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Reaffirmation of variation (Approval report) – Urgent Proposal P1057

Review of the kava standard

Food Standards Australia New Zealand (FSANZ) has assessed an urgent proposal it prepared to clarify the existing permission for kava in the Australia New Zealand Food Standards Code to ensure continued protection of public health and safety. This proposal was raised 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 approved a draft variation on 7 March 2022. The draft variation was prepared and approved as part of Proposal P1057, which had been declared as an Urgent Proposal under section 95 of the *Food Standards Australia New Zealand Act 1991* (the FSANZ Act).

The FSANZ Act required FSANZ to assess, and then call for public submissions on, the approved variation. FSANZ assessed the approved variation in accordance with section 99 of the FSANZ Act and then called for public submissions on 6 October 2022.

After considering all the submissions received, FSANZ decided on 15 March 2023 to reaffirm its earlier decision to approve the variation. This report sets out the reasons for its decision to reaffirm the variation and is provided pursuant to section 101 of the FSANZ Act.

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Supporting documents

The following documents¹ which informed the assessment of this Proposal are available on the FSANZ website:

Final consideration report – Urgent proposal P1057 (March 2022)

Call for submissions 12 month review (October 2022)

- SD1 Risk and technical assessment (unchanged from Call for Submissions)
- SD2 Social science evidence summary (unchanged from Call for Submissions)
- SD3 Consideration of labelling matters about kava (at Approval)

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 kava standard in the Australia New Zealand Food Standards Code (the Code). The amendments to the Code took effect on 23 March 2022 in Australia but have yet to be adopted in New Zealand. The NZ Government conducted its own consultation on implications for NZ stakeholders.

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, and
- 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.

These amendments arose out of Urgent Proposal P1057. That proposal was prepared to consider whether the Code's existing permissions for kava needed to be clarified to ensure continued protection of 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 Pilot².

The *Food Standards Australia New Zealand Act 1991* (the FSANZ Act) provides that FSANZ must, within 12 months of notification of the approved 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. FSANZ assessed the variation in accordance with section 99 of the FSANZ Act and then called for public submissions on 6 October 2022.

FSANZ's assessment of the approved variation included consideration of whether:

- the existing warning statements about kava are appropriate and whether new warning and/or advisory statements are needed, and
- the application of warning/advisory statements to foods not required to bear a label e.g. a bowl of kava beverage served in a bar.

After considering all submissions received, FSANZ has decided to reaffirm its earlier decision to approve the variation.

The express prohibition on the use of food additives and processing aids in kava manufacture or processing restates and clarifies the regulatory approach that has been in place since 2002 when the Standard was first developed. 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 that relevant Codex standard.

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

FSANZ's assessment remains that it is premature to mandate additional warning/advisory statements for kava at this time, particularly given the evidence has not changed. Additionally, any new mandatory warning/advisory statements could be considered trade restrictive in the context of the limited evidence base for health risks. Existing requirements for warning statements, including for kava foods for retail sale that are not required to bear a label, will remain.

FSANZ intends 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.

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 Food Standards Australia New Zealand (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 Pilot³. The Australian Government Department of Health and Aged Care has commissioned external agencies⁴ to undertake the evaluation of the pilot over a 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 protect public health and safety as noted above. In particular it was to consider whether the 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* (the FSANZ Act) (Attachment C). 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 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 enzymes⁷. This is not the situation for the occasional consumption of kava beverage prepared according to historically safe practices by communities familiar with its consumption.

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>

- 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.

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 2021⁸ are available on the FSANZ website⁹.

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 approval decision are set out in the final consideration report, as is FSANZ consideration of issues raised in the submissions received in 2021.

The approved variations (Attachment A) to the Code were publicly notified on 23 March 2022. In approving the variations, FSANZ committed to considering labelling requirements for permitted kava foods as part of the required 12 month review and further assessment of the approved variation.

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 assessed the approved variation in accordance with section 99 of the FSANZ Act and called for public submissions on 6 October 2022 until 16 November 2022.

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:

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

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>

(b) dried or raw kava root.

This means both the above foods may be sold.

The labelling requirements within Standard 2.6.3 have also not been amended (see section 2.2.3 and SD3).

1.2.1 The approved variation

The approved variations to the Code resulting from 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 amended 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.

In summary 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
- clarified that the use of food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages is prohibited.

1.3 Reasons and procedure for assessing the variation

Sections 99 and 101 of the FSANZ Act requires FSANZ to, within 12 months of notification of an approved variation made under section 97 of the FSANZ Act, 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.

2 Summary of the assessment of the variation

FSANZ’s assessment of the variation was detailed in the [call for submissions](#) (CFS) issued by FSANZ on 6 October 2022.

The CFS noted that:

- 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's assessment of the approved variation, based on the best available scientific evidence, 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 for the addition and use of food additives and processing aids 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 proposed to maintain the existing warning statements (see Section 2.2.3) for permitted kava foods. This assessment was based on the fact that there has been little change in the evidence base compared with that in 2002 when the original standard was developed. There is also insufficient evidence of health risks from the consumption of kava beverage to justify additional warning or advisory statements on kava foods.
- FSANZ also proposed 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.

2.1 Summary of issues raised in submissions

Public submissions were invited on the assessment proposing the reaffirmation of the variation which was released as the CFS report with three Supporting Documents (SD1, SD2 and SD3) between 6 October and 16 November 2022.

Fourteen submissions were received. Of the submissions, 6 were from Australia, 7 from New Zealand and 1 from Samoa. Seven submissions were received from industry, 5 from government agencies and 2 from individuals.

The issues raised in submissions and FSANZ's responses to them are provided in Table 1.

Table 1: Summary of issues and FSANZ response

Issue	Raised by	FSANZ response
Support for the amendments		
Supports the amendments made to the Code, so supports reaffirming them.	New South Wales Food Authority	Noted
Supports the 'proposed draft variations' made to the Code, to: <ul style="list-style-type: none"> • prescribe that kava food products must only be obtained from the Noble varieties of <i>Piper methysticum</i> named in the Codex Regional Standard for Kava • explicitly prohibit the addition of food additives and processing aids in the manufacture or processing of dried or raw kava root and kava beverages. 	Western Australia Department of Health	Noted
Supports reaffirming the amendments to the Code made in March 2022.	Victorian Department of Health, and Department of Jobs, Precincts and Regions	Noted
Issues outside scope of the proposal		
The submission raised issues relating to the use of kava extracts for therapeutic use.	Viktual+	FSANZ's understanding is that kava extracts for therapeutic purposes do not fall within the Food Act's definition of what constitutes a food. As such, they are not regulated by the Code. As noted in the submission, their products are not foods but nutraceutical supplements and as also stated are a matter for MedSafe New Zealand, not FSANZ.
Kava should only be able to be imported by registered businesses with an import licence, and they should have a NZQA food safety certificate. Kava should only be sold in pre-packed sealed packages with full	JC Enterprises trading as Flatbush kava supplies	These comments are noted. However, some of the matters mentioned are not FSANZ's direct responsibility but those of enforcement agencies and so are not matters directly for this proposal. Kava products, like all food sold, must comply with all requirements of the Code including Chapter 3 standards.

Issue	Raised by	FSANZ response
<p>information on the label. Kava bars that prepare kava beverages in-house must comply with strict food safety rules like for all processed foods. It should not be sold in bottles, which is an abuse of a traditional drink. Kava should be restricted for importation for personal use to only 4 kg. Such personal importation should not be allowed to be sold on the black market.</p>		
<p>Risk assessment conclusions or evidence used</p>		
<p>No new evidence assessed as part of the review since the amendment was made.</p>	<p>Individual</p>	<p>As part of the assessment of the variation, FSANZ reviewed the scientific literature for any safety data made available since the urgent phase of the proposal.</p> <p>No new information relevant to the initial toxicological or microbiological assessments was identified. However, using the Social Science Evidence in SD2, additional analysis was possible exploring health and safety risks for sensitive subpopulations, co-consumption with alcohol and kava's sedative properties.</p>
<p>Kava abuse is not a public health and safety issue in New Zealand, which was not the case in Australia which caused the original restrictions. The current proposal continues the unfair trading restrictions on a natural product which has been accepted as a traditional food. The amendments are trade restrictive and do not address food safety.</p>	<p>Samoa Herbs</p>	<p>The current kava standard applies in both Australia and New Zealand and has done so since 2002. The original development of the standard was for public health and safety reasons.</p> <p>The only change to the Code requirements for kava that has occurred due to this urgent proposal was for a public health and safety reason, to ensure kava products can only be prepared from safe Noble varieties consistent with the relevant Codex kava standard. The prohibitions on using food additives and processing aids is to ensure regulatory clarity as they have not been permitted to be used since the standard was first developed. FSANZ therefore does not consider these changes create trade restrictions.</p>
<p>Concern was expressed that some of the research findings used in the risk assessment analysis used for the proposal are produced using tablet forms of kava (kava extracts), which is quite different to traditional kava beverages extracted from kava (the focus of the proposal).</p>	<p>Individual</p>	<p>After consideration of submissions, FSANZ remains satisfied that the kava extract studies that FSANZ used are relevant as part of its risk assessment. FSANZ and other international agencies including the 2016 FAO/WHO report note the lack of studies performed on kava beverages and so have needed to supplement using studies of kava extracts. FSANZ concluded that some studies using kava extracts were relevant to the total weight of evidence supporting kava beverage safety. More information explaining this issue is provided within SD1 or the earlier Urgent Phase</p>

Issue	Raised by	FSANZ response
<p>Suggests that FSANZ not rely upon Australian research reports addressing kava usage in Arnhem Land in Australia by Australian First Nations communities in the 1980s and 1990s which reported health concerns. It is claimed these studies are highly subjective and contestable. It is further claimed such studies scapegoated kava usage when other factors were more important to the health issues First Nation communities suffered during this time.</p>	<p>Individual</p>	<p>Risk and technical assessment document (SD1 for the Final assessment report).</p> <p>FSANZ has considered published reports of kava consumption in Arnhem Land as part of the total body of evidence relating to kava in Australia and New Zealand (see SD1). This is consistent with the FSANZ risk analysis framework which follows international best practice. The body of evidence considered by FSANZ for its risk assessment is comparable with the information considered for the 2016 FAO/WHO technical report on kava.</p> <p>FSANZ recognises there are potential confounders associated with these studies and has considered the findings within that context. Notably, after reviewing the total evidence available, including the Arnhem Land reports, FSANZ concluded that it is possible to safely consume kava beverage in moderation, when prepared and consumed in line with historically safe cultural practices.</p>
<p>Suggests that FSANZ review studies that have been provided with the submission on the effect kava has on cognition. This request is to limit misrepresenting kava's impact and the use of the term 'kava intoxication' which perpetuates misinformation.</p>	<p>Individual</p>	<p>FSANZ understands that kava consumption does not result in a state of intoxication comparable to that induced by alcohol consumption. The term 'intoxication' in SD2 (Social Science Evidence Summary) was used in the context of direct quotes from individuals, or in relation to alcoholic intoxication when alcohol is mixed with kava. FSANZ does not consider its section on kava consumption and driving within SD2 misrepresents kava's impact on cognition.</p>
<p>General comments and issues raised</p>		
<p>The proposal kills the innovative use of kava as an herbal remedy in a palatable manner (the example used is a kava-banana smoothie). It is not for New Zealand or Australia to determine what is historically safe and culturally appropriate. Samoan culture is a growing culture and it is not for anyone to tell the market what is acceptable or not.</p>	<p>Samoa Herbs</p>	<p>The amendments clarified existing requirements that have been in place and part of Australian and New Zealand foods laws since being approved by Australian and New Governments in 2002. The regulatory approach and intent set by Governments when making that decision was not changed by the amendments.</p> <p>FSANZ notes that key objectives of the Australian and New Zealand Food Acts and of the Code include the protection of public health and safety and ensuring that consumers can make informed decisions. As noted by other submitters, the prohibition set by Food Ministers on adding kava to other foods or other ingredients to kava products ensures, among other things, that unsuspecting consumers are not misled into consuming food products containing kava and then having the unexpected reaction that kava provides.</p> <p>FSANZ notes that anyone can apply to vary the Code, including the restriction noted</p>

Issue	Raised by	FSANZ response
<p>Requests that:</p> <ul style="list-style-type: none"> FSANZ provide reasoning for why the proposal is only considering amendments to existing Standard 2.6.3 to ensure it continues to protect public health and safety following the commencement of commercial importation of kava into Australia the FSANZ Board does not consider the proposal until such time as they have appointed a team, similar to that of an ANZ [Aotearoa New Zealand] <i>Royal Commission</i>, to fully review kava research, policy and regulation in that country [to address various issues listed in the submission] the urgent P1057 proposal amendment, which was pushed through without consultation with ANZ, is called out and publicly responded to. 	<p>Individual</p>	<p>by the submitter. Information on making an application to amend the Code is available on FSANZ's website: Changing the Code (foodstandards.gov.au)</p> <p>The reasons for the Proposal's scope are detailed in this report and in the previous consideration reports and call for submissions and related supporting documents.</p> <p>FSANZ is required to assess the proposal in accordance with the FSANZ Act. That Act requires FSANZ to review the approved draft variation and provide a decision and a report to Australian and New Zealand Food Ministers within 12 months (i.e. by date 23 March 2023).</p> <p>The establishment of royal commissions or similar types of inquiries are a matter for Government, not FSANZ.</p> <p>FSANZ also notes the consultation being undertaken by the New Zealand Government on this issue.</p> <p>FSANZ does not agree that the approved variation was 'pushed through without consultation'. The proposal and variations have been the subject of two public calls for submissions. Public notification and consultation occurred in both Australia and New Zealand, and submissions from both countries were received and taken into account. All related documents were and are publicly available.</p>
<p>Arguments are made that kava usage should not be seen as having negative social impacts as kava is not addictive so attendance at social gatherings is voluntary. This is in relation to FSANZ's statement that 'Kava is acknowledged to have potential negative social effects associated with the psychological effects of tiredness and lethargy, which can reduce heavy users' involvement in familiar, community, and economic life'. There are also social benefits from such gatherings as being 'cultural classrooms' and quality discussions</p>	<p>Individual</p>	<p>The relevant section in SD2 (Social Science Evidence Summary) reports the findings from ethnographies conducted by and within Pasifika communities who have experience with kava. The participants in these ethnographies reported kava as having negative social effects in addition to beneficial sociocultural impacts. FSANZ has considered this qualitative information as part of the total body of evidence relating to kava in Australia and New Zealand, as is consistent with the FSANZ risk analysis framework and international best practice.</p>

Issue	Raised by	FSANZ response
<p>occur.</p> <p>Notes that the cultural and commercial experiences of kava may be different in New Zealand to Australia. The suggestion is that more data on current patterns of kava consumption and hazard data is needed to properly characterise the risk to public health. Furthermore, more information is required on how kava is commonly consumed currently by traditional users.</p>	<p>New Zealand Food Safety (part of the Ministry for Primary Industries)</p>	<p>FSANZ's assessment was and is based on the best available scientific evidence, as required by the FSANZ Act.</p> <p>FSANZ notes that this proposal was the result of a request by Australian and New Zealand Governments to prepare an urgent proposal to review the Code provisions relating to kava for the reasons and in the circumstances stated elsewhere in this report. Having prepared a proposal in accordance with that request, FSANZ must assess it in accordance with the FSANZ Act. That Act requires FSANZ to review the approved draft variation and provide a decision and a report to Australian and New Zealand Food Ministers within 12 months (i.e. by 23 March 2023).</p> <p>FSANZ also notes that MPI and other relevant New Zealand government agencies are undertaking their own 12-month review of the kava amendments in terms of their application in New Zealand¹⁰.</p>
<p>A number of comments and arguments are made requesting the removal of the amendment to the kava standard preventing the takeaway of kava beverage from the place of preparation, for example their business.</p>	<p>Kumete Group Limited</p>	<p>The approved variation did not contain such an amendment. FSANZ removed the earlier suggestion to only allow immediate consumption of kava beverage at the place of preparation and so prevent the takeaway of prepared kava beverage. See the Final consideration report of March 2022.</p>
<p>Prohibition of use of processing aids</p>		
<p>Shelf stable kava beverage has been produced using research developed in New Zealand. The beverage was prepared using the traditional cold water extraction method and stabilised using a processing aid. This research work culminated with the commercial release of products permitted by MPI. It therefore opposes the amendment to prevent the use of processing aids in the production of kava food products which it</p>	<p>Kava Society</p>	<p>Noted.</p> <p>As stated above, the amendments made by the approved variation - including the express prohibition on the use of food additives and processing aids - clarified existing requirements that have been in place and part of Australian and New Zealand Foods laws since being approved by Australian and New Governments in 2002. The regulatory approach and intent set by the Australian and New Zealand Governments when making that decision was not changed by the amendments. It has also been a matter of public record since that decision (see documents, specifically the Final Assessment Report (FAR) for Proposal P256 – Review of kava and the earlier history of the kava standard 2.6.3 summarised within the FAR</p>

¹⁰ <https://www.mpi.govt.nz/legal/compliance-requirements/food-standards/>

Issue	Raised by	FSANZ response
<p>feels is unjustified. There is not evidence or arguments provided to indicate that using processing aids to stabilise via pasteurisation makes the kava beverage less safe. It should actually make it safer by reducing any microbial contamination. Pasteurising without processing aids produces a substantially different kava product with dramatically higher viscosity and altered flavour and aroma. It is also very hard (if not impossible) to determine whether processing aids were used in the manufacture of a packaged product so enforcement becomes very difficult.</p> <p>Questions how the use of processing aids can cause a kava beverage produced in the traditional cold water method with kava powder that meets import requirements to become a threat to public health. Processing aids are used to increase the quality and hygiene of the kava beverage produced and processed in a commercial food packaging facility.</p> <p>It is proposed that premixed kava beverage in a package (plain bottle) that has been stabilised to increase the shelf life be permitted.</p> <p>Supports preparing a new proposal to repeal or amend the variation to remove the prohibition on using food additives and processing aids in the manufacture or preparation of kava food products. It notes that the Codex Regional Standard for Kava does not permit the use of food additives in kava products captured by it, though it is silent on the use of processing aids. It notes that some manufacturers [of</p>		<p>https://www.foodstandards.gov.au/code/proposals/Documents/P256_Kava_FAR.pdf.</p> <p>FSANZ is unable to comment on what may or may not have been decided or approved by regulators under their particular legislation.</p> <p>Anyone can make an application at any time to amend the Code, including to permit the use of a food additives or processing aids in the manufacture of kava food products. Information on making an application to amend the Code is available on FSANZ's website: Changing the Code (foodstandards.gov.au)</p>
<p>Questions how the use of processing aids can cause a kava beverage produced in the traditional cold water method with kava powder that meets import requirements to become a threat to public health. Processing aids are used to increase the quality and hygiene of the kava beverage produced and processed in a commercial food packaging facility.</p> <p>It is proposed that premixed kava beverage in a package (plain bottle) that has been stabilised to increase the shelf life be permitted.</p>	<p>Kumete Group Limited</p>	<p>Noted. See above.</p>
<p>It is proposed that premixed kava beverage in a package (plain bottle) that has been stabilised to increase the shelf life be permitted.</p>	<p>Individual</p>	<p>Noted. See response above. FSANZ also notes its response to this issue in the previous reports for this proposal.</p>
<p>Supports preparing a new proposal to repeal or amend the variation to remove the prohibition on using food additives and processing aids in the manufacture or preparation of kava food products. It notes that the Codex Regional Standard for Kava does not permit the use of food additives in kava products captured by it, though it is silent on the use of processing aids. It notes that some manufacturers [of</p>	<p>Complementary Medicines Australia (CMA)</p>	<p>Noted. See response above.</p>

Issue	Raised by	FSANZ response
<p>kava extracts or kava therapeutic products] may add small amounts of flow agents [anti-caking food additives] or other excipients to maintain the desired compositional characteristics (such as free flowing powder) or stability of commercial products.</p>		
<p>Prohibition of use of food additives</p>		
<p>The only argument provided that food additives should not be permitted to be added to kava food products is that their use is inconsistent with historical safe use. There does not seem to be any explicit safety concern. However, it is noted that adding flavours, which are food additives, to mask the flavour of kava to allow broader consumption of kava by consumers not familiar or aware of its unique effects should not be permitted. This argument is similar to that made not to prohibit the addition of other foods to kava food products or kava as an ingredient to other foods.</p>	<p>Kava Society</p>	<p>Noted.</p> <p>As stated above, the amendments made by the approved variation - including the express prohibition on the use of food additives and processing aids - clarified existing requirements that have been in place and part of Australian and New Zealand Foods laws since being approved by Australian and New Governments in 2002. The regulatory approach and intent set by the Australian and New Zealand Governments when making that decision was not changed by the amendments. It has also been a matter of public record since that decision. The earliest publicly available documents are those for P256 – Review of kava¹¹.</p> <p>In its assessment and decision, FSANZ has regard to among other things the best available scientific evidence. This includes evidence of risk - see in this regard the supporting document (SD1) and studies cited therein.</p> <p>FSANZ notes that anyone can make an application at any time to amend the Code, including to permit the use of a food additive in the manufacture of kava food products. Information on making an application to amend the Code is available on FSANZ's website: Changing the Code (foodstandards.gov.au)</p>
<p>The same comments to those related to the prohibition on using processing aids are made.</p>	<p>CMA</p>	<p>Refer above comments regarding the prohibition on using processing aids.</p>
<p>Noble varieties of kava plant</p>		

¹¹ [Proposal P256 - Review of Kava \(Standards O10/2.6.3\) \(foodstandards.gov.au\)](http://www.foodstandards.gov.au)

Issue	Raised by	FSANZ response
<p>Agree with requiring that kava food products are only obtained from the Noble varieties of the species of <i>Piper methysticum</i> that are named in the Codex Regional Standard for Kava. This is consistent with international standards, being Codex, Vanuatu's Kava Act (2002) and national kava standards of Vanuatu, Fiji, Samoa and Tonga.</p>	<p>Kava Society Fiji Kava Ltd CMA</p>	<p>The support is noted.</p>
<p>Requests the variety of the kava is required to be declared on the label as it is not possible to analytically determine whether kava has been sourced from Noble varieties for checking compliance at the border.</p>	<p>DAFF</p>	<p>Noted.</p> <p>FSANZ's view, having regard to the evidence is that such a measure would be unwarranted.</p> <p>A requirement that the label state the specific kava Noble variety cannot of itself guarantee that the kava food is actually that variety.</p> <p>Advice to FSANZ is that analytical methods are available that can distinguish whether the kava food is from a Noble variety or not. See the submission from Fiji Kava Ltd. In subsequent correspondence with FSANZ, that submitter also provided references for these analytical methods and noted that the Analytical Research Laboratory at Southern Cross University in Lismore, NSW uses these methods.</p>
<p>Suggests that if the amendment is introduced that a market survey be conducted and stakeholders worked with to ensure there are transitional or other arrangements in place.</p>	<p>CMA</p>	<p>Noted.</p> <p>FSANZ notes that the approved variations commenced in March 2022.</p>
<p>Labelling – advisory/warning statements and claims</p>		
<p>Does not support FSANZ's proposal to defer consideration of additional warning statements until the conclusion of the kava pilot. Considers a proposal should be prepared now.</p>	<p>New South Wales Food Authority</p>	<p>FSANZ is required to assess the approved draft variation in accordance with the FSANZ Act which requires among other things, that FSANZ have regard to the best available scientific evidence.</p> <p>The data available, particularly in terms of consumption, does not support the</p>

Issue	Raised by	FSANZ response
<p>Recommends additional warning/advisory statements about kava beverage consumption are required in relation to sensitive subpopulations (pregnant and lactating women, children, individuals with reduced liver function) and kava consumption with alcohol.</p>		<p>additional warning/advisory statements. The risk assessment concludes there is limited data available to identify sub-populations at greater risk of adverse effects from kava beverage consumption. In addition, while kava beverage consumption appears to be increasing in Australia and New Zealand, there is limited consumption data available.</p> <p>FSANZ has decided the limited available evidence does not support mandating additional warning/advisory statements on kava foods at this time (see SD1, SD3). However, FSANZ plans to prepare information on the consumption of kava and potential health risks for dissemination to the public, in support of education activities by public health agencies.</p> <p>Furthermore, as other overseas countries and the Codex Standard for kava do not require warning/advisory statements, mandating any new statements could be considered trade restrictive in the context of the limited evidence base for health risks.</p>
<p>Suggests warning statements about kava in relation to vulnerable populations (e.g. children, pregnant and lactating women and people with reduced liver function) should be required on food products similar to requirements for therapeutic goods so there is a consistent message. The Australian Alcohol and Drug Foundation, the New Zealand Kava Society, and the Victorian Better Health Channel provide similar messages.</p> <p>Does not understand FSANZ's explanation of why it might not be appropriate for warning statements about kava beverage to be the same as those on kava complementary medicines or therapeutic goods (see SD3, p10).</p> <p>FSANZ's risk import statement states that kava should not be consumed by pregnant or lactating females, adolescents or</p>	<p>NSW Food Authority Victorian Dept Health and Victorian Dept Jobs, Precincts and Regions</p>	<p>FSANZ plans to prepare educational materials about the potential risks of consuming kava foods. FSANZ considers there is not sufficient evidence to mandate additional warning statements on kava food products. See section 5.1.2 in SD3.</p> <p>Kava foods and kava therapeutic products are different products. While both have a physiological effect, they are each consumed for different reasons/purposes. See sections 3.3.1 and 5.1.2 in SD3. As discussed above, the limited evidence does not support mandating additional warning/advisory statements.</p>
<p>FSANZ's risk import statement states that kava should not be consumed by pregnant or lactating females, adolescents or</p>	<p>DAFF Dept Health WA</p>	<p>See first labelling response above.</p>

Issue	Raised by	FSANZ response
<p>children. Recommends FSANZ consider requiring such a warning statement to be included in the label.</p> <p>Considers a precautionary approach is warranted in respect to the inclusion of additional public safety warnings and advisory statements as a mandatory requirement for the sale of kava food products. Given the potential for changing consumption patterns amongst the general population, there is a clear need for advisory/ warning/cautionary statements. For example, statements aimed at children, adolescents, pregnant or lactating women, individuals sensitive to kava.</p> <p>Questions the existing warning statements in the context that FSANZ has not undertaken any studies about kava consumption and has acknowledged the lack of significant risk.</p>	<p>Dept Health WA</p>	<p>See first labelling response above.</p> <p>The data available, particularly in terms of consumption, does not support the additional warning/advisory statements. The risk assessment concludes there is limited data available to identify sub-populations at greater risk of adverse effects from kava beverage consumption. In addition, while kava beverage consumption appears to be increasing in Australia and New Zealand, there is limited consumption data available.</p>
<p>Proposes a third warning statement (<i>Combining kava with alcohol, or drinking alcohol in the hours immediately following kava, can cause liver damage</i>) for the following reasons:</p> <ul style="list-style-type: none"> - solvent extracted kavalactones for use in nutraceutical forms of kava are suspected of causing a chemotype disruption to properties in kava that may cause damage to the liver - some people mix alcohol with, or drink alcohol after, kava and alcohol is known to potentiate the effects of kava and is anecdotally reported to cause hepatotoxicity in some users. 	<p>Individual</p>	<p>FSANZ is required to consider the best available evidence in its risk assessments. Given the similar nature of the evidence identified in the current risk assessments (SD1, SD2) to that presented in P256, FSANZ considers the existing warning statements are justified (see section 5.1.1 in SD3).</p>
<p>Proposes a third warning statement (<i>Combining kava with alcohol, or drinking alcohol in the hours immediately following kava, can cause liver damage</i>) for the following reasons:</p> <ul style="list-style-type: none"> - solvent extracted kavalactones for use in nutraceutical forms of kava are suspected of causing a chemotype disruption to properties in kava that may cause damage to the liver - some people mix alcohol with, or drink alcohol after, kava and alcohol is known to potentiate the effects of kava and is anecdotally reported to cause hepatotoxicity in some users. 	<p>Individual</p>	<p>There is insufficient evidence currently available to establish a causal link between instances of hepatotoxicity and the co-consumption of alcohol with kava beverage. On this basis, FSANZ considers a warning statement about kava and alcohol co-consumption potentially causing liver damage is unjustified (see section 4.3 in SD1 and section 5.1.2 in SD3).</p>

Issue	Raised by	FSANZ response
<p>Current evidence does not warrant a liver toxicity warning.</p> <p>While evidence for impairment of driving from kava beverage consumption is mixed at best, a warning related to driving and operating heavy machinery has been added to all drinking kava products.</p>	Fiji Kava	Noted
<p>Changes in labelling at the mid-point of the pilot trial period would place an unreasonable and unnecessary burden on importing companies.</p>	Fiji Kava	FSANZ has not proposed changes to the labelling requirements.
<p>Due to the border prohibition having been in place for many years, the availability and type of kava food products in Australian marketplace has been significantly restricted. Therefore, it is unlikely that food businesses would be adversely impacted to any significant degree by new warning labelling requirements, that is, labelling costs would be minimal.</p>	Dept Health WA	As required under the FSANZ Act, FSANZ has to consider costs and benefits of proposed changes to the Code. As discussed above and in section 5.1.2 of SD3, FSANZ has decided that there is limited evidence about health risks and kava consumption (SD1, SD2, SD3), it is premature to mandate additional warning statements at this time. The two year kava pilot will also be reviewed ¹² so it is unclear what the future of kava importation to Australia will be at the end of the trial.
<p>FSANZ should allow limited claims for kava products presented as foods in line with the established body of evidence. For example: 'soothing the nerves', 'supporting relaxation', 'natural sleeping aid' and 'stress relief.</p>	Fiji Kava	Section 1.2.7—4 of the Code prohibits nutrition content and health claims made about kava. Consideration of permissions for claims about kava is out of scope of this proposal.
Importance to Pasifika communities		
<p>Care is needed to be exercised by FSANZ when considering any amendments in regulations that could lead to restrictions to access and availability of kava, particularly</p>	Individual	Noted Submissions from Pacific peoples and Māori were welcome to this proposal and have been considered.

¹² <https://www.dfat.gov.au/sites/default/files/australia-commercial-kava-pilot-monitoring-evaluation.docx>

Issue	Raised by	FSANZ response
<p>for Pacific peoples and Māori [both in New Zealand and Australia].</p> <p>Any future changes to the regulation of kava in New Zealand should actively consult with New Zealand-based Pacific health researchers who have studied the use of kava among Pacific peoples, together with the kava using community themselves.</p> <p>A number of comments were made which can be summarised as the culture of kava drinking practices evolve and it is not up to FSANZ to define what is traditional kava consumption.</p>	<p>Individual</p> <p>Kumete Group Limited</p>	<p>Noted.</p> <p>As noted above, the amendments made by the approved variation clarified existing requirements that have been in place and part of Australian and New Zealand food laws since being approved by Australian and New Governments in 2002. The regulatory approach and intent set by Governments when making that decision was not changed by the amendments.</p> <p>That regulatory intent was and is that wholesale and retail sale of kava in Australia and New Zealand should only allow sales of kava in line with its historically safe preparation and use. This policy recognises that kava beverage has significant cultural importance for communities throughout Micronesia, Melanesia and Polynesia, and has been consumed for more than 1000 years. It policy acknowledges the long history of kava beverage consumption in the Pacific and its important and ongoing role as an integral part of the evolving cultural practices of many Pacific peoples. This significant history of use demonstrates that it is possible to safely consume kava beverage in moderation when prepared and consumed in line with historically safe practices.</p> <p>FSANZ notes that anyone can make an application at anytime to amend the Code, including to permit the use of food additives in the manufacture of kava food products. Information on making an application to amend the Code is available on FSANZ's website: Changing the Code (foodstandards.gov.au)</p>
<p>A number of comments were made that amendments to the Code due to the proposal which cause any restriction on kava use in New Zealand would:</p> <ul style="list-style-type: none"> • counter the New Zealand Bill of Rights, and • counter Māori cultural rights under 	<p>Kumete Group Limited</p>	<p>Noted.</p>

Issue	Raised by	FSANZ response
the Treaty of Waitangi. States that 'Australia and New Zealand have had different rules regarding kava for many years'.		

2.2 Risk assessment and risk management conclusions

Additional detail on reasons for the amendments to the Code taken at the urgent stage of the proposal, as well as explanations related to labelling considerations at the CFS stage, is provided below.

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

However, kava beverage has a demonstrated potential to become a substance of abuse in certain contexts, and high consumption can result in intakes of kavalactones (the active ingredient of kava) that adversely impact health and well-being. Evidence of negative health outcomes have been observed in communities with established patterns of ongoing high-level consumption of kava beverage. Such ongoing high-level consumption has been associated with a scaly skin rash, altered liver function and other general reductions in overall health. Kava is acknowledged to have potential negative social effects as a result of the tiredness and lethargy it can cause, which can reduce heavy users' involvement in familial, community, and economic life (SD2).

2.2.1 Prohibition on using food additives and processing aids

The intent of the Code and in particular the Kava Standard was and is to limit the use of kava to historically safe practices. The Code did not permit use of food additives or processing aids. Persons wishing to use food additives or processing aids in kava products had the option of applying to FSANZ to vary the Code to provide the required permission.

The approved variation clarified that intent and maintained that situation.

Persons wishing to use food additives or processing aids in kava products remain free to apply to FSANZ to vary the Code to provide the required permission.

2.2.2 Require kava to be sourced only from Noble varieties

The approved variation amended the Code to require that only Noble kava varieties 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.

It is understood that there are methods to differentiate between kava varieties. The submitter Fiji Kava Ltd noted it gets its kava products analytically tested to ensure they are sourced from Noble varieties at the Analytical Research Laboratory at Southern Cross University in Lismore, NSW. It also provided a number of references relating to such analytical

methods^{13,14,15}. 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.

2.2.3 Labelling considerations

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. a bowl of kava beverage served in a bar.

The Code requires dried or raw kava root or a beverage in a package for retail sale (that is not otherwise exempt 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 labelling matters (see SD3), 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
- 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.

While industry submitters were generally supportive of maintaining the existing warning statements and not requiring any new warning/advisory statements, some government submitters asked for further consideration of new warning/advisory statements for a range of health risks. FSANZ maintains that since there is limited evidence about health risks and kava consumption (see SD1, SD2, SD3), it is premature to mandate additional warning/advisory statements at this time. The two year kava pilot will also be reviewed¹⁶ so it is unclear what the future of kava importation to Australia will be at the end of the trial. Additionally, any new mandatory warning/advisory statements could be considered trade

¹³ Lebot, V., Legendre, L. 2016. Comparison of kava (*Piper methysticum* Forst.) varieties by UV absorbance of acetonitrile extracts and high-performance thin-layer chromatography. *J Food Compos. Anal.* 48, 25-33

¹⁴ Lhuissier, T., Mercier, P-E, Michalet, S, Lebot, V. 2017. Colorimetric assessment of kava (*Piper methysticum* Forst.) quality. *J Food Compos. Anal.* 59, 27-34

¹⁵ Lebot, V., Michalet, S., Legendre, L. 2019. Kavalactones and flavokavins profiles contribute to quality assessment of kava (*Piper methysticum* Forst.), the traditional beverages of the Pacific. *Beverages*, 5, 34. <https://doi.org/10.3390/beverages5020034>.

¹⁶ <https://www.dfat.gov.au/sites/default/files/australia-commercial-kava-pilot-monitoring-evaluation.docx>

restrictive in the context of the limited evidence base for health risks. The existing warning statements provide consumers with information about moderating consumption and an impact on the body (drowsiness) that is reportedly commonly experienced (SD1).

FSANZ is also maintaining 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. Due to the limited evidence about consumption practices, FSANZ considers it is not appropriate to mandate the display of warning statements when kava beverage is not required to bear a label.

FSANZ intends 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 Decision

Section 101 of the FSANZ Act requires FSANZ, after the public submission period and after taking into account all submissions made in that period, to do one of the following:

- (a) reaffirm its decision to approve the P1057 variation, or
- (b) prepare a proposal for the further variation of the Code as amended by that variation.

Section 101 requires the above to occur within 12 months of the date that the P1057 variation came into effect i.e. by 23 March 2023.

Having regard to all the submissions received and to other matters prescribed by the FSANZ Act (see below), FSANZ has reaffirmed its decision to approve the variation made to Standards 1.1.2 and 2.6.3 in March 2022. The March 2022 approved variation and accompanying explanatory statement can be found at Attachments A and B respectively.

2.4 Risk communication

2.4.1 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 channels.

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 has been considered by the FSANZ Board. All comments were valued and contribute to the rigour of our assessment.

2.4.2 World Trade Organization (WTO)

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.

Therefore, a notification to the WTO under Australia's [and New Zealand's] obligations under the WTO Sanitary and Phytosanitary (SPS) Agreement was made to enable other WTO members to comment on the amendments. No comments were received.

2.5 FSANZ Act assessment requirements

2.5.1 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.

2.5.1.1 Consideration of costs and benefits

The Office of Impact Analysis (OIA)¹⁷ has indicated in an email dated 4 April 2022 that the changes being proposed to the Code were consequential changes to give effect to the intention of the Government's decision to conduct a 2-year trial on the commercial importation of kava¹⁸, 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 OIA and has been published¹⁹. Given this, OIA 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 and industry that may arise from the variation in order to meet the requirements of the FSANZ Act.

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, limit the kava varieties used, 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

¹⁷ Formerly known as the Office of Best Practice Regulation (OBPR)

¹⁸ It is important to note that the 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 until any amendments as a result of any future proposal or application.

¹⁹ [Pilot program to allow commercial importation of kava | OBPR \(pmc.gov.au\)](https://www.pmc.gov.au/pilot-program-to-allow-commercial-importation-of-kava)

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 and SD3). 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.

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. Benefits from the importation of kava such as providing more economic opportunities in our region and allowing Pacific diaspora to more easily practice their culture are maintained. However, the health risks associated with its inappropriate use outside of its historically safe uses have been significantly reduced.

2.5.1.2 Other measures

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 Section 1 above).

2.5.1.3 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 below²⁰.

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 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 are directly related.

²⁰ <https://www.mpi.govt.nz/legal/compliance-requirements/food-standards/>

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.

2.5.1.4 Any other relevant matters

Other relevant matters are considered below.

2.5.2 Subsection 18(1)

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

2.5.2.1 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 current labelling requirements were originally mandated as a risk management response.

The risk assessment also concluded that Noble varieties are the safe varieties of kava for food. Kava food products can therefore only be obtained from Noble varieties as a result of the approved variation. The risk assessment and additional risk management considerations were critical in justifying the amendment to the Code to ensure public health and safety.

2.5.2.2 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.

2.5.2.3 The prevention of misleading or deceptive conduct

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

2.5.3 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 1.2.1.1, 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 will require that kava be sourced from Noble varieties 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 use imported kava. Such businesses include kava bars, retailers of kava products (e.g. 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 opportunity. 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 assist in the promotion of fair trading in kava and kava products.

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

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

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 8 November 2022

Attachments

- A. Approved variation to the Australia New Zealand Food Standards Code
- B. Explanatory Statement
- C. Declaration of urgency

Attachment A – Approved 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 9 March 2022

A handwritten signature in black ink, appearing to read "Dr Matthew O'Mullane".

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.

Attachment B – Explanatory Statement

1. Authority

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

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

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

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

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

2. Purpose

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

3. Documents incorporated by reference

The variation in this instrument incorporates a document by reference.

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

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

4. Consultation

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

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

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

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

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

5. Statement of compatibility with human rights

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

6. Variation

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

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

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

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

Transitional arrangements

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

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

Attachment C – Declaration of Urgency

COMMONWEALTH OF AUSTRALIA

FOOD STANDARDS AUSTRALIA NEW ZEALAND

FOOD STANDARDS AUSTRALIA NEW ZEALAND ACT 1991

DECLARATION OF URGENCY

I, Glen Neal, an authorised Delegate for the purposes of section 95 of the Food Standards Australia New Zealand Act 1991 (the FSANZ Act), hereby declare under paragraph 95(1)(b) of the FSANZ Act that, in order to protect public health and safety, **Proposal P1057 – Review of the kava standard** is an urgent proposal for the purposes of Part 3, Division 4 of the FSANZ Act.



GLEN NEAL
GENERAL MANAGER – RISK MANAGEMENT AND INTELLIGENCE

12 November 2021