kava for food additive permissions. The regulatory approach to control kava products is stated to be best done by definitions and not by food additive permissions. It is considered that it is not the food additives themselves that are the cause of any public health and safety concern.</p> <p><i>Carry over</i></p> <p>A question was whether carry-over of food additives from other components in kava products is still permitted.</p> <p><i>Other substances</i></p> <p>A separate question raised was about the permissions to add nutritive substances including vitamins and minerals to kava and kava beverages. There is no discussion on these substances in the report, nor any draft variations.</p> <p>An additional example of a potential complication was whether the addition of caffeine, not for the technological purpose of a food additive (flavouring) but as a</p>	<p>South Australia Health</p>	<p><i>Amendment not required</i></p> <p>Noted. This view is not shared by other jurisdictions. FSANZ shares the majority view that there is a need to provide certainty both for industry and for regulators given the evidence that kava products containing processing aids and/or food additives may be available on the market.</p> <p><i>Amendment inconsistent</i></p> <p>Noted. FSANZ does not agree. Including an express prohibition in Standard 2.6.3 is consistent with kava being a distinct commodity with specific and unique issues associated with its use, and with jurisdictions previous agreement through the Food Ministers’ Meeting that a separate commodity standard - Standard 2.6.3 - was appropriate means to regulate kava.</p> <p><i>Alternative amendment</i></p> <p>Noted. FSANZ welcomes the suggestion. However, for the reasons stated above, FSANZ considers Standard 2.6.3 to be the appropriate location for the amendment. FSANZ also understands that the definitions in Schedule 15 cannot limit the processing aid permissions provided in Standard 1.3.3.</p> <p><i>Carry over</i></p> <p>The issue of carry-over of food additives is not relevant since the kava standard does not permit the addition of any other components to be added to kava or kava products (except for cold water used in the preparation of kava beverage).</p> <p><i>Other substances</i></p> <p>The potential ambiguity identified by jurisdictions and which FSANZ was asked to consider related to processing aids and food additives.</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
stimulant, would be permitted by the current and proposed draft variations.		<p>The same issues do not arise in relation to nutritive substances or caffeine. The use of the latter in kava food products has not been identified as an issue to date. Nor is FSANZ aware of or been provided of any evidence of kava products containing the latter being on the market. The situation is different for food additives and processing aids where from internet searching FSANZ has identified the availability of kava products containing these substances.</p> <p>The Code provides that a food for sale (such as a kava beverage) cannot contain, as an ingredient or component, a substance that was used as a nutritive substance unless expressly permitted by the Code. FSANZ is not aware of an express permission in the Code for the use of a nutritive substance in kava beverages. In addition, section 2.6.3—3 imposes a requirement that the sole permitted beverage must be one that is 'obtained' or produced 'by the aqueous suspension of kava root using cold water only'. The requirement 'by the aqueous suspension of kava root using cold water only' limits the beverage's production itself to this means or method of production or processing only and, as such, the addition, use or presence of substances other than water or kava root is not permitted.</p>
Assessment inconsistent with FSANZ Act 1991 requirements		
<p>Issues relating to the policy framework of the FSANZ Act 1991 were raised. The policy statement within the Initial Consideration document is unhelpful as it presupposes the outcome before receipt of public submissions. The proposal document is inconsistent with sections of the FSANZ Act in regard to all foods and harmful substances in particular, being subsection 18(2) considerations (a) (the need for standards to be based on risk analysis using the best available scientific evidence); (c) (the desirability of an efficient and internationally competitive food industry) and (d) (the promotion of fair trading in food) [within section 2.4.5 of the Initial Consideration document].</p>	Individual	FSANZ notes the comments but for the reasons stated in this report, does not agree. See in particular section 3.4 of the report.
Dispute risk assessment conclusions about health concerns		
<p>New Zealand Medsafe raised concern that the SD1 Risk and Technical Assessment incorrectly implied that kava extracts can be legally added to dietary supplements in New Zealand.</p> <p>Medsafe acknowledges there are a number of products currently marketed in New</p>	New Zealand Food Safety	Noted. FSANZ has changed the SD1 Risk and Technical Assessment to reflect the position of Medsafe regarding dietary supplements.

Issue	Raised by	FSANZ response (including any amendments to drafting)
Zealand as dietary supplements, but its view is they do not meet the dietary supplements definition.		
The risk assessment is not based on the best available scientific evidence, is inconsistent with FSANZ's earlier 2004 assessment and there are a lack of updated scientific findings to support the proposed changes.	A number of individuals, Inasi Inc.	The SD1 Risk and Technical Assessment describes FSANZ's evaluation of the current evidence base relating to kava beverage, and includes additional studies published since the FSANZ technical assessment in 2004. The current assessment, which considers the overall weight of evidence available for the hazard identification, hazard characterisation, exposure assessment and risk characterisation, is consistent with the FSANZ risk analysis framework and international best practice.
There are no high quality clinical trials using kava beverage and three clinical trials considered by FSANZ in the Risk and Technical Assessment were based on kava extracts prepared from hot water. The submission disputes the conclusions based on these clinical trials as both the 2016 FAO/WHO technical report and the 2004 FSANZ risk assessment stated that kava extracts were not appropriate for understanding risks associated with kava beverage.	Individual	<p>Consistent with the 2016 FAO/WHO technical report and the 2004 FSANZ risk assessment, FSANZ differentiated between kava beverage and kava extracts.</p> <p>As part of the Risk and Technical Assessment, three human clinical trials using formulated hot-water kava extracts were considered. The preparation methodology in these clinical trials used an aqueous extraction method to produce a standardised test item that closely reflected kava beverage, rather than kava extracts prepared using organic solvent. Analytical analysis confirmed that the kavalactone (the biologically active component of kava) quantities in the clinical trial test item mirrored the composition of kava beverage. For this reason, all three clinical trial were considered relevant for assessment.</p>
FSANZ has relied on studies conducted in Arnhem Land as evidence of negative health impacts due to kava beverage. Submitters felt that these communities had some of the poorest health outcomes and should not be used as evidence for potential impact of kava beverage consumption on other communities. Of additional concern was the use of Mathews et al. (1988), a refuted and potentially dated research study.	A number of individuals, Inasi Inc.	<p>FSANZ has considered the results of Mathews et al. (1988), as well as other published studies undertaken in Arnhem Land as part of the available body of evidence relevant to kava consumption in Australia and New Zealand.</p> <p>Understanding the outcomes of the past introduction of kava beverage into sensitive subpopulations and communities was essential for undertaking a thorough risk analysis of the potential impacts of kava beverage on public health and safety. However, to better reflect the evidence considered in the FSANZ risk analysis, the P1057 Risk and Technical Assessment has been amended to specify the range of kava intakes associated with negative health outcomes (240 – 440 g/week or more) in Arnhem Land, rather than stating the intake as suggested by Butt (2019) (>400 g/week).</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
<p>Public health and safety concerns were raised and a proposal that only regulated (accredited) premises be permitted to produce and sell takeaway kava beverages as they are experienced in ratios and potency, and can mix kava to a kavalactone level that is safe for use. Significant labelling restrictions can be introduced to ensure understanding of the product and recommended use levels.</p>	<p>Individual</p>	<p>Noted. Some of these matters are beyond FSANZ's remit and outside the scope of this proposal. For the reasons stated in this report, FSANZ has approved a draft variation that confirms the regulatory intent of the Code's long-standing kava provisions and generally preserves the regulatory status quo in relation to kava. Anyone can make an application at any time to amend these provisions and the Code's requirements in relation to kava.</p>
<p>FSANZ was proposing amendments due to the erroneous idea that kava consumption is addictive. Studies refuting this concept were provided.</p>	<p>Inasi Inc., a number of individuals</p>	<p>The P1057 Risk and Technical Assessment (SD1) states explicitly that: <i>kava beverage does not demonstrate the same addictive properties as other substances of abuse.</i></p>
<p>The Risk and Technical Assessment misrepresents the research by Aporosa (2012), incorrectly linking kava consumption in Indo-Fijian communities with significant adverse health outcomes from heavy kava consumption.</p>	<p>Individual</p>	<p>Aporosa (2012) contains important reflections on the place of kava in Fijian cultures. FSANZ has not used the data presented or analysis performed by Dr Aporosa to infer significant adverse health outcomes occurring as result of kava beverage consumption in Indo-Fijian communities.</p> <p>However, of relevance to the analysis of kava introduction into communities, Aporosa (2012): 1) observed that Indo-Fijian communities incorporated kava beverage consumption into their custom, 2) compared their consumption quantities to Native-Fijian communities and 3) examined hangover effects on Indo-Fijian teacher performance, identifying that over-consumption of kava has social and economic implications.</p> <p>To avoid misunderstanding, FSANZ has amended the language used in the P1057 Risk and Technical Assessment (SD1) to better reflect how Aporosa (2012) has been considered in the overall weight-of-evidence.</p>
<p>The FAO/WHO 2016 report which FSANZ references concludes there is insufficient data to prove any damaging effects of kava consumption.</p>	<p>Individual</p>	<p>The FSANZ Risk and Technical Assessment agreed that kava has a long history of safe use in Pacific cultures and when consumed in moderation can be permitted into communities safely.</p> <p>Indicators of causality exist between kava consumption and a number of negative health outcomes, which has been assessed through a systematic literature review by Rychetnik & Madronio, (2011), referenced by the FAO/WHO technical report (2016).</p>

Issue	Raised by	FSANZ response (including any amendments to drafting)
An issue was raised with FSANZ's statement that 'there is insufficient information on the prevalence of pathogenic microorganisms on fresh or dried/powdered kava root or in kava beverages; and on the potential for persistence or growth of any such pathogens on the product'. Two studies are provided that relate directly to this question.	Individual	FSANZ thanks the submitter for bringing to its attention the two studies. These studies have been considered and are referenced in the SD1.
Kava has fewer negative impacts compared to alcohol, over the counter drugs and some foods		
Multiple individual submitters and the Vanuatu Kava Industry Association felt that FSANZ's focus on misuse when considering potential public health and safety risks associated with kava beverage was misleading. Kava has fewer documented social and individual harms than other foods and drugs widely available in Australia and New Zealand. Alcohol, sugar, soft drinks, paracetamol and white flour were provided as examples of available commodities where excessive consumption is associated with negative health outcomes.	The Vanuatu Kava Industry Association, a number of individuals	The comments are noted. FSANZ has amended the P1057 Risk and Technical Assessment to note that: <i>Kava beverage does not demonstrate the same addictive properties as other potential substances of abuse, and is seen to be far less harmful to individual users and the community.</i> However, FSANZ is not considering the requirements that apply to other food commodities in Australia and New Zealand as part of this urgent proposal to review Standard 2.6.3.
Kava is an alternative to conventional medicines such as anti-anxiety and sleep medications and can improve state of mind, sleep and mode of being for those with disabilities, as well as allowing a reduction in medication usage. This is confirmed by a successful trial of kava extract allowing reduction in benzodiazepine treatment.	Individual	The proposal and proposed amendments to Standard 2.6.3 are not directly related to kava extracts that are used as complementary medicines or therapeutic products and as such the comments and information provided in the submissions are considered out of scope. To date, FSANZ is not aware of any registered published clinical trials demonstrating the efficacy of kava beverage as a treatment for anxiety or sleeping disorders.

3 Summary of the final consideration

3.1 Risk assessment summary

FSANZ examined the risks associated with the consumption of kava and kava beverage as foods, including historically safe preparation and use. This relates to the permitted consumption of kava as permitted in Section 2.6.3—3 of the Code. This is specifically for the consumption of a beverage obtained by the aqueous suspension of kava root using cold water only, or dried or raw kava root. The risk assessment is provided in SD1, with a summary below.

Cultural significance of kava

Kava beverage has significant cultural importance for communities throughout Micronesia, Melanesia and Polynesia, and has been consumed for more than 1000 years. Kava beverage is an integral part of the dynamic and evolving cultural practices of many Pacific peoples, and is often regarded as an icon of national and/or ethno-cultural identity.

In recent times, kava has been consumed as a recreational beverage in both the Pacific community as well as the wider international community. Kava beverage is not a widely consumed food in either Australia or New Zealand, except in some Pacific communities and select First Nation communities in Australia.

Historical method of preparation

Historically, kava beverage in Pacific communities has been prepared by aqueous extraction using fresh or dried roots of the kava plant to produce a brew in a communal bowl. The beverage is then typically consumed immediately or shortly thereafter. FSANZ's risk assessment considers kava beverage to be defined by this method of preparation that has a long history of safe use in Pacific communities. The risk assessment did not consider the safety of kava (such as kava extracts) used in complementary medicines as this is outside the scope of the proposal and indeed FSANZ's remit in food regulation.

Identity and composition of kava

'Noble' kava varieties have been safely used by Pacific communities for kava beverage production. These varieties are distinguished by their geographical distribution, physical characteristics and the properties of the kava beverage they produce. Other kava varieties are not suitable for making kava beverage.

The pharmacologically active compounds in kava are kavalactones, which are extracted from the root of the kava plant during the preparation of kava beverage. The total kavalactone content of kava plants varies from 3% to 20% of dry weight, depending on variety, growth conditions and part of the plant. Kavalactones have been reported to have psychopharmacological effects as well as muscle relaxant, local anaesthetic, anxiolytic and anticonvulsive properties. Moderate to high doses of kavalactones can lead to drowsiness and sedation.

Flavokawains and piperidine alkaloids are documented minor compounds found in the kava plant. It has been suggested these compounds present a toxicity risk when consuming kava beverage extracted from leaves, stems or bark of the kava plant, or from non-Noble kava plant varieties, but little toxicological data is available.

Potential for drug interactions

Limited information is available on the potential for drug interactions. However, substances in kava have been shown to inhibit important Cytochrome P450 liver enzymes *in vitro*, suggesting the potential for drug interactions. Caution is recommended when consuming kava beverage in combination with alcohol, medicines (particularly benzodiazepines, opioids, barbiturates and paracetamol) or other herbal preparations.

Health effects associated with cultural or recreational use of kava beverage

The long history of use, with minimal evidence of adverse health events from consumption, demonstrates that kava beverage can be safely consumed in communities in line with historical preparation and consumption practices. Kava does not demonstrate the same addictive properties as other substances of abuse, and is seen to be far less harmful to both individual users and the community.

However, the consumption of kava beverage results in kavalactone intakes greater than the recommended daily intake for therapeutic goods, and kava beverage has the potential to become a substance of abuse in certain contexts. Evidence of negative health outcomes have been observed in communities with established patterns of ongoing high-level consumption of kava beverage. Such ongoing high-level consumption has been associated with a scaly skin rash, altered liver function and other general reductions in overall health, however these changes are reversible.

No information was available to allow an assessment of the use of kava beverage in pregnant or lactating women, or in adolescents or children.

Microbiological assessment

The microbiological risk from the consumption of kava beverages obtained by aqueous suspension of dried or raw kava root is low when kava is produced and prepared in line with current risk management measures, including the application of Good Agricultural Practices and Good Handling Practices.

Limitations in the available data

While the assessment noted a number of data gaps in relation to the toxicity and microbial safety of kava beverage, as well as the pharmacokinetics of each biologically-active chemical constituent in kava beverage, there remains significant population-based evidence demonstrating that cultural and recreational consumption of kava beverage in moderation is safe.

Conclusion

Kava beverage has a long history of consumption in the South Pacific and plays an integral role in maintaining the cultural continuity and identity of many Pacific peoples. This significant history of use demonstrates it is possible to safely consume kava beverage in moderation when prepared and consumed in line with historically safe cultural practices.

No information was available to allow an assessment of the safety of kava beverage consumption in pregnant or lactating women or in adolescents or children. Therefore it is not possible to draw a conclusion on the safety of kava beverage consumption by these population subgroups.

3.2 Risk management

As explained above in section 1.1, the Food Regulation System policy underpinning the Code's current provisions is to limit the use of kava to the preparation of a historically safe beverage consumed by sub-populations familiar with its occasional and ceremonial use, not to promote broad consumption of kava.

A similar expression of this intent was contained in the earlier FSANZ kava review Proposal P256 Final Assessment Report (FSANZ, 2004) i.e. 'that the use of kava should be restricted to the traditional consumed beverage to minimise the widespread use in the general population of Australia and New Zealand, which is unlikely to be aware of the intoxicating properties of kava'. The proposal therefore seeks to allow the historically safe preparation and consumption of kava in Australia and New Zealand, while minimising adverse public health and social impacts due to widespread consumption.

FSANZ's risk assessment (SD1) has concluded that there is a history of safe kava beverage use in the Pacific where kava has long been prepared and consumed in accordance with historically safe cultural practices.

The risk assessment has identified some data gaps and uncertainties in the safety of additional types of kava and kava products. Some of the food safety concerns identified from excess kava beverage consumption and misuse were already understood and taken into account when the original kava standard in the Code was first developed and then subsequently amended through Proposal P256. The risks identified by the risk assessment conclusions have been risk managed. However, some other matters that are not explicitly risk assessed have also been risk managed. FSANZ's risk management considerations for this proposal are considered below.

3.2.1 Is permission explicit to only historically safe preparation and consumption of kava beverage?

The Code provides that a food for sale must not be, or have as an ingredient or a component, kava or any substance derived from kava unless expressly permitted by the Code. The only express permission provided in the Code for kava is section 2.6.3—3. It provides that the following may be a food for sale:

- a beverage obtained by the aqueous suspension of kava root using cold water only, and not using an organic solvent.
- dried or raw kava root.

Only cold water is permitted to be used to extract the active constituents from the kava root. Organic solvent can extract more active constituents from the kava root but this method is inconsistent with historically safe preparation practices. In addition, the kava root is defined in the standard as the peeled root or peeled rootstock of kava, which is separately defined as the plants of the species *Piper methysticum*. Again this is the specific species of kava used historically. For safety reasons, it is important that only the peeled root and rootstock of the kava plant is used and not the leaves or other parts of the plant. These restrictions are to ensure that kava and kava beverages for food use are prepared and consumed in the historically safe manner. As noted in the Codex Regional Standard for Kava and in the literature on kava, the safe varieties of kava for food are required to be what are called the Noble cultivars (see section 3.2.4 for discussion on Noble cultivars).

A suggestion from some jurisdictional enforcement agencies was to require the kava beverage to be unpackaged to limit the potential of processing, as processing would be

inconsistent with historical use and the intent of the current standard. However, on further consideration, making such a change would be inconsistent with the definition for 'package' (see the footnote to the Code in the labelling section in section 1.2.1). 'Package' includes the container that kava beverages would be presented to consumers after preparation i.e. in a traditional serving bowl or cup, a glass or other form of package that consumers would receive and from which they would then consume the kava beverage.

FSANZ considers that the current definitions and preparations for food use of kava and kava beverages in section 2.6.3—2 are consistent with historically safe preparations and uses.

However, FSANZ considers there needs to be further consideration of tightening of the permission to ensure it meets the original policy intent of the standard to ensure the historically safe preparation and consumption of kava beverage. These additional considerations are addressed below and relate to: pre-packaged as well as takeaway beverages; use of food additives and processing aids; and requiring only Noble varieties of kava plants to be used for kava food products.

3.2.2 Consideration of further tightening of permission to ensure historically safe preparation and consumption of kava beverage applies

An internet search revealed there are many types of pre-prepared and packaged kava beverages available for purchasing, but produced outside Australia. This indicates the potential broadening of kava products available for the general Australian and New Zealand community, which is inconsistent with the policy intent of the long-standing Code provisions for kava (see above). Because kava beverages do not store well some form of shelf-life extension processing or treatment may be needed, such as pasteurisation to ensure a safe, palatable and commercially acceptable product. An additional type of kava beverage was also identified, being a beverage produced via processing (high pressure processing) extraction of the juice from the frozen fresh kava root as a bottled shelf-stable beverage^{8,9}.

To limit wider consumption of kava beverages beyond historically safe use, it was proposed at the Initial Consideration report to include an additional requirement to the current permission to produce kava beverages in section 2.6.3—3(a) of the Code. This proposed amendment to the Standard was to require the produced kava beverage be 'for immediate consumption at the place of preparation'. This was considered to better describe the historically safe use of kava and to be consistent with the original policy intent of the Standard.

A large proportion of submissions to the Initial Consideration report expressed strong opposition to the proposed draft variation, which in effect would prohibit takeaway kava beverage from kava beverage businesses. Submitters argued that purchasing kava beverage for later consumption is a current and accepted practice for many kava beverage consumers. It is also disrespectful to discard any unused kava beverage, so taking away any unused beverage is culturally appropriate. It was also explained that this practice is not inconsistent with historical practices as suggested by FSANZ.

Evidence was provided in submissions that takeaway kava beverage is very common in some Pacific countries, including New Zealand, and for some of these countries it can be considered as a historically-safe preparation practice and use and is therefore consistent with the regulatory policy intent of the standard. There was also no evidence of any public

⁸ <https://kalmwithkava.com/what-is-green-kava/#:~:text=Green%20kava%20is%20kava%20made,then%20ground%20into%20a%20powder>

⁹ <https://www.stuff.co.nz/business/116751529/auckland-kava-bar-goes-global-exporting-bottles-of-the-sedating-drink-overseas>

health and safety issues with this practice, noting that the takeaway kava beverage in compliance with the Standard has only a limited shelf life.

FSANZ reconsidered this aspect and agreed that there would be no public health and safety concerns with permitting the takeaway of a kava beverage produced on premises in compliance with the requirements of the Standard. Therefore, FSANZ has removed the requirement that the beverage is consumed at the place of preparation from the amended draft variation.

3.2.3 Exclusion of food additives and processing aids in kava and kava beverage

In asking FSANZ to consider preparing and declaring urgent a proposal to review the current kava permissions in the Code, the Chair of the Food Ministers' Meeting request noted the need to consider whether the Code should expressly prohibit the use of food additives and processing aids in kava and kava beverages.

Are food additives and processing aids being used in kava and kava beverages?

An internet search was conducted to identify if there are kava products (pre-packaged kava beverages or kava root powders) that contain food additives (or were produced using processing aids) on the market, whether via internet purchase or available in Australia or New Zealand.

There are a number of kava products, including beverages, available that include unspecified flavourings^{10,11,12}. It was mentioned on product websites that the addition of flavours to the instant kava powder (processed to micronise the size of the powder particles or freeze dried) to produce the kava beverage was to make the drink more palatable. It was also mentioned on some websites that the kava powder could be mixed directly with water or a soft drink (which would be inconsistent with the Code permissions if sold as a mixed beverage). There is an additional question about whether processing aids are required for the processing to produce micronised or freeze dried kava powders.

A UK patent (GB2507270A)¹³ was also located where it was proposed to use the food additive cyclodextrins to remove (irreversible binding) the bitter component of the kava aqueous extract to make the beverage more palatable. Additionally, the patent proposed the addition of the food additive lecithin as an emulsifier (see next paragraph). It is not known if this patent has been commercialised.

To improve the extraction of the active kavalactones from kava powder, which are poorly soluble in cold water, there are suggestions on the internet to use an emulsifier or an oil-based food ingredient. Kavalactones are more soluble in fats and oils than water, while emulsifiers assist in mixing the aqueous and oil phases. One such substance proposed is the food additive emulsifier, soy lecithin. The use of other fat-containing ingredients including coconut milk, soy milk, cow's milk and many others, would not be consistent with the Code

¹⁰ Kava shots: <https://rootofhappineskava.com/blogs/articles/root-of-happiness-kavashot-500mg-kavalactones-in-a-2-oz-shot>

¹¹ Kava tea bags; contain other ingredients: [Kava Kava Stress Relief Tea 16 Bags | Kava Kava Tea for Anxiety | PipingRock Health Products](#)

¹² Micronised or freeze dried kava powder; extra flavour may be added to make the beverage more palatable: [Best Instant Kava & Micronized Powder to Buy: Reviews & Preparation Guide - Kava Guides](#)

¹³ <https://www.google.com/url?esrc=s&q=&rct=j&sa=U&url=https://patents.google.com/patent/GB2507270A/en&ved=2ahUKEwii0NDq1bL0AhUvTWwGHWL-APUQFnoECAQQAg&usq=AOvVaw1MIC6y6MMkDvzMUS0YmEVu>

as they are ingredients not permitted to be added to kava beverage. Commercially-prepared kava beverages containing the food additive emulsifier soy lecithin were not identified.

Are food additives and processing aids recommended to be used by Codex?

The Codex Regional Standard for Kava explicitly does not recommend the addition of food additives to products covered by the standard i.e. fresh or dried kava products used to prepare a kava beverage when mixed with potable water, not the kava beverage itself. It states that 'no additives are permitted in the products covered by this Standard', noting that Codex standards do not have formal regulatory status. The Codex standard does not mention processing aids, either to exclude or recommend their use. However, since food additives are not permitted to be added to kava products it is reasonably likely and expected that processing aids would also not be expected to be used in the production or processing of kava products.

Does the Code permit the use of food additives and processing aids in kava and kava beverages?

Section 1.2.1 sets out the relevant provisions of the Code in relation to food additives and processing aids. Additionally, FSANZ notes the following comments.

The Code states that a food for sale (such as a kava beverage) cannot contain, as an ingredient or component, a substance that was used as a food additive or a processing aid unless that substance's use as a food additive or processing aid is itself expressly permitted by the Code. There is no express permission in the Code for the use of a food additive or a processing aid in kava.

Section 2.6.3—3 imposes a requirement that the sole permitted beverage must be one that is 'obtained' or produced 'by the aqueous suspension of kava root using cold water only'. The requirement 'by the aqueous suspension of kava root using cold water only' limits the beverage's production itself to this means or method of production or processing only and, as such, the addition, use or presence of substances other than water or kava root is not permitted.

The above is consistent with the regulatory policy intent to permit the sale of kava as a food in line with its historically safe preparation and use.

The use or presence of food additives and processing aids in kava in the same manner as they are used in 'commercial beverages' would be inconsistent with this policy intent.

Jurisdictions have raised concerns in relation to the Code permissions relating to the use of 'additives permitted at GMP' as food additives in certain non-alcoholic beverages and whether this creates the potential for an interpretation that these permissions allow the use of additives permitted at GMP in kava beverages. Examples cited include the food additive permissions for food class 14.1.3 – water based flavour drinks, 14.1.2.2 – fruit and vegetable juice product and 20 – foods not included in items 0 – 14. The definition of 'vegetable' in the Code is quite broad. The Macquarie Dictionary, often used for definitions if the Code is not explicit, defines vegetable as *any herbaceous plant, annual, biennial, or perennial, whose fruit, seeds, roots tubers, bulbs, stems, leaves, or flower parts are used as food would appear to capture kava root from the kava plant.*

To address these concerns, and for the reasons stated in this report, FSANZ has approved an amendment to Standard 2.6.3 to remove any doubt that food additives and processing aids cannot be used in kava food products permitted by the Code and to provide certainty for both regulators and industry related to compliance.

Before making this decision, FSANZ gave careful consideration to the support expressed in some submissions from business and consumers for the use of enzyme processing aids to be allowed as this assists in treating prepared kava beverage for further processing to produce shelf stable product. This current urgent proposal is not the appropriate regulatory vehicle to assess and determine whether the use of one or more categories of processing aids should be permitted for use in kava, particularly in the absence of the required data as to safety and reliability of use of each of the processing aids for the proposed purpose. As noted earlier, anyone wishing to use substances in kava food products as processing aids or food additives may apply at any time to vary the Code to permit that use.

3.2.4 Should permission be limited to only Noble kava cultivars?

The Codex Regional Standard for Kava refers explicitly to the Noble cultivars of the kava species *Piper methysticum*, as the safe cultivars for food kava products. FSANZ's risk assessment came to the same conclusion that other (non-Noble) kava varieties are not suitable for making kava beverage for public health and safety reasons. The question was raised in the Initial Consideration report whether the Code also needs to restrict permissions only to Noble cultivars of the kava plant.

This issue was also considered during the assessment of P256 and discussed in the Final Assessment Report (FSANZ, 2004; sections 5.5.1.2 and 5.5.2.4). It was noted that a systematic classification of all known suitable varieties may be possible in the future however such a classification system would need to be developed by experts familiar with the different varieties and be acceptable to all impacted Pacific Island countries before FSANZ could consider referring to such a list.

There was support provided in submissions from a number of government enforcement agencies and some kava exporting countries to require only Noble kava cultivars, being the safe varieties for food use, to be mandated in the Code. The justification for the request was to ensure public health and safety, and allow the enforcement of kava products produced from non-safe varieties of kava to be identified at the border or in the market if required. The submission from the Vanuatu Kava Industry Association noted there are a few published methods to clearly differentiate Noble from other kava cultivars. It further noted that Vanuatu kava has been systematically tested to be from Noble cultivars before being exported for several years.

After considering submissions, FSANZ noted and supported the justifications to amend the Code to require that the permitted forms of kava must be only from a Noble kava cultivar named in the Codex Regional Standard for Kava. This amendment was considered warranted given the potential public health and safety risk posed by other varieties of kava cultivars. As explained in submissions, it is understood that there are methods to differentiate between kava varieties. This amendment also provides greater certainty for industry and jurisdictions in compliance and enforcement, and the measure would promote consistency with international standards, specifically the Codex Regional Standard for Kava.

Making this amendment required a definitive and exhaustive list of such Noble cultivars to be referenced in Standard 2.6.3, which has been achieved by a new draft variation referring to a Noble kava cultivar that is expressly named in the Codex Regional Standard for Kava.

3.2.5 Cold water vs potable water

Standard 2.6.3 refers to an aqueous suspension of kava root using cold water only, while the Codex Regional Standard for Kava refers to mixing dried kava powder or ground or macerated fresh kava with potable water.

The question FSANZ has considered is whether to amend the Code to replace 'cold water' with 'potable water' to harmonise with the Codex Regional Standard for Kava. FSANZ considers that any reference to water when used as an ingredient or used in direct contact with ingredients or surfaces during manufacture or processing of food will be potable i.e. suitable for human consumption. The Food Act requirement is that food for sale is both safe and suitable for human consumption. Therefore, FSANZ does not consider this explicit qualification is required. However, it is important to use the qualifier 'cold' as the extractability of the water when mixed with the kava root increases with the temperature of the water. The historically safe preparation of kava beverage is not to heat the water but to only use cold water. This condition is considered important so it has not been changed.

3.3 Risk communication

3.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. All calls for submissions were notified via the Food Standards Notification Circular, media release and FSANZ's social media tools.

The process by which FSANZ considers standards' development matters is open, accountable, consultative and transparent. Public submissions were called to obtain the views of interested parties on issues raised by the proposal and the impacts of regulatory options.

The draft variation was considered for approval by the FSANZ Board taking into account all public comments received from the call for submissions.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this proposal in the short timeframe. Every submission on this proposal was considered by the FSANZ Board. All comments were valued and contribute to the rigour of our assessment.

3.4 FSANZ Act considerations

In addition to the submissions received, FSANZ had regard to the following matters when considering approving the draft variation.

3.4.1 Whether the measure's costs may outweigh its benefits

The Office of Best Practice Regulation (OBPR) has indicated in an email dated 26 November 2021 that the changes being proposed to the Code are consequential changes to give effect to the intention of the Government's decision to conduct a 2-year trial on the commercial importation of kava¹⁴, rather than a new or independent regulatory decision. The Government's decision to proceed with the trial was subject to a Regulation Impact Statement (RIS) process, which has been assessed as adequate by the OBPR and has been published¹⁵. Given this, OBPR do not consider a RIS is required in this case, because the decision around importation has already been subject to regulatory analysis.

Regardless of this, FSANZ had regard to the costs and benefits to the community,

¹⁴ It is important to note that the proposed amendments to the Code due to this proposal are not tentative for a 2 year period and are not dependent on the evaluation of the trial; they will remain, if accepted and gazetted until any amended as a result of any future proposal or application.

¹⁵ [Pilot program to allow commercial importation of kava | OBPR \(pmc.gov.au\)](https://www.pmc.gov.au/pilot-program-to-allow-commercial-importation-of-kava)

government or industry that may arise from developing the proposed measure in a manner that was commensurate with the time and data available in order to meet the requirements of the FSANZ Act.

A range of difficult to quantify benefits are likely to exist as a result of allowing additional kava imports. These include providing more economic opportunities in our region and allowing Pacific diaspora to more easily practice their culture. However, some health risks in relation to its inappropriate use outside of its historically safe uses suggest that some limits may need to be placed around this food.

After considering the costs and benefits, FSANZ decided that a regulatory approach to amend the Code to more explicitly limit the preparation and consumption of kava beverages to historically safe use, and to clarify that the Code does not permit food additives and processing aids to be added to dried or raw kava root or kava beverages was appropriate. This was on the basis that there is an identified risk to public health and safety of unlimited commercial importation of kava into Australia from December 2021, due to the potential of kava beverage to become a substance of abuse. Ongoing high consumption can result in negative health outcomes. Non-regulatory options were not considered appropriate given the potential serious consequences of consumption of kava beverages outside the historically safe preparation and use. Government enforcement agencies have expressed concern that the current Code requirements may not be suitable to prevent the use of kava beyond historically safe use. There are also likely to be some small additional government regulatory costs; how much they differ from the present regulatory costs is uncertain.

The direct and indirect benefits that would arise from a food regulatory measure developed or varied as a result of the proposal are likely to outweigh the costs to the community, Government or industry that would arise from the development or variation of the food regulatory measure given the benefits identified and the steps proposed to manage any potential harm.

3.4.2 Whether there are other more cost effective measures available

There were no other measures (whether available to FSANZ or not) that would be more cost-effective than a food regulatory measure developed or varied as a result of the proposal, relating explicitly to whether the existing Code provisions for kava needed to be amended to better reflect and implement the stated kava regulatory policy.

3.4.3 Whether there are any relevant New Zealand standards

The draft variation will apply in both Australia and New Zealand.

Standards 1.1.1 and 2.6.3 apply in both Australia and New Zealand. Kava is regulated as a food under the *New Zealand Food Act 2014* which applies the requirements set by the Code for kava. The *New Zealand Food (Supplemented Food) Standard 2016* also provides that kava must not be added to supplemented food subject to that standard.

In New Zealand, when used in accordance with historically safe practices, kava is regulated as a food under the *New Zealand Food Act 2014*. These provisions are linked to the specific kava compositional and labelling requirements of the Code, so they are directly related.

Certain foods may be sold under the *New Zealand Food (Supplemented Food) Standard 2016*. Kava must not be added to a New Zealand supplemented food. Also the kava standard of the Code does not apply to supplemented foods in New Zealand.

3.4.4 FSANZ's statutory objectives in standards development

FSANZ also had regard to the three objectives in subsection 18(1) of the FSANZ Act during its final consideration.

3.4.4.1 Protection of public health and safety

The FSANZ Act requires FSANZ to have regard to the fact that the primary objective in standards development is the protection of public health and safety. FSANZ's risk and technical assessment of kava (SD1) concludes that it is possible to safely consume kava beverage in moderation when associated with historically safe preparation and use. However, kava beverage has a demonstrated potential to become a substance of abuse in certain contexts and high consumption can result in adverse health and wellbeing outcomes. The risk assessment also concluded that the safe varieties of kava for food are required to be what are called the Noble cultivars, which was mandated in the Code via the draft variation. The risk assessment and conclusions as well as additional risk management considerations were critical in justifying preparing the urgent proposal and amending the Code to ensure public health and safety.

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

The current labelling requirements for kava as detailed in section 1.2.1, including prescribed warning statements, provide information to enable consumers to make informed choices.

3.4.4.3 The prevention of misleading or deceptive conduct

There are no issues identified with this proposal relevant to this objective.

3.4.5 Subsection 18(2) considerations

FSANZ has also had regard to:

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

FSANZ has prepared a risk and technical assessment which considered the public health and safety risks associated with the consumption of kava, including historically safe preparation and use (SD1). This risk assessment used the best available scientific evidence.

- **the promotion of consistency between domestic and international food standards**

As noted in section 1.2.2 there is a Codex Regional Standard for Kava. This standard applies to kava which is used to prepare a kava beverage when mixed with water for human consumption. It is noted that the Codex Regional Standard for Kava does not apply to the final kava beverage as such so it has some differences to the Code.

The variation will promote consistency between the Code and the Codex standard to the extent that the variation will amend the Code to include an express prohibition on food additives (consistent with the Codex Standard) and processing aids and will require that kava be sourced from Noble cultivars named in the Codex Standard.

- **the desirability of an efficient and internationally competitive food industry**

This consideration is not relevant since there are no kava plant based industries in Australia and New Zealand, as the kava plant is not grown in these countries. All primary sources of kava products are imported, usually from Pacific countries. The Australian Government kava pilot plant initiative announced in 2019 was to assist Pacific countries export kava to Australia as an economic benefit to those countries. Kava imported into Australia under this initiative must comply with relevant Code requirements when sold. This includes the amendments proposed in the draft variation. These amendments are similar to those set by the Codex Regional Standard for Kava. To that extent, the proposed amendments can be considered consistent with international regulation represented by the Codex Regional Standard for Kava and, thereby, as enhancing an efficient and internationally competitive international food industry in the Pacific.

- **the promotion of fair trading in food**

As noted above changes to the Code proposed as an outcome of this urgent proposal will make the Code more consistent with international kava regulations, in the form of the Codex Regional Standard for Kava. This can only assist in the promotion of fair trading in kava and kava products.

- **any written policy guidelines formulated by the Food Ministers' Meeting¹⁶**

There are no specific policy guidelines relevant to this urgent proposal.

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¹⁶ Formerly the Australia and New Zealand Ministerial Forum on Food Regulation

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Attachments

- A. Approved draft variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement
- C. Draft variation to the Australia New Zealand Food Standards Code (call for submissions)

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



Food Standards (Proposal P1057 – Review of the kava standard) Variation

The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 97 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of the Delegate]

Delegate of the Board of Food Standards Australia New Zealand

Note:

Public notice of the approval of the variation will be given in the *Food Standards Australian New Zealand Notification Circular* Number **XXX-22** published and issued on **XX March 2022**. This means that this date is the date of public notice for the purposes of clause 3 of the variation.

1 Name

This instrument is the *Food Standards (Proposal P1057 – Review of the kava standard) Variation*.

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

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

3 Commencement

The variation commences on the date of public notice of the approval of the variation.

4. Transitional arrangements

Section 1.1.1—9 of the *Australia New Zealand Food Standards Code* does not apply to the variations made by this instrument.

Schedule

Standard 1.1.2

[1] Subsection 1.1.2—3(2) (definition of *kava root*)

Repeal the definition, substitute:

kava root means the peeled root or peeled rootstock of a Noble variety of kava that is named in section 3.1 of the *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020).

Standard 2.6.3 Kava

[2] Section 2.6.3—2 (note)

Omit “of kava”, substitute “of a Noble variety of kava that is named in section 3.1 of the *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020)”.

[3] At the end of the instrument

Add:

2.6.3—5 Prohibition on food additives and processing aids in kava

A food referred to in paragraph 2.6.3—3(a) or 2.6.3—3(b) must not have as an ingredient or a component, any of the following:

- (a) a substance that was *used as a food additive;
- (b) a substance that was *used as a processing aid.

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 2 of Part 3 of the FSANZ Act specifies that the Authority may prepare a proposal for the development or variation of food regulatory measures, including standards. This Division also stipulates the procedure for considering a proposal for the development or variation of food regulatory measures.

The Authority prepared Proposal P1057 to consider whether existing Code provisions for kava needed to be amended to better reflect and implement stated regulatory policy and to ensure that they continue to protect public health and safety given the potential increased availability of kava in the wider community following the Australian Government's decision to allow the commercial importation of kava into Australia from 1 December 2021.

Following its preparation, Proposal P1057 was declared an Urgent Proposal for the purposes of the Division 4 of Part 3 of the FSANZ Act.

The Authority considered the proposal in accordance with sections 96 and 97 of the FSANZ Act and has approved a variation.

2. Purpose

The Authority has approved a variation that amends Standard 1.1.2 and to Standard 2.6.3 of the Code. The variation will amend Standard 1.1.2 to require that kava for food use be obtained from a Noble cultivar of the species of *Piper methysticum* that is named in the Codex Regional Standard for Kava. The variation will amend Standard 2.6.3 to include an express prohibition on the presence, as an ingredient or component, in kava or kava beverages permitted by the Code of substances used as a food additive or as a processing aid.

3. Documents incorporated by reference

The variation in this instrument incorporates a document by reference.

The variation will amend the Code to define kava by reference to a specific document that is or will be in force or existing at the commencement of the variation; namely, the *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020). The approved draft variation amends the definition of kava in subsection 1.1.2—3(2) of the Code to provide that kava for food use be obtained from a Noble cultivar of the species of *Piper methysticum* that is named in section 3.1 of that specific edition of the Regional Standard.

This reference by incorporation is consistent with the current practice in the Code, such as in section S11—4 and Schedule 3.

4. Consultation

The Authority considered the proposal in accordance with the procedure in Division 4 of Part

3 of the FSANZ Act. That consideration included one round of public consultation following an initial consideration and the preparation of a draft variation and associated assessment summary. After that public consultation, the Authority had regard to all submissions received and approved an amended version of the draft variation.

The approved variation must be reviewed by the Authority within 12 months of its notification in accordance with Subdivision B of Division 4 of Part 3 of the FSANZ Act. Further public consultation is required as a part of that assessment.

Correspondence has been received from the Office of Best Practice Regulation (OBPR) related to this Proposal. The OBPR has advised that the changes being proposed to the Code are consequential changes to give effect to the intention of the Commonwealth Government's decision to conduct a 2-year trial on the commercial importation of kava into Australia. That is, FSANZ's proposed changes to the Code are not new or independent regulatory decision. The proposed changes support the trial being run in a fashion consistent with the Government's intention.

The Government's decision to proceed with the trial was subject to a Regulation Impact Statement (RIS) process, which has been assessed as adequate by the OBPR. Therefore, the OBPR did not consider a separate RIS is required in this case, because the decision around importation has already been subject to regulatory analysis.

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

The Schedule to the approved variation will vary Standards 1.1.2 and 2.6.3 of the Code.

Item [1] of the Schedule varies the definition of 'kava root' in subsection 1.1.2—3(2). The Item repeals and substitutes that definition with amended definition. The amended definition states that kava root means the peeled root or peeled rootstock of a Noble variety of kava that is named in section 3.1 of the *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) as adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020). The effect of the amended definition will be that kava food products permitted by the Code can only be obtained from Noble varieties listed in that specific edition of the Codex Regional standard.

Item [2] of the Schedule to the variation repeals and substitutes the note to section 2.6.3—2 to reflect the amendment made by Item [1] above.

Item [3] of the Schedule adds a new section 2.6.3—5 to Standard 2.6.3. The effect of the new section is to prohibit a food referred to in paragraphs 2.6.3—3(a) and 2.6.3—3(b) from having, as an ingredient or a component, a substance used as a food additive and/or a substance used as a processing aid. The phrases 'used as a food additive' and 'used as a processing aid' as stated in the new section are currently defined in the Code by sections 1.1.2—11 and 1.1.2—13 respectively.

Transitional arrangements

The above variations will commence on the date of public notice of the approval of the variation. See clause 3 of the instrument of variation.

The stock-in-trade exemption provided by section 1.1.1—9 of Standard 1.1.1 will not apply to any of the above variations. See clause 4 of the instrument of variation.

Attachment C – Draft variation to the Australia New Zealand Food Standards Code (call for submissions)



Food Standards (Proposal P1057 – Review of the kava standard) 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 variation commences on the date specified in clause 3 of this variation.

Dated [To be completed by the Delegate]

[Name and position of the Delegate]

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 (Proposal P1057 – Review of the kava standard) Variation*.

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

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

3 Commencement

The variation commences on the date of gazettal.

4. Transitional arrangements

Subsection 1.1.1—9(1) of the *Australia New Zealand Food Standards Code* does not apply to the variations made by this instrument.

Schedule

Standard 2.6.3 Kava

[1] Paragraph 2.6.3—3(a)

Repeal the paragraph, substitute:

- (a) a beverage that is:
 - (i) prepared by the aqueous suspension of kava root using cold water only, and not using any organic solvent; and
 - (ii) for immediate consumption at the place of preparation; or

[2] At the end of the instrument

Add:

2.6.3—5 Prohibition on food additives and processing aids in kava

A food referred to in paragraph 2.6.3—3(a) or 2.6.3—3(b) must not have as an ingredient or a component, any of the following:

- (a) a substance that was *used as a food additive;
- (b) a substance that was *used as a processing aid.