6 October 2022
216-22

Call for submissions – Urgent Proposal P1057

Review of the kava standard

On 7 March 2022, the Food Standards Australia New Zealand (FSANZ) Board approved a variation to the Australia New Zealand Food Standards Code (the Code), including the kava standard, after considering an urgent proposal. The proposal sought 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. The amendments to the Code took effect on 23 March 2022 in Australia but not in New Zealand where the previous standard remains in effect. New Zealand will undertake further engagement with the Pasifika community while FSANZ assesses the amendments.

Under the urgent proposal provisions, FSANZ has assessed the resulting variation and is calling for submissions to help decide whether to reaffirm the variation or to prepare a proposal to amend or repeal the variation.

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 and 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) 16 November 2022

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
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Food Standards Australia New Zealand
PO Box 10559
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Supporting document

The following documents[1] which informed the assessment of this proposal are available on the FSANZ website:

Final consideration report – Urgent Proposal P1057 – Review of the kava standard

SD1 Risk and technical assessment report (at Call for Submissions)

SD2 Social science evidence summary

SD3 Labelling assessment

[1] https://www.foodstandards.gov.au/code/proposals/Pages/Proposal-P1057--Review-of-the-kava-standard-.aspx

Executive summary

In March 2022, the Food Standards Australia New Zealand (FSANZ) Board approved a variation to the Australia New Zealand Food Standards Code (the Code), including the kava standard. The reasons for the Board's decision are set out in the final consideration report of the urgent Proposal P1057 – Review of the kava standard. This report also summarises FSANZ's consideration of issues raised in public submissions and the subsequent amendments to the variation to the Code. The amendments to the Code were made on public notice on 23 March 2022.

The variation of the Code was approved 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

- explicitly 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.

FSANZ prepared Proposal P1057 to consider whether the Code's existing permissions for kava needed to be clarified 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. FSANZ declared the proposal urgent.

The *Food Standards Australia New Zealand Act 1991* (the Act) 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 the variation, repeal the variation, or to make other amendments to the Code. The variation remains until such time as it may be changed via the above process. The Act requires FSANZ to call for public submissions after making its assessment and review of the variation but before making the decision. FSANZ has now completed its full assessment of the approved variation.

FSANZ assessment of the approved variation based on the best available scientific evidence has concluded that it is appropriate to reaffirm the variation. The regulatory and policy intent has been and is to limit kava beverages to historically safe preparation and use which does not permit food additives or processing aids. Making the prohibition explicit ensures regulatory certainty consistent with the original policy intent of the kava standard. The amendment to ensure kava is only sourced from Noble varieties named in the Codex Regional Standard for Kava has been made on safety grounds since other kava varieties pose potential public health and safety risks. It is also consistent with the relevant international Codex standard.

FSANZ also has considered specific labelling matters as part of the full assessment of the approved variation. This assessment of labelling requirements examined whether:

- the existing warning statements about kava are appropriate and whether new warning and/or advisory statements are needed as risk management options, and

- the application of warning/advisory statements to foods not required to bear a label e.g. bowl of kava beverage.

Given there has been little change in the evidence base for the current health risk assessment compared with that in 2002, and there is limited evidence about consumption patterns, FSANZ is proposing to maintain the existing warning statements for permitted kava foods. FSANZ also considers there is insufficient evidence of health risks from the consumption of kava beverage to justify additional warning or advisory statements on kava foods. Additionally, since the kava pilot is for a two-year duration, it was considered pre-emptive to propose additional changes to those already legislated. The Australian Government Department of Health and Aged Care has commissioned external agencies[2] to undertake the evaluation of the pilot during this two year period.

FSANZ also proposes to maintain the current requirements for application of warning statements to kava foods for retail sale that are not required to bear a label. This includes that the warning statements have to be displayed in association with the sale of unpackaged root but not kava beverage when it is not required to bear a label. Retailers have the option of providing the warning statements voluntarily when kava beverage is prepared and packaged (e.g. in a bowl) on the premises from which it is sold or packaged in the presence of the purchaser.

FSANZ now calls for submissions to assist its decision on whether to reaffirm the variation, or to prepare a proposal to amend the variation, repeal the variation, or to amend other variations to the Code.

[2] NDARC at the University of New South Wales (https://ndarc.med.unsw.edu.au/) and Ninti One Limited (https://www.nintione.com.au), an indigenous owned organisation

1 Introduction

1.1 Background

Urgent Proposal P1057 – Review of the kava standard was prepared in November 2021 following a request from the then 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 continued 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 Pilot[3]. The Australian Government Department of Health and Aged Care has commissioned external agencies[4] to undertake the evaluation of the pilot over the two year period.

The policy intent of the Code's current kava provisions is to restrict the sale of kava as a food in line with historically safe preparation and use practices. FSANZ prepared the proposal to consider whether these provisions need to be amended to better reflect this regulatory policy intent and to ensure that, consistent with that policy and with historically safe preparation and use practices, food additives and processing aids may not be added to dried or raw kava root or kava beverages.

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 adverse health, safety, social and economic problems in some Australian First Nations communities[5,6], which could be exacerbated with the potential increased availability.
- The public health and safety risks posed by excessive 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[7]. 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

[3] https://www.dfat.gov.au/geo/pacific/economic-prosperity-in-the-pacific/australia-kava-pilot
[4] NDARC at the University of New South Wales (https://ndarc.med.unsw.edu.au/) and Ninti One Limited (https://www.nintione.com.au), an indigenous owned organisation
[5] See information in the earlier FSANZ Final Assessment Report for Proposal P256 (Review of kava) 2004, including Attachment 4 and references of studies conducted https://www.foodstandards.gov.au/code/proposals/Documents/P256_Kava_FAR.pdf
[6] Butt, J. (2019) Review of kava use among Aboriginal and Torres Strait Islander people, *Australian Indigenous Health Bulletin*, 19(2) http://healthbulletin.org.au/wp-content/uploads/2019/04/kava-bulletin-web.pdf
[7] See further information within SD1 of the final assessment report for P1057, including references https://www.foodstandards.gov.au/code/proposals/Documents/P1057%20SD1%20Risk%20Assessment.pdf

connection to family and community and diversion of financial resources from essentials.

In December 2021, FSANZ prepared an initial consideration report with proposed draft variations to the kava permissions in the Code. Submissions received on the proposed draft variations and report between 10 and 23 December 2021[8]are available on the FSANZ website[9].

In March 2022, the FSANZ Board approved the amended variations to the Code set out in the final consideration report of the urgent stage of the proposal. The reasons for the Board's decision to approve the latter are also set out in that consideration report, as is FSANZ consideration of issues raised in submissions. The approved variations to the Code were publicly notified on 23 March 2022.

The approved variations to the Code:

- added 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

- to clarify that the use of food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages.

The FSANZ Act provides that FSANZ must, within 12 months of notification of the approved variations 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 the variation, repeal the variation, or to make other variations to the Code. The approved variation remains in force until such time as it is changed or repealed by the above process.

FSANZ has now completed its assessment of the approved variation for the purposes of that review.

1.2 The approved variation and other relevant standards

1.2.1 Original kava Code requirements that are unchanged

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:

[8] Section 96 of the FSANZ Act stipulates a maximum of 10 business days comment period on the initial consideration for urgent proposals.
[9] https://www.foodstandards.gov.au/code/proposals/Pages/Proposal-P1057--Review-of-the-kava-standard-.aspx

(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.

1.2.1 The approved variation

The approved variations to the Code for kava made due to this proposal are described below.

1.2.1.1 Noble varieties of kava

Standard 1.1.2 of the Code provides a definition of kava and kava root.

The approved variation varied the definition of 'kava root' in subsection 1.1.2—3(2). The amended definition now 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 is 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.

The same variation to subsection 1.1.2—3(2) was also made to the note to section 2.6.3—2.

1.2.1.2 Prohibition of food additives and processing aids

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.

Amendments made by the approved variation

A new section 2.6.3—5 has been added 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.

1.3 Reasons and procedure for assessing the variation

The FSANZ Act requires FSANZ to - within 12 months - assess the variation and then decide whether to reaffirm the decision to approve the variation or to prepare a proposal to develop a further variation (i.e. amend or revoke the variation, or make other variations). The FSANZ Act also requires FSANZ to call for public submissions after making its assessment, but before making that decision.

1.4 Scope of the review

1.4.1 Focus of the review

Section 99 of the FSANZ Act requires that FSANZ 'must assess the standard or variation' during the 12-month review. The amendments were designed to ensure kava beverage is prepared and consumed in line with historically safe practices. The amendments:

- make explicit the current prohibition on the use of processing aids and food additives in the manufacture or processing of dried or raw kava root and kava beverages, and
- require that kava is sourced from Noble varieties of the kava plant, which have a history of safe use.

It is important to note that the 12-month review is specific to the original purpose and scope of the proposal (noted earlier) and the requirements of the FSANZ Act. It is not an opportunity to conduct a broad review of kava regulation in Australia and New Zealand. If there is a desire to amend the kava standard further than the scope of this proposal (i.e. to permit the addition of food additives e.g. colours or flavours, or the use of processing aids e.g. enzymes in the processing or production of kava beverage) then a food business would need to submit an application to FSANZ to amend the Code.

1.4.2 Other matters

The final consideration report prepared in relation to urgent proposal P1057 – Review of the kava standard stated FSANZ would give consideration to labelling requirements as part of the further assessment of the approved variation (see section 2.2).

The assessment of labelling requirements examined whether the existing warning statements about kava are appropriate and whether new warning and/or advisory statements are needed as risk management options. As noted in the final consideration report (page 17), the application of warning/advisory statements to foods not required to bear a label e.g. bowl of kava beverage, is also considered.

2 Summary of the assessment of the variation

2.1 Review and assessment of the approved variation

FSANZ must decide whether to reaffirm the variation to Standard 1.1.2 and to Standard 2.6.3 (available in Attachment A), or to prepare a proposal to amend the variation to Standard 1.1.2 and to Standard 2.6.3, to repeal the variation, or to make other variations to the Code.

The specific options for the assessment are to:

1. Reaffirm the variation; or
2. Prepare a proposal to further amend the Code to:
    - A Repeal the amendments made by the variation, or
    - B Amend the amendments made by the variation, or
    - C Amend other provisions in the Code.

The review of the specific amendments made by the variation are addressed at section 2.1.1 (Prohibition of processing aids and additives) and section 2.1.2 (Requiring kava to be sourced from Noble varieties) below.

2.1.1 Prohibition on the use of processing aids and food additives

For the reasons set out in the final consideration report, the approved variation amended the Code to prohibit the addition of food additives and the use of processing aids in the manufacture or processing of dried or raw kava root and kava beverages. The justification was that this measure ensures consistency with historically safe kava preparation and consumption practices in line with the original policy intent of the current standard. It is also consistent with the *Codex Regional Standard for Kava Products for use as a Beverage When Mixed with Water* (CXS 336R-2020) (Codex Regional Standard for Kava) as it does not permit the use of food additives in kava products. FSANZ has 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 government enforcement agencies for the explicit prohibition of food additives and processing aids as it provides regulatory clarity.

The regulatory policy intent of the kava standard has been to limit the use of kava to historically safe practices. This standard does not permit nor has it ever permitted the use of food additives or processing aids. Persons wishing to use food additives or processing aids in kava products 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 food additives and processing aids in kava products.

2.1.1.1 FSANZ review assessment

Further desktop research has been conducted by FSANZ during the 12-month review stage of the proposal after the variation to the Code was made.

The final consideration report prepared in relation to urgent proposal P1057 – Review of the kava standard, identified that commercial kava beverage products are on the market or available in Australia and New Zealand via the internet that contain food additives or have been produced using processing aids.

A number of these kava beverage products appear to be manufactured in the USA and available for purchase online. One such product is a flavoured, carbonated canned kava beverage that contains L-theanine (an amino acid) and vitamin B-12[10]. It also contains food additives such as flavourings and carbon dioxide.

A USA bottled kava beverage contains the food additives vegetable glycerine (glycerol) and lecithin[11].

A USA patent from USA and New Zealand partners proposes to use processing aids (enzymes) to process kava beverage as part of processing of the kava beverage to extend the shelf life of the packaged product including at ambient temperature. The patent also proposes pasteurisation (to 65°C or more) and aseptic packaging of the treated beverage[12].

The presence or availability of these products on the market demonstrates the need to more explicitly prohibit the use of processing aids and the addition of food additives to kava beverages in order to achieve the original policy intent of the kava standard. Clarification of the standard in this manner will ensure commercial kava producers are in no doubt of the requirements in the Code that processing aids and food additives are not permitted for use nor have they ever been permitted for use in kava beverages.

2.1.1.2 Risk management options

There are two main options for the management of the review assessment conclusions, being:

- the status quo (maintain the variation), or
- prepare a new proposal to repeal or amend the variation or amend other provisions of the Code.

The assessment of the two options follows.

Option 1: Status quo, reaffirm the approved variation

[10] https://www.leilo.com/
[11] Kava Drink Mix To - Make Kava Drink Recipes - Root of Happiness (rootofhappinesskava.com)
[12] PROCESSING AND PRESERVING A KAVA PRODUCT AND PROCESS OF MAKING IT STABLE

This option will reaffirm the variation so that a prohibition for adding and using food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages is maintained. The further assessment confirms that there are kava beverages available for online purchase by Australian and New Zealand consumers that contain food additives or have been produced using processing aids. The regulatory intent and policy has been to limit kava beverages to historically safe preparation and use practices and this does not permit food additives or processing aids.

Option 2: Prepare a proposal to repeal or amend the variation, or amend other provisions of the Code

This option does not reaffirm the variation to prohibit adding and using food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages. If the assessment at the review stage indicated that it was inappropriate to prohibit the use of food additives or processing aids in the manufacture and production of kava beverages, then a new proposal would be prepared for the development of amendments of the Code to permit this use of food additives or processing aids.

2.1.1.3 Preferred option

The intent of the Code has always been not to permit the use of processing aids (including enzymes), as well as food additives, in kava beverages. Prior to the approved variation being made the Code stated 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 (section 1.2.1.2). There was, and still is, no express permission in the Code.

In addition, section 2.6.3—3 of the Code imposed 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 same rationale is applicable to the use of food additives.

This position was and 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.

The amendments made by the approved variation provide regulatory certainty in relation to the original policy intent of the kava standard. Retaining 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 that, as previously agreed a separate commodity standard - Standard 2.6.3 – still being the appropriate means to regulate kava.

Therefore, FSANZ has not changed its original risk management conclusion and the justification for the variation amendment on the requirement to have regulatory certainty that using food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages should be prohibited. Therefore Option 1 is the preferred option. This ensures consistency with historically safe kava preparation and consumption in line with the original policy intent of the current standard.

2.1.2 Require kava to be sourced only from Noble varieties

For the reasons set out in the final consideration report, the approved variation amended the

Code to require that only Noble kava cultivars named in the Codex Regional Standard for Kava, being the safe varieties for food use, are permitted as sources of kava. This amendment was considered warranted given the potential public health and safety risk posed by other varieties of kava 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 would be consistent with international standards such as the Codex Regional Standard for Kava.

As noted in the SD1 for the final consideration report, there is international acceptance of the importance of using noble kava plant varieties to make kava beverage, outlined in the Codex Regional Standard for Kava, Vanuatu's Kava Act (2002) and national kava standards of Vanuatu, Fiji, Samoa and Tonga. Kava beverage prepared from kava plant material that is contaminated with leaves, stems or bark, or that is not of a noble kava plant variety, can contain higher concentrations of flavokawains and piperidine alkaloids, which can be toxic. Further explanation related to the safety of consuming kava beverage from different varieties of kava and why noble varieties are safe is provided within section 1.3 (varieties of kava plants) of the SD1 of the final consideration report, along with specific references.

There was support provided in submissions from a number of government enforcement agencies and some kava exporting countries for kava only to be sourced from Noble variants. The justification for the request was to ensure public health and safety, and for enforcement purposes, allow kava products produced from non-safe varieties of kava to be identified at the border or in the market if required.

2.1.2.1 FSANZ review assessment

As part of the current review assessment, further investigation was undertaken into why noble varieties of kava are appropriate for food safety reasons. The Kava Society of New Zealand noted: "... the highly desirable kava varieties that have been traditionally consumed daily are known as "noble" kava cultivars. According to Vanuatu's legislation (Kava Act 2002), only noble cultivars can be legally exported from the islands in order to protect the country's kava reputation. The other arguably undesirable cultivars are known as "non-noble"/"other" (in Vanuatu this term encompasses groups of varieties known as "two-day/tudei" and wild kava). While non-noble varieties might have some potential ceremonial or medicinal use, they have not been traditionally consumed due to their higher potential for causing adverse reactions (for example: higher risk of nausea, next day hangover and lethargy) and less pleasant psychoactive effects. Non-noble kavas have undesirable high concentrations of other compounds (flavokavains) that could potentially produce adverse reactions"[13].

No supplementary information was identified that required FSANZ to reconsider the amendment made to the Code that kava should be sourced only from Noble variants. As already noted, there was support from government enforcement agencies and some kava exporting countries for requiring the use of noble cultivars.

2.1.2.2 Risk management options

There are two main options for the management of review assessment conclusions, being the status quo (maintain the variation) or prepare a new proposal to repeal or amend the variation, or amend other provisions of the Code.

Option 1: Status quo, reaffirm the approved variation

[13] https://kavasociety.nz/purity-and-quality

This option reaffirms that only Noble kava cultivars named in the Codex Regional Standard for Kava be permitted as sources of kava.

Further assessment has confirmed that it is appropriate to mandate Noble kava cultivars as sources of kava due to safety concerns related to other varieties of kava. Listing the Noble kava variants referenced in the Codex Regional Standard for Kava is an appropriate approach to identifying the Noble variants.

Option 2 Repeal or amend the variation

This option proposes repealing or amending the variation that only Noble kava cultivars named in the Codex Regional Standard for Kava be permitted as sources of kava. If the assessment at the review stage indicated that it was inappropriate to mandate that only Noble kava cultivars named in the Codex Regional Standard for Kava be permitted as sources of kava then a new proposal would be prepared for the development of amendments of the Code to remove the requirement imposed by the approved variation. No new information has been identified that warranted this option.

2.1.2.2 Preferred option

Further investigation confirmed that only Noble kava cultivars named in the Codex Regional Standard for Kava, being the safe varieties for food use, should be permitted as sources of kava. The explanation and justification provided above still apply. As such, Option 1 is FSANZ's preferred option.

2.2 Assessment of labelling matters

FSANZ assessment of labelling requirements (see SD3) examined:

- whether the existing warning statements about kava are appropriate and whether new warning and/or advisory statements are needed as risk management options, and

- the application of warning/advisory statements to foods not required to bear a label e.g. bowl of kava beverage.

The Code requires dried or raw kava root or a beverage in a package for retail sale (that is not otherwise exempted from labelling) to have a label with the following warning statements:

- *Use in moderation*
- *May cause drowsiness.*

These warning statements must also accompany or be displayed with unpackaged dried or raw kava root for retail sale.

To support the consideration of these labelling matters, FSANZ completed a risk assessment (see SD1 and SD2) which examined:

- how kava beverage is typically consumed in Australia and New Zealand and in what contexts
- understanding of the use of kava beverage amongst Australians and New Zealanders
- kava consumption patterns in Australia and New Zealand
- whether certain population subgroups in Australia and New Zealand (e.g. pregnant

women, lactating women, adolescents, children) are at increased health risks from kava beverage consumption compared with the general population
- whether the co-consumption of kava beverage with alcoholic beverages increases the health risk compared with alcohol consumption alone, and if so, what the risks are
- the evidence for kava beverage consumption causing drowsiness.

Given there has been little change in the evidence base since the risk assessment undertaken by FSANZ in 2002, and there is limited evidence about consumption patterns, FSANZ is proposing to maintain the existing warning statements for permitted kava foods. FSANZ considers there is insufficient evidence of additional health risks from the consumption of kava beverage to justify additional warning or advisory statements on kava foods. Additionally, since the kava pilot is for a two-year duration, it was considered pre-emptive to propose additional changes to those already legislated.

FSANZ also proposes to maintain the current requirements for the application of warning statements to kava foods for retail sale that are not required to bear a label. This includes that the warning statements must be displayed in association with the sale of unpackaged root but not kava beverage when it is not required to bear a label. Retailers have the option of providing the warning statements voluntarily when kava beverage is prepared and packaged (e.g. in a bowl) on the premises from which it is sold or packaged in the presence of the purchaser.

FSANZ expects to prepare information on the consumption of kava and possible health risks for dissemination to the public, in support of education activities by public health agencies.

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 were called to obtain the views of interested parties on issues raised by the proposal and the impacts of regulatory options.

FSANZ acknowledges the time taken by individuals and organisations to make submissions on this full assessment of the approved variation made under the urgent proposal. Every submission on this proposal will be considered by the FSANZ Board. All comments were valued and contribute to the rigour of our assessment.

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.

In the December 2021 initial consideration report FSANZ had concluded that a notification to the WTO was not required. This conclusion was reached noting there is a relevant international kava standard (the Codex Regional Standard for Kava) which was considered to be consistent with the amendments to the Code.

After further consideration, including communications with the Australian Department of Foreign Affairs and Trade, FSANZ concluded that WTO notification was required as the variation may have an effect on trade, especially as the amendments may be considered trade restrictive.

Therefore, a notification to the WTO under Australia's and New Zealand's obligations under the WTO Sanitary and Phytosanitary (SPS) Agreement has been made to enable other WTO members to comment on the amendments.

2.4 FSANZ Act assessment requirements

FSANZ's options under the full assessment are to reaffirm the variation to Standard 1.1.1 and to Standard 2.6.2, available in Attachment 1, or to prepare a proposal to amend the variation, to repeal the variation, or to amend other variations to the Code. In making its assessment, FSANZ had regard to the following matters under section 99 and section 18 of the FSANZ Act.

2.4.1 Section 99

Subsection 99(2) of the FSANZ Act requires FSANZ to have regard to certain specific matters when assessing the variation:

a) whether the costs that have arisen, or will arise, from the variation outweigh the direct and indirect benefits to the community, government or industry that have arisen, or will arise, from the variation
b) whether other measure (available to the Authority or not) would be more cost-effective than the standard or variation
c) all relevant New Zealand standards
d) any other relevant matters.

These matters are considered below.

2.4.1.1 Whether the measure's costs outweigh the benefits

The Office of Best Practice Regulation (OBPR) has indicated in an email dated 4 April 2022 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 kava[14], 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 published[15]. 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, government or industry that may arise from the variation 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

[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)

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. The consideration to address the identified risk concluded that the existing warning statements are appropriate (section 2.2). Ongoing high consumption can result in negative health outcomes. Non-regulatory options, beyond education material proposed as part of the consideration of labelling, 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 the variation are likely to outweigh the costs to the community, Government or industry that would arise from the variation given the benefits identified and the steps proposed to manage any potential harm.

2.4.1.2 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 the variation, which amended the Code to better reflect and implement the stated kava regulatory policy (see above).

2.4.1.3 Whether there are any relevant New Zealand standards

The current regulatory situation related to the kava standard in the Code in New Zealand has been outlined in a notice from the New Zealand Ministry for Primary Industries from 31 March 2022, with the relevant section copied below[16].

In March 2022, amendments were made to the kava standard in the Australia New Zealand Food Standards Code (the Code). While the amendment (number 206) took immediate effect in Australia, the Minister for Food Safety has not adopted the amendment into New Zealand law. New Zealand will do further engagement with the Pasifika community during the next 12 months while Food Standards Australia New Zealand assesses the amendments.

Amendment 206 relates to Proposal P1057. This was an urgent proposal to review the regulation of kava in the Code to ensure it adequately addressed public health and safety – related to the potential increased availability of kava to the wider community.

Kava is a product of significance for New Zealand's Pasifika communities so any changes to the Food Standards Code relating to kava require sufficient time to consider. Further engagement will take place with the Pasifika community to understand the aspirations of the communities and industry, to feed into the review in 12 months and ensure the regulations

[16] https://www.mpi.govt.nz/legal/compliance-requirements/food-standards/

for kava remain fit for purpose in New Zealand. More information on next steps will be available soon.

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.

2.4.1.4 Any other relevant matters

Other relevant matters are considered below.

2.4.2 Subsection 18(1)

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

2.4.2.1 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 while it is possible to safely consume kava beverage in moderation when associated with historically safe preparation and use, there are also risks. 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 Noble cultivars are the safe varieties of kava for food, so they have been mandated in the Code via the variation. The risk assessment and additional risk management considerations were critical in justifying the preparation of the urgent proposal and amending the Code to ensure public health and safety.

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

The current labelling requirements for kava including the prescribed warning statements, provide information to enable consumers to make informed choices.

2.4.2.3 The prevention of misleading or deceptive conduct

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

2.4.3 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 is the case with 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**

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.

However, it is understood that there are domestic kava food industries, especially in New Zealand, that uses imported kava. Such businesses include kava bars, retailers of kava products (essentially kava powder) and kava beverage retailers. As noted earlier, the regulatory situation in New Zealand in relation to this proposal is being separately considered during the 12 months. It is recognised that kava is an integral part of the dynamic and evolving cultural practices of New Zealand's Pasifika communities. The aim of the proposal and variation to the Code was to allow the sale of kava in both Australia and New Zealand for traditional cultural use, while minimising potential health and safety impacts.

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 variations to the Code which 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 the amendments to the Code as an outcome of this urgent proposal 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' Meeting[17]**

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

[17] Formerly the Australia and New Zealand Ministerial Forum on Food Regulation

3 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 26 July 2022

Attachment

A. Approved variation to the Australia New Zealand Food Standards Code

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

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

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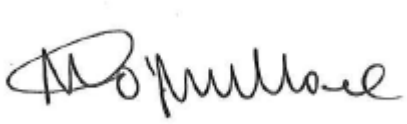
The Board of Food Standards Australia New Zealand gives notice of the making of this variation under section 92 of the *Food Standards Australia New Zealand Act 1991*. The variation commences on the date specified in clause 3 of this variation.

Dated 9 March 2022



Dr Matthew O'Mullane
Delegate of the Board of Food Standards Australia New Zealand

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.