

# Imported food risk statement

## Kava (Piper methysticum) as a food

**Scope:** Kava (*Piper methysticum*) as defined in <u>Standard 1.1.2—3</u> of the Australia New Zealand Food Standards Code, and that meets the meaning of a food as described in section 5 of the <u>Australia New Zealand Food Standards Act (1991)</u>.

#### **Recommendation and rationale**

Does kava present a potential medium or high risk to public health:

🗹 Yes

 $\Box$  No

#### Rationale:

Kava (*Piper methysticum*) root or kava beverage obtained by aqueous suspension of kava root, as permitted for sale in Standard 2.6.3 of the Australia New Zealand Food Standards Code, consumed in-line with historical preparation and consumption practices, does not itself pose significant risk to public health.

However, consumption of kava food products that are not consistent with Standard 2.6.3 and the intent of FSANZ's P1057 Urgent Proposal work, are considered potential medium or high risks to public health and safety. These include:

- kava beverage prepared using kava plant varieties without a history of safe use (i.e. not using Noble kava varieties), or using aerial parts of the kava plant
- shelf-stabilised ready-to-drink kava beverage products, herbal extracts of kava, kava used as an ingredient in foods or kava beverage that contains food additives or processing aids
- kava beverage consumption that is inconsistent with historical preparation and consumption practices.

Kava root and kava beverage is required by Standard 2.6.3 to have a label with, or when unpackaged be accompanied by, the warning statements 'use in moderation' and 'may cause drowsiness'. These warning statements provide consumers with information about consumption and the impact reportedly experienced when consuming kava.

Additionally, kava plant and kava beverage are potentially susceptible to microbiological contamination and should be cultivated, stored and prepared accordingly. Kava beverage should be consumed soon after preparation.

#### **General description**

#### Nature of the product:

Kava beverage has significant cultural importance for communities throughout Micronesia, Melanesia and Polynesia, and has been consumed for more than 1000 years (Lebot et al., 1992).

Historically, kava beverage in Pacific communities has been prepared by aqueous extraction using fresh or dried roots of the kava plant to produce a brew in a communal bowl. The beverage is then typically consumed immediately or shortly thereafter (Aporosa, 2019; Cairney et al., 2002). Drinkers of kava beverage report a sense of relaxation and tranquillity, and the drink is taken to promote a sociable attitude.

There are more than 200 varieties of kava plant (Singh, 1992). 'Noble' kava varieties have been safely used by Pacific communities for kava beverage production (Appendix 1). These varieties are distinguished by their geographical distribution, physical characteristics and the properties of the kava beverage they produce (FAO/WHO, 2016). Other kava varieties are not suitable for making kava beverage (FAO/WHO, 2016; Lebot & Lèvesque, 1989).

The pharmacologically active compounds in kava are kavalactones, which are extracted from the root of the kava plant during the preparation of kava beverage. The total kavalactone content of kava plants varies from 3% to 20% of dry weight, depending on variety, growth conditions and part of the plant (Lebot & Levesque, 1996). Kavalactones have been reported to

FSANZ provides risk assessment advice to the Department of Agriculture, Fisheries and Forestry on the level of public health risk associated with certain foods. For more information on how food is regulated in Australia refer to the <u>FSANZ website</u> or for information on how imported food is managed refer to the <u>Department of Agriculture</u>, Fisheries and Forestry website.

#### **General description**

have psychopharmacological effects as well as muscle relaxant, local anaesthetic, anxiolytic and anticonvulsive properties (Cairney et al., 2002). These psychotropic effects appear to occur without reducing cognitive performance (Cairney et al., 2002; LaPorte et al., 2011).

Flavokawains and piperidine alkaloids are documented minor compounds found in the kava plant (Dragull et al., 2003; Lebot et al., 2014; Lechtenberg et al., 2008). It has been suggested these compounds present a toxicity risk when consuming kava beverage extracted from leaves, stems or bark of the kava plant, or from non-Noble kava plant varieties, but little toxicological data is available (FSANZ, 2021).

The quantities of kavalactones, piperidine alkaloids and flavokawains removed from kava plant varies depending on: 1) extraction methods (cold water kava beverage preparation, compared with other extraction methods) (Tang & Fields, 2019; Teschke & Lebot, 2011); 2) the kava plant variety (if the kava is of a Noble variety) (Lebot et al., 2014); or 3) specific kava plant organs used for extraction (roots rhizomes or basal stems, compared with aerial portions) (Dragull et al., 2003).

Substances in kava have been shown to inhibit important Cytochrome P450 liver enzymes *in vitro*, suggesting the potential for drug interactions (Anke & Ramzan, 2004; Mathews et al., 2005). Caution is recommended when consuming kava beverage in combination with alcohol, medicines (particularly benzodiazepines, opioids, barbiturates and paracetamol) or other herbal preparations (FSANZ, 2021). The co-consumption of kava and alcohol intensifies the effects of alcohol on cognition, and alcohol and kava co-consumption has been identified as a risk factor in motor vehicle accidents on Fijian roads (Foo & Lemon, 1997; Li & Ramzan, 2010; Wainiqolo et al., 2016).

There is evidence that kava beverage is highly susceptible to microbial growth and is unsuitable for storage, even with refrigeration (Dong et al., 2011; Kandukuru et al., 2009). Kava beverage should be consumed soon after preparation (FSANZ, 2021).

The approved regional Codex standard for kava products states that kava root should be free from visible moulds, soil and foreign odour (Codex, 2020). Mould-produced aflatoxin has been detected in kava root (Weaver & Trucksess, 2010). Contamination of kava plant product with aflatoxin-producing moulds is a suspected cause of hepatotoxicity events (Teschke et al., 2012).

Herbal extracts of kava are used in complementary medicines listed on the <u>Australian Register of Therapeutic Goods</u>. Such kava-containing products are commonly marketed for the treatment of anxiety, insomnia, premenstrual syndrome and stress. The chemical composition of kava extracts differs from kava beverage and is outside the scope of this imported food risk statement.

Kava (both plant and beverage, including extracted kavalactones) is listed as a Schedule 4 substance in the current <u>Poisons</u> <u>Standard</u>. Kava products that are listed on the Australian Register of Therapeutic Goods are exempt from scheduling.

#### Adverse health effects:

Infrequent consumption of kava beverage in-line with historical preparation and consumption practices does not pose significant risk to public health. Kava beverage does not demonstrate the same addictive properties as other potential substances of abuse and is seen to be far less harmful to individual users and the community (FAO/WHO, 2016; FSANZ, 2021).

However, excessive and recurrent consumption of kava is associated with adverse outcomes.

Consuming high quantities of kava beverage within a short timeframe can cause reversible (Rychetnik & Madronio, 2011):

- sedation
- ataxia
- paralysis of the extremities
- extra pyramidal movements
- hearing loss
- impaired vision
- unconsciousness.

Ongoing high-consumption of kava beverage (240–440 g/week or more of dried kava powder) is associated with adverse outcomes for both individuals and communities (Clough, 2003; Clough et al., 2003; Rychetnik & Madronio, 2011), such as:

• Ichthyosiform skin rash - the most commonly observed side effect of ongoing high-quantity kava beverage consumption is a form of ichthyosiform skin rash or kava dermopathy. Kava dermopathy is characterised by dry, flaky skin and yellow discolouration of skin and nails. These effects are reversible once consumption has been discontinued.

#### **General description**

- Altered liver function The health effects of kava beverage consumption in First Nations communities documented consistent changes in liver function tests in heavy kava drinkers. These changes appear reversible, returning to normal within 1-2 months after kava use is stopped.
- General physical health effects Other effects on overall health of ongoing heavy consumers of kava have been reported with varied levels of evidence quality. These include decreased body weight, nausea, loss of appetite, conjunctivitis, loss of sexual drive and raised cholesterol.

No information was available to allow an assessment of the safety of kava beverage consumption in pregnant or lactating females, adolescents or children (FSANZ, 2021). Therefore it is not possible to draw a conclusion on the safety of kava beverage consumption by these population subgroups. Kava should not be consumed by these population groups.

Reports of hepatotoxicity associated with medicinal products containing kava extracts emerged in Europe in 1998 (WHO, 2008). The method of extraction for herbal kava preparations, drug interactions with other medications, the use of non-Noble kava varieties in the manufacture of herbal preparations and potential contamination of kava used for herbal preparations with aflatoxin-producing fungi, have all been proposed as the cause for a sudden appearance of these adverse events (FSANZ, 2021). The chemical composition of kava extracts differs from kava beverage and there is little evidence of significant adverse health effects in Pacific communities with high levels of kava beverage consumption.

Kava consumption may impair the ability to safely operate a motor vehicle (Wainiqolo et al., 2016).

#### **Consumption patterns:**

Following export restrictions being imposed in 2007, kava was not available in Australia as a commercial food commodity until December 2021. No information on kava consumption is captured by the 2011-2012 Nutrition and Physical Activity Survey (ABS, 2014) or the 2012-2013 Australian Aboriginal and Torres Strait Islander Health Survey (ABS, 2015).

In the 2007 National Drug Strategy Household Survey, 1.8 % of Australians 14 years and older reported being offered or having the opportunity to use kava within the last 12 months (AIHW, 2008). This was highest for males in the 20-29 year old age group at 3.4%.

As part of the advice provided in 2016 to the then Department of Health, the Advisory Committee on Medicine Scheduling highlighted that several jurisdictions have had historical problems with kava misuse, especially with powder and liquid forms (Dept. of Health, 2016).

#### Risk factors and risk mitigation:

Key risk factors:

- Contamination of imported product with parts of the kava plant that are not peeled roots, rhizomes or basal stems, or with non-Noble kava varieties.
- Potential contamination or spoilage of kava through the supply chain (from primary production though to the final kava beverage preparation) with bacterial and/or viral pathogens, mycotoxin-producing moulds or other toxin-producing microorganisms. Noting however, there was insufficient information available on the persistence or growth of pathogens in kava beverage for risk assessment.
- Kava beverage products that are not prepared and consumed in-line with historical practices, such as shelf-stabilised pre-prepared kava products, kava extracts or kava products containing food additives or processing aids.
- Introduction of kava into a population without culturally established consumption patterns.
- Influx of kava into communities that demonstrate kava beverage consumption levels indicative of substance abuse, such as select communities in West and East Arnhem land.

Risk mitigation strategies:

- Imported kava for sale should be made with peeled roots, rhizomes or basal stems. Harvested product should be free of leaves, bark, pests and mould, and be stored and transported under conditions that minimise spoilage and/or mould growth.
- Kava plants should be cultivated using Good Agricultural Practices and Good Handling Practices, and be a kava variety with a history of safe use (Appendix 1).
- Only potable water should be used to prepare kava beverage.

#### **General description**

- Kava beverage should be prepared in-line with historical cultural practices, not stored or transported, and should be consumed soon after preparation.
- Products for sale in Australia should display the requisite warnings, as specified in the Australia New Zealand Food Standards Code.
- Continued enforcement of individual State and Territory-specific restrictions on the import and sale of kava.

#### Surveillance information:

From 1 December 2021, commercial importation of kava resumed in Australia under the kava pilot program. While the kava pilot program has since concluded, the import arrangements that were established under the program remain in place.

Since commencement of the kava pilot program, 415.6 tonnes of commercial kava for human consumption was imported into Australia between December 2021 and October 2024. Kava imports into Australia were primarily from Tonga, Fiji, Vanuatu and New Zealand.

#### Standards or guidelines

#### Australia

Standard 1.1.1 of the Australia New Zealand Food Standards Code (the Code) states that food for sale must not consist of, or have as an ingredient or a component, kava or any substance derived from kava, unless expressly permitted by Standard 2.6.3.

Standard 1.1.2 defines kava root as 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).

Standard 2.6.3 of the Code states that the prohibition of kava does not apply to kava root (raw or dried), or the beverage obtained by aqueous suspension of kava root, and must not contain as an ingredient or component any substance used as a food additive or processing aid. Kava products are required to display the warning statements 'use in moderation' and 'may cause drowsiness'.

The references to Noble varieties of kava, and the expressed prohibition of any ingredient or component any substance used as a food additive or processing aid, were changes introduced by Amendment No. 206 to Standard 2.6.3 of the Code, following FSANZ urgent review under Proposal P1057.

#### New Zealand

New Zealand did not adopt Amendment No. 206 to Standard 2.6.3 of the Code, which were changes made by Proposal P1057. The previous Standard 2.6.3 Kava, following Amendment No. 200, remains in effect in New Zealand.

Therefore, there are no Code requirements in New Zealand that kava must be from a Noble variety, nor are food additives and enzyme processing aids expressly prohibited in kava food products.

#### Codex

Regional Standard for Kava Products for use as a Beverage When Mixed with Water (CXS 336R-2020) was adopted by the 43rd Session of the joint Food and Agriculture Organization and World Health Organization Codex Alimentarius Commission (2020). This standard applies to the roots, rhizomes or basal stems, fresh or dried, of Noble cultivars of the kava plant (*P. methysticum* G. Forst) (Codex, 2020).

The following Codex Standards are also relevant in the prevention of foodborne illnesses associated with kava:

- Codex general principles of food hygiene (CXC 1-1969)
- Code of Hygienic Practice for Low-Moisture Foods (CC 75-2015).

#### **Pacific Nations**

Funded by the Australian and New Zealand Governments, the Pacific Horticultural & Agricultural Market Access (PHARMA) Program has worked with Pacific Nations to develop standards for kava to ensure product safety. Through this program, Vanuatu (*The National Quality Standard for Kava Export*, 2017), Fiji (Fiji Ministry of Agriculture, 2017), Samoa (*Samoa 'Ava Standard*, 2018) and Tonga (Government of Tonga, 2020) have developed standards for the production of kava suitable for export to produce a food beverage.

#### Management approaches

Australia – Kava is currently classified as a drug under the <u>Customs (Prohibited Imports) Regulations 1956</u> and requires permission to be imported commercially into Australia.

Kava (including extracted kavalactones) is listed as a Schedule 4 medicine in the current Poisons Standard when used in preparations for human use, except when included in products on the Australian Register of Therapeutic Goods. Prior to 2007, the whole or peeled rhizome of kava was exempt from scheduling in the poisons standard, instead being managed under the National Code of Kava Management. However, following an Australian Government policy effort to reduce the kava abuse in select First Nations communities, import restrictions were imposed that stopped the commercial importation of kava into Australia. In 2008, the National Drugs and Poisons Schedule Committee (NDPSC) concluded that the whole or peeled rhizome form of kava should no longer be exempt from scheduling, recognising the hazards to public health associated with kava substance abuse and that import restrictions were in place. This position was reaffirmed by the NDPSC in 2009 and again by the Advisory Committee on Medicine Scheduling in 2016.

From 1 December 2021 commercial importation of kava occurred under phase 2 of the kava pilot program. Kava import permits can be obtained from the Narcotics Control Section in the Office of Drug Control (ODC, 2022). Incoming passengers into Australia are allowed to bring up to 4kg of kava (in the root or dried form) into Australia in their accompanied baggage (*Customs (Prohibited Imports) (Kava) Approval 2019*).

Vanuatu - The Kava Act No. 7 (2002) prohibits the sale or export of tudei kava and wild kava, unless requested to do so by a person outside Vanuatu ("The Kava Act," 2008).

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Appendix 1 – Noble kava plant varieties with a history of safe use as kava	beverage
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Samoa	Vanuatu	<sup>‡</sup> Hawaii
Ava La'au	Ahouia	Hanakapi'ai
Ava Le'a	Amon	Hiwa
Ava Loa	Asiyai	Honokane Iki
Ava Mumu	Bir Kar	Kumakua
Ava Talo	Bir Sul	Mahakea
	Biyaj	Mapulehu
Fiji	Borogoru	Моі
Damu	Borogu	Nene
Dokobana loa	Ge gusug	Opihikao
Dokobana vula	Ge vemea	Pana'ewa
Loa kasa balavu	Ge wiswisket	Papa 'Ele'ele
Loa kasa leka	Gorgor	Papa 'Ele'ele Pu 'upu'u
Matakaro balavu	Kelai (or Miaome)	Papa kea
Matakaro leka	Leay	
Qila balavu	Melmel (or Sese)	<sup>‡</sup> Papua New Guinea
Qila leka	Melomelo	Kau kupwe
Vula kasa balavu	Miela	
Vula kasa leka	Naga miwok	<sup>‡</sup> Federated States of Micronesia
Yalu	Olitao	Rahmwahnger
Yonolulu	Palarasul	
	Palasa	<sup>‡</sup> Solomon Islands
Tonga	Palimet	Feo
Kava 'Akauhina	Pia	Tahu
Kava 'Akaukula	Poivota	Temo
Kava Fulufulu	Pualiu	
Kava Kofe	Puariki	
Kava Lekahina	Silese	
Kava Lekakula	Urukara	
Kava Valu		

<sup>+</sup> FSANZ is unaware of any local kava quality and safety standards that are specific to kava produced in this region.

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