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Te Mana Kounga Kai – Ahitereiria me Aotearoa

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Supporting document 3

Consideration of labelling matters about kava

12 month review of Proposal P1057

Executive summary

In late 2021 and early 2022, Food Standards Australia New Zealand (FSANZ) prepared urgent proposal P1057 – Review of kava standard. The purpose of the proposal was to consider whether the kava provisions in the Australia New Zealand Food Standards Code (the Code) needed to be amended following the Australian Government's decision to allow the commercial importation of kava from 1 December 2021 under Phase 2 of the Pacific Step-up Kava Pilot.

In March 2022 the FSANZ Board approved the variations to the Code in the Final consideration report of the urgent stage of the proposal. In the Final consideration report FSANZ stated it would consider specific labelling matters as part of the further assessment of the approved variation which has to be undertaken within 12 months of notification of the approved variation.

This assessment of labelling requirements examines:

- 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.

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 (SD1,SD2), it is premature to mandate additional warning/advisory statements at this time. Additionally, any new mandatory warning/advisory statements could

be considered trade restrictive in the context of the limited evidence base for health risks. The two year kava pilot will also be reviewed[1] so it is unclear what the future of kava importation to Australia will be at the end of the trial. The existing warning statements provide consumers with information about moderating consumption and an impact on the body (drowsiness) that is reportedly commonly experienced.

FSANZ is also maintaining the current requirements for application of warning statements to kava foods for retail sale 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. 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 general public, in support of education activities by public health agencies.

[1] https://www.dfat.gov.au/sites/default/files/australia-commercial-kava-pilot-monitoring-evaluation.docx

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1 Introduction

In late 2021, Food Standards Australia New Zealand (FSANZ) prepared urgent proposal P1057 – Review of kava standard. The purpose of the proposal was to consider whether the kava provisions in the Australia New Zealand Food Standards Code (the Code) needed to be amended following the Australian Government's decision to allow the commercial importation of kava from 1 December 2021 under Phase 2 of the Pacific Step-up Kava Pilot.

In March 2022 the FSANZ Board approved the variations to the Code in the Final Consideration report of the urgent stage of the proposal.

FSANZ decided it would consider specific labelling matters as part of the further assessment of the approved variation which has to be undertaken within 12 months of notification of the approved variation.

2 Approach for consideration of labelling matters

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.
- 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.

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 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.

Views from submitters to the Call For Submissions (Urgent Proposal and for this Review) and other relevant information have also been considered in this labelling assessment.

3 Background

3.1 Labelling requirements for kava[2]

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

[2] All the labelling requirements for kava are on the FSANZ website. Proposal P1057 - Review of the kava standard (foodstandards.gov.au)

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

- not in a package[3] (e.g. kava root may be sold unpackaged)
- made and packaged on the premises from which it is sold (e.g. a beverage in a bowl or glass or bottle)
- packaged in the presence of the purchaser (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 exempt from labelling as set out in 1.2.1—8(1)) to have a label with the following warning statements (sections 1.2.1—6, 1.2.1—8, 2.6.3—4):

- *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 (section 1.2.1—9, paragraph 1.2.1—9(3)(f)).

For food sold to caterers in a package, the two warning statements about kava must be provided on the label (if any) or in documentation (subsection 1.2.1—16(1)).

3.2 Previous consideration of warning statements about kava

The warning statements (*use in moderation*; *may cause drowsiness)* were included in Standard O10 in Volume 1 of the Australia Food Standards Code in 1997 under Application A242 - Kava. While a risk assessment was undertaken, the rationale for mandating warning statements and the specific wording are unknown. When the joint Australia New Zealand Food Standards Code was prepared, Standard O10 was converted into Standard 2.6.3.

A full review of Standard 2.6.3, including labelling requirements, commenced in 2002 under Proposal P256 – Review of Kava. A safety assessment was undertaken for traditionally prepared kava beverage and kava extracts. The risk assessment concluded that *while traditional kava use may contribute to overall poor health due to associated poor nutrition, kava use in this form does not itself cause irreversible liver damage. However, use of kava during pregnancy or lactation is generally not recommended since kavalactones may be present at concentrations which would likely have an effect on the foetus or infant.* No specific evidence about health risks from consuming kava during pregnancy was reported.

In discussing the existing warning statements, FSANZ stated in the Draft Assessment Report: *The statement 'use in moderation' provides the consumer with the context in which the product should be used and is commonly understood, particularly due to the use of the term in conjunction with alcohol. The statement 'may cause drowsiness' provides the consumer with information about the potential effects of consumption, particularly excessive consumption.* FSANZ also justified retaining the statements with prescribed text based on the following:

1. *To ensure consistency and uniformity in the presentation of messages associated with the appropriate use of kava and to eliminate potential uncertainty or variability of messages between suppliers.*
2. *Consumers of kava in the Northern Territory may have a limited knowledge of*

[3] 'Package' is defined in subsection 1.1.2—2(3) of the Code and includes:
any container or wrapper in or by which food for sale is wholly or partly encased, covered, enclosed, contained or packaged.

the English language and are more likely to understand and recognise simple, clear text that does not vary from package to package.

3. *The economic conditions in the countries that produce kava (Pacific Island countries) are difficult and it is likely to be more feasible for these countries to incorporate simple, clear and unvarying text on packages of kava.*
4. *The statements prescribed currently are used for enforcement purposes. Since it is proposed to remove the requirement for the inclusion of the reference to the NCKM* [National Code of Kava Management]*, enforcement may be more difficult if the text for the statements in question is not prescribed.*

There was no discussion of the outcomes from the risk assessment in the context of possible warning/advisory statements about health risks of kava consumption during pregnancy or lactation.

3.3 Warning statements required on dietary supplements, complementary medicines and medicines containing kava

3.3.1 Australia

Kava is permitted to be used in listed medicines, over the counter products, prescription medicines and as a homeopathic ingredient in listed medicines.[4]

When used in oral medicines, the maximum daily dose of kavalactones must be no more than 250 mg. If the dosage form is a tablet or capsule then the quantity of kavalactones must be no more than 125 mg per tablet or capsule. Oral medicines containing more than 25 mg kavalactones per dose require the following statements on the medicine label:

> *Not for prolonged use. If symptoms persist - seek advice from a healthcare practitioner. Not recommended for pregnant or lactating women* [or words to that effect]. *May harm the liver*

Following an evaluation of kava, in 2002 the warning statements for kava were initially mandated for listed medicines only and legislated via Schedule 4 to the *Therapeutic Goods Regulations 1989*. The warning statements were subsequently also applied to other medicines via the Poisons Standard.[5,6]

Information about the Therapeutic Goods Administration's (TGA) evaluation of kava and any evidence that was considered is not publicly available.

3.3.2 New Zealand

Kava is not permitted to be added to supplemented food[7] or dietary supplements[8] in New Zealand and there are no medicines in New Zealand that contain kava. Warning statements for such products have therefore not been considered.

3.4 Labelling requirements overseas

3.4.1 Codex regional standard for kava

[4] Therapeutic goods determinations | Therapeutic Goods Administration (TGA)
[5] Poisons Standard
[6] Therapeutic Goods Regulations 1990 (legislation.gov.au)
[7] Clause 1.11 of New Zealand Food (Supplemented Food) Standard 2016. New Zealand Legislation
[8] See submission from the New Zealand Food Safety Authority (December 2021). Proposal P1057 - Review of the kava standard (foodstandards.gov.au)

In 2020, Codex Alimentarius Commission approved *the Regional standard for kava products for use as a beverage when mixed with water* (CXS 336R-2020)[9]. There are no labelling requirements for warning-type statements. The Codex standard states: *Kava products may have a clear marking to indicate that they are not intended for medicinal purposes*.

3.4.2 Vanuatu

The Vanuatu Kava Act 2002[10] sets out rules for growing, harvesting and marketing kava.

Labelling for local market: A person must not sell or offer for sale in Vanuatu any bag, container or other receptacle containing kava or kava products unless the name of the variety and the island of origin of the kava is clearly marked on it.

Labelling for export: A person must not export from Vanuatu any bag, container or other receptacle containing kava or kava products unless each of the following is clearly marked on it:

(a) the name of the variety of the kava;
(b) the island of origin of the kava;
(c) the distinct organs of the kava;
(d) the words “Original Vanuatu Kava”.

Advisory or warning labelling statements about a potential health risk from kava consumption are not specified.

3.4.3 USA

There are no requirements warning or advisory type statements for kava root, beverage or supplements. Such products must comply with general labelling rules for foods or supplements.

In 2002, the Food and Drug Administration (FDA) issued an advisory notifying consumers that kava-containing dietary supplements may be associated with severe liver injury.[11] This advisory remains in place and some dietary supplements in the US have voluntarily placed the advisory on labels.

3.5 Information about kava available in Australia and New Zealand

The Australian Alcohol and Drug Foundation[12] provides information about reducing harm from kava consumption including advice to drink kava in moderation and that children, pregnant and breastfeeding women should not use kava.

The Better Health Channel[13] funded by the Victorian Government also advises not to take kava if you are pregnant, breastfeeding or a child.

The New Zealand Kava Society provides information about health effects on its website[14]. A reference is made to a FSANZ report cautioning the use of kava during pregnancy and

[9] Codex Regional Standard for Kava Products (CXS336R-2020)
[10] Vanuatu - Legislation - Kava Act 2002 (fao.org)
[11] Kava (nih.gov)
[12] Kava - Alcohol and Drug Foundation (adf.org.au)
[13] Kava - Better Health Channel
[14] The Kava Society | Learn About Kava | Kava Basics | Kava Science | Kava History — The Kava Society

lactation. The Kava Society states that if consumers have any health concerns they should consult a qualified medical professional.

4 Risk assessment outcomes

Key outcomes from the risk assessment are:

- Kava is typically prepared according to historically safe practices and consumed in both formal (e.g. royal ceremonies, funerals, weddings, church functions) and informal social contexts (e.g. commercial kava bars, within people's homes) informed by Pasifika cultural customs.

- Kava is often regarded as a preferable alternative to alcohol among the Tongan community in New Zealand as it is believed to be physiologically safer, associated with more socially acceptable behaviour, and is often consumed in a safe, culturally appropriate, and familiar social environment.

- Kava is believed to have health benefits in the areas of stress relief, sleep and the prevention or relief of illness or pain by consumers. Kava is also acknowledged to have negative effects on health such as headaches and sleepiness/lethargy. Kava beverage consumers report that kava causes drowsiness and lethargy. The impact on drowsiness and lethargy is supported by published observational studies, however, it is not possible to quantify the physiological effects from the limited data available. Consumers state the lethargy reduces heavy users' involvement in family, community and economic life.

- Limited and generally old data are available on the consumption amounts of kava beverage in Australia and New Zealand and consequent exposure to the psychotropic substances in kava.

- The most recent NZ data available (2007-8) reports that 6.3 % of adults aged 16-64 yrs had ever used kava in their lifetime. In addition, kava consumption was most prevalent among men and Pasifikans. However, ethnographic evidence from long-term consumers of kava beverage suggest male associations with kava common to Pasifika cultures may not be as influential among Māori and Pakeha drinkers. This may mean the proportion of women drinking kava will increase if kava consumption becomes more widespread.

- In Australia, from the most recent data available (2010) 1.9 % of people (1.4 % females; 2.5 % males) aged over 14 years had the opportunity to consume kava in the past 12 months. There is evidence of kava use among Pasifika in Australia and in the Aboriginal and Torres Strait Islander population. Kava consumption in the latter population has been steady from 2008 to 2019, at around 1.4% of the total population reported having used kava in the previous 12 months.

- Kava beverage contains psychotropic substances (e.g. kavalactones) which promote a sense of relaxation, tranquillity and a sociable attitude. Ongoing consumption of high quantities of kava beverage (240 - 440 g/week of dried kava power or more) is associated with a form of dry scaly skin rash, altered liver function and a decline in general health. Nonetheless the significant history of use in Pacific communities demonstrates that is possible to safely consume kava beverage in moderation.

- Insufficient data were available to establish if kava beverage can be safely consumed by children and adolescents. In addition, no data were identified to support the safety

or potential negative developmental consequences to the fetus or infant of kava beverage consumption by pregnant or lactating women. In the absence of evidence of safety, and given the pharmacological properties of the substances in kava and their potential to influence cognitive development, FSANZ considers kava consumption may pose a risk to pregnant and lactating women, children and adolescents and therefore recommends kava is not consumed by these population subgroups.

- Kava beverage consumption by individuals with reduced liver function is not recommended based on their expected decreased capacity for hepatic metabolism plus the potential for the beverage to further inhibit xenobiotic metabolism.

- Kava is not typically mixed with alcohol within the same cup or bowl. However, there is evidence that in informal social contexts it is sometimes alternated with or followed by alcohol, with the practice more common in commercial kava bars and among younger consumers. Kava beverage increases the impact of alcohol on cognition. No data were available to understand the short- or long-term impact of co-consumption of kava and alcohol on public health and safety.

5 Risk management

5.1 Advisory/warning statements

5.1.1 Existing warning statements

As outlined in section 3.2 above, requirements for warning statements about kava were last considered under P256 in 2002. The decision was made to retain the statements on the basis they provide consumers with the context in which the product should be used particularly since a similar statement is also used in conjunction with alcohol (*Use in moderation*) and information about a potential effect of consumption (May cause drowsiness).

In P256 assessment reports FSANZ discussed criteria used for establishing advisory and warning statements in relation to food. It was stated that warning statements are generally only required when the risk to the public of consuming a food may result in death and that the text for warning statements are prescribed.

In 2014, FSANZ published *Risk Analysis in Food Regulation*[15] which describes the risk analysis process used by FSANZ. It was clarified that warning statements, which require a prescribed labelling statement are generally reserved for well-characterised potentially life-threatening risks when the target population is likely to be unaware of the potential risk. In contrast, mandatory advisory statements (where specific wording is not prescribed) are used to advise the general or target population of a potential risk associated with a food.

While it was noted in P256 that kava consumption is unlikely to result in death, it was considered there was merit in retaining the warning statements with prescribed text primarily to ensure consistency and uniformity in the presentation of the messages so as to eliminate uncertainty or variability of message between suppliers and that consumers were exposed to a consistent message. The benefit of mandatory prescribed statements for enforcement was also noted.

Given the similar nature of the information identified in the current risk assessments (SD1, SD2) to that presented in P256, FSANZ is maintaining the existing warning statements for

[15] Risk Analysis in Food Regulation (foodstandards.gov.au)

permitted kava foods (*Use in moderation; May cause drowsiness*). The warning statements provide consumers with information about moderating consumption and an impact on the body that is reportedly commonly experienced (SD1). FSANZ also maintains the text for the warning statements should continue to be prescribed for the reasons articulated in P256. This approach will provide continuity in messaging with the likely increased importation of kava into Australia.

5.1.2 Are new advisory/warning statements appropriate?

The risk assessment for P256 noted use of kava during pregnancy or lactation is generally not recommended since kavalactones may be present at concentrations which would likely have an effect on the fetus or infant. However, there was no specific evidence identified about possible effects on the foetus or infant.

The current risk assessment (SD1) makes a similar conclusion. There is a concern that kava consumption may pose a risk to pregnant and lactating women, children, adolescents and individuals with reduced liver function. It is recommended these population sub groups do not consume kava beverage. However, it is also noted there is insufficient data available to establish whether or not kava beverage can be safely consumed by these population sub groups.

While the risk assessment concludes that ongoing consumption of high quantities of kava beverage is associated with a form of dry scaly skin rash, altered liver function and a decline in general health, the significant history of use in the Pacific communities demonstrates it is possible to safely consumer kava in moderation. The co-consumption of kava and alcohol has been proposed as a risk factor in motor vehicle accidents on Fijian roads, however a significant interaction has not been established from available data.

The current risk assessment identifies little new data and information on kava beverage consumption and its impacts on health over the last 20 years. While there is some consumption data from studies reported since 2002 (SD1, SD2), most of these data are now at least 10 years old. There is limited evidence of the current kava consumption patterns by the general population and amongst population sub groups of interest in Australia and New Zealand.

In response to the Call for Submissions for the P1057 Urgent Proposal, government agencies commented that given dietary supplements and medicines in Australia are required to have a warning statement not recommending kava consumption during pregnancy and lactation, permitted kava foods should also carry such statements. Similar comments were also provided by government agencies in response to the Call for Submissions for this Review. FSANZ considers kava foods and kava therapeutic products are different products. While both have a physiological effect, they are each consumed for different reasons/purposes. As noted earlier, information about the TGA's evaluation of kava and any evidence that was considered is not publicly available.

In response to the Call for Submissions for this Review, while there was some support for maintaining the existing warning statements, some government agencies suggested advisory/warning statements about a number of other potential risks from drinking kava beverage should be required. For example, they requested statements in relation to:

- a scaly skin rash, altered liver function and a general reduction in overall health from a high level of kava consumption
- not mixing kava with alcohol
- not drinking kava when operating a motor vehicle or machinery.

Submitters suggested such statements are warranted because of a potential change in consumption patterns in Australia, including amongst at risk populations and a potential lack of knowledge of kava risks.

Industry submitters to both Call for Submissions Reports were generally supportive of maintaining the existing warning statements and not requiring any new warning statements. Some noted they have statements about not drinking kava if pregnant or nursing, if drinking alcohol and if driving or operating heavy machinery on labels.

FSANZ maintains that since there is limited evidence about health risks and kava consumption (SD1,SD2), it is premature to mandate additional warning/advisory statements at this time. Additionally, any new mandatory warning/advisory statements could be considered trade restrictive in the context of the limited evidence base for health risks. The two year kava pilot will also be reviewed[16] so it is unclear what the future of kava importation to Australia will be at the end of the trial.

FSANZ recognises that public health agencies in Australia are currently advising that kava not be consumed by pregnant and lactating women and children and give information about possible health risks more generally. These messages reflect the concerns identified in current risk assessment. It is expected public health agencies will continue providing such messages, particularly in Australia where kava consumption may increase following the Australian Governments' decision to allow the commercial importation of kava.

FSANZ is not aware of any education materials prepared by government agencies in New Zealand. The importation of kava is subject to biosecurity measures[17] but there has never been restrictions on the quantity of kava that can be imported.

FSANZ intends to prepare information on the consumption of kava and possible health risks for dissemination to the general public. This will support public health agencies and community groups in their education activities about kava.

5.2 Application of warning statements to kava foods for retail sale not required to bear a label

Currently, the Code requires the warning statements to accompany or be displayed with unpackaged dried or raw kava root for retail sale (see section 3.1 above). There is not a similar requirement for kava beverage (not required to bear a label) for retail sale, that is, when kava beverage is either:

- made and packaged on the premises from which it is sold (e.g. a beverage in a bowl or glass or bottle); or
- packaged in the presence of the purchaser (e.g. a bowl of kava beverage served in a bar).

Kava bars are the main example of where kava beverage may be sold in the above retail situations. Due to the limited evidence about consumption practices, FSANZ considers it is not appropriate to mandate the display of warning statements in these retail situations.

[16] https://www.dfat.gov.au/sites/default/files/australia-commercial-kava-pilot-monitoring-evaluation.docx
[17] NZ Government (mpi.govt.nz)