

10 December 2021
183–21

Call for submissions – Urgent Proposal P1057

Review of the kava standard

INITIAL CONSIDERATION REPORT

Food Standards Australia New Zealand (FSANZ) has assessed a proposal to review the Australia New Zealand Food Standards Code (the Code) to clarify the existing permission for kava to ensure it continues to protect public health and safety in response to the commercial importation of kava into Australia becoming unlimited from December 2021 as part of the Government's commitment to the Pacific. It has prepared a draft food regulatory measure. Pursuant to section 96 of the *Food Standards Australia New Zealand Act 1991* (FSANZ Act), FSANZ now calls for submissions to assist consideration of the draft food regulatory measure.

For information about making a submission, visit the FSANZ website at [current calls for public comment and how to make a submission](#).

All submissions on applications and proposals will be published on our website. We will not publish material that we accept as confidential. In-confidence submissions may be subject to release under the provisions of the *Freedom of Information Act 1982*. Submissions will be published as soon as possible after the end of the submission period.

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

For information on how FSANZ manages personal information when you make a submission, see FSANZ's [Privacy Policy](#).

Submissions should be made in writing; be marked clearly with the word 'Submission'. You also need to include the correct application or proposal number and name. Electronic submissions can be made through the FSANZ website via the link [how to make a submission](#). You can also email your submission to submissions@foodstandards.gov.au. FSANZ also accepts submissions in hard copy to our Australia and/or New Zealand offices.

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

DEADLINE FOR SUBMISSIONS: 6pm (Canberra time) 23 December 2021

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

Questions about making a submission or application and proposal processes can be sent to standards.management@foodstandards.gov.au.

Submissions in hard copy may be sent to the following addresses:

Food Standards Australia New Zealand
PO Box 5423
KINGSTON ACT 2604
AUSTRALIA
Tel +61 2 6271 2222

Food Standards Australia New Zealand
PO Box 10559
WELLINGTON 6140
NEW ZEALAND
Tel +64 4 978 5630

Table of contents

EXECUTIVE SUMMARY	2
1 INTRODUCTION.....	4
1.1 THE PROPOSAL.....	4
1.2 THE CURRENT STANDARDS	5
1.2.1 <i>The Code</i>	5
1.2.2 <i>Code's interaction with other kava related laws</i>	6
1.2.3 <i>Codex standard</i>	7
1.3 REASONS FOR PREPARING THE PROPOSAL	7
1.4 PROCEDURE FOR CONSIDERATION	8
2 SUMMARY OF THE INITIAL CONSIDERATION	8
2.1 RISK ASSESSMENT	8
2.2 RISK MANAGEMENT	11
2.2.1 <i>Is permission explicit to only traditional preparation and consumption of kava beverage?</i>	12
2.2.2 <i>Consideration of further tightening of permission to ensure traditional preparation and consumption kava beverage applies</i>	12
2.2.3 <i>Exclusion of food additives and processing aids in kava and kava beverage</i>	13
2.2.4 <i>Can permission be limited to only Noble kava species?</i>	15
2.2.5 <i>Cold water vs potable water?</i>	15
2.3 RISK COMMUNICATION.....	15
2.3.1 <i>Consultation</i>	15
2.3.2 <i>World Trade Organization</i>	16
2.4 ISSUES	16
2.4.1 <i>Whether the measure's costs may outweigh its benefits</i>	16
2.4.2 <i>Whether there are other more cost effective measures available</i>	17
2.4.3 <i>Whether there are any relevant New Zealand standards</i>	17
2.4.4 <i>FSANZ's statutory objectives in standards development</i>	17
2.4.5 <i>Subsection 18(2) considerations</i>	18
3 DRAFT VARIATION	19
4 REFERENCES.....	19
ATTACHMENT A – DRAFT VARIATION TO THE AUSTRALIA NEW ZEALAND FOOD STANDARDS CODE.....	20
ATTACHMENT B – DRAFT EXPLANATORY STATEMENT.....	22

Supporting documents

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

SD1 Risk and technical assessment report

Executive summary

Proposal P1057 was prepared by Food Standards Australia New Zealand (FSANZ) to consider whether the provisions of the Australia New Zealand Food Standards Code (the Code) that relate to kava need to be amended in light of the Australian Government's decision to allow the commercial importation of kava into Australia from 1 December 2021 as part of the Government's commitment to the Pacific. FSANZ has declared the proposal urgent.

At present, the Code in effect prohibits the sale of food that consists of, or have 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 allow only sales of kava for its traditional preparation and use. This policy recognises: the deep cultural significance of kava for Pacific communities both in Australia and New Zealand, and across the Pacific region; that kava consumption in line with traditional cultural practice is generally considered safe; and 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 related request by the Chair of the Food Ministers' Meeting to consider whether current Code provisions relating to kava remain appropriate.

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 role in traditional community ceremonies. In recent times, kava beverages have become more widely consumed as a recreational beverage in both the Pacific community as well as the wider international community. This significant history of use demonstrates that it is possible to safely consume kava beverage in moderation for traditional purposes.

However, kava beverage has a demonstrated potential to become a substance of abuse, 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.

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 of only permitting the sale of kava as food for traditional preparation and use. FSANZ therefore prepared a proposed draft variation to amend the Code's kava provisions for this purpose.

The proposed draft variation seeks to amend the current permission for kava beverages in paragraph 2.6.3—3(a) of the Code to require that permitted kava beverages be produced 'for

immediate consumption at the place of preparation'. This proposed amendment would be consistent with traditional kava preparation and consumption.

The proposed draft variation seeks to add a new section to Standard 2.6.3 to 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. This proposed measure would also be consistent with traditional kava preparation and consumption. FSANZ's assessment identified some ambiguity in the Code about the use of food additives and processing aids in relation to kava. FSANZ's assessment also found some 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 seeks submissions on its assessment and the proposed draft variation. Submissions received will inform FSANZ's decision whether to reject, amend or approve the proposed draft variation.

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 for the review was to ensure the Code's kava provisions can 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 2021¹.

As explained below, the Code's provisions relating to kava generally restrict the sale of kava as a food for traditional 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 clarify that the addition of food additives and processing aids to dried or raw kava root or kava beverages was not consistent with traditional preparation and use.

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 Code provisions relating to kava – and the policy position on which they are based – limit the use of kava to the traditionally-prepared beverage consumed by sub-populations familiar with its occasional and ceremonial use. The Code and related regulatory policy was not to promote broad consumption of kava.
- 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 traditionally prepared kava beverage for ceremonial purposes 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 proposal. If FSANZ decides to approve the draft variation (or an amended version of that variation), then consideration would be given to labelling as part of the further assessment of the approved variation which includes public consultation.

¹ <https://www.pm.gov.au/media/stepping-trade-and-cultural-ties-pacific>

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'.

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 package² (e.g. kava root may be sold unpackaged)

² 'Package' is defined in subsection 1.1.2—2(3) of the Code: *package*:

- (a) means any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged; and
- (b) if food is carried or sold or intended to be carried and sold in more than one package—includes each package; and
- (c) does not include:
 - (i) a *bulk cargo container; or
 - (ii) a pallet overwrap; or
 - (iii) a crate and packages which do not obscure labels on the food; or

- 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 (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 2.6.3³, 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 2kg to 4kg. Phase 1 commenced in December 2019.

(iv) a transportation vehicle; or

(v) a vending machine; or

(vi) a hamper; or

(vii) a container or wrapper (including a covered plate, cup, tray or other food container) in which food is served in a prison, hospital or *medical institution; or

(viii) for Standard 2.9.5—a covered plate, cup, tray or other food container in which food for special medical purposes is served by a *responsible institution to a patient or resident.

³ Standard 2.6.3 – Kava [Australia New Zealand Food Standards Code – Standard 2.6.3 – Kava \(legislation.gov.au\)](https://www.legislation.gov.au)

- 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 2021⁴). This phase commenced on 1 December 2021. This legislation refers specifically to '**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), for example, prohibits the importation into and sale of kava in the Northern Territory.

1.2.3 Codex standard

There is a relevant international standard for kava which is the regional Codex standard for *Kava products for use as a beverage when mixed with water* CXS 336R-2020 (Codex Alimentarius Commission 2020). This is a draft international standard for kava, which is used to prepare a kava beverage when mixed with water for human consumption. It is noted that the regional Codex standard does not apply to the final kava beverage as such. Kava products are derived from selected parts of the Noble⁵ 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 regional Codex standard also does not apply to kava products used for 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 regional Codex standard. It allows that potable water can be used to prepare kava beverage from dried kava powder, or if prepared from fresh kava the ground or macerated kava is again mixed with potable water. Both methods of production may be filtered prior to consumption.

The regional Codex standard 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 and not specifically for 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 provisions of the Code relating to kava to ensure they can 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 as part of the Australian Government's commitment to the Pacific.

⁴ <https://www.legislation.gov.au/Details/F2021L01659> commenced on 1 December 2021

⁵ a non-exhaustive list of various Noble varieties from different regions are listed in the regional Codex standard. These are the safe kava varieties used to produce kava and kava products for food use.

1.4 Procedure for consideration

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

In the event that, after considering responses to this initial consideration, FSANZ decides to approve the draft variation (or an amended version of that variation), the approved amendment will be gazetted and take effect. If that occurs, the FSANZ Act will then require FSANZ to undertake a further assessment of that approved variation to decide whether it should be repealed, amended or reaffirmed. In doing so, FSANZ must undertake further public consultation. This further assessment process – which must be completed within 12 months of the draft variation’s approval – provides an opportunity to consider the regulatory issues.

2 Summary of the initial consideration

2.1 Risk assessment

FSANZ completed a risk assessment, which examined the risks associated with the consumption of kava and kava beverage as foods, including traditional preparation and use. This relates to the permitted consumption of kava as provided 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 assessment is provided as SD1 with a summary provided below.

Traditional and recreational use of kava

Kava beverage has significant traditional and cultural importance for communities throughout Micronesia, Melanesia and Polynesia. Believed to originate in Northern Vanuatu, kava was likely carried across Oceania by early maritime explorers and traders, and has been consumed for more than 1000 years. Its place in traditional Pacific cultures is central to social ceremonies and gatherings.

Kava beverage is not a widely consumed food in Australia or New Zealand, except in some Pacific communities, or select First Nations communities in Australia. Kava was introduced into Arnhem Land in the 1980s.

Method of preparation for traditional and recreational use

Traditional kava beverage is prepared by aqueous extraction using fresh or dried roots of the kava plant to produce a brew in a communal bowl. Fresh material is peeled before being chewed or ground until it is fine and fibrous, and infused with water. Dried material is ground finely, wrapped in cloth and infused in water. The beverage is then typically consumed immediately.

Complementary medicines are manufactured differently and often involve extraction with organic solvents resulting in different chemical profiles to that of aqueous beverages. A consideration of the safety of kava in complementary medicines is outside the scope of this proposal.

Identity and composition of kava plants

There are more than 200 varieties of kava plant. ‘Noble’ kava varieties have been safely used by Pacific cultures for kava beverage production. Noble varieties are distinguished by

their geographical distribution, physical plant 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 - 4-methoxy-2-pyrone with phenyl or styryl substitutes at the 6th position. There are six major kavalactones and up to thirteen minor kavalactones that 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.

Flavokawains and piperidine alkaloids, also found in kava plants, generally make up less than 1% of the dry weight. It has been suggested (FAO/WHO 2016) that these compounds may be more toxic than kavalactones, however little toxicological data is available for either flavokawains or piperidine alkaloids.

Pharmacology

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. The mechanism of action of kavalactones has not been well established, but may involve direct interactions with voltage-operated ion channels or activities through the cognate receptors for γ -aminobutyric acid, serotonin, endocannabinoids and glycine.

Pharmacokinetics

Limited information is available on the pharmacokinetics of kavalactones. In a rat study, kavain, the major kavalactone in kava beverage, was well absorbed and approximately 50% bioavailable. In humans, kavain is extensively metabolised in the liver by CYP-mediated biotransformation, before sulfonation, glucuronidation or glutathione (GSH) conjugation. More than 90% of a 100 mg/kg bodyweight (bw) dose of kavain was excreted within 72 hours as either unchanged kavain or kavain metabolites in the urine and faeces of rats. There is no evidence of bioaccumulation in humans, rats or mice.

Potential for drug interactions

Limited information is available on potential for drug interactions. However substances in kava have been shown to inhibit CYP isoforms 1A2, 2C9, 2C19, 2D6, 3A4 and 4A9/11 *in vitro* demonstrating 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.

Toxicological studies in laboratory animals

A non-guideline, four week oral administration study in rats using an aqueous extract of kava intended to be representative of kava beverage, did not report any adverse effects at doses of up to 500 mg/kg bw/day kavalactones.

An U.S. National Toxicology Program (NTP) report assessed the chronic toxicity and carcinogenic potential of an orally administered pharmaceutical kava extract in mice and rats. Increased liver weights and hepatocellular hypertrophy were observed in both species. In male mice, there was a dose-related increase in the incidence of hepatoblastoma at doses above 500 mg/kg bw/day. In female rats, hepatocellular adenoma or carcinoma were observed in all treatment groups. A small but statistically significant dose-related increase in testicular interstitial (Leydig) cell adenoma was seen in all male treatment groups. The findings demonstrate a potential for kava extracts to elicit hepatotoxicity but the relevance of the test article to an aqueous extract is unknown.

No genotoxicity studies were available for aqueous kava extracts. The kava extract assessed by the U.S. NTP was not genotoxic in bacterial mutagenicity or *in vivo* micronucleus studies.

No reproductive or developmental studies are available in laboratory animals.

Studies in humans

There were no high quality clinical trials that used kava beverage as the test item. Three clinical trials were available using a capsule prepared from hot-water kava extract, which provided the best comparator for understanding kava beverage safety.

A 16-week randomised, double-blind, placebo-controlled clinical trial investigated the effects of hot water kava extract tablets (240 mg/day kavalactones) in participants with diagnosed generalised anxiety disorder. The kava group self-reported more frequent occurrences of poorer memory and tremor/shakiness. Statistically significant increases in the proportion of liver function tests reporting above baseline abnormalities were observed in the kava group, measured by increases in γ -glutamyl transferase (GGT), aspartate transaminase (AST) and alanine aminotransferase (ALT).

In two separate three- and six-week clinical trials using a similar aqueous extract (250 mg/day kavalactones), no treatment-related changes in liver abnormalities or adverse events were observed.

A number of cases of liver toxicity have been reported in association with kava extracts used for medicinal purposes in Germany and Switzerland. These cases varied in severity from abnormal liver function (high levels of GGT and alkaline phosphatase (AP), with associated increases of ALT) to liver failure, including fatality and liver transplants. The causative factor of these observed hepatotoxicity events remains unknown. In all of these reported cases, kava had been consumed as complementary medicines, supplements or herbal medicines.

Health effects associated with traditional or recreational use of kava beverage

Kava beverage is culturally significant to communities in the South Pacific, where it has a long history of consumption. Kava beverage is not a widely consumed food in Australia or New Zealand, except in some Pacific communities, or select First Nations communities in Australia. Acceptance of kava beverage as a safe recreational beverage in traditional kava consuming communities (FAO/WHO 2017) has increased kava consumption in non-traditional communities. The long tradition of use with minimal evidence of adverse health events from kava beverage consumption in moderation demonstrates that it is possible to allow kava beverage consumption into communities safely.

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. 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. Altered liver function is observed as an increase in the liver enzymes GGT and AP. These changes are reversible, and occur without an observed increase of ALT or other signs of liver toxicity. Changes in liver function associated with kava beverage consumption are not consistent with the severe hepatotoxicity events observed in consumers of herbal medicines.

It has been suggested that the negative health effects associated with kava beverage become pronounced with consumption in excess of 400 g/week of dried kava powder.

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

Kava beverage is not consumed for nutritional benefit, rather as part of cultural practices and for its intoxicating properties. There are no known nutritional issues associated with the moderate use of kava.

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

Data gaps exist in the available scientific literature to understand the toxicity, potential dosage and pharmacokinetics of each biologically-active chemical constituent in kava beverage. The majority of available data relate to herbal extracts of kava, which are chemically distinct from the kava beverage.

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.

However, in the absence of this information, there remains significant population-based evidence demonstrating that traditional and recreational consumption of kava beverage in moderation is safe.

Conclusion

Kava beverage has a long history of consumption in the Pacific and has an important role in traditional community ceremonies. In recent times, it has become more widely consumed as a recreational beverage in both the Pacific community as well as in the wider international community. This significant history of use demonstrates that it is possible to safely consume kava beverage in moderation for traditional and recreational purposes.

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

2.2 Risk management

As explained above in section 1.1, the policy underpinning the Code's current provisions relating to kava are to ensure the preparation and consumption of kava beverages is consistent with traditional and ceremonial purposes, especially for Pacific communities. This was expressed in the earlier FSANZ kava review Proposal P256 Final Assessment Report (FSANZ, 2004) 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. This is also understood to be the current policy intent related to kava; that is, to allow the sale of kava in Australia and New Zealand for traditional cultural use by Pacific communities, while also minimising adverse public health and social impacts.

FSANZ's risk assessment (SD1) has concluded that kava beverage traditionally prepared

and consumed has a significant history of safe use.

The risk assessment has identified some data gaps and uncertainties in the safety of additional types of kava and kava products. Also 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 due to Proposal P256. FSANZ risk management considerations for this proposal are considered below. A number of the risk management considerations are additional to the risks identified in the risk assessment.

2.2.1 Is permission explicit to only traditional preparation and consumption of kava beverage

The only permitted use of kava as a food is the exception to the prohibition (paragraph 1.1.1—10(5)(e)) and as an ingredient or component (paragraph 1.1.1—10(6)(i)) provided by section 2.6.3—3 allowing the use of:

- 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.

These foods and preparations of the foods are for traditional uses. 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 traditional preparation practices, but can be used to produce kava extracts for other purposes. 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 traditionally. 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 safe traditional manner.

A preliminary suggestion from some jurisdictional enforcement agencies was to require the kava beverage to be unpackaged to limit the potential of processing, which would be inconsistent with traditional use and the intent of the current standard. However, on further consideration it was clear that making such a change would be inconsistent with definitions already in the Code for the term ‘package’ (see the footnote to the Code in the labelling section in section 1.2.1). Package already encompasses the form that kava beverages will 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 then consume the kava beverage from.

FSANZ considers that the current definitions and preparations for food use of kava and kava beverages are safe and consistent with traditional preparations and uses.

However, FSANZ considered there needs to be further consideration of tightening of the permission for the preparation and consumption of kava beverage to ensure it meets the original intent of the permission to continue to be for the traditional preparation and consumption of kava beverage. One of the main concerns relates to whether pre-prepared and packaged kava beverages complies with the policy intention. This is considered further in the next section.

2.2.2 Consideration of further tightening of permission to ensure traditional

preparation and consumption kava beverage applies

An internet search revealed there are many types of pre-prepared and packaged kava beverages available for purchasing, but produced outside of Australia. The availability of such beverages indicates the broadening of kava products for the general Australian and New Zealand community, which is inconsistent with the policy intent of the 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 high pressure processing to ensure a safe, palatable and commercially acceptable product is produced.

To limit wider consumption of kava beverages beyond traditional use, it is proposed to add an additional requirement to the current permission to produce kava beverages in section 2.6.3—3(a) of the Code. It is proposed to require the produced kava beverage be 'for immediate consumption at the place of preparation'. This is considered to better describe the traditional use of kava.

2.2.3 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

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

An internet search was conducted to identify if there were any 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^{6,7,8}. 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). 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)⁹ 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 it proposed the addition of the food additive lecithin as an emulsifier (see next paragraph). It is not known if this patent has been commercialised.

⁶ Kava shots: <https://rootofhappinesskava.com/blogs/articles/root-of-happiness-kavashot-500mg-kavalactones-in-a-2-oz-shot>

⁷ Kava tea bags; contain other ingredients so non-compliant anyway: [Kava Kava Stress Relief Tea 16 Bags | Kava Kava Tea for Anxiety | PipingRock Health Products](#)

⁸ 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](#)

⁹

<https://www.google.com/url?esrc=s&q=&rct=j&sa=U&url=https://patents.google.com/patent/GB2507270A/en&ved=2ahUKEwil0NDq1bL0AhUvTWwGHWL-APUQFnoECAQQAg&usq=AOvVaw1MIC6y6MMkDvzMUS0YmEVu>

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 two phases, aqueous and oil. One such substance proposed is the food additive emulsifier, soy lecithin. Other fat containing ingredients include coconut milk, soy milk, cow's milk and many others, which would not be consistent with the Code as they are ingredients. Commercially-prepared kava beverages containing the food additive emulsifier soy lecithin were not identified. However, it would not be unexpected that such products could already be available or could be developed.

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

The regional Codex kava standard explicitly prohibits 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. The Codex standard does not mention processing aids, either to exclude or permit 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. Some substances can be both food additives and processing aids, but processing aids themselves are not a subset of food additives.

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

The Code does not expressly prohibit the addition of food additives or processing aids to kava and kava products. Nor is there an express permission.

Permissions for the addition of food additives to different classes of foods are provided in the table to section S15—5 of the Code. Government agencies responsible for the application and enforcement of the Code have expressed concern that the absence of an express prohibition in the Code on the use of food additives in kava food products, coupled with the broad nature of the Code's food additive permissions, could lead to claims by some stakeholders that these permissions allow the use of food additives in kava food products. Examples noted 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 is often used for definitions if the Code is not explicit and its definition of *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.

FSANZ also notes that the use or presence of food additives in kava in the same manner as they are used in 'commercial' beverages' would be inconsistent with, and defeat the Code's policy objectives for the use, sale and consumption of kava as a food. The stated policy intent for Standard 2.6.3 and its regulation of the use, sale and consumption of kava was to only permit the consumption of the traditionally prepared kava beverages and the use of kava as a food for traditional preparation and use. This intent is stated in FSANZ's Final Assessment Report for P256 (FSANZ 2004), which reviewed Standard 2.6.3. Permitting the use in kava of substances that are not traditionally used in kava preparation and which are found in commercially manufactured food products is at odds with that policy.

For these reasons, FSANZ proposes to provide regulatory certainty by amending the Code to provide an express prohibition on the use of food additives and processing aids to be added to or used in the manufacture or processing of dried or raw kava root, or kava beverages. FSANZ has prepared a draft variation that will include this prohibition as a new section in Standard 2.6.3.

2.2.4 Can permission be limited to only Noble kava species

The regional Codex standard for kava refers explicitly to the Noble cultivars of kava. This begs the question whether the Code also needs to restrict permissions only to Nobel cultivars of the kava plant.

This issue was also considered during the assessment of P256 and discussed in the Final Assessment Report (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.

FSANZ notes that the regional Codex kava standard lists a number of Noble varieties but indicates this is a non-exhaustive list and includes examples of vernacular terms used to describe some Noble varieties in the various regions. It further notes that the Noble variety shall be confirmed using their morphological characteristics. Because of these comments it seems such a definitive list of Noble varieties is not possible. Making a requirement that the kava product must be a Noble cultivar would not be easily enforceable for regulatory purposes so seems to not be appropriate.

FSANZ does not propose to require that the permitted forms of kava must be only from Noble cultivars of the kava species *Piper methysticum*. This is because there is not a well-defined all Noble cultivars that can be readily referred to making the enforcement of such a requirement impractical.

2.2.5 Cold water vs potable water

Standard 2.6.3 refers to an aqueous suspension of kava root using cold water only, while the regional Codex kava standard 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 regional Codex kava standard. 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; that is 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 traditional preparation for kava beverage is not to heat the water but to only use cold water. This condition is considered important so it will not be changed.

It is not proposed to amend the condition in Standard 2.6.3 that cold water is used to produce the aqueous suspension of kava root. There is no need to use the term potable as it is required that when water is referred in the Code as an ingredient or substance used in the processing or manufacture of food it will be potable to ensure safe and suitable inputs during food manufacture.

2.3 Risk communication

2.3.1 Consultation

Consultation is a key part of FSANZ's standards development process. All calls for submissions are 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 are called to obtain the views of interested parties on issues raised by the proposal and the impacts of regulatory options.

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

2.3.2 World Trade Organization

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

There is a relevant international standard, being the regional Codex standard for *kava products for use as a beverage when mixed with water*. However, amending the Code to ensure that it protects public health and safety when the commercial import of kava into Australia becomes unlimited is unlikely to have a significant effect on international trade since any changes are proposed to be consistent with the scope of the Codex regional standard. It is noted that the Codex regional standard does not directly relate to kava beverages per se, but to kava powder used to produce kava beverage. Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Technical Barriers to Trade or Application of Sanitary and Phytosanitary Measures Agreement was not considered necessary.

2.4 Issues

FSANZ has had regard to the following matters when considering this proposal and in preparing the draft variation.

2.4.1 Whether the measure's costs may outweigh its benefits

The Office of Best Practice Regulation (OBPR) have 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 kava¹⁰, 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 published¹¹. Given this, they 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, 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 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

¹⁰ 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 amendments proposed as an outcome of any future proposal or application.

¹¹ [Pilot program to allow commercial importation of kava | OBPR \(pmc.gov.au\)](#)

to its inappropriate use outside of its traditional 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 traditional use, and to ensure that food additives and processing aids may not be added to dried or raw kava root or kava beverages was appropriate. This was on the basis that there is an identified immediate risk to public health and safety of unlimited commercial importation of kava into Australia from December 2021. Non-regulatory options were not considered appropriate given the potential serious consequences of consumption of kava beverages outside the traditional 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 the traditional 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. However, FSANZ would welcome any evidence-based information received from submitters which will help inform its final consideration of cost and benefits and may result in FSANZ arriving at a different conclusion.

2.4.2 Whether there are other more cost effective measures available

There are 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.

2.4.3 Whether there are any relevant New Zealand standards

The proposed 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 traditionally kava is regulated as a food under the *New Zealand Food Act 2014*. These provisions are linked to the specific kava labelling and compositional 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.

2.4.4 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 initial consideration.

2.4.4.1 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 there is a history of safe use of preparing

and consuming kava beverage for traditional uses. FSANZ's assessment of this proposal has identified some regulatory gaps and uncertainties in the application of the Code provisions relating to kava. The risk assessment and conclusions as well as additional risk management considerations are critical in justifying preparing the urgent proposal and amending the Code to ensure public health and safety.

2.4.4.2 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.

2.4.4.3 The prevention of misleading or deceptive conduct

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

2.4.5 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 traditional consumption and use (SD1). This risk assessment was based on 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 regional Codex standard for *Kava products for use as a beverage when mixed with water*. 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 regional Codex standard does not apply to the final kava beverage as such so it has some differences to the Code.

Relevant criteria in this regional Codex standard have been incorporated in the proposed amendments to the Code as drafting variations, as considered appropriate noting the slight differences in the standards. These are the requirements that no food additives are permitted in products covered by that standard, which FSANZ proposes to expand to also include the kava beverage produced from kava. FSANZ has also proposed to also exclude permissions for any processing aids covered by products in the standard (i.e. Standard 2.6.3), being kava beverage as defined in the standard, and dried or raw kava root. The regional Codex standard allows that potable water can be used to prepare kava beverage from dried kava powder, while the Code requires the extraction occurs only using cold water (which needs to be potable). It is not proposed to change this condition.

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

This consideration is not relevant since there are not 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 if approved. These amendments are similar to

those set by the regional Codex standard. To that extent, the proposed amendments can be considered consistent with international regulation represented by the Codex standard 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 regional Codex kava standard. This can only assist in the promotion of fair trading in kava and kava products.

- **any written policy guidelines formulated by the Food Ministers' Meeting¹²**

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

3 Draft variation

The draft variation to the Code is at Attachment A and is intended to take effect on gazettal.

A draft 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.

4 References

Codex Alimentarius Commission (2020) CXS 336R-2020 *Regional Standard for Kava Products for use as a Beverage When Mixed with Water* https://www.fao.org/fao-who-codexalimentarius/sh-proxy/en/?lnk=1&url=https%253A%252F%252Fworkspace.fao.org%252Fsites%252Fcodex%252FStandards%252FCXS%2B336R-2020%252FCXS_336Re.pdf accessed 6 December 2021

FAO/WHO (2016). *Kava: a review of the safety of traditional and recreational beverage consumption.*: Technical Report. Rome. <http://www.fao.org/3/i5770e/i5770e.pdf>

FSANZ (2004) Proposal P256 – Review of Kava, Final Assessment Report, Food Standards Australia New Zealand, Canberra [Proposal P256 - Review of Kava \(Standards O10/2.6.3\)](http://www.foodstandards.gov.au/propose/P256/P256_Review_of_Kava_Standards_O10_2.6.3) ([foodstandards.gov.au](http://www.foodstandards.gov.au)) accessed 3 December 2021

Attachments

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

¹² Formerly the Australia and New Zealand Ministerial Forum on Food Regulation.

Attachment A – 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 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.

Attachment B – Draft Explanatory Statement

1. Authority

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

Division 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 review the provisions of the Code that relate to kava 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 section 96 of the FSANZ Act and has prepared a draft variation.

2. Purpose

The Authority prepared a draft variation to amend Standard 2.6.3 of the Code to: require permitted kava beverages be, among other things: prepared for immediate consumption at the place of preparation; and to prohibit 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 variations to food regulatory measures do not incorporate any documents by reference.

4. Consultation

In accordance with the procedure in Division 4 of Part 2 of the FSANZ Act, the Authority's consideration of Proposal P1057 will include 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 will consider whether to approve, amend or reject the draft variation, having regard to all submissions received. If the Authority approves the draft variation or an amended draft variation, that approved variation will be gazetted and will take effect. The FSANZ Act requires the Authority then to assess that approved variation in accordance with Subdivision 4 of Part 3 of the FANZ 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 does 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 draft variation will vary Standard 2.6.3 of the Code.

Item [1] of the draft variation will repeal and substitutes paragraph 2.6.3—3(a) to include a requirement that a kava beverage permitted by the Code be prepared for immediate consumption at the place of preparation.

Item [2] of the draft variation will add new section 2.6.3—5 to Standard 2.6.3. The effect of the new section, if approved, will be 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 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 or take effect on the date of gazettal. 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.