

12/03

8 October 2003

DRAFT ASSESSMENT REPORT

PROPOSAL P256

REVIEW OF KAVA

DEADLINE FOR PUBLIC SUBMISSIONS to FSANZ in relation to this matter:

19 November 2003

(See 'Invitation for Public Submissions' for details)

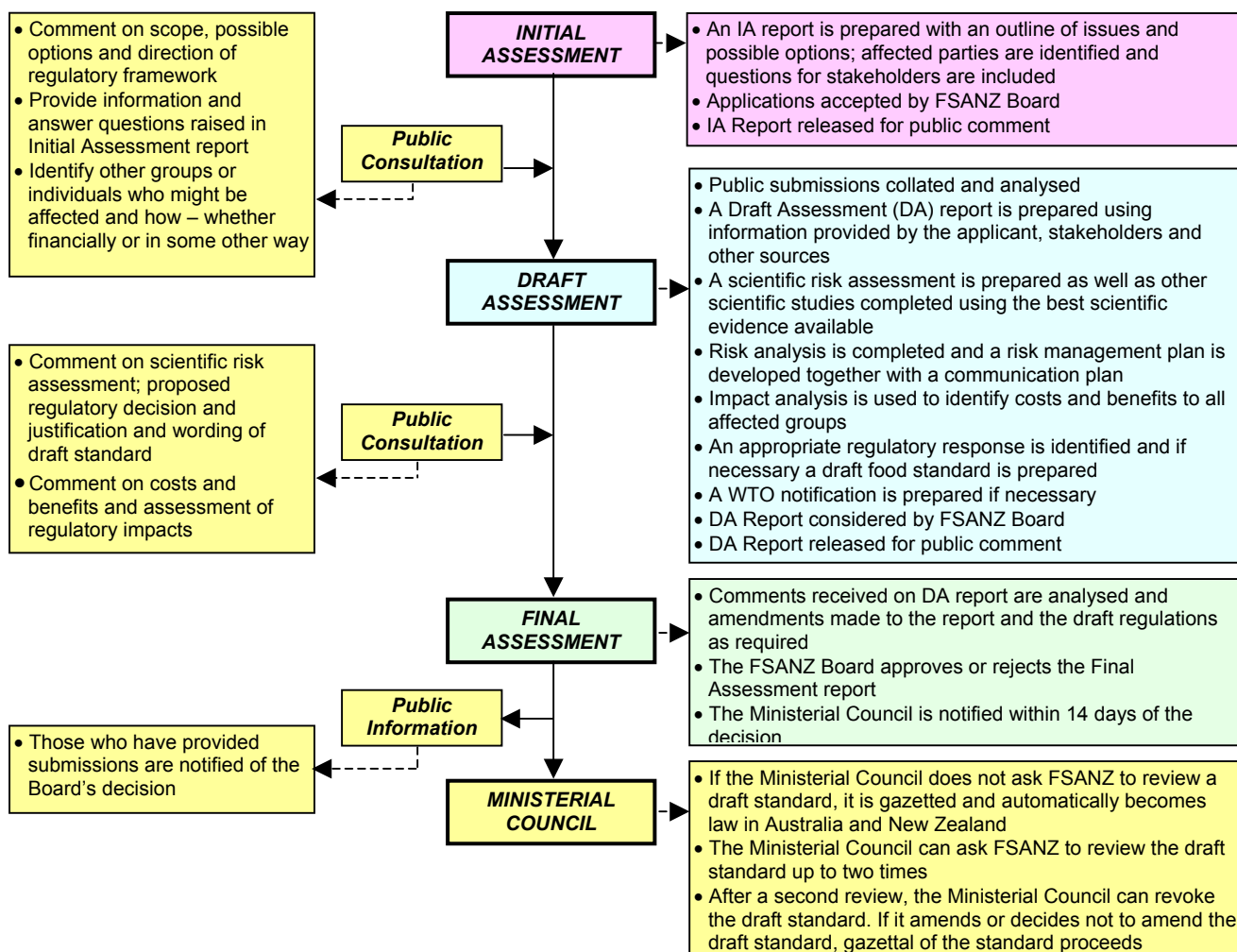
FOOD STANDARDS AUSTRALIA NEW ZEALAND (FSANZ)

FSANZ's role is to protect the health and safety of people in Australia and New Zealand through the maintenance of a safe food supply. FSANZ is a partnership between ten Governments: the Commonwealth; Australian States and Territories; and New Zealand. It is a statutory authority under Commonwealth law and is an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards and for developing codes of conduct with industry for food available in Australia and New Zealand covering labelling, composition and contaminants. In Australia, FSANZ also develops food standards for food safety, maximum residue limits, primary production and processing and a range of other functions including the coordination of national food surveillance and recall systems, conducting research and assessing policies about imported food.

The FSANZ Board approves new standards or variations to food standards in accordance with policy guidelines set by the Australia and New Zealand Food Regulation Ministerial Council (Ministerial Council) made up of Commonwealth, State and Territory and New Zealand Health Ministers as lead Ministers, with representation from other portfolios. Approved standards are then notified to the Ministerial Council. The Ministerial Council may then request that FSANZ review a proposed or existing standard. If the Ministerial Council does not request that FSANZ review the draft standard, or amends a draft standard, the standard is adopted by reference under the food laws of the Commonwealth, States, Territories and New Zealand. The Ministerial Council can, independently of a notification from FSANZ, request that FSANZ review a standard.

The process for amending the *Australia New Zealand Food Standards Code* is prescribed in the *Food Standards Australia New Zealand Act 1991* (FSANZ Act). The diagram below represents the different stages in the process including when periods of public consultation occur. This process varies for matters that are urgent or minor in significance or complexity.



INVITATION FOR PUBLIC SUBMISSIONS

FSANZ has prepared a Draft Assessment Report of Proposal P256; and prepared a draft variation to the *Australia New Zealand Food Standards Code* (the Code).

FSANZ invites public comment on this Draft Assessment Report based on regulation impact principles and the draft variation to the Code for the purpose of preparing an amendment to the Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist FSANZ in preparing the Draft Assessment/Final Assessment for this Application/Proposal. Submissions should, where possible, address the objectives of FSANZ as set out in section 10 of the FSANZ Act. Information providing details of potential costs and benefits of the proposed change to the Code from stakeholders is highly desirable. Claims made in submissions should be supported wherever possible by referencing or including relevant studies, research findings, trials, surveys etc. Technical information should be in sufficient detail to allow independent scientific assessment.

The processes of FSANZ are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of FSANZ and made available for inspection. If you wish any information contained in a submission to remain confidential to FSANZ, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. Section 39 of the FSANZ Act requires FSANZ to treat in-confidence, trade secrets relating to food and any other information relating to food, the commercial value of which would be, or could reasonably be expected to be, destroyed or diminished by disclosure.

Submissions must be made in writing and should clearly be marked with the word 'Submission' and quote the correct project number and name. Submissions may be sent to one of the following addresses:

Food Standards Australia New Zealand
PO Box 7186
Canberra BC ACT 2610
AUSTRALIA
Tel (02) 6271 2222
www.foodstandards.gov.au

Food Standards Australia New Zealand
PO Box 10559
The Terrace WELLINGTON 6036
NEW ZEALAND
Tel (04) 473 9942
www.foodstandards.govt.nz

Submissions should be received by FSANZ by **19 November 2003**. Submissions received after this date may not be considered, unless the Project Manager has given prior agreement for an extension. While FSANZ accepts submissions in hard copy to our offices, it is more convenient and quicker to receive submissions electronically through the FSANZ website using the [Standards Development](#) tab and then through [Documents for Public Comment](#). Questions relating to making submissions or the application process can be directed to the Standards Liaison Officer at the above address or by emailing slo@foodstandards.gov.au.

Assessment reports are available for viewing and downloading from the FSANZ website. Alternatively, requests for paper copies of reports or other general inquiries can be directed to FSANZ's Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au.

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Executive Summary and Statement of Reasons

Kava is an intoxicating non-alcoholic beverage prepared from the root of the plant *Piper methysticum*. Kava has a long history of use as a beverage in social ceremonies, particularly by South Pacific communities. Kava was also introduced into Aboriginal communities, predominantly in Arnhem Land in the 1980s as an alternative to alcohol.

An integrated system to control the importation, distribution and sale of kava was instituted in Australia in 1997. This system consists of a standard in the Code, which operates in conjunction with the National Code of Kava Management on the Restriction of Sale and Advertising of Kava (the National Code of Kava Management, NCKM). The NCKM enables states and territories to introduce more restrictive measures if considered necessary. Both the Northern Territory and Western Australia have introduced such legislation. ANZFA was not able to undertake a complete review of the standard regulating kava before the release of the Code, therefore Standard O10 of Volume 1 was transported to Standard 2.6.3 of Volume 2 with one significant amendment to recognize the addition of kava to food-type dietary supplements regulated under the New Zealand *Dietary Supplement Regulations 1985* (NZDSR). Prior the Code, kava as a food was not regulated in New Zealand under the now repealed *New Zealand Food Regulations 1984*.

Whilst the Northern Territory has implemented its own legislation regulating kava control, Standard 2.6.3 – Kava and the NCKM are still relevant in that a breach of either of these constitutes a breach of the license conditions issues by that jurisdiction. NSW, the largest importer of kava, has indicated that Standard 2.6.3 and the NCKM are relevant to their operational functions.

There have been recent cases of liver toxicity associated with the use of kava containing herbal preparations in capsule/tablet form presented as dietary supplements/complementary medicines. In these cases, a concentrated ethanol or acetone extract of kava has been used. The mechanism of kava-related liver toxicity is not clear although it appears to be linked to the nature of kavalactone preparations together with alterations to certain metabolic pathways. The exact steps which lead to liver damage remain unclear. In response to these cases of liver toxicity, several countries have initiated voluntary or mandatory recalls of kava products. There have been no cases of liver toxicity noted in association with the traditionally prepared kava beverage. However, given the heightened concerns, safety assessments have been conducted on both the traditionally prepared kava beverage and kava extracts.

The safety assessment indicates that while consumption of the traditional kava beverage has some adverse health effects such as kava dermatopathy, these are reversible and there is no indication of acute liver inflammation indicative of liver toxicity. There is sufficient evidence to suggest that excessive consumption of kava extracts (prepared using ethanol or acetone extraction) pose a significant risk to public health.

A number of regulatory options were proposed. The preferred regulatory option is Option 2, namely, to retain Standard 2.6.3 – Kava, to operate in conjunction with the NCKM, to retain the prohibition on the mixing of kava with other foods (with the exception of food type dietary supplements regulated under the NZDSR), to amend the definition of kava and to retain the labelling statements related to public health. It is proposed also to prohibit the use in food of organic solvent extracts of kava and the aerial parts and root peelings of the plant.

Statement of Reasons

This review of Standard 2.6.3 – Kava, recommends that an amended Standard 2.6.3 be retained to operate in conjunction with the NCKM for the following reasons:

- The safety assessment indicates that consumption of the traditional kava beverage has a long history of safe consumption. Changes in liver enzyme function that have been reported in association with drinking the traditional kava beverage, and a skin condition known as kava dermatopathy are both reversible. It is considered safe for the consumption of the traditionally prepared kava beverage to continue.
- This regulatory framework provides an effective mechanism for minimising the abuse of kava as indicated by state and territory enforcement agencies.
- The Northern Territory, which has a high proportion of Australia's kava users, and NSW, which imports the largest quantity of kava of any Australian state or territory, have indicated that Standard 2.6.3 and the NCKM are still relevant and effective for their operational purposes.
- There will be a minimal impact on enforcement agencies, consumers and industry by retaining a separate commodity standard for kava and the NCKM.
- Kava is a distinct commodity with specific issues associated with its use. A separate commodity standard is appropriate for regulating kava.

Standard 2.6.3 should continue to retain a prohibition on the mixing of kava with other foods (other than those foods regulated under the NZDSR) for the following reasons:

- The majority of submitters indicated that the prohibition on mixing kava with other foods should remain in order to minimise the abuse and widespread use of kava.
- Government enforcement agencies expressed the view that the use of kava should be restricted to the traditionally consumed beverage to minimise the widespread use in the general population of Australia and New Zealand, which is likely to be unaware of the intoxicating properties.

A definition for kava should continue to be provided in Standard 2.6.3 however; the definition has been reviewed and amended for the following reasons:

- Submitters expressed concerns that the current definition for kava is too broad for enforcement purposes.
- An amended definition will exclude the use of kava extracts prepared by organic solvent extraction because of safety issues that associate the use of kava extracts with hepatotoxicity.
- An amended definition will restrict kava to the whole or peeled root of the plant because these plant parts have a tradition of safe use as a traditional beverage.

Labelling requirements should continue to be provided in Standard 2.6.3 for the following reasons:

- To provide consumers with important information on public health and safety.
- Required labelling is an important tool for enforcement agencies.

These labelling statements have been reviewed to consider their appropriateness in New Zealand where kava as a food was not regulated prior to the Code.

1. Introduction

Proposal P256 reviews the current standard that regulates kava in the food supply. This Proposal has been raised under section 12A of the FSANZ Act. Kava is an intoxicating non-alcoholic beverage prepared from the root of the plant *Piper methysticum* which grows throughout Melanesia, Polynesia and Micronesia.

In response to the potential health and social problems associated with kava use, an integrated national system to restrict the importation, distribution and sale of the traditional form of kava (i.e. powdered root) was instituted in Australia in 1997 including the so-called National Code of Kava Management. As part of this integrated national system, the provisions for kava within the then current Australian *Food Standards Code* provided a definition for kava, mandated labelling statements and mandated compliance with the National Code of Kava Management.

During the development of the joint *Australia New Zealand Food Standards Code* (the Code) this standard was amended to recognise the addition of kava to food type dietary supplements regulated under the New Zealand *Dietary Supplement Regulations 1985* (NZDSR). It should be noted that kava used in dietary supplements is usually a concentrated ethanol or acetone extract of the plant.

This standard will now be reviewed to:

- (i) consider whether it effectively provides a mechanism for controlling kava in Australia;
- (ii) consider whether current scientific data supports its safety in the food supply; and
- (iii) to harmonise regulations between Australia and New Zealand.

2. Regulatory Problem

In the development of the Code, Standard O10 – Kava, from Volume 1 was transported into Standard 2.6.3 – Kava, without a comprehensive review. This proposal has been raised to review Standard 2.6.3 – Kava. The various regulations, which control kava use in Australia and New Zealand, are described below.

2.1 Current Regulations

2.1.1 Import Regulations

The Australian *Customs (Prohibited Imports) Regulations 1956* were amended in 1997 to make kava a controlled substance. As a consequence, to import kava for commercial purposes into Australia, it is necessary to obtain both a licence to import kava, and a permit for each consignment of kava. Both the license and permit are obtained from the Treaties and Monitoring Unit within the TGA. In addition to commercial importation of kava, individuals arriving in Australia can import up to two kilograms of kava for personal use without a permit.

2.1.2 Standard 2.6.3 - Kava

Standard 2.6.3 provides a definition for kava and mandates labelling statements to be included on the package of kava. Standard 2.6.3 also prohibits kava from being used as an ingredient in processed foods but recognises that kava can be present in products regulated under the NZDSR.

Standard 2.6.3 operates in conjunction with the National Code of Kava Management on the Restriction of Sale and Advertising of Kava (the National Code of Kava Management, NCKM), which regulates the sale and distribution of kava in Australia (Attachment 2). The NCKM does not apply in New Zealand. The NCKM enables States and Territories to introduce more restrictive measures if considered necessary. Both the Northern Territory and Western Australia now have such legislation.

2.1.3 The National Code of Kava Management

The NCKM regulates the sale and distribution of kava in Australia and seeks to minimise any potential detrimental effects associated with kava abuse. Some features of the NCKM include:

- In order for a person to import, sell, or use kava in Australia, that person must be a signatory to the NCKM.
- In order for a person to import kava into Australia, that person must obtain a licence to import and a permit for each consignment. The TGA maintains a register of licensees. States and Territories have also undertaken to maintain a register of licensees for their respective jurisdiction.
- Kava must only be sold to a person who is a signatory to the NCKM.
- Kava must not be sold to a person under the age of 18 years.
- The promotion or advertising of kava for sale is prohibited.

The Kava Committee Management Group (KCMG) was also formed at the same time to oversee the National Code of Kava Management. They were required to monitor compliance with the Code, provide advice to the Commonwealth and recommend action in relation to any failure to comply with the Code. This advisory group consisted of representatives from Commonwealth, State and Territory Health Officials, the TGA, and Customs and was chaired by ANZFA. As the implementation of the management scheme is now complete, there is no longer any need for this committee and it has recently been disbanded. Upon disbanding the KCMG, States and Territories undertook to maintain a list of licensees for their respective jurisdiction.

2.1.4 Standard O10 and the development of the Code

In 1999, it was decided that ANZFA would not be able to undertake a complete review of the kava standard before the release of the Code. However, it was agreed that the kava standard was needed in the Code therefore, Proposal P216 proposed to transport Standard O10 – Kava (as well as R10 Formulated Supplementary Sports Foods) into what became Standard 2.6.3 of Volume 2 of the *Food Standards Code* (R10 became Standard 2.9.4). It was agreed that this would not constitute a complete review of Standard O10, which would be conducted at a later point.

2.1.5 Transitional changes to Standard 2.6.3

It was recognised that kava was not prohibited from being added to foods regulated under the NZDSR and thus could be present in food type dietary supplements in New Zealand. In contrast, in the Australian *Food Standards Code*, kava was not permitted to be added to any food and therefore, to harmonise regulatory measures between Australia and New Zealand, one major change was made to Standard O10.

This amendment of the kava standard in its transportation into the Code was to recognise kava addition to dietary supplements but its use as an ingredient in other foods remained

prohibited. Ingredients permitted in dietary supplements in the Joint Code are being reviewed as part of the Proposal P235 - Review of Dietary Supplements.

2.1.6 Regulation of kava in New Zealand

Use of kava in New Zealand is subject to Standard 2.6.3 however; the NCKM does not apply in New Zealand.

Standard 2.6.3 of the Code recognises the addition of kava to those products permitted under the NZDSR. Thus while the NZDSR remains in effect, kava can be used in products meeting those regulations. Food-type dietary supplements containing kava manufactured in accordance with the NZDSR can subsequently be imported into Australia without the requirement to further comply with the Code under the trans-Tasman Mutual Recognition Agreement (TTMRA). FSANZ has initiated a review of food-type dietary supplements (Proposal P235).

2.1.7 Regulation of kava in the Northern Territory

The Northern Territory developed the *Northern Territory (NT) Kava Management Act 1998* after an Inquiry into Territory management of kava in the Northern Territory. The legislation is administered by the Racing, Gaming and Licensing Division of the Northern Territory Treasury. This Act allows for communities to apply for a licence to sell and use kava. To obtain a licence, there must be demonstrated support in the community for the selling of kava within that community.

Standard 2.6.3 in the Code and the NCKM is still relevant to the Northern Territory since a person holding a kava license issued by the Racing, Gaming and Licensing Division is also required to comply with the NCKM. Breaches of the Code or the NCKM constitute a breach of licence conditions.

2.1.8 Regulation of kava in Western Australia

In Western Australia, kava has been regulated under the *Poisons Act 1964* since 1988, which prohibits the sale of kava unless permission is sought and granted for specific cultural events.

2.1.9 Regulation of kava containing complementary medicines and dietary supplements

As mentioned in section 2.1.3 above, the use of kava in dietary supplements in New Zealand is permitted under the NZDSR. Kava containing products manufactured in accordance with these regulations could include both food-type dietary supplements, e.g. beverages or lozenges, and products in tablet or capsule form containing dried kava root in powdered form or extracts (acetone or ethanol). No pre-approval is required before these products can be supplied on the market. Those kava containing products in food form only, may be imported into Australia under the TTMRA.

Kava containing supplements such as capsules and tablets are regulated as complementary medicines in Australia by the TGA. Kava is approved for use in listable therapeutic goods with restrictions on the amounts of kavalactones present. In 2002, the TGA, acting on the advice of the Complementary Medicines Evaluation Committee (CMEC) and the Adverse Drug Reaction Advisory Committee (ADRAC), initiated a voluntary withdrawal of all complementary medicines containing kava based on concerns linking liver toxicity with kava-containing herbal preparations (discussed further in section 4.6 of this Report). Prior to the voluntary withdrawal of kava-containing medicines, the maximum recommended daily

dose permitted for listed medicines was 250 mg of kavalactones with a maximum amount of kavalactones per tablet or capsule of 125 mg and a maximum amount of dried rhizome per tea bag of 3 g.

3. Objective

The objective of this proposal is to review Standard 2.6.3 – Kava to ensure that the regulation of kava meets the requirements of the FSANZ Act. This Proposal arises from the review of the Australian *Food Standards Code* initiated as part of the development of the *Australia New Zealand Food Standards Code*. It aims to harmonise the regulation of kava in both countries. Given recent reports of adverse effects associated with extracts of kava, the safety of kava has also been considered.

In developing or varying a food standard, FSANZ is required by its legislation to meet three primary objectives which are set out in section 10 of the *FSANZ Act 1991*. These are:

- the protection of public health and safety;
- the provision of adequate information relating to food to enable consumers to make informed choices; and
- the prevention of misleading or deceptive conduct.

In developing and varying standards, FSANZ must also have regard to:

- the need for standards to be based on risk analysis using the best available scientific evidence;
- the promotion of consistency between domestic and international food standards;
- the desirability of an efficient and internationally competitive food industry;
- the promotion of fair trading in food; and
- any written policy guidelines formulated by the Ministerial Council.

4. Background

4.1 What is kava?

The kava plant (*Piper methysticum*) is a member of the pepper family. The term ‘kava’ is primarily used to refer to the kava plant and the drink prepared from the fresh or dried roots of that plant. The term ‘kava’ is also used to refer to other preparations such as: powdered kava made up as the traditional drink and for use in medicinal products; and acetone or ethanol extracts of the plant for use in medicinal products. The number of uses of the word kava has caused confusion, as it is not always clear what is being referred to. The botanical characteristics, varieties and geographical distribution of kava are discussed in Attachment 4.

4.2 Traditional use of kava

Kava has a long history of use as a beverage in social ceremonies, particularly by South Pacific communities and as a traditional medicine in several cultures. The drink is consumed for the sense of relaxation and tranquillity and to manifest a sociable attitude. Traditional medicinal uses include: treatment of gonorrhoea, syphilis, cystitis, boils, asthma, headache and urinary infections; and the induction of muscle relaxation and sleep. Kava was also introduced in Aboriginal communities, predominantly in Arnhem Land in the 1980s as an alternative to alcohol. Kava is consumed by Pacific Islanders living in both Australia and New Zealand.

It is traditionally prepared from fresh or dried roots. Fresh material is chewed or ground until it is fine and fibrous, soaked in water, strained and drunk. Dried material (as is primarily imported into Australia) is ground finely, wrapped in cloth and infused in water. The degree of dilution affects the potency of the kava preparation. The leaves and branches have also been used in folk medicine for topical applications. More details on the preparation of the traditional kava beverage are at Attachment 4.

4.3 Other uses of kava

Outside of the traditional use of kava by South Pacific communities and the monitored use by Aboriginal communities, the remaining exposure of humans to kava occurs primarily through its use as a dietary supplement in New Zealand or as a complementary medicine in Australia. Such dietary supplements containing kava are commonly marketed for the treatment of anxiety, insomnia, premenstrual syndrome and stress.

Commercial extracts of kava are generally prepared from the root, although more recently stem peelings have been used as raw material in kava products due to the high demand of the pharmaceutical industry. This extract is generally standardised to contain approximately 30% kavalactones compared to between 3-20% kavalactone content in root material. However various dosage forms with a range of indications are available. Acetone or ethanol are used as solvents for the extraction of kavalactones. More details on the preparation of kava extracts are at Attachment 4. Such extracts are used primarily in complementary medicines such as in capsules, powders/teas, liquids and in combination products that contain a variety of herbs and/or vitamins.

Low alcohol tinctures used by herbal practitioners are prepared by macerating dried kava in a mixture of water and ethanol. Such extracts using 25% ethanol solvent for extraction, contain approximately 30 times fewer kavalactones than the concentrated standardised preparations.

4.4 Chemistry and Pharmacology

The active ingredients of kava are kavalactones (or kava pyrones) (see Attachment 4 for the structure), which are pharmacologically active compounds naturally present in the kava plant. Nineteen kavalactones have been isolated from the kava root, of which six are the major constituents of kava (kawain, dihydrokawain, methsticin, dihydromethsticin yangonin, and demethoxyyangonin). The proportions and potency of kavalactones can vary according to the plant variety and also the method of preparation. The kavalactone content varies from 3% to 20% dry weight, even within the same subspecies. The concentration of kavalactones is generally highest in the lateral roots (approximately 15%) and decreases progressively toward the aerial part of the plant. The effects of kava may also depend on how it is consumed in terms of whether it is used concomitantly with other drugs, food, alcohol or physical activity.

The absorption of kavalactones in the gastrointestinal tract is poor and variable. Kavalactones appear to be hydroxylated by the cytochrome P450 system and are eliminated by the kidneys and in the faeces.

Kava is known to have several actions; the primary action is as a mild sedative. Other actions include local anaesthesia of the mouth and tongue, analgesia, ocular effects, anticonvulsive effects and antimycotic properties. It has also been reported as an effective anti-anxiety treatment. More details are provided in Attachment 4.

4.5 Recent concerns regarding liver toxicity associated with kava extracts for medicinal use

In November 2001 the German Federal Institute for Drugs and Medicinal Products (BfArM) published evidence that suggested an association of kava consumption with liver damage in 24 cases reported from Germany and Switzerland. These included one death and three liver transplants. These cases varied in severity from abnormal liver function to liver failure, including fatality and liver transplants. Although kava has been implicated in causing these adverse effects, the evidence in some cases is compounded by other factors including the use of concomitant drugs also linked with liver problems (e.g. alcohol), previous history of compromised liver function, and missing information in relation to patient history, co-medication and consumption of alcohol. In all of these reported cases, kava had been consumed as dietary supplements or herbal medicines.

Subsequently, reports of liver toxicity in other western countries emerged. As of the end of 2002, the UK Medicines Control Agency and Committee on Safety of Medicines (MCA/CSM) had compiled a total of 68 cases of liver damage associated with the use of kava as a medicinal herb, complementary medicine or medicinal dietary supplement. Of these, the association between kava and liver damage was categorised as 'probable' in 14 cases (including 3 liver transplants) and 'possible' in 30 others, while the rest were categorised as 'unassessable'.

In addition to these European reports of liver damage associated with kava use, one woman in Australia died recently after taking an herbal supplement that contained kava and passion flower¹. The herb skullcap² was also reported in the ingredients list but was not detectable. The woman presented with liver failure after taking the medicine containing kava for four months and received a liver transplantation, which was unsuccessful and the woman subsequently died. There are now a total of 82 cases of liver damage associated with kava-containing medicines internationally, including 4 deaths.

These reports contrast significantly to the effects of consuming traditionally prepared beverages, as in Arnhem Land and New Caledonia, as discussed above. This may be due to the fact that a standardised extract of kava, prepared using alcohol or acetone, differs in kavalactone content to the traditional extract (as well as potentially in other constituents of kava). This highlights the difficulty of comparing the effects of traditional extracts to standardised extracts, which can contain up to 30 times the kavalactone concentration. The relevance of safety and efficacy studies on traditional extracts in assessing the safety of standardised extracts has been questioned.

4.5.1 Response of regulatory bodies

Several countries have initiated either a mandatory or voluntary withdrawal of complementary medicines containing kava including: Germany; UK; Canada; and Singapore. In some countries, this prohibition extends to all products containing kava and can include food uses as well. The UK Food Standards Agency has recently raised a proposal to prohibit the sale of foods containing or consisting of kava. The Commission of the European Communities has released a preliminary draft proposal for regulation of the addition of vitamins and minerals and of certain other substances to foods, which proposes to prohibit the use of kava as a food.

The US FDA has released a statement advising consumers of the potential risk of liver injury associated with the use of kava-containing dietary supplements. They have also written to

¹ Passion flower (*Passiflora incarnata*)

² Skullcap (*Scutellaria lateriflora*)

health care professionals that they be alert to any potential cases of liver damage and to report these. South Africa took similar action in December 2002.

The TGA initiated a voluntary withdrawal of all complementary medicines containing kava in August 2002. The voluntary recall was a precautionary measure to enable the TGA in consultation with the complementary medicines industry, to evaluate the use of kava and if its use is associated with liver damage. The TGA has further considered if any additional regulatory action on such products needs to be taken and this is discussed in section 5.6.

The New Zealand Food Safety Authority (NZFSA) has released a statement that advises New Zealanders using dietary supplements containing kava (i.e. both food and medicinal types) to carefully consider whether to continue taking them. The NZFSA has not withdrawn the products from the market.

4.5.2 *Implications for FSANZ*

A recall of foods containing kava was not considered necessary because no food-type dietary supplements containing kava were found in Australia. Food-type dietary supplements manufactured in accordance with the NZDSR containing kava could potentially be on the Australian market and it was noted that one kava containing beverage manufactured in New Zealand had previously been found on the Australian market, however, no products were identified recently. In New Zealand, a confectionery was found that contained kava extract. This product was not produced in great quantities and is not exported to Australia.

5. **Relevant Issues**

5.1 **Safety**

Safety evaluations have been undertaken separately for the **traditionally prepared kava drink** and **kava extracts** (see Attachment 4). This is summarised below.

5.1.1 *Kava in the form of the traditionally prepared drink*

Traditionally, kava drink is prepared from the roots of the *Piper methysticum* plant where: the root is chewed or ground until it is fine and fibrous, soaked in water, strained and drunk; or dried material (as is primarily imported into Australia) is ground finely, wrapped in cloth and fused in water.

Previous considerations by the then National Food Authority

A toxicological evaluation of kava by the then National Food Authority in 1995 concluded that when consumed in moderation, long-term kava use does not appear to cause ill effects (NFA 33, Item 3.1). It was generally accepted that long-term consumption of large amounts of kava (heavy use is defined as 310 - 440 g dried powder/week) could lead to toxic effects.

- The most symptomatic effect of chronic kava drinking is the appearance of dry and scaly skin with yellow or white discolouration, known as kani kani. This condition develops after regular, almost daily consumption of kava and takes from a few months to a year to develop. It is readily reversible by reducing kava intake.
- Although use of kava in certain communities in the Northern Territory (and in New Caledonia) is now well established and there are reports of heavy usage (i.e. 10-50 times daily therapeutic dose, 60-120 mg kavalactones/day which can be derived from 310 – 440 g dried powder/week), no reports of irreversible liver damage have been

observed. Elevated levels of liver enzymes documented in kava users were found to return to normal levels upon ceasing or reducing kava consumption.

- Concerns about abuse of kava as a recreational drug leading to poor nutrition and subsequently, poor health were raised.

Safety evaluation prepared for this Report

FSANZ has conducted a safety evaluation of the traditional kava beverage as part of this review, at Attachment 4.

- Consistent with the findings of the previous toxicological evaluation in 1995, the most common side effect of heavy kava consumption over an extended period is an ichthyosiform skin rash known as kava dermatopathy or kani kani, characterised by flaky, dry skin with a yellowish discolouration of both the skin and nails. This condition is reversible.
- There have been no reported cases of liver toxicity associated with consumption of the traditional kava beverage, despite the recent heightened awareness. Changes in liver function parameters, including liver enzyme levels have been reported with the traditional kava beverage however, these have not been indicative of acute liver inflammation and changes have returned to normal within 1-2 months of cessation of use. An early study of the health effects of kava use in Aboriginal communities documented changes in liver function tests in kava drinkers. A recent study confirmed these findings, with increased serum γ -glutamyl transferase (GGT) and alkaline phosphatase (ALP) activity in 61% and 50% of kava users respectively. These enzyme changes generally returned to normal within 1-2 months of stopping kava use. Serum levels of alanine aminotransferase (ALT) were not raised in any kava drinkers in the study, which included very heavy users. In contrast, ALT levels were high in cases of hepatotoxicity associated with herbal products containing kava extracts.
- Other effects experienced by some kava drinkers such as headache, loss of appetite, indigestion, and visual effects were considered minor and reversible.
- Cognitive and saccade (eye movement) function tests were performed on a group of current, ex and non-kava users among an indigenous population in northern Australia, with some kava users being identified as heavy users. No impairment in cognitive or saccade function was found in individuals who were currently heavy users or those who had been heavy kava users in the past.

On the basis of current evidence, it is generally accepted 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.

5.1.2 Kava extracts and kava in food-type dietary supplements

Acetone or ethanol extracts of the roots of the plant *Piper methysticum*, which are concentrated standardised kavalactone preparations, are commonly used in complementary medicine in Australia and in dietary supplements in New Zealand and may also be used in food-type dietary supplements.

FSANZ has conducted a safety evaluation of kava extracts for use in food and this is at Attachment 4. The following points can be made about the safety of kava extracts.

- There have been 82 case reports of liver toxicity worldwide associated with herbal preparations containing kava extracts. These ranged in severity from liver abnormalities to liver failure associated with liver transplantation and death. Elevated ALT levels were noted in cases of hepatotoxicity, which were not seen with heavy consumers of the traditionally prepared kava drink. The three main forms of acute liver damage that can result from adverse drug reactions were seen: necrosis; drug-induced hepatitis; and cholestatic hepatitis.
- The mechanism of kava-related liver toxicity is not clear and there are no definitive predictors of liver damage however, some contributing factors have been suggested.
- Interindividual variability (ascribed to genetic differences) in drug absorption, disposition, metabolism or excretion may be associated with adverse drug reactions. Deficiency in CYP2D6, a cytochrome P450 enzyme, was observed in some of the cases of liver toxicity. In a Caucasian population 7-9% of individuals are homozygous deficient in CYP2D6 and, when deficiency occurs kavalactone metabolism may be decreased and thus contribute to liver toxicity, particularly when other medication or alcohol are also taken.
- The high kavalactone concentration in standardised extracts and the absence of glutathione (which is naturally present in the root of the kava plant) has the potential to saturate the enzymatic detoxification pathways, resulting in undue stress on the liver.
- It has been noted that the aerial parts of the kava plant have been used for kava containing herbal preparations. The aerial parts of the plant contain piperidine alkaloids, the structure of which is similar to pyridine alkaloids. Pyridine alkaloids have been shown to be cytotoxic and also features of 2,5-dihydroxypyridine, which has been shown to affect DNA integrity. There is no direct evidence of piperidine alkaloids in kava dietary supplements at this time however, research has identified the potential for adverse effects should the aerial parts of the plant be used in preparations.

While the mechanism of kava-induced liver toxicity remains unclear, the available published studies provide compelling circumstantial evidence that high exposure to kava extracts is associated with hepatotoxicity.

5.2 Dietary Intake and Nutrition

5.2.1 Dietary Intake

Kava, as a food (i.e. raw, ground or dried root), is not widely used in Australia except in communities such as some Pacific Islander or Aboriginal communities. In the broad community it would be predominantly used as a complementary medicine. Kava is not permitted to be added as an ingredient in other foods (with the exception of food-type dietary supplements regulated under the NZDSR).

Published commentary and the some literature on kava use in Australia have declared that Aboriginal people in Arnhem Land have consumed it at extremely high levels, far greater than in Pacific Island societies and that consumption takes place outside of a context of social controls (Alan Clough, personal communication). Normal dietary modelling of kava consumption in Australia cannot be undertaken, as kava is not listed in the 1995 National Nutrition Survey. The following information on import data, consumption data and kavalactone content provides some indication of the dietary exposure.

5.2.1.1 Import data

An early indication of the extent of kava consumption in the Northern Territory, total kava sales to Aboriginal communities have been reported for 1986 (3,688 kg), 1987 (7,216 kg),

1988 (11,165 kg), 1989 (23,893 kg), 1990 (23,077 kg), 1991 (19,235 kg) and 1992 (10 months only) (15,263 kg). Total kava imports were estimated in 1998 to be 23,405 kg, imported mainly through NSW, Queensland and Victoria. This estimate was made from reports by signatories to the KCMG, and is assumed to be significantly underreported as only 20% of the total signatories made a report to the Management Group. Estimates from imported food data are less reliable because only a small fraction of kava imports are referred to AQIS for testing. No data is available on New Zealand consumption is available.

5.2.1.2 Consumption data

Early studies (1986-87)³ reported a prevalence of kava use of 42% of the population and more recently 56%⁴ and 66%⁵ with a greater proportion of males (from 53% to 71%) than females (from 6% to 51%)^{4,6}.

Recent changes in the diversity and patterns of substance use, including kava, in eastern Arnhem Land was recently investigated, with consumption measured in both 1999 and 2000 (the samples surveyed differed)⁷. In 1999 46% of males and 18% of females were kava users, while in 2000, 52% of males and 11% of females were kava users. However, when comparing kava use in the Miwatj region only, men's kava consumption had declined. During this time, the estimated size of the informal kava trade in Arnhem Land has dropped from \$6-8 million in 1997-98 to \$5 million in 1999 to \$3.8 million in 2000⁸.

5.2.1.3 Kavalactone dose from traditionally prepared beverage

Clough et al. (2000)⁵ estimated the quantity of kavalactones consumed by Aboriginal kava drinkers. Total kavalactone content of kava powder may be 10-15% (average 12.5%) of dry weight depending on factors such as plant growth conditions and age of plant at harvesting.⁹ The effectiveness of kavalactone extraction is not standardised and is subject to social-contextual as well as physical variations in the substance. The efficacy of extraction of the active constituents in infusions of 33 g/L of kava powder in water is from 81% to 83%¹⁰. The major active constituents all seem to deteriorate at varying rates in storage¹¹. In one hour each person drank approximately 670 mL (633-715 mL) (i.e. just under 7 cups of 100 mL) of liquid containing 37 g (34 -39 g) of kava powder⁵. Given that extraction efficiency is likely to be around 82%, approximately 3800 mg kavalactones would be consumed⁵.

5.2.1.4 Summary

Contrary to anecdotal evidence, weekly consumption of kava in Arnhem Land appears

³ Alexander, K., Watson, C. and Fleming, J. (1988) **Kava in the north: a study of kava in Arnhem Land Aboriginal communities**. *Aboriginal health Inform Bull*, 10, pp 32-37

⁴ Mathews, J., Riley, M., Fejo, L, et al. (1988) **Effects of the heavy usage of kava on physical health: summary of a pilot survey in an Aboriginal community**. *Med J Aust*, 148, pp 548-555.

⁵ Clough, A.R., Burns, C.B. and Mununggurr, N. (2000) **Kava in Arnhem Land: a review of consumption and its social correlates**. *Drug Alcohol Rev*, 19, pp 319-328.

⁶ d'Abbs, P. (1993) A review of kava control measures in the Northern Territory. Report no. 3/95. Darwin: Menzies School of Health Research.

⁷ Clough, A.R., Guyula, T., Yunupingu, M. and Burns, C.B. (2002) **Diversity of substance use in eastern Arnhem Land (Australia): patterns and recent changes**. *Drug Alcohol Rev*, 21, pp 349-356

⁸ Clough, A.R. (2000) Response to issues paper. National Competition Policy Review of the Kava Management Act. Darwin: Northern Territory Government.

⁹ Lebot, V., Merlin, M. and Lindstrom, L. **Kava – the Pacific Elixir**. VT: Healing Arts Press (1997)

¹⁰ Duve, R.N. and Prasad, J. (1984) **Efficacy of extraction of constituents in the preparation of yaqona beverage. Part 2: major active constituents**. *Fiji Agric. J.* 46, pp 11-16.

¹¹ Duve, R.N. and Prasad, J. (1983) **Changes in the chemical composition of “yaqona” (*Piper methysticum*) with time**. *Fiji Agric. J.* 45, pp 45-50.

similar to consumption levels in Pacific Island populations⁵. The highest levels of consumption in Arnhem Land have been reported to be up to 900 g/week of kava powder with heavy consumers drinking at least 610 g/week, levels comparable to estimates for Pacific Island countries. 37g of kava powder was estimated to contain around 3800 mg of kavalactones which would typically be consumed in 670 mL of water in an hour⁵. This dose of kavalactones in the traditional beverage which would be typically consumed on one occasion far exceeds the doses of kavalactones in kava-extract preparations (less than 250 mg) implicated in liver toxicity.

5.2.2 Nutrition

The Full Assessment Report (now known as Draft Assessment Report) for A242, which was completed by the then National Food Authority in 1995 assessed the nutritional issues associated with kava consumption. At this time the following conclusion was made:

“There are reports that malnutrition is higher amongst kava users than non-users in NT Aboriginal communities. This (like the toxicological aspects of kava consumption) appears to be a result of kava abuse where some users fail to maintain adequate intake of other foods rather than a consequence of kava ingestion per se. There are no known nutritional problems associated with the moderate use of kava”.

FSANZ’s assessment indicates that this is largely still the case. To provide clarity to the last sentence in the aforementioned paragraph, there are nutritional problems associated with kava (i.e. malnutrition) but it is not clear that the malnutrition is caused by kava consumption.

The possibility of kava dermopathy (skin condition also referred to as kani kani) being caused by a niacin deficiency was recently investigated. The results of the study indicated that niacin deficiency was not responsible for the scaly rash, which is characteristic of an acquired ichthyosis.

Assessing the nutritional impact of kava consumption is difficult since the background diet of consumers is often compromised and may have been for a number of years. One research group has investigated kava use and the biomarkers of dietary quality and coronary heart disease and nutritional status in Aboriginal people in Arnhem Land (personal communication from Alan Clough). Skin fold thickness, body mass index and body fat were decreased in kava users compared with non-kava users. Total and LDL cholesterol were elevated in kava users compared to both former users and those who had never used kava. HDL cholesterol was higher in current users versus never users. Plasma levels of carotenoids were extremely low compared to other populations (e.g. non-Aboriginal populations) but did not vary with kava usage. High plasma homocysteine levels across all groups were consistent with low dietary folate intake and increased coronary heart disease risk.

5.3 Importation and distribution of kava through the NCKM

While the Code permits the sale of raw kava in Australia and New Zealand, Australian States and Territories are able to impose conditions on its supply and sale as currently occurs with the supply and sale of alcoholic beverages.

For example, since the implementation of the NCKM, the Northern Territory has imposed stricter regulations for kava and Western Australia was able to retain its regulations that came into effect in 1988. Both of these jurisdictions control the supply, sale and possession of kava throughout the State or Territory beyond that which is outlined in the provisions of the

NCKM. Additionally, the Code Management Advisory Group that oversaw the implementation of the Management Code, disbanded in October 2000 as their function was largely redundant following the commencement of the *Northern Territory Kava Management Act* in 1998.

At the time of the release of the Initial Assessment Report, it was suggested that the NCKM had been made redundant by the Northern Territory legislation and that the only function that Standard 2.6.3 fulfils is in stipulating labelling requirements, providing a definition for kava and prohibiting its use as an ingredient in other foods. It is now clear, based on information received from the Northern Territory, that the NCKM is still relevant. A person holding a kava licence in the Northern Territory, which is issued by the Racing, Gaming and Licensing Division, is also required to comply with the NCKM and a breach of the NCKM constitutes a breach of licence conditions. Removing the reference to the NCKM in the Code would impact on the Northern Territory. NSW, who have indicated that they import the largest quantity of kava of any of the state or territory jurisdictions, have also indicated that the NCKM works well for their purposes and removal of the reference to the NCKM will have an adverse impact on their operational activities.

5.3.1 *Kava as a controlled substance*

Kava is generally consumed for its intoxicating affects. As such, a discussion of the regulation of alcohol, another intoxicating substance, is relevant for the purposes of comparison.

The composition and labelling of alcoholic beverages are regulated in the Code. Definitions of different alcoholic beverages are provided in the Code, as are permissions for the addition of other foods in the final product and during production, and food additive permissions. Labelling of alcoholic beverages regulated by the Code include: declaration of alcohol by volume; standard drink labelling; and representations in relation to alcohol. However, the control of supply and distribution of alcohol is regulated by individual state and territory liquor licensing bodies. These control measures include restrictions on where alcohol can be sold, how alcohol can be advertised, and the sale of alcohol to minors.

Kava is regulated in a similar way in that the Code provides a definition for kava along with compositional and labelling requirements, while the control of supply and distribution are managed through another mechanism, namely the NCKM, noting that the Northern Territory and Western Australia have implemented stricter control measures. It could be argued that theoretically kava supply and distribution could be regulated through agencies in states and territories, which also regulate substances such as alcohol and/or tobacco. However, there are also some disadvantages with this approach:

1. The NCKM has worked well to achieve its intended outcome, i.e. limit the widespread availability of kava to the general community, and so there is little incentive to change this approach.
2. It would be difficult to gain agreement from all states and territories that legislation restricting sale and availability is required since kava use or abuse is only an issue in a minority of jurisdictions. It is unlikely that implementing kava control outside the existing framework will be seen as a national priority.
3. If all references to the NCKM were removed and any state or territory failed to act to implement restrictions on supply and distribution, there is a considerable risk that kava use will become more widespread through the general community.

So while the approach taken with kava regulation shares similarities with alcohol regulation,

it differs in others. Overall, FSANZ favours retaining the reference to the NCKM, which addresses the supply and control issues because:

1. Kava use is not widespread in the general community, but restricted to certain community areas and groups.
2. The NCKM has been effective at preventing the widespread use of kava in the community.

5.4 Labelling issues

Standard 2.6.3 currently prescribes three labelling statements on a label on or attached to a package containing kava:

- ‘Use in moderation’
- ‘May cause drowsiness’
- ‘The sale and distribution of kava in Australia is subject to the National Code of Kava Management’

Further, where kava is offered for sale other than in a package, those statements must be displayed in connection with the food.

The following points received from Alan Clough, of the Menzies School of Research, Northern Territory, in a personal communication are applicable to labelling considerations:

- Kava is always sold as packaged powder and it is mixed with water by the people who consume it.
- Labelling statements required by Standard 2.6.3 distinguish legal kava from the black market trade in the Northern Territory and so their presence is important for enforcement purposes.

While not all consumers are able to read the statements on the label, the formality provides the package with an important legal status and consumers feel assured by the involvement of a regulatory body.

5.4.1 Issues raised by submitters

NZFSA raised concern about the current mandatory statement relating to the NCKM applying in Australia and suggested that the basis for any mandatory labelling should be assessed considering the New Zealand environment. The NCKM does not apply in New Zealand.

Labelling should be encouraged and can assist in control measures. The Pacific Islands Forum Secretariat suggested that labelling of kava could include quality standards developed by Pacific Islander countries.

The NSW Health Department suggested two additional labelling requirements be mandated in the Code: i) ‘not to be sold to minors’; and ii) a prohibition on advertising of kava. NSW Health noted that breaches on the prohibition on advertising in the NCKM have been difficult to enforce. Incorporating these requirements into the Code would make direct enforcement action by States and Territory health departments possible.

5.4.2 Assessment of issues

FSANZ has reviewed all of the current labelling requirements for kava and assessed these requirements against general criteria for labelling.

5.4.2.1 Prescribed statement: ‘The sale and distribution of kava in Australia is subject to the National Code of Kava Management’

The NCKM applies in Australia (and this Report proposes that the NCKM should continue to apply) but does not apply in New Zealand. As such, the requirement for a statement referring to the existence of the NCKM needs to be reviewed.

This statement is not related to public health and safety and does not serve a clear purpose for the consumer. The statement merely draws attention to the existence of the NCKM and does not explain the implications of the NCKM for the consumer. In other words, while the consumer of kava is required to comply with the NCKM, inclusion of this statement on the label of a package of kava does not inform the consumer of this obligation.

The statement may assist in enforcement action but the reference to the NCKM does not guarantee the legality of the product, which is subject to additional requirements being met. In addition, the NCKM refers back to Standard 2.6.3, providing a suitable link to regulation requirements for importers, consumers and enforcement officers.

Since the NCKM does not apply in New Zealand, it is not logical to require a statement of this nature on kava sold in New Zealand. If New Zealand were to be exempt from this prescribed statement while it is retained in Australia, the implication of TTMRA is that kava sold in New Zealand without the statement could be imported into Australia and subsequently sold. This means that the requirement to refer to the NCKM could not be used as a criterion for assessing the legality of kava in Australia.

Conclusion: The statement should not be required.

5.4.2.2 Prescribed statements: ‘Use in moderation’ and ‘May cause drowsiness’

These statements are considered together as they both convey information that is relevant to public health and safety. There are risks associated with the inappropriate or excessive consumption of kava as set out in the safety assessment (Attachment 4). 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 notes that kava was not regulated under the *New Zealand Food Regulations 1984*, which have since been repealed, and it has been reported that there have not been any significant problems with kava use in the absence of any labelling requirements.

FSANZ has established criteria for the inclusion of advisory or warning statements in relation to food. The text for advisory statements is generally not prescribed, while the text for warning statements is prescribed. Warning statements are generally only required when the risk to the public of consuming a food may result in death, however, it is possible to argue that certain statements that are not considered warning statements should be prescribed in the Code. Consumption of kava is not likely to result in death, however, arguments can be put forward for retaining these statements with prescribed text as follows:

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 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, enforcement may be more difficult if the text for the statements in question is not prescribed.

Conclusion: Retain the statements, ‘use in moderation’ and ‘may cause drowsiness’ as prescribed statements in Standard 2.6.3. For the purpose of consistency and providing additional protection to public health and safety, these statements should apply in New Zealand as well as Australia.

5.4.2.3 Requirement for statements to be supplied in conjunction with unpackaged kava

FSANZ is aware that kava is generally sold in packages of a size that would require general labelling requirements in addition to the prescribed statements. However, it is potentially possible for kava to be sold unpackaged or in very small packages.

If this requirement was not included, unpackaged kava would currently still be required to contain the prescribed statements discussed above, but would not be required to provide all the other labelling requirements set out in the Code (which will be discussed in a subsequent section). Since it is proposed that the statement referring to the NCKM will not be retained, it would be useful for unpackaged kava or kava that would otherwise be exempt from general labelling requirements to have supplier details provided in conjunction with that kava to establish the legality of the product for enforcement purposes (establishing whether or not the supplier holds an import licence and permit or is a signatory to the NCKM).

Conclusion: Retain this requirement for kava that would otherwise be exempt from labelling requirements and include a requirement for the inclusion of supplier details also.

5.4.2.4 General labelling requirements

A number of general labelling requirements set out in Part 1 of the Code will apply as follows:

- legibility requirements;
- supplier details;
- name of the food;
- lot identification and/or date marking; and
- directions for use and storage required for public health and safety.

Kava will be exempt from ingredient labelling as it is a single ingredient food and the name of the food would otherwise be the ingredients in the food. Country of origin requirements are currently under review. However, current country of origin labelling requirements apply in Australia but do not apply in New Zealand. Country of origin labelling is generally supplied on packaged kava and some Pacific Island countries (e.g. Vanuatu) require kava for export to include country of origin labelling. Packages of powdered kava typically include

statements such as ‘original product of (e.g. Vanuatu)’.

5.4.2.5 Nutrition information

Kava will be exempt from the requirement to display a nutrition information panel as described in Standard 1.2.8 – Nutrition information requirements. There are two main reasons for exempting kava from the requirement to display nutrition information as follows:

- Kava is consumed for its intoxicating properties rather than for satisfying thirst or hunger and would not contribute significant nutrients to the diet. Information about its nutritional value would not be considered relevant or used by consumers.
- It is not practical for the producer or importer to provide this information due to the variable nutrient composition. The composition of kava varies between different varieties, and within the same variety differs with growing conditions, age of the plant and preparation techniques.

5.4.2.6 Quality standards

In relation to suggestions about incorporating quality standards developed in Pacific Islander countries, FSANZ considers that this information is more appropriate for the definition of kava and the information provided by submitters has assisted in clarifying the definition of kava.

5.4.2.7 Additional suggested labelling statements

The two additional labelling requirements suggested by NSW Health (i.e. ‘not to be sold to minors’ and a prohibition on advertising of kava) duplicate requirements set out in the NCKM. The NCKM prohibits an importer or distributor of kava from selling to anyone under the age of 18 and from advertising.

While incorporating these requirements into the Code would make direct enforcement action by States and Territory health departments possible, the existing national framework already addresses these issues of advertising and sale to minors. The national framework for managing kava use provides minimal regulation in the Code (including a definition, a prohibition on mixing kava with other foods and labelling information related to public health issues) and is supported by the NCKM, which sets out more detailed requirements and restrictions. This national framework allows State and Territory jurisdictions to legislate in order to further strengthen restrictions on kava use if deemed necessary for public health reasons, which both the Northern Territory and Western Australia have done. FSANZ believes that it is not appropriate to further strengthen restrictions on kava use through the Code since this would be inconsistent with the nationally agreed framework in which issues such as these are dealt with at a State or Territory level.

5.5 Additional issues raised in submissions

A summary of the issues raised by submitters is at Attachment 5.

5.5.1 Safety and the distinction between the traditional and medicinal use of kava

Submitters generally, particularly those representing Pacific Island Countries and business interests, highlighted the need to distinguish between different varieties and uses of kava. It was noted that there are significant differences in the chemical composition of the traditionally prepared kava beverage and the kava extracts present in medicinal/dietary supplement use and this should be considered during the safety assessment. In particular, the

concentrations of kavalactones are considerably different in the traditional kava beverage compared to pharmaceutical products. Submitters highlighted that the traditional kava beverage has not been implicated in liver damage.

Consideration by FSANZ

FSANZ agrees that it is important to consider the different uses of kava and the different cultivars of the plant in discussions on safety. As such, FSANZ has conducted separate safety reviews for:

- (i) the traditionally prepared kava beverage; and
- (ii) kava extracts.

5.5.2 Definitions

Some submitters believed that kava is defined too broadly in Standard 2.6.3 – Kava, and that the distinction between ‘kava’ and ‘kava products’ (such as extracts) should be clarified. The submission from the Tongan government suggests that kava products and their intended use should be internationally classified instead of using the general term ‘kava’ and a classification system was recommended. The submission from Vanuatu Kava Exporters Association noted that kava is used as a generic term to refer to all kava beverages, all kava cultivars, all organs and all extracts that are added to herbal products.

Consideration by FSANZ

FSANZ recognises that the definition for kava in the Code is broad and should be refined. FSANZ considered restricting the definition of kava to certain varieties, those of the nobles kava varieties as defined in the *Republic of Vanuatu Kava Act No. 1 2002*. In order to obtain further input on the reference to varieties of kava in the definition, FSANZ wrote to all submitters to the Initial Assessment Report from Pacific Island countries, seeking their views on elements of the proposed definition. Very comprehensive and helpful responses were received and were taken into consideration in arriving at the proposed definition.

The first point to be made from responses is that as the names used for nobles kava in that Act are specific to Vanuatu and in other Pacific Island countries these names would have no relevance. This raises the need for universally accepted nomenclature for referring to kava varieties. While responses indicated that referring to nobles kava by name for the purposes of regulation has merit, it is a complex task to establish a protocol for the naming of different varieties and the number of nobles kava is likely to be too long to include in regulation. Some suggestions for naming varieties include the use of: traditional names; plant morphology and/or analytical methods. FSANZ believes that it is not currently feasible to develop a system for naming kava varieties within the scope of this review. As such, the following definitions are proposed in this Report:

cold water extraction means the aqueous suspension of kava using cold water only and excludes the use of any organic solvent.

kava means:

- (a) a beverage obtained by cold water extraction of, or
- (b) the dried or fresh form of

the whole or peeled root, but excluding any root peelings and any of the aerial parts, of plants of the species *Piper methysticum*.

5.5.3 *Economic impacts*

Extensive economic data was provided from the Pacific Islands Forum Secretariat which give details on the loss of earnings that have occurred since the restrictions on the sale of kava that have been instituted by the European Union. The Republic of Vanuatu, Department of Trade, Industry and Investment and the Fiji Ministry of Agriculture, Sugar and Land Settlement have also provided economic data in relation to the size of their domestic and export markets.

Consideration by FSANZ

FSANZ is grateful for this economic data and this has been considered in the impact analysis (section 7 of this report).

5.5.4 *Legislation governing Kava in Pacific Island countries*

The governments of the Kingdom of Tonga (Tonga) and Vanuatu have developed or are in the process of developing legislation in relation to kava. Tonga has developed a Model Quality Assurance Manual and the government is taking steps to implement the manual. The Tongan government is also in the process of drafting; Export Quality Regulations under the *Agricultural Export Commodities Act*; and a *National Food Standard Code* (noting that the kava standard will be harmonised with any international standards relating to kava). The Vanuatu government recently passed the *Kava Act No 1 of 2002* in which kava cultivars have been identified and divided into 4 categories.

Consideration by FSANZ

FSANZ is grateful for access to this legislation which has assisted in the development of this Report. One particular section of the Vanuatu Kava Act has been considered for incorporation into the definition for kava. Progress made by Pacific Island countries in developing such legislation has provided assurance of the quality of kava being imported into Australia and New Zealand.

5.6 TGA consideration of the safety of kava-containing medicines

Following the voluntary recall of kava-containing medicines in August 2002 initiated by the TGA, sponsors of kava-containing medicines were asked by the TGA to provide evidence of the safety of their products. The question whether kava should be permitted for use in listable therapeutic goods needed to be addressed. The TGA has conducted an evaluation of the safety data for kava. The Kava Evaluation Group was formed to review the safety data available for kava and make recommendations to the Complementary Medicines Evaluation Committee (CMEC) on whether or not kava is suitable for use as an ingredient in listed medicines and if so, under what conditions. The Kava Evaluation Group met on 30 June 2003 and consisted of representatives from the Adverse Drug Reaction Unit, TGA, the Adverse Drug Reaction Advisory Committee, the Complementary Healthcare Council, the Australian Self-Medication Industry, the Australian Centre for Complementary Medicine Education and Research, NZ Medsafe, NZ Medicines Adverse Reactions Committee and NZ industry.

CMEC subsequently considered the recommendations of the Kava Evaluation Group on 1 August 2003 (Meeting 41) and the following decision record is published on the TGA website¹²:

¹² Sourced from <http://www.health.gov.au/tga/docs/html/cmec/cmecdr41.htm>

The CMEC endorses the following four recommendations made by the Kava Evaluation Group and recommends to the TGA:

Recommendation 41.2

Recommendation 1

That:

- i. aqueous dispersions of whole or peeled rhizome of *Piper methysticum*;
- ii. aqueous extracts of whole or peeled rhizome of *Piper methysticum*; and
- iii. dried whole or peeled rhizome of *Piper methysticum*

are suitable for use as ingredients in Listed medicines for oral use, subject to the following conditions:

- a. the preparation does not contain, for its recommended daily dose, more than 250 mg of kavalactones; and
- b. if the preparation is in a tablet or capsule – the amount of kavalactones does not exceed 125 mg for each tablet or capsule; and
- c. if the preparation is in a tea bag – the amount of dried whole or peeled rhizome does not exceed 3 g for each tea bag; and
- d. if the preparation contains more than 25 mg of kavalactones per dose – the label on the goods includes the following **warnings** (or words to the same effect):
 - Not for prolonged use. If symptoms persist, seek advice from a healthcare practitioner;
 - Not recommended for use by pregnant or lactating women; and
 - May harm the liver.

Recommendation 2

That *Piper methysticum* may be used in homeopathic preparations more dilute than a thousand fold dilution of a mother tincture.

Recommendation 3

That:

- i. aqueous dispersions of whole or peeled rhizome of *Piper methysticum*;
- ii. aqueous extracts of whole or peeled rhizome of *Piper methysticum*; and
- iii. dried whole or peeled rhizome of *Piper methysticum*

are suitable for use in Listed medicines for topical application to the rectum, vagine and by spray to the throat.

Recommendation 4

That *Piper methysticum* may be used as an ingredient in Listed medicines for topical application to the skin.

Recommendation 41.3

The CMEC recommends to the TGA that products containing *Piper methysticum* must be Registered prior to their supply, other than:

- i. aqueous dispersions of whole or peeled rhizome of *Piper methysticum*;
- ii. aqueous extracts of whole or peeled rhizome of *Piper methysticum*;
- iii. dried whole or peeled rhizome of *Piper methysticum*;
- iv. products for topical application to the skin; and

- v. homoeopathic preparations more dilute than a thousand fold dilution of a mother tincture.

These recommendations do not represent the decisions of the TGA. The TGA will consider the policy implications of the CMEC recommendation in due course.

6. Regulatory Options

Four regulatory options were posed at Initial Assessment. These have been refined to give the following regulatory options which have been investigated during the draft assessment.

6.1 Option 1 - Maintain the Status Quo

This option represents the current regulations described in section 2.1 of this Report. Standard 2.6.3 – Kava would be retained without modification and the NCKM would continue to apply in Australia. The addition of kava to other foods would continue to be prohibited however, food-type dietary supplements containing kava manufactured in accordance with NZDSR could remain on the market in New Zealand and be imported into Australia under the TTMRA. Current labelling requirements set out in Standard 2.6.3 and the existing definition for kava would continue to apply.

6.2 Option 2 - Maintain Standard 2.6.3 – Kava (with suggested amendments) in conjunction with the NCKM

There are three sub-options within Option 2. All sub-options involve retaining Standard 2.6.3 – Kava, to operate in conjunction with the NCKM. The different sub-options represent different amendments to the Code, in particular, Standard 2.6.3.

6.2.1 Option 2(a)

Amend definitional and labelling aspects of Standard 2.6.3 and prohibit the use of acetone and ethanol extracts of kava in food through Standard 1.4.4.

The NCKM would apply in Australia in its existing form without amendment. The following changes to the Code would apply:

- Definition of Kava in Standard 2.6.3 – Kava, would be amended to read as follows:
 - cold water extraction** means the aqueous suspension of kava using cold water only and excludes the use of any organic solvent.
 - kava** means:
 - (a) a beverage obtained by cold water extraction of, or
 - (c) the dried or fresh form ofthe whole or peeled root, but excluding any root peelings and any of the aerial parts, of plants of the species *Piper methysticum*.
- The labelling requirements set out in Standard 2.6.3 – Kava, would be amended such that the following should apply:
 - The statements ‘may cause drowsiness’ and ‘use in moderation’ will be retained as prescribed statements. Where kava is offered for sale other than in a package,

- these statements will be required to be displayed in connection with the food.
 - The statement ‘the sale and distribution of kava in Australia is subject to the National Code of Kava Management’ will no longer be required.
 - Nutrition information will not be required to be displayed on a package of kava.
- The use of organic solvent extracts of kava in food would not be permitted in food, by exclusion from the scope of the definition of kava.

The current prohibition on the mixing of kava with other foods would be retained however food-type dietary supplements containing kava manufactured to the NZDSR could remain on the market in New Zealand and be imported into Australia under the TTMRA.

6.2.2 Option 2(b)

Amend Standard 2.6.3 – Kava, to prohibit the addition of kava to any food (i.e. remove recognition that, in New Zealand, kava can be added to dietary supplements)

This option could theoretically be with or without the aforementioned amendments described in Option 2(a).

This option was presented in the Initial Assessment Report as Option 2 and was preferred by more submitters than the other options presented. This option essentially reverts Standard 2.6.3 to its original version: that kava is prohibited as an ingredient in any food, including food-type dietary supplements manufactured in accordance with the NZDSR. This option could also incorporate the amendments suggested in Option 6.2 in relation to the definition and labelling. The NCKM would continue to apply in Australia.

In order to remove food-type dietary supplements containing kava from the market in New Zealand and from being imported into Australia, the New Zealand Food Safety Authority (NZFSA) would need to support the amendment of the NZDSR to prohibit kava as an ingredient in these products as an interim measure until such times as the future of the NZDSR is decided. NZFSA has indicated in their submission to the IAR that this option will not be supported even though it was the favoured regulatory option for the majority of submitters. They indicated that dietary supplements containing kava will remain on the market in New Zealand until further risk information becomes available or until there is a regulatory change revoking the NZDSR. NZFSA also note that the inclusion of kava in food-type dietary supplements is so insignificant that it is almost a non-issue, is not unique and this trans-Tasman anomaly can wait until Proposal P235 – Review of food-type dietary supplements is resolved.

It does not appear possible to pursue this option given the lack of support from NZFSA and as such, the impacts of this option have not been explored in section 7 of this report.

6.2.3 Option 2(c)

Amend Standard 2.6.3 – Kava, to allow the addition of kava to other foods

The option involves removing the current prohibition on the addition of kava to other foods. The importation and distribution of kava would still be subject to the NCKM however, kava (not including kava extracts) could then be added to other foods and sold. The widespread use of kava in Australia would still be curtailed by the NCKM since the recipient is required to comply with the NCKM and 18 years of age or older. It is unlikely that there is much demand for this permission of being able to add kava to other foods since there the market is probably not sufficiently large to meet the manufacturing costs involved. It is worth noting

that there would still be an uneven playing field with respect to Australia and New Zealand since food-type dietary supplements manufactured to the NZDSR may contain kava extracts (which would not be permitted to be added to foods in Australia) and these could continue to be sold in Australia without restriction by the NCKM or labelling requirements.

This option would incorporate the definitional, compositional (prohibition on use of organic solvent extracts in food) and labelling changes described in Option 2(a).

6.2.4 Option 2(d)

Amend Standard 2.6.3 – Kava, and allow the addition of kava extracts in foods

This option would remove the current prohibition on mixing kava with other foods as well as permitting the addition kava extracts to foods. The use of kava in the making of the traditional drink would continue to be subject to the NCKM while the addition of kava extracts to foods would not since the same abuse problems with these ‘food-type dietary supplements’ have not been seen in New Zealand and are not anticipated. In order for this option to work, the definition would need to clearly distinguish between kava and kava extracts. As such, the definitional and labelling amendments suggested in option 2(a) would need to be incorporated as well as a definition with words to the effect that kava extracts include the organic solvent extracts of the whole or peeled root of the plant, *Piper methysticum*.

This option would harmonise the trans-Tasman regulations relating to kava however it is at odds with the conclusions of the safety assessment that acetone or ethanol extracts of kava could pose a risk to health and safety.

6.3 Option 3 - Remove Standard 2.6.3 – Kava, and accommodate definitions and labelling requirements in other parts of the Code

Standard 2.6.3 would be removed from the Code. Amended labelling requirements and definitions suggested in options 6.2 and 6.5 would be set out in Part 1 of the Code. Two sub-options could be considered:

- a) Prohibit the addition of organic solvent extracts to foods through Standard 1.4.4 – Prohibited and Restricted Plants and Botanicals.
- b) Allow the addition of organic solvent extracts to foods.

This would mean the removal of the reference to NCKM and as such the importation and distribution of kava would no longer be subject to the NCKM. The prohibition on mixing kava with other foods would be removed.

7. Impact Analysis

7.1 Affected parties

Parties that potentially are affected by this Proposal include:

- Traditional users of raw or ground dried kava.
- Importers and distributors of raw kava.
- State, territory and New Zealand governments involved in kava management.
- Public health workers contributing to kava management.
- Rural farmers and the agricultural sector in Pacific Island countries.

- Those sectors of the food industry wishing to produce or market dietary supplements containing kava, particularly in New Zealand.
- Consumers of food type dietary supplements containing kava.

7.1 Data Collection

Economic data has been used to inform the impact analysis of various regulatory options. Economic data was provided by submitters from Pacific Island countries and was sourced from:

- Fiji Islands Bureau of Statistics¹³;
- Statistics Office, Vanuatu Government¹⁴; and
- Tonga Bureau of Statistics.

The safety of the traditional kava drink and kava extracts most commonly used in dietary supplements and pharmaceutical products have been investigated (Attachment 4) and used to inform the impact analysis of various regulatory options.

The possible impacts of various regulatory options for enforcement agencies have been investigated through consultation with state and territory governments in Australia and the New Zealand government.

7.2 Impact Analysis

A detailed impact analysis is at Attachment 6. A summary presented in terms of the overall net benefit or cost to each affected party is included below.

7.2.1 Option 1 – Maintain status quo

The regulation of kava through Standard 2.6.3 and the NCKM has been effective in restricting kava use to a small section of the community, which is a benefit to the community in terms of minimizing abuse and any follow on health care costs. The regulatory framework is manageable and an overall benefit for enforcement agencies although it is a complicated system that is somewhat confusing. It has also allowed those state and territory jurisdictions with specific issues related to kava to implement stricter legislation. However, a number of costs with the status quo have been identified:

- Jurisdictions and submitters from Pacific Island countries have indicated that the definition for kava is inadequate for enforcement purposes, a cost to government enforcement agencies, and is sufficiently broad to encompass kava extracts, a cost to public health.
- The NCKM does not apply in New Zealand and kava was not regulated in New Zealand prior to the Code so labelling poses a cost to New Zealand industry.

7.2.2 Option 2

Option 2(a)

Traditional users would benefit from the increased quality assurance provided through clarification of the definition of kava and prohibition of kava extracts in foods. The clarified

¹³ Overseas Merchandise Trade Statistics May 2002; Statistical News No. 35, 2002 of 2 July 2002; Fiji Islands Bureau of Statistics, Suva, Fiji.

¹⁴ Overseas Trade, April 2002; Statistics Office, Vanuatu Government, April 2002.

definition for kava and the prohibition of kava extracts represents a benefit to agencies involved in kava management in addition to the benefit of retaining the overall existing regulatory framework currently supported by these agencies. The situation for public health workers is unlikely to change under this regulatory option. The credibility of the kava manufacturing industry could potentially benefit from this regulatory option in comparison with Option 1 however, it is unlikely that there will be any change to the amount of exports/imports of kava. The restrictions on kava sale and distribution which represent a cost to the food-type dietary supplement industry will be the same as with Option 1. Overall, Option 2(a) represents a benefit in comparison with Option 1.

Option 2(b)

It does not appear possible to pursue this option given the lack of support from NZFSA and so a cost-benefit analysis has not been undertaken.

Option 2(c)

Consumers of kava may benefit from this option in terms of increased availability of kava however there is also likely to be a cost to this group in terms of worsening or more widespread adverse effects of kava abuse. The potential benefits of increasing possibilities for innovation are unlikely to be realised to any great extent in Australia due to the restrictions of the NCKM. This option represents a cost to government agencies involved in kava management and enforcement and to public health workers due to the potential increase in the widespread use of kava. Kava exporting countries could potentially benefit from slightly broadened permissions however, they have generally not supported this option through submissions. Food-type dietary supplement industry in Australia may benefit slightly from this option however, there will still be some discrepancy between Australia and New Zealand. Overall, Option 2(c) is a cost in comparison with Option 2(a) and is not clearly favoured over Option 1.

Option 2(d)

This option would be a benefit to food industry in Australia and New Zealand, as it would allow them to develop innovative products, and the labelling burden would be reduced. The enforcement burden on states and territories would be reduced as the restrictions intended to maintain a very small market for kava would be eased. Countries exporting kava and importers of kava into Australia and New Zealand could potentially benefit because of increased demand however these countries generally indicated in submissions that this option poses too many risks at present since there is insufficient knowledge to allow the safe use of kava extracts in foods.

The potential cost to public health of reduced restriction on kava use is too high to warrant the benefits this option would afford the aforementioned parties. Many countries have implemented voluntary and mandatory recalls of medicines containing kava extracts and FSANZ would be taking a position against the scientific evidence and opposed to other regulatory bodies. While the concentrations of these extracts in foods are likely to be less there is not enough known about the contribution of kava containing products to liver hepatotoxicity.

7.2.3 Option 3

This option will provide increased availability of kava to consumers, which can be seen as a benefit however, there would also likely be a cost in terms of public health due to the substantially increased availability of kava in the general community. This option will be a cost to government enforcement agencies and public health workers due to confusion, lack of

knowledge about kava in the broader community, increased number of products and increased use. Importers and distributors and the food-type dietary supplement industry would benefit from this option. The option represents the breaking down of the existing regulatory framework which state and territory enforcement agencies have supported and as such (in combination with other costs), is not supported.

7.2.4 *Summary*

Option 2(a) is the preferred option based on:

- the benefit to enforcement agencies of the clear definition and the retaining of both Standard 2.6.3 and the NCKM;
- the benefit to consumers of increased protection of public health and safety afforded by the refined definition for kava.

8. Consultation

8.1 Submissions received in response to the IAR

A total of 12 submissions were received in response to the IAR. Submissions were received from:

- Health Departments of Western Australia and New South Wales;
- New Zealand Food Safety Authority (NZFSA);
- Food Technology Association of Victoria;
- Pacific Island Forum Secretariat representing the views of producers and exporters of kava from Forum Island Countries;
- Government departments of Fiji, Vanuatu, Tonga and Papua New Guinea; and
- exporters of kava from Vanuatu and Tonga.

Submissions from the Pacific Island Countries all highlighted the social and cultural significance of kava, the distinction between traditional and medicinal use, and the importance of kava to rural farmers as an agricultural crop.

The majority of supporters felt that permission for broader use of kava in the food supply (i.e. both the addition of kava to other foods and the use of kava extracts in food-type dietary supplements) should not be given, due to concern related to liver toxicity associated with medicinal use.

8.2 Technical Advisory Group (TAG)

The TAG comprises, amongst others, senior food officers in Australian State and Territory jurisdictions and New Zealand involved in enforcement activities. TAG members were consulted in October 2002 by teleconference. At this meeting TAG members were asked for their views on who should be consulted as the review progresses, whether the current regulatory framework is effective in managing the sale and distribution of kava in Australia, whether the NCKM is still required and the likely impact of removing reference to it in the Code, whether Standard 2.6.3 – Kava is now redundant, and appropriate regulatory options. TAG members noted the release of the IAR however little direction was received in relation to the issues raised. New South Wales, Western Australia and New Zealand subsequently made submissions to the IAR.

In May 2003 letters were sent to each Australian State and Territory jurisdiction seeking further comment on the effectiveness of the current regulatory system, whether there is an ongoing need for the NCKM now that the Northern Territory and Western Australia have more restrictive legislation in place, and, in particular, the likely impact on jurisdictions of removing the reference to the NCKM in the Code.

Responses to this letter from the Northern Territory indicated that the NCKM is still relevant. A person holding a kava licence in the Northern Territory, which is issued by the Racing, Gaming and Licensing Division, is also required to comply with the NCKM and a breach of the NCKM constitutes a breach of licence conditions. Removing the reference to the NCKM in the Code would impact on the Northern Territory. Also in response to this letter NSW, who have indicated that they import the largest quantity of kava of any of the state or territory jurisdictions, have also indicated that the NCKM works well for their purposes and removal of the reference to the NCKM will have an adverse impact on their operational activities. Responses from the ACT and South Australia indicated support for retaining Standard 2.6.3 and the NCKM. Tasmania, where there is little use of kava, indicated that removal of either Standard 2.6.3 or the NCKM would not have a significant impact on enforcement activity.

The regulation of kava was subsequently raised by FSANZ at a TAG teleconference in June 2003 and the proposed regulatory framework was discussed. A couple of issues were raised as follows:

- The NCKM is no longer being administered by the KCMG, but TAG had been identified as the appropriate forum to discuss enforcement of breaches of the NCKM.
- The appropriateness of health departments or equivalent having responsibility for administering the NCKM which essentially manages an intoxicating beverage. This issue was discussed in section 5.3.1.

8.3 Kahui Kounga Kai

No submissions from Maori groups were received in response to the IAR. FSANZ consulted with the Kahui Kounga Kai (Maori Reference Group) who indicated that kava use is not an issue for the Maori community and no further consultation was required.

8.4 Consultation on the definition for kava

FSANZ considered restricting the definition of kava to certain varieties, those of the nobles kava varieties as defined in the Vanuatu Kava Act No. 1 2002. In order to obtain further input on the reference to varieties of kava in the definition, FSANZ wrote to all submitters to the Initial Assessment Report from Pacific Island countries, seeking their views on elements of the proposed definition. The Department of Foreign Affairs and Trade coordinated the distribution of letters sent to government departments in Pacific Island countries. Very comprehensive and helpful responses were received and were taken into consideration in arriving at the proposed definition.

The first point to be made from responses is that the names used for nobles kava in the aforementioned Act are specific to Vanuatu and in other Pacific Island countries, these names would have no relevance. This raises the need for universally accepted nomenclature for referring to kava varieties. While responses indicated that referring to nobles kava by name for the purposes of regulation has merit, it is a complex task to establish a protocol for the naming of different varieties. Some suggestions for naming varieties include the use of: traditional names; plant morphology and/or analytical methods. FSANZ believes that it is not feasible to develop a system for naming kava varieties within the scope of this review.

8.5 Menzies School of Health Research, Northern Territory

FSANZ is appreciative of the assistance provided by Alan Clough of the Menzies School of Health Research and Northern Territory University, Darwin, Northern Territory. Alan Clough has undertaken extensive research in the areas of kava use and Aboriginal health and is currently preparing his doctoral thesis on kava.

8.6 World Trade Organization (WTO)

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

There are not any relevant international standards and amending the *Food Standards Code* to allow refinement of the definitions and amendment of the labelling requirements is unlikely to have a significant effect on international trade as the sale, distribution and consumption of kava will continue to be managed by the existing mechanisms, Standard 2.6.3 – Kava, in conjunction with the NCKM. It is not considered necessary to notify the agencies responsible in accordance with Australia and New Zealand's obligations under the WTO Technical Barrier to Trade (TBT) or Sanitary and Phytosanitary Measure (SPS) Agreements.

10. Conclusion and Recommendation

This review of Standard 2.6.3 – Kava, recommends that an amended Standard 2.6.3 be retained to operate in conjunction with the NCKM for the following reasons:

- The safety assessment indicates that consumption of the traditional kava beverage has a long history of safe consumption. Changes in liver enzyme function that have been reported in association with drinking the traditional kava beverage, and a skin condition known as kava dermatopathy are both reversible. It is considered safe for the consumption of the traditionally prepared kava beverage to continue.
- This regulatory framework provides an effective mechanism for minimising the abuse of kava as indicated by state and territory enforcement agencies.
- The Northern Territory, which has a high proportion of Australia's kava users, and NSW, which imports the largest quantity of kava of any Australian state or territory, have indicated that Standard 2.6.3 and the NCKM are still relevant and effective for their operational purposes.
- There will be a minimal impact on enforcement agencies, consumers and industry by retaining a separate commodity standard for kava and the NCKM.
- Kava is a distinct commodity with specific issues associated with its use. A separate commodity standard is appropriate for regulating kava.

Standard 2.6.3 should continue to retain a prohibition on the mixing of kava with other foods (other than those foods regulated under the NZDSR) for the following reasons:

- The majority of submitters indicated that the prohibition on mixing kava with other foods should remain in order to minimise the abuse and widespread use of kava.
- Government enforcement agencies expressed the view that the use of kava should be restricted to the traditionally consumed beverage to minimise the widespread use in the general population of Australia and New Zealand, which is likely to be unaware of the intoxicating properties.

A definition for kava should continue to be provided in Standard 2.6.3 however; the definition has been reviewed and amended for the following reasons:

- Submitters expressed concerns that the current definition for kava is too broad for enforcement purposes.
- An amended definition will exclude the use of kava extracts prepared by organic solvent extraction because of safety issues that associate the use of kava extracts with hepatotoxicity.
- An amended definition will restrict kava to the whole or peeled root of the plant because these plant parts have a tradition of safe use as a traditional beverage.

Labelling requirements should continue to be provided in Standard 2.6.3 for the following reasons:

- To provide consumers with important information on public health and safety.
- Required labelling is an important tool for enforcement agencies.

These labelling statements have been reviewed to consider their appropriateness in New Zealand where kava as a food was not regulated prior to Volume 2 of the Code.

11. Implementation and review

Following the consultation period for this document, the Final Assessment of the Proposal will be completed. Following the preparation of the Final Assessment Report and consideration by the FSANZ Board, a notification will be made to the Ministerial Council and it is anticipated that this will be completed by the end of the first quarter 2004. The revised Standard 2.6.3 – Kava, would come into effect shortly thereafter upon gazettal, subject to any request from the Ministerial Council for a review.

FSANZ does not propose to develop and implement an evaluation strategy designed to collect data on the consumption of Kava. Access to kava by the broad community is limited due of the requirements of the NCKM and use of kava is mostly confined to Pacific Islanders living in Australia and New Zealand and some Australian Aboriginal communities in the Northern Territory. Therefore, neither a national or bi-national approach to evaluating the use and impact of kava is appropriate. The Menzies School of Health Research in the Northern Territory is active in researching and addressing Aboriginal health issues, including investigating kava use and its impacts, and the Northern Territory Government actively monitors the effectiveness of kava controls in place. FSANZ considers it more appropriate that these bodies continue to monitor issues related to kava.

ATTACHMENTS

1. Draft variation to the *Australia New Zealand Food Standards Code*
2. National Code of Kava Management
3. History of kava regulation in Australia
4. Safety Assessment Report
5. Summary of submissions to the IAR
6. Detailed cost-benefit analysis

Draft Variation to the *Australia New Zealand Food Standards Code*

[1] *Standard 2.6.3 of the Australia New Zealand Food Standards Code is varied by –*

[1.1] *omitting from clause 1 the definition of kava*

[1.2] *inserting in clause 1 –*

cold water extraction means the aqueous suspension of kava using cold water only and excludes the use of any organic solvent.

kava means:

- (a) a beverage obtained by cold water extraction of, or
- (b) the dried or fresh form of

the whole or peeled root, but excluding any root peelings and any of the aerial parts, of plants of the species *Piper methysticum*.

[1.3] *omitting paragraph 3(1)(c)*

[1.4] *omitting paragraph 3(2), substituting –*

(2) Where kava is offered for sale other than in a package, there must be displayed in connection with the food the name and business address in Australia or New Zealand of the supplier of the food and the statements that would, if the kava were packaged, be required by subclause (1) to be included in the label on or attached to the package.

[2] *Standard 1.2.8 of the Australia New Zealand Food Standards Code is varied by –*

[2.1] *inserting in clause 3 –*

(p) kava as standardised in Standard 2.6.3 of this Code.

National Code Of Kava Management

Introduction

Purpose

Commonwealth, State and Territory Governments are concerned about the potential health impacts and social consequences of kava abuse in Australia. In recognition of these concerns, the Australian New Zealand Food Standards Council, which is a Council comprising Commonwealth, State and Territory health Ministers, has endorsed the use of the National Code Of Kava Management as part of a national strategy to promote the responsible sale distribution and advertising of kava in Australia.

The Code of Management applies to all those involved in the supply of kava as a food including importers, wholesalers, distributors and retailers. Kava imported into Australia and presented as a therapeutic good (eg. in a pharmaceutical dosage form with a stated dose and specified therapeutic use) is not subject to this Code of Management.

While Commonwealth, State and Territory Governments recognise the cultural importance of kava to the Australian South Pacific community, the National Code of Kava Management seeks to minimise the negative consequences of kava abuse in Australia. It has been developed in co-operation with governments, communities and industry. It provides a national framework within which all stakeholders can participate in, and take responsibility for, minimising the detrimental effects associated with the abuse of kava.

The National Code of Kava Management is to be read in association with State or Territory legislation addressing specific issues on kava, which apply in that jurisdiction.

The National Code of Kava Management has been prepared by the Commonwealth Department of Health and Family Services and the Australia New Zealand Food Authority. It sets out the conditions under which kava can be sold and advertised. It demonstrates:

- the commitment of the Commonwealth, State and Territory Governments to work with industry and community groups to minimise the detrimental health and social effects associated with the abuse of kava in Australia: and
- the commitment of stakeholders to take responsibility, and act responsibly, in accordance with its terms.

Regulatory framework

The National Code of Kava Management should be read in conjunction with the provisions of food law including the *Food Standards Code*. The National Code of Kava Management is intended to supplement the provisions of food regulation and is not taken as overriding or derogating from those provisions.

The Commonwealth Department of Health and Family Services, the Australian Customs Service and relevant State and Territory authorities expect signatories to comply with all requirements of the Code of Management. Compliance with the National Code of Kava Management will be monitored by the Code Management Group. This Group will also take action in relation to any failure to comply with the Code.

If compliance with the National Code of Kava Management is not achieved through self-regulation, State and Territory authorities will consider incorporating mandatory provisions to regulate the sale and advertising of kava in their separate jurisdictions.

PART 1 - GENERAL

Definitions

1. In this Code of Management:

‘Authority’ refers to the Australia New Zealand Food Authority and has the same meaning as in section 3 of the *Australia New Zealand Food Authority Act 1991*;

‘Code Management Group’ means the group established to administer the National Code of Kava Management;

‘confidential commercial information’ has the same meaning as in section 3 of the *Australia New Zealand Food Authority Act 1991* and is described in the Glossary of this document;

‘kava’ means the plant, or a derivative of the plant, *Piper methysticum*, whether or not mixed with water;

‘licence’ means a licence to import kava granted by the Commonwealth Department of Health and Family Services;

‘signatory’ means a person who has signed the Code of Management;

‘supplier’ means the importer, distributor and/or retailer who supplies kava for sale, and

‘supporter’ means any individual or organisation which endorses the *National Code of Kava Management* and may or may not be a supplier of kava.

PART 2 - OBLIGATIONS OF SIGNATORIES

Restrictions on the sale of kava

2. A supplier of kava must be a signatory.

In addition to being a signatory, an importer must have a licence.

An importer must only sell kava to a supplier who is a signatory.

A supplier of kava must not sell or otherwise provide kava to any person under the age of 18 years.

Suppliers, including importers, of kava must take all reasonable efforts to ensure that kava is only available for sale from signatories; and sale is in accordance with State and Territory requirements where they exist.

Records

3. A licensee (importer) must keep records of the:

- (a) quantity of kava imported;
- (b) quantity of kava sold to signatories, and their names and address, during the reporting period; and
- (c) dates of all transactions described in (a) and (b) in relation to the sale and receipt of kava

A licensee must provide the records described above to the Code of Management Group on request by a designated officer.

A licensee must keep records for three years.

Restriction on advertising and promoting kava

4. Kava is not to be advertised or promoted in any journal, magazine, television or radio or any other written or oral media, or in any retail advertising, or through the provision of samples.

PART 3 - CODE MANAGEMENT

Constitution

5. Management of the National Code of Kava Management will, for the first two years, be vested in the Code Management Group. The Group will comprise State and Territory Health authorities:

- an officer from the portfolio of the Northern Territory Department of Health;
- an officer from the portfolio of the Commonwealth Department of Health and Family Services; and
- a Member be drawn from nominees from a State or Territory food authority.

Terms of reference

6. The terms of reference for the Code Management Group are to:

- monitor and review compliance, including any complaints and their status; and
- review and evaluate the Code of Management and role of the Group at the end of the period of operation (i.e. two years).

PART 4 - RESPONSIBILITIES OF MANAGEMENT GROUP

Use of records provided to the Code Management Group

7. Records received by the Code Management Group will not be available to people or bodies other than members of the Code Management Group. Where appropriate, records will be summarised in reports. The Code Management Group may refer any breach of this Code, offences under other legislation, or other relevant information to appropriate authorities as it sees fit.

Where comparison of records indicates that a signatory to the Code of Management is not complying with the Code, the Code Management Group may:

- Upon notification in writing, require the signatory to give a written undertaking to discontinue, within a specified time frame, any practice which has been determined to constitute a breach or breaches of the Code.
- Upon notification in writing of a breach of the advertising restriction in this Code, require the signatory to issue corrective statements as appropriate. The wording and mode of publication and distribution of such will be subject to the approval of the Code Management Group or a designated State or Territory officer, prior to release/publication.

- When information regarding the breach of the Code by suppliers of kava is received that supplier will be warned by the Code Management Group or a designated State or Territory officer to cease the activity constituting the breach or have their name struck off the list of signatories.
- When information regarding the breach of the Code by a supplier of kava is received, importers will be warned by the Code Management Group or a designated State or Territory officer not to sell to them or face having their licences revoked.
- Where a second breach of the Code of Management is reported to the Code Management Group, the Group or a designated State or Territory officer (after appropriate investigation) can recommend to DHFS that an importer's licence be revoked.
- Loss of a licence to import kava will be publicised to all signatories.

Signing clause

8. Please read and complete the attached Signatory Declaration and return it either by:

Fax: 02 6271 2278

or

Mail: The Kava Code of Management Advisory Group
c/- Monitoring & Surveillance Program
ANZFA
PO Box 7186
CANBERRA MC ACT 2610

Glossary

ACS Australian Customs Service

AQIS Australian Quarantine and Inspection Service

DPSC Drugs and Poisons Scheduling Committee

DHFS Commonwealth Department of Health and Family Services

FST Food Science and Technology Subcommittee

IFIP Imported Food Inspection Program

ANZFA Australia New Zealand Food Authority

ANZFSC Australia New Zealand Food Standards Council (a Council comprising Commonwealth, New Zealand and State and Territory Ministers) Health

NHMRC National Health and Medical Research council

PHC Public Health Committee (NHMRC)

US FDA United States Food and Drug Administration

‘confidential commercial information’ in relation to food means:

(a) a trade secret relating to food; or

(b) any other information relating to food that has a commercial value that would be, or could reasonably be expected to be, destroyed or diminished if the information were disclosed.

Attachment to National Code of Kava Management

Standard O10 Kava

Purpose

This Standard, in conjunction with the “*National Code of Management on the Restriction of the Sale and Advertising of Kava*” (the National Code of Kava Management), regulates the sale and distribution of kava in Australia. While Commonwealth, State and Territory Governments recognise the cultural importance of kava to the Australian South Pacific community, this Standard and the National Code of Kava Management seek to minimise the detrimental effects associated with kava abuse.

Table of Provisions

1. Interpretation
2. Prohibition
3. Labelling

Interpretation

1. In this Standard ‘kava’ means the plant, or a derivative of the plant, *Piper methysticum*, whether or not mixed with water.

Prohibition

2. Kava must not be used as an ingredient in another food.

Labelling

3. (1) There shall be written in the label on or attached to a package containing kava, in type of 3 mm, the following statements:
 - (a) ‘USE IN MODERATION’
 - (b) ‘MAY CAUSE DROWSINESS’; and
 - (c) ‘THE SALE AND DISTRIBUTION OF KAVA IN AUSTRALIA IS SUBJECT TO THE NATIONAL CODE OF KAVA MANAGEMENT

(2) Where kava is offered for sale other than in a package, there must be displayed in connection with the food, in type of not less than 9 mm, the statements that would, if the kava were packaged, be required by subclause (1) to be included in the label on or attached to the package.

ATTACHMENT 3

HISTORY OF KAVA REGULATION IN AUSTRALIA

Date	Action
Pre-1985	Kava included in the old "Herbal Safe List"
March 1986	Aboriginal Health Section sought comment on pharmacological and toxicological aspects of kava from the Environmental Health Branch/NHMRC
April 1986	Kava referred to Ministerial Council on Drug Strategy (MCDS)
May 1986	MCDS noted that kava was used by aboriginal communities and requested a report of survey currently being conducted by NT Drug and Alcohol Bureau
April 1987	Noted in <i>Food Chemical News</i> that FDA would be taking no action regarding kava provided there was no evidence of toxic effects on consumers
November 1987	NHMRC resolution re kava stated that because of its psycho-active properties and potential for harm, use of kava should be actively discouraged.
November 1987	MCDS issued resolution: noted information regarding kava use and marketing in NT, noted approach of NT Government re kava, noted November NHMRC resolution regarding kava.
March 1988	MCDS recommended that use of kava should be actively discouraged, education programs for health workers in NT and WA
June 1988	Food Science and Technology Sub committee (FST) concluded that kava was a drug
July 1988	Public Health Executive Committee (PHC) agreed with FST that kava is a drug and referred matter to Drugs and Poisons Scheduling Committee (DPSC).
July 1988	Gazetted by WA Government – kava sale and supply restricted under <i>Poisons Act 1964</i> to cultural uses and medical/scientific research.
August 1988	DPSC agreed that scheduling was not appropriate at this time. (No tox concerns, can be controlled under State law, e.g. WA)
September 1988	PHC agreed that scheduling of kava was not appropriate at this time – WA approach better
January 1990	NT Department of Health and Community Services requested urgent consideration of kava in scheduling context.
February 1990	DPSC discussion of kava scheduling deferred to May meeting with States and Territory (other than NT) encouraged to make detailed comments.
May 1990	NT Health Minister (Steve Hatton) announced he had power under Section 19 of the Consumer Protection Act to prohibit or restrict sale of kava in NT from 15 June.
May 1990	DPSC considered formal request from NT Department of Health and Community Services to schedule kava. This was aimed at complementing mechanism under the Consumer Protection Act. Schedule 4 of the Standard for the Uniform Scheduling of Drugs and Poisons was proposed. Action: kava placed in Schedule 4: PHC and industry to be advised.
August 1991	National Food Authority (NFA) inherits proposal from the NHMRC Food Science and Technology Subcommittee for a Standard of prohibited botanicals to be incorporated in Standard A12 – Metals and Contaminants in Food.
August 1991	MCDS wrote to DPSC expressing concern that kava was S4 scheduled stating that this action too severe with implications for traditional users and other mechanisms of control (e.g. in WA0 are better).
November 1991	DPSC (63). It was noted that kava was placed in S4 due to representation from NT. In view of control under Consumer legislation the NT member of DPSC was asked if S4 still appropriate an to advise committee.
May 1992	NT Department of Health and Community Services advises DPSC that they have no objection to kava being removed from S4.

August 1992	DPSC (66) kava deleted from S4
History of kava in the Food Standards Code	
November 1992	NFA calls for public submission with regard to the proposed Standard for Prohibited Botanicals. (1 st round)
June 1993	NFA calls for public submissions with regard to the proposed Standard for Prohibited Botanicals. (2 nd round)
July 1993	Removal of kava from S4 effective from 14 July
August 1993	NFA recommends draft Standard for Prohibited Botanicals to NFSC (National Foods Standards Council).
November 1993	National Coordinating Committee on Therapeutic Goods (NCCTG) recommended that kava not be considered a therapeutic good.
January 1994	TGA inform NFA that kava will be de-listed as a therapeutic good.
March 1994	Kava gazetted as a Prohibited Botanicals on March 9.
February 1995	Northern Territory Department of Health and Community Services apply to NFA requesting change to A12 (8)a to allow kava to be sold in NT. Also request fast-tracking of application.
April 1995	<ul style="list-style-type: none"> • NFA Board reject request from NT Health for fast-tracking under sections 36 or 37 of <i>National Food Authority Act 1991</i>. • NFA gazette acceptance of application from NT Health • NFA calls for public submission on A242 - the proposed amendment to remove kava from Standard A12 Metals and contaminants in food
July 1995	NFA releases Information paper to promote discussion and submissions on proposed amendment.
December 1995	During assessment of A12, NFA agrees to remove kava from A12 and incorporates a new standard O10 – Kava.
October 1997	NT Government conducts Parliamentary Inquiry into Kava Management in the NT. This coincided with policy that no further permits would be issued for selling kava in NT.
October 1997	<ul style="list-style-type: none"> • Standard O10 – Kava gazetted in FSC: prohibits the addition of kava as ingredient in foods. Stipulates labelling requirements. Standard to operate in conjunction with National Code of Kava Management • National Code of Kava Management (NCKM): strategy to promote responsible sale, distribution and advertising of kava in Australia. • Compliance with NCKM and FSC monitored by the Code Management Advisory Group. • Kava prohibited under <i>Customs (Prohibited Imports) Regulations</i> & requires an import permit before it can be imported into Australia & used in a listable good. • Kava permitted as listed medicine with limitations (Part 5, Division 2 of Schedule 4 of Therapeutic Goods Regulations). Restrictions on maximum amount per dosage form and comply with maximum daily dose apply. Importers must obtain a License to Import Controlled Substances from the TGA. A separate permit to import is also required for each shipment of kava and will not be issued unless a license is held.
May 1998	<i>Kava Management Act 1998</i> comes into effect in NT - restricts use and sale of kava in NT. Selling of kava without a licence becomes illegal. Communities to apply to the Liquor Commission to become licensed to sell and use kava. Strategy is to obtain community support of the selling of kava.

Development of <i>Australia New Zealand Food Standards Code</i>	
October 1999	<ul style="list-style-type: none"> • P216 - Review of Standard O10 – Kava (Volume 1) to include in Volume 2 of FSC. (During development of joint Australia New Zealand food standards). • Standard O10 amended during transportation to Standard 2.6.3 to permit the addition of kava to foods regulated under NZDSR (i.e. food type dietary supplements).
October 2000	Code Management Advisory Group that oversees Code of Kava Management disband: decision reached because State controls now in place and effective.
Emerging cases of liver toxicity associated with use of complementary medicines	
Feb 2001	<ul style="list-style-type: none"> • Swiss withdraw marketing authorisation of Laitan, the acetonetic kava extract. • Status in Switzerland of other alcoholic kava extracts changed from OTC to OTC – pharmacy only (Schedule 2 medicine) • German Federal health authority (BfArM) proposes withdrawal of marketing authorisation for kava
Dec 2001	<ul style="list-style-type: none"> • UK FSA/UK MCA issue warning to consumers; consider voluntary withdrawal of complementary medicines; <ul style="list-style-type: none"> - MCA & CSM call for information on safety of kava and conduct assessment of evidence on kava and liver toxicity. • USA Medwatch issue warning; • FDA investigating if use of kava dietary supplements poses safety concerns; writes to healthcare professionals in USA. • German voluntary withdraw kava products; assess data • French suspend all kava containing products in pharmacies and homeopathic drugs above 5CH • Canada monitoring situation
January 2002	UK MCA products containing kava voluntarily withdrawn
July 2002	TGA initiates voluntary withdrawal of all complementary medicines containing kava following the death of a woman who was taking kava herbal preparation.
August 2002	<ul style="list-style-type: none"> • Full Review of Standard 2.6.3 – Kava (as part of development of harmonised standards between Australia and New Zealand) • NZFSA advises NZ consumers to avoid taking dietary supplements (food and medicinal types) containing kava • Canada withdraws all kava products from market

Safety Assessment Report Kava

1 Botanical Name and Characteristics

The kava plant (*Piper methysticum* Forst.) is a robust, fairly succulent, well-branching and erect, perennial shrub belonging to the Black pepper family *Piperaceae*. The generic name *Piper* comes from the Latin for “pepper”, and the species name *methysticum* from the Greek meaning “intoxicant”, thus *Piper methysticum* when translated into English means “intoxicating pepper”. Other names used to refer to kava include: kava kava; kawa; ava; awa; yati; yagona; and yangona.

The leaves are heart shaped, pointed, smooth and green on both sides, being about 15cm in length. Up to about 60cm above the ground, the root becomes 5 to 8 cm thick at maturity. The plant reaches maturity about 3-5 years after planting and the plant is usually cultivated at around this age. The Vanuatu government requires that kava for export must have been planted at least 5 years before it is harvested and kava for domestic use must have been planted at least 3 years before it is harvested. The plant is usually about 2 to 2.5m tall when it is harvested (Singh, 1992).

Although kava is a dioecious species, only male plants are known and no fruits or seeds have been reported. The plant is cultivated through vegetative propagation.

2 Varieties

There are approximately 115 different cultivars of *Piper methysticum*, with 80 in Vanuatu, 7 in Tonga, 12 in Fiji, 5 in Samoa and 11 in Hawaii (SPC report, 2001). The Vanuatu government has recently passed the Kava Act No.1 of 2002, which identifies and categorises the different chemotypes or cultivars into: Noble kavas which have a long history of safe use as a traditional social beverage; medicinal varieties which have a long and proven history of beneficial properties amongst traditional Pacific herbalists; ‘Tu Dei’ kavas (two day intoxication) which, in the absence of direct requests, are banned as an export commodity; and ‘Wichmannii’ varieties (wild kava) which are also banned as an export commodity. Medicinal kavas are rarely used as a social beverage because they do not satisfy the kava drinker’s desire for the required physiological effect. This categorisation of kava varieties is at Appendix 1.

3 Geographical distribution

Kava is indigenous to the tropical Pacific Island region including Melanesia, Micronesia and Polynesia, with the exception of New Zealand, New Caledonia and most of the Solomon Islands (Singh, 1992). It thrives at altitudes of between 150m and 300m above sea level and grows well in stony ground.

4 Preparation of traditional kava beverage

The traditional kava beverage is prepared by soaking the pulverized root in a bowl of water and/or coconut milk solution and filtering the mix to produce a brew in a communal bowl. The kava is then drunk from a cup, sometimes a coconut shell. In parts of Vanuatu and Papua New Guinea today, and in other regions across the Pacific in the past, the root is pulverised through mastication, whereas the 'Fijian method' involves pounding the root rather than chewing it (Cairney et al. 2002). Alternatively, dried powdered kava is mixed with water and/or coconut milk solution and consumed from a cup.

5 Preparation of kava extracts

Kava used for medicinal purposes is a concentrated standardized extract designed to maximise extraction of the kavalactones that have been identified as the 'active constituent'. In the manufacture of the concentrated extract either ethanol (60% or above) or acetone (60% or above) and water is used as the solvent to obtain the maximum yield of kavalactones. Kavalactone standardized extracts are likely to contain only kavalactones and no proteins, amino acids, or sugars. Kava root extracted in: acetone yielded 100% kavalactones; 96% ethanol yielded 100% kavalactones; 25% ethanol yielded 15 % kavalactones; water yielded 2.97% kavalactones (Denham et al. 2002). Extraction rates also vary depending on the temperature at which the products are prepared.

5.1 Low alcohol tinctures

Tinctures used traditionally in Polynesia and by herbal practitioners are prepared by macerating dried kava in a mixture of water and ethanol. Such extracts using 25% ethanol/75% water contain up to 30 times fewer kavalactones than the concentrated standardised preparations. A wider range of other natural kava constituents are extracted.

6 Chemistry

More than 40 compounds belonging to the classes of kavapyrones, alkaloids, steroids, chalcones, long-chained fatty acids and alcohols have been isolated and identified from *Piper methysticum* (Palmer et al. 1997). Fresh kava rootstock contains 80% water, while dried rootstock consists of approximately 43% starch, 20% fibre, 12% water, 3.2% sugars, 3.6% proteins, 3.2% minerals and 15% (3-20%) kavalactones (Lebot et al., 1992). Among these compounds, kavalactones have been recognized as the constituents responsible for the reported biological activities in kava.

Kavalactones

Kavalactones are 4-methoxy-2-pyrones with phenyl or styryl substitutes at the 6th position (Lebot et al., 1997). They are found in the lipid soluble portion. Total kavalactone content varies from 3% to 20% dry weight, even within the same subspecies. Different cultivars have different mixtures of kavalactones. The concentration of kavalactones is generally highest in the lateral roots (15%) and decreases progressively toward the aerial part of the plant (10% in the stump and 5% in the basal stems(Lebot et al., 1992)).

Nineteen different kavalactones have been reported from the root extracts of kava, with the nineteenth reported in 2002 (Dharmaratne et al., 2002). The most abundant kavalactones are: desmethoxyyangonin, yangonin (achiral enantiomers); and chiral enantiomers (+)-dihydrokawain, (+)-kawain, (+)-dihydromethysticin, and (+)-methysiticin. Structures of these kavalactones are at Appendix 2.

Duve and Prasad (1983) investigated the stability of kavalactones in powdered kava root stored in screw-capped glass bottles at room temperature for 22, 36 and 39 months. After 39 months of storage 93.9% of dihydrokavain, 81.6% of kavain, 72.4% of dehydrokavain, 54.9% of tetrahydroyangonin, 25.8% of dihydromethysticin, 32.1% of yangonin and 29.5% of methysticin had deteriorated in the powdered root samples.

Alkaloids

Two alkaloids were isolated from a methanolic extract of kava root and were identified as 1-cinnamoylpyrrolidine and 1-(*m*-methoxycinnamoyl)pyrrolidine (Achenbach and Karl, 1970). A third alkaloid, pipermethystine, was isolated from leaves by Smith (1983). Singh (1992) reported that this compound is also present in small amounts in the stems and roots of the plant. Dragull et al. (2003) report the presence of pipermethystine in the stem peelings and leaves. These authors also report 2 new piperidine alkaloids: 3 α , 4 α -epoxy-5 β -pipermethysticine; and awaine.

7 Pharmacology and pharmacokinetics

Drinkers of the traditionally prepared kava beverage in the South Pacific report a sense of relaxation and tranquillity, and the drink manifests a sociable attitude (Chanwai, 2000). Kavalactones have muscle relaxant, local anaesthetic, anxiolytic and anticonvulsive properties (Cairney et al., 2002). Herbal preparations are marketed for the treatment of anxiety, insomnia, premenstrual syndrome and stress (Centres for Disease Control and Prevention, 2002). The traditional medicinal uses of kava include treatment of gonorrhoea, syphilis, and cystitis, induction of muscle relaxation and sleep (Ernst et al., 2001), treatment of boils, asthma, headache and urinary infections (Harvard Medical Health Letter, 2000).

Animal studies have established that kavalactones act to directly alter neuronal excitability through voltage-dependent ion (probably Na⁺) channels, causing a release of muscle tension. Inhibition of voltage-operated ion channels can account for the anaesthetic and anticonvulsive pharmacological actions of kavalactones (in Cairney et al., 2002).

Psychopharmacological effects of kava have also been reported and the mood-altering effects of kavalactones have been described as hypnotic (Schultes and Hoffman, 1992). The pharmacological properties of kavalactones are comparable to those of benzodiazepines, however, kavalactones bind very weakly to the gamma-aminobutyric acid (GABA_A) and benzodiazepine (Bilia et al. 2002). The authors propose that N-methyl-D-aspartate receptors and/or voltage dependent calcium channels may also be involved in the elementary mechanism of action.

Kavalactones are poorly soluble in water and their absorption in the gastrointestinal tract is poor and variable (Rasmussen et al., 1979), although it is remarkably rapid given their lipophilic nature (Malani, 2002). Kavalactones appear to be hydroxylated by the cytochrome P450 system and their metabolism may be enhanced by the presence of glutathione (Rusmann et al., 2001; Tinsley, 1999; Whitton et al., 2002).

Kavalactones are eliminated in part by the kidneys (metabolites and unchanged pyrones) and in part by the faeces (unchanged pyrones). In humans, a complex mixture of metabolites and unchanged kavalactones have been identified in human urine following ingestion of kava

prepared by the traditional method of aqueous extraction of *Piper methysticum* (Duffield et al., 1989).

8 Safety and effects

8.1 Traditional kava beverage

8.1.1 Skin conditions

The most commonly observed side effect of heavy kava consumption over an extended period is an ichthyosiform skin rash known as kava dermatopathy or kani kani in Fijian (Lebot et al., 1992), characterised by flaky, dry skin with a yellowish discolouration of both the skin and nails. The onset typically begins in the face and moves in a descending fashion towards the feet, with subsequent dequarnation and cracking in a scaly pattern. In addition to the desquamating keratosis, palmar and plantar keratoderma and ocular photosensitivity can also develop (Singh, 1992). Kava dermatopathy should not be confused with skin conditions that can be the result of acute allergic effects of *Piper methysticum*, which have also been reported in the literature (Suss and Lehmann, 1996).

The possibility of kava dermatopathy being caused by niacin deficiency has been investigated (Ruze, 1990). The results of the study indicated that niacin deficiency was not responsible for the scaly rash and that the rash is characteristic of an acquired ichthyosis.

8.1.2 Liver abnormalities

Clinical evidence of liver toxicity from traditional use in Pacific countries has not been documented. However, there have been no systematic studies into sub-clinical forms of liver toxicity in Pacific Island countries, so it is possible that mild toxicity could be present without having been recognised (Moulds and Malani, 2003). An early study of the health effects of kava use in Aboriginal communities documented consistent changes in liver function tests in heavy kava drinkers, characterised by elevated serum γ -glutamyl transferase (GGT) (Mathews et al., 1988).

A recent study confirmed these findings, with elevated levels of GGT and alkaline phosphatase (AP) activity in 61% and 50% of kava users respectively (Cairney et al., 2003). However, serum alanine aminotransferase (ALT) activity was not raised in any kava drinkers. These indicators of liver function generally returned to normal within 1-2 months of stopping kava use. In contrast, ALT levels were high in cases of hepatotoxicity associated with herbal products. This suggests that elevated ALT evidence that liver function changes (increased GGT and AP) in users of aqueous kava extracts are reversible and begin to decrease after 1-2 weeks abstinence from kava. In this case no evidence for irreversible liver damage was found even in those who had used kava more or less continuously for up to 18 years (personal communication from Alan Clough, 2003).

8.1.3 General physical health effects

A survey conducted in Fiji examined the physical health of kava drinkers (Kava, 2001). The degree of kava consumption was classified according to the classification system used in the study on the impact of kava use on Australian Aborigines as follows: Non-user; occasional user (100g/week); heavy user (310g/week); and very heavy user (440g/week) (Mathews et

al., 1988). The occasional user experienced little side effects: 3% experienced headaches; 10% experienced indigestion; and 7% experienced lack of coordination. There are increasing health problems associated with heavy and very heavy use: 78% of very heavy users and 65% of heavy users experienced kani kani; 72% of very heavy users and 57% of heavy users experienced watery eyes. Other symptoms experienced by heavy and very heavy users included: headache; chest pain; loss of appetite; indigestion; and loss of coordination.

The health status of 39 kava users and 34 non-users in a coastal Aboriginal community in Arnhem Land was assessed in 1988 (Mathews et al., 1988). Kava users were more likely to complain of poor health and a “puffy” face and were more likely to suffer from kani kani. Very heavy users were 20% underweight and their levels of γ -glutamyl transferase were increased greatly. Albumin, plasma protein, urea and bilirubin levels were decreased in kava users, and high-density lipoprotein cholesterol levels were increased. Kava users were more likely to show haematuria, and to have urine which was poorly acidified and of low specific gravity. The use of kava was also associated with an increased red-cell volume, with a decreased platelet volume and a decreased lymphocyte count. Shortness of breath in kava users was associated with an altered resting electrocardiogram suggestive of pulmonary hypertension.

8.1.4 Gastric effects

Use of kava has been shown to be associated with gastritis, an inflammation of the stomach. Kava was also shown to have synergistic effects when used with alcohol. Kava users aged 15-24 years were found to have an increased risk of developing gastritis than others (Ngirasowei and Malani, 2002).

8.1.5 Visual Effects

Visual functions have been measured (on one subject) following consumption of the kava beverage. A reduced near point of accommodation and convergence, an increase in pupil diameter and disturbance to the oculomotor balance were observed. No changes were recorded in visual or stereoacuity, or ocular refractive error (Garner and Klinger, 1985).

8.1.6 Melioidosis

Kava consumption has been implicated as a risk factor for Melioidosis, or infection with *Burkholderia pseudomallei*, in the Northern Territory. Kava consumption occurred in 8% of the subjects with Melioidosis (Currie et al., 2000). Melioidosis is a common cause of community-acquired pneumonia in the tropical north of the Northern Territory and cases occur in the wet season.

A recent cross-sectional study within a kava using East Arnhem Land Aboriginal community established that kava use (both current and recent users) was associated with lower lymphocyte counts with 51% of users below the normal range (personal communication from Alan Clough). The authors suggest a possible kava related immunological predisposition to certain infections such as melioidosis.

8.1.7 Social effects

The survey into the physical health of kava drinkers in Fiji (Kava, 2001) also investigated the social and economic impact of kava drinking on the families of kava drinkers and employment performance.

Wives of kava drinkers interviewed indicated loss of libido and impotence. Some heavy consumers spent as much as 20% of household income on kava, putting an additional financial burden on the family. It was also noted that the children of heavy kava drinkers perform poorly at school due to lack of proper educational materials and parental supervision. Some employers stated that because of heavy consumers of kava tended to be irregular and not punctual for work, they were against the consumption of kava by their employees. Driving an automobile under the influence of kava was also noted as a concern.

8.1.8 Cognitive and saccade function

There is some evidence to suggest that kava use is associated with brain impairment. There have been case reports of severe choreoathetosis (involuntary movements) following kava use (Schelosky et al., 1995; Spillane et al., 1997) and an association has between heavy kava use and seizures either from toxicity or on withdrawal has been raised (Clough et al., 2001). Cognitive tests and saccade function (eye movement) tests were performed on a group of current, ex, and non-kava users among an indigenous population in northern Australia, with some of the current kava users being identified as heavy users (Cairney et al., 2003). No impairment in cognitive or saccade function was found in individuals who were currently heavy kava users or those who had been heavy kava users in the past. No cognitive indicators of dysfunction were found that may precede, or lead to, the choreoathetotic movements reported among kava users in the literature, suggesting that these involuntary movement reactions occur from acute rather than chronic changes.

8.2 Kava extracts

8.2.1 Liver Toxicity in humans

There have been reports of liver toxicity associated with use of kava extracts, first from Switzerland and Germany and later from most other western countries including Australia. In November 2001, the German health authority *Bundesinstitut für Arzneimittel und Medizinprodukte*, or German Federal Institute for Drugs and Medical Products (BfArM) published evidence that suggested an association between kava consumption and liver damage in 24 case studies reported from Germany and Switzerland. These included one death and three liver transplants. The case reports from the BfArM include all three of the main forms of acute liver damage that can result from adverse drug reactions: necrosis; drug-induced hepatitis; and cholestatic hepatitis (Hodgson and Levi, 1997). Detailed review of the original cases published by BfArM, particularly by German industry, suggested that a causal link between kava and liver toxicity was inconclusive and existing data on the benefit/risk assessment of kava containing products did not justify withdrawal of marketing authorisations. Detailed information on the patients' history, co-medication, consumption of alcohol and other particulars were missing (Mills and Steinhoff, 2003).

At the end of 2002, the UK Medicines Control Agency and Committee on Safety of Medicines (MCA/CSM) had compiled a total of 68 cases of liver toxicity associated with

kava consumption. Of these, the association between kava and liver damage was judged to be 'probable' in 14 cases (including 3 liver transplants) and 'possible' in 30 others, the rest were 'unassessable'.

Since these case studies were published, the acute liver failure and death of an Australian woman has been described (Gow et al., 2003) and associated with the use of a preparation containing *Piper methysticum* and passionflower (*Passiflora incarnate*). The woman received a liver transplant after she presented with jaundice and a liver biopsy showed non-specific severe acute hepatitis with pan-acinar necrosis and collapse of hepatic lobules. The liver transplantation was unsuccessful. Histological examination of the explanted liver confirmed the presence of massive hepatic necrosis. There are now a total of 82 cases of liver toxicity associated with kava-containing medicines internationally, including 4 deaths.

Evaluations by the TGA (personal communication, June 2003) of reported case studies indicate that there is a possibility of a causal relationship between hepatotoxicity and kava-containing products. Many of the serious reports described kavalactone doses in the range of 180-240 mg/day, although there are reports at doses as low as 60-70 mg/day, which is less than the previous maximum recommended daily dose of 250 mg/day for kavalactones in listed medicines. All but one of the reports described a duration of use of 2 months or more.

While the exact causative factors in kava extract-induced liver toxicity remain unknown, possible contributing factors are discussed below.

8.2.1.1 Range of kava constituents

Kava contains a wide range of chemical components as well as the active constituents, kavalactones. These other components of plants can affect the stability, solubility and bioavailability of the active components (Denham et al., 2002). The use of non-traditional methods of preparation can change the component profile, which may in turn affect the safety of the kava preparation. Different extraction techniques and preparation methods may result in extracts where the presence and relative concentration of each kavalactone is altered considerably compared to the kava root and the traditionally prepared kava beverage.

Research currently in progress is assessing the profiles of kava constituents with non-traditional extraction methods and the hepatotoxicity of kava constituents using Hep G2 cells and human hepatocytes with different markers, and investigating different solvent extraction techniques (personal communication from Professor Stephen Myers¹⁵). Preliminary results indicate some support for altered profiles of kava constituents with non-traditional extraction methods and that traditional methods of preparation in water are safer by orders of magnitude from kava prepared in organic solvents (ethanol, acetone and hexane).

8.2.1.2 Absence of glutathione in kava extracts

Whitton et al. (2002) suggest that extraction procedures that maximize and standardize kavalactone content using high concentrations of either acetone or ethanol are likely to contain only kavalactones and no protein, amino acids or sugars. The authors identified glutathione in both aqueous extract and 25% ethanol extract while negligible amounts of

¹⁵ Australian Centre for Complementary Medicine, Education and Research, a joint venture of the University of Queensland and Southern Cross University

glutathione are present when higher concentrations of ethanol or acetone are used. It is postulated that glutathione may have an important role in the metabolism of kavalactones.

Kavalactones are normally metabolised by lactone hydrolases, the activity of which is increased by the presence of glutathione. Glutathione occurs naturally in kava root in approximately the same concentration as kavalactones. In contrast, standardised extracts contain negligible amounts of glutathione while the kavalactone concentration is concentrated some 30-fold (Denham et al., 2002) (glutathione is not soluble in ethanol extractions above 50% (Merck Index, 1996)).

It is postulated that the ring-opened kavalactones may bypass the phase I enzymatic detoxification pathway in the liver thus not causing any depletion of intracellular glutathione in the hepatocyte (Denham et al., 2002). Glutathione is required for phase II conversion of kavalactones into excretal waste products. The high concentration of kavalactones introduced by concentrated standardised extracts has the potential to saturate the enzymatic detoxification pathways by depleting stores of glutathione and resulting in undue stress on the liver.

Glutathione is normally present in adequate amounts in most cells in the body but some individuals have a genetic deficiency (Lomaestro and Malone, 1995). In these cases, high doses of kavalactones will lead to rapid depletion in glutathione levels and result in free lactone exposure in the hepatocytes and potentially tissue damage (Zheng et al., 2000). Oral glutathione supplementation has been shown to correct the deficiency (Kidd, 1997).

In summary, it appears that the high kavalactone content in concentrated standardised extracts and the absence of the glutathione (which is naturally present in the root of *Piper methysticum*) may deplete the endogenous reserves of glutathione in the hepatocytes, which could contribute to toxicity. Individuals with glutathione deficiency are at increased risk of depletion of glutathione stores if a highly standardised kavalactone extract is taken.

8.2.1.3 Genetic polymorphism in drug metabolizing enzymes

Interindividual variability to drug response ascribed to genetic differences in drug absorption, disposition, metabolism or excretion can be a factor in adverse drug reactions. The most studied variability is genetic polymorphism in drug metabolizing enzymes in the hepatocyte. Cytochrome P450 enzymes are responsible for phase I (oxidation, reduction and hydrolysis) metabolism of a wide number of compounds and for transforming lipophilic drugs into more polar compounds that can be excreted by the kidneys (Denham et al., 2002).

CYP2D6 is one of the most extensively studied genetic polymorphisms involving cytochrome P450 enzymes. Individuals may be poor (slow) metabolises, intermediate, extensive (fast) or ultra fast metabolises. In a Caucasian population 7-9% of individuals are homozygous deficient in CYP2D6 and are, thus, poor metabolises, while the incidence of CYP2D6 deficiency in Asian populations is 1% (Poolsup, 2000), and in a sample of 100 persons of pure Polynesian decent, there was no CYP2D6 deficiency (Wanwirolmuk et al., 1998). A poor metabolise is at risk of having adverse effects to drugs if their rate of biotransformation inadequate. In some of the cases of liver toxicity reported by BfArM, the individuals were CYP2D6 deficient.

When CYP2D6 deficiency occurs, use of kava products with enhanced kavalactones has the potential to affect the liver as a result of slow metabolism, particularly when a concomitant medication or alcohol are also taken.

8.2.3 Other adverse reactions in humans

Aside from liver abnormalities or toxicity, adverse effects attributed to kava extracts include: gastrointestinal complaints; restlessness; mydriasis; allergic skin reactions; dermatomyositis (Ernst et al., 2001); visual accommodation disorders; pupil dilation; and disorders of oculomotor equilibrium (Singh and Blumenthal, 1997). Toxic doses (several times the therapeutic dose of approximately 70 mg of kavalactones three times daily) can cause progressive ataxia, muscle weakness, and ascending paralysis (Spillane et al., 1997). Chronic heavy consumption can cause kani kani, or kava dermatopathy, described in section 8.1.1. All of these symptoms are reversible and disappear within several weeks of discontinuation of kava extract.

Various clinical trials have been carried out to determine whether kava is an effective symptomatic treatment for anxiety and a number of these trials have reported adverse effects. A Cochrane review by Pittler and Ernst (2003) reviewed 11 clinical trials. Eight of the 11 clinical trials reviewed reported adverse events experienced by patients receiving kava extract. The most frequent reports were stomach complaints, restlessness, drowsiness, tremor, headache and tiredness. Six of the trials reviewed measured liver enzyme levels, and these didn't demonstrated hepatotoxicity. Bilia et al. (2002) reviewed nine clinical trials and found that three of these trials reported no adverse events, while the other six studies reported gastrointestinal symptoms, tiredness, restlessness, tremor and headache, but the authors point out that the number of patients reporting the complaints was similar in the placebo groups.

8.2.4 Animal toxicity data

Animal toxicity studies on kava have been limited mainly to acute and subchronic studies in rats and mice. Toxicology studies in animals indicate that the oral LD₅₀ is between 800 and 1000 mg/kg bw for the different kavalactones investigated. An NIH report on Kava Chemistry and Toxicology (1998) summarised acute toxicity LD₅₀ values for 6 major kavalactones that were obtained from the Registry of Toxic Effects of Chemical Substances. These values are shown in Table 1. There are no long-term toxicity studies of kava in animals available and no information on its genotoxic potential.

Table 1: LD₅₀ (mg/kg) values for kavalactones (NIH Report, 1998)

Species (route)	Kavain	Dihydro-kavain	Methysticin	Dihydromethysticin	Yangonin	Demethoxy-yangonin
Mouse (oral)	1130	920	-	1050	>1500	>800
Mouse (ip)	420	325	530	420	>1500	>800
Mouse (iv)	69	53	49	-	41	55
Dog (ip)	-	>200	-	>200	-	-
Cat (ip)	-	>250	-	-	-	-
Rabbit (ip)	-	>350	-	300	-	-

8.2.5 Piperidine alkaloids in kava plant stem and leaves

The major plant parts in traditional use of kava have been the rootstock and roots although leaves and branches have been used in folk medicine primarily for topical applications (Cambie and Ash, 1994). There are suggestions that in recent years, stem peelings have been included as raw material in kava products due to the high demand by the pharmaceutical industry. Also, kava leaf tea has recently appeared in health food stores in Hawaii (Dentali, 1997).

Piperidine alkaloids in *Piper methysticum* and their potential activities on human physiology were investigated by Dragull et al. (2003). Pipermethysticine (**1**), 3 α , 4 α -epoxy-5 β -pipermethysticine (**2**) and awaine (**3**) have been isolated from the aerial parts of *Piper methysticum*. **1** was concentrated in the stem peelings and leaves, **2** and **3** are new alkaloids with **2** only found in one cultivar of those examined, and **3** occurred primarily in young leaves of all cultivars investigated. The authors note that while the effects of these piperidine alkaloids on human physiology are unknown and their possible toxicity on the liver has not been investigated, however, several pyridine alkaloids with structures similar to **1** have been shown to be cytotoxic (Duh and Wu, 1990; Duh et al., 1990). Furthermore, **1** decomposes on standing at room temperature due to hydrolysis of the amide, to give 3-phenylpropionic acid and the dihydropyridone **4** (Smith, 1979). Compounds **1** and **4** exhibit structural features of 2,5-dihydropyridine, which has been shown to affect DNA integrity in vitro due to its ability to redox cycle (Kim and Novac, 1990). None of the three piperidine alkaloids were detected in the commercial root powders from Fiji, Tonga or Hawaii in the analyses by the authors (Dragull et al, 2003). The use of the alkaloid-rich stem peelings is generally avoided by the Pacific peoples. Dragull et al. (2003) do not have any direct evidence of the presence of piperidine alkaloids in kava dietary supplements however, caution is advised on using the aerial plant parts for human consumption.

9 Contraindications

Several pharmacological effects of kava have been observed, including platelet inhibition, difficulties with visual accommodation and phytosensitivity, and possible dopaminergic antagonist activity. Recommendations have been made that kava not be used in conjunction with anticoagulants, antiplatelets or antipsychotics because of potential additive effects, or in patients with Parkinson's disease, apparently because of dopamine antagonist (MacKinnon, 2000; Meseguer et al., 2002). Kava may also enhance the effects of other centrally acting agents such as benzodiazepines and alcohol (Almeida and Grimsly, 1996).

10 Cautions on use

However, use of kava during pregnancy or lactation has been cautioned since kavalactones may be present at concentrations, which would likely have an effect on the foetus or infant (Brinker, 1998). Despite this caution, it has been reported that Pacific Island women have, at least in the past, drunk kava during pregnancy in the hope that it will give an easy labour and produce a fine child and also during lactation to induce milk flow (Presidential address by Dr A.S. Frater, 1952).

Use of kava in patients with endogenous depression should be avoided, since it has been speculated that the herb may increase these patients' risk of suicide (Pepping, 1999). Use of kava by children is generally not recommended. In some patients therapeutic doses of kava

can affect motor function and may impair the ability to operate machinery, including driving a car.

11 Conclusion and recommendation

There have been no cases of diagnosed liver toxicity associated with consumption of the traditional kava beverage although increases in liver enzyme activity have been observed. These changes in liver enzyme activity returned to normal within 1-2 months of cessation of use and may be indicative of an adaptive response in the liver rather than evidence of toxicity.

The most common side effect of heavy consumption of the traditional kava beverage over an extended period is an ichthyosiform skin rash known as kava dermopathy or kani kani in Fijian, characterised by flaky, dry skin with a yellowish discolouration of both the skin and nails. Other reported adverse effects include headache, chest pain, loss of appetite, loss of weight, impaired visual functions, indigestion, and loss of coordination. These effects are also reversible following discontinuation of use.

The mechanism of kava-related liver toxicity is not clear and there are no definitive predictors of liver damage however, some contributing factors have been suggested. One of these is that the high kavalactone concentration in standardised extracts and the absence of glutathione (which is naturally present in the root of the kava plant) has the potential to saturate the enzymatic detoxification pathways, resulting in undue stress on the liver.

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Kava varieties as classified in the Vanuatu Kava Act No. 1 of 2002

Table 1: Nobles kava

Variety	Origin
Melomelo	Ambae
Asiyai Biyaj	Aneityum
Paliment Miela Olitao	Emae
Kelai	Epi
Ge wiswisket Gegusug	Gaua
Borogoru	Maewo
Silese	Malekula
Melmel Borogu Sese	Pentecost
Urukara Bir Sul Bir Kar Palarasul Palasa Poivota	Santo
Pia Ahouia Leay Amon	Tanna
Puariki Pualiu	Tongoa
Naga miwok Ge vemea	Vanua Lava

Table 2: Medicinal kava

Variety	Origin
Mologuei	Ambae East
Ngwanganu	Ambae East
Bisuiboe	Ambae West
Mavute	Ambae West
Ketche	Aneityum
Mokom	Aneityum
Riki	Aneityum
Oleikaro	Emae
Pualapa	Emae
Ulutao	Emae
Bagavia 1	Epi
Bagavia 2	Epi
Meoler	Epi
Pakaewa	Epi
Purumbue	Epi
Tinbokai	Epi
Liki	Erromango
Pic	Erromango
Pore	Erromango
Bumalotu	Maewo North

Hawerara	Maewo North
Malokai	Maewo North
Raimelmelo	Maewo North
Resres	Maewo North
Maloglelab	Maleluka North East
Maloglaslas	Maleluka North East
Nemleu	Maleluka North East
Tafandai	Maleluka North West
Baan	Maleluka North West
Daou	Maleluka North West
Tapoka	Malo
Hig	Mere Lava
Lab	Mota Lava
Nagame	Mota Lava
Loa	Nguna
Malakesa	Nguna
Pilake	Nguna
Meihang	Paama
Teiha	Paama
Toh	Paama
Borogu tememe	Pentecost Central
Bukulit	Pentecost Central
Borogu temit	Pentecost Central
Borogoru maita	Pentecost North
Borogoru memea	Pentecost North
Vabugai	Pentecost North
Bugolita	Pentecost North
Gorogoro entepal	Pentecost South
Gorogoro entemet	Pentecost South
Kerakra	Pentecost South
Tamaevo	Pentecost South
Aigen	Tanna Central
Mita	Tanna Central
Saosao	Tanna Central
Tuan	Tanna Central
Kiskisnian	Tanna Central
Yalon	Tanna Central
Awor	Tanna Central
Malamal	Tanna Central
Paama	Tanna Central
Wapil	Tanna Central
Pusan	Tanna South East
Marangmarang	Tanna South East
Kokoffe	Tanna South East
Kowariki	Tanna South East
Malamala	Tanna South East
Paama	Tanna South East
Ewo	Tongoa
Metolei	Tongoa
Tau	Tongoa
Nimau	Tongoa
Bualap	Tongoariki
Buarik	Tongoariki
Milake	Tongoariki
Ngako	Ureparapara
Ngasien	Ureparapara
Nol	Ureparapara
Gemime	Vanua Lava

Ranranre	Vanua Lava
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Table 3: Two days kava

Variety	Origin
Gawoboe	Ambae East
Ronriki	Ambae East
Tarivoravora	Ambae East
Valeiboe	Ambae East
Qoro	Ambae East
Sulusulu	Ambae East
Ganono	Ambae East
Garaeto	Ambae East
makura	Ambae East
Mologomavute	Ambae East
Tarimvute	Ambae East
Taritamaewo	Ambae East
Memea	Ambae West
Mindo	Ambae West
Rogorogopula	Ambae West
Tolu	Ambae West
Tari	Ambae West
Tariporo	Ambae West
Laklak	Ambrym North
Apeg	Aneityum
Nisginekrai	Aneityum
Tchap	Aneityum
Nidinolai	Aneityum
Metche	Aneityum
Yag	Aneityum
Nakasara	Emae
Meawmelo	Epi
Lo	Epi
Mage	Epi
Kaviui	Epi
Mitiptip	Epi
Vila	Epi
Wari	Epi
Vip	Epi
Meawlake	Epi South
Meawmeia	Epi South
Avia	Erromango
Vila	Erromango
Gumaito	Maewo North
daumangas	Maewo North
Rairairegi	Maewo North
Tariparaus	Maewo North
Tufagi	Maewo North
Tumpuinakapmato	Maewo North
Tarihani	Maewo North
Rongrongvula	Maewo South
Tarivarusi	Maewo South
Vabu	Maewo South
Mologubanano	Maewo South and Pentecost North
Mologubanga	Maewo South and Pentecost North
Malokrok	Maleluka North East

Pade	Maleluka North West
Malatuwas	Maleluka North West
Nalimliune	Maleluka North West
Poua	Maleluka North West
Vasa	Malo
Roge	Malo
Namtemplao	Mota Lava
Nipunstaban	Mota Lava
Tarivarus	Mota Lava
Take	Pentecost Central
Tabal	Pentecost Central
Malmalbo	Pentecost Central
Rongrongwul	Pentecost Central
Abogae	Pentecost Central
Fabulakalaka	Pentecost Central
Lalahk	Pentecost Central
Renkaru	Pentecost Central
Sese	Pentecost North
Vabulagaga	Pentecost North
Rara	Pentecost North
Baraeto	Pentecost North
Rabualeva	Pentecost North
Kavik	Pentecost North
Mangaru	Pentecost North
Rongrongvula	Pentecost North
Sese Iaralara	Pentecost North
Tarivarusi	Pentecost North
Sese	Pentecost South
Takere	Pentecost South
Lalahk	Pentecost South
Tarivarusi	Pentecost South
Marino	Santo Central
Merei	Santo Central
Fock	Santo Central
Malogro	Santo Central
Thyei	Santo Central
Tudey	Santo Central
Yevoet	Santo Central
Palavoke	Santo South West
Pirimerei	Santo West
Aheyoke	Santo South West
Palisi	Santo West
Woko	Santo West
Awke	Tanna Central
Fare	Tanna Central
Kalawas	Tanna Central
Tikisikis	Tanna Central
Apin	Tanna Central
Gnare	Tanna Central
Fiji	Tanna Central
Pentecost	Tanna Central
Rhowen	Tanna Central
Tudey	Tanna Central
Vila	Tanna Central
Apol	Tanna South East
Kowarwar	Tanna South East
Ring	Tanna South East
Tapuga	Tanna South East

Pentecost	Tanna South East
Tudey	Tanna South East
Vila	Tanna South East
Oleikaro	Tongoa
Raro	Tongoa
Nakasara	Tongoa
Maet	Tongoariki
Elot	Tongoariki
Lulu	Tongoariki
Hin	Torres
Hinyanie	Ureparapara
Ngawo	Ureparapara
Tarivarus	Ureparapara
Gelava	Vanua Lava
Nambalao	Vanua Lava
Tarvarus	Vanua Lava
Wisabana	Vanua Lava

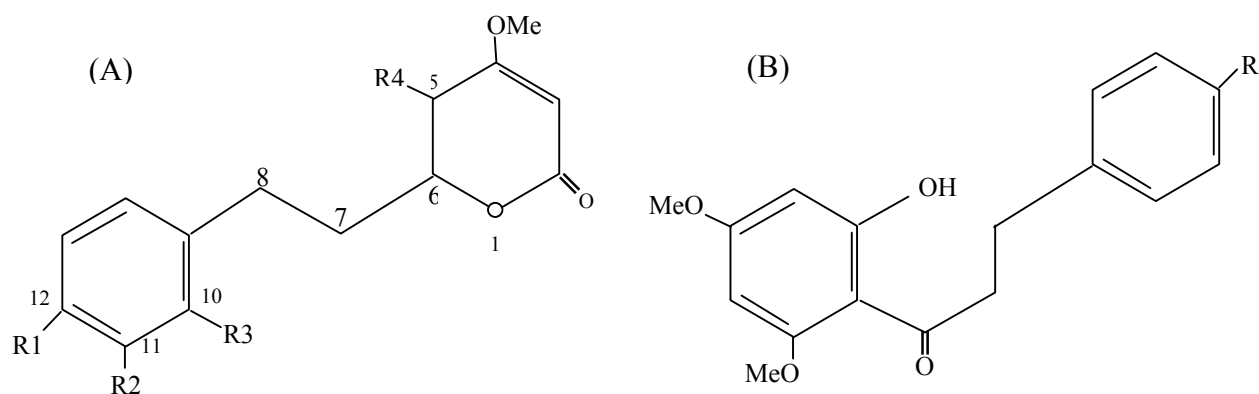
Table 4: Wichmannii kava

Variety	Origin
Vambu	Ambae East
Tchai	Aneityum
Bamboo	Maewo North
Buara	Maewo North
Tangurlava	Maewo North
Kau	Tongoa
Vambu	Vanua Lava
Giemonlagakris	Vanua Lava
Bogong	Pentecost Central
Mele liap	Pentecost Central
Sini Bo	Pentecost Central
Bogongo	Pentecost North

Appendix 2

Kavalactone structures

(A) Kavalactones and (B) Chalcones present in Kava root (Xian-guo He *et al.*, 1997)



Kavalactone	R1	R2	R3	R4	C5-C6	C7-C8	MW
11-Hydroxy-12-methoxydihydrokavain	OMe	OH	H	H	-	-	278
7,8-Dihydro-5- hydroxykavain			H	β OH	=	-	248
11,12 Dimethoxydihydrokavain	OMe	OMe	H	H	-	-	292
Methysticin	OCH ₂ O		H	H	-	=	274
Dihydromethysticin	OCH ₂ O		H	H	-	-	276
Kavain		H	H	H	-	=	230
7,8-Dihydrokavain		H	H	H	-	-	232
5,6-Dehydromethysticin	OCH ₂ O		H	H	=	=	272
5,6-Dehydrokavain (Demethoxyyangonin)		H	H	H	=	=	228
Yangonin	OMe	H	H	H	=	=	258
5,6,7,8-Tetrahydroyangonin	OMe	H	H	H	-	-	262
5,6-Dihydroyangonin	OMe	H	H	H	-	=	260
7,8-Dihydroyangonin	OMe	H	H	H	=	-	260
10-Methoxyyangonin	OMe	H	OMe	H	=	=	288
11-Methoxyyangonin	OMe	OMe	H	H	=	=	288
11-Hydroxyyangonin	OMe	OH	H	H	=	=	274
Hydroxykavain	H	H	H	OH	-	=	246
11-Methoxy-12-hydroxydehydrokavain	OH	OMe	H	H	=	=	274

Chalcones	R	MW
Flavokavain A	OMe	314
Flavokavain B	H	284
Flavokavain C	OH	300

Summary of submissions to P256 – Initial Assessment Report

A total of 12 submissions were received in response to the Initial Assessment Report (IAR) for Proposal P256 – Review of Kava. Submissions were received from: Australian state health departments (NSW and WA); the New Zealand Food Safety Authority (NZFSA); the Food Technology Association of Victoria; the Pacific Islands Forum Secretariat representing the views of producers and exporters of kava from the Forum Island Countries; government departments of Fiji, Vanuatu, Tonga and Papua New Guinea; and exporters of kava from Vanuatu and Tonga. Notable omissions from the list of submitters include government departments from both the Northern Territory and Queensland.

Submissions from the Pacific Island Countries all highlighted: the social and cultural significance of kava; the distinction between traditional and pharmaceutical use; and the economic importance of kava to rural farmers as an agricultural crop. Submissions argued that rural farmers of kava should be considered as an affected party of this review.

A number of submissions argued that kava is not adequately defined currently. The term ‘kava’ is currently used as a generic term referring to all kava beverages, all cultivars, organs and extracts that are used in herbal and pharmaceutical products. A number of submissions suggest alternative terminology and classification systems that are worthy of investigation for incorporation into either regulation in the Food Standards Code or the Australian National Code of Kava Management.

Option 2 (amend Standard 2.6.3 to prohibit the addition of kava to any food, i.e. remove recognition that in NZ kava can be added to food-type dietary supplements) is the favoured option for four (five) of the submitters. Option 4 (remove Standard 2.6.3 and incorporate mandatory labelling provisions into the appropriate labelling standard) is the favoured option for 2 of the submitters and one further submitter suggested regulation similar to what is proposed by Option 4. Neither Option 1 or Option 3 were supported by submitters.

It is clear from some of the submissions and from conversations with the submitters that the implications of Option 2 were not well understood by some of the submitters. The confusion may have arisen from the description that this Option would revert to Standard O10 of Volume 1 of the Code.

Table 1: Summary of submissions to the Initial Assessment Report for P256 – Review of kava

Submitter	Preferred Regulatory Option	Costs and Benefits	Labelling/advertising	Safety and usage issues	Other issues
NSW Health Department (contact: Marianne Tegel, Project Officer, Food Branch)	Option 2 (submission stated support for both Option 1 and Option 2 however, a telephone conversation confirmed that Option 2 is NSW Health's preferred option).		<ul style="list-style-type: none"> • Suggest an additional labelling requirement: 'not to be sold to minors'. • Prohibition on advertising should be mandated in the Code. 		<ul style="list-style-type: none"> • Breaches on the restriction on advertising have been difficult to control. • National Code of Management on the restriction of the Sale and Advertising of Kava (NCKM) should be retained – it should be clearly stated in the FSC that the sale of kava is subject to the NCKM.
Department of Health, Government of Western Australia (contact: Dr Margaret Stevens, Chair, Western Australian Food Advisory Committee)	Option 2 (Committee feels that there is some merit in Option 4 however, it could not be assessed without further toxicological and safety data)				
Food Technology Association of Victoria Inc (contact: David Gill, President)	Option 2 – the NZDSR should be amended to prohibit the use of kava as an ingredient in any food.				<ul style="list-style-type: none"> • The measures taken in the NT and WA should be introduced in all states and territories since they are well policed and apparently effective. This would promote uniformity.
New Zealand Food Safety Authority (contact: Carole Inkster, Director, Policy and Regulatory Standards (Labelling and Composition))	Option 4 – no need for a standard to regulate the traditional use of dried root or stems of kava in NZ. FTDS containing kava will remain until such times as there is further information		<ul style="list-style-type: none"> • The basis for any mandatory labelling should be assessed for the NZ environment. • Concern expressed about the mandatory statement relating to 	<ul style="list-style-type: none"> • There have been no reports of adverse health effects associated with the traditional form of kava consumption in NZ. • There have been no reports of liver damage 	<ul style="list-style-type: none"> • FSANZ should make special effort to consult with Pacific Islander people resident in NZ as part of the review however, an appropriate reference group for

	<p>regarding safety or there is a regulatory change revoking the NZDSR – this comment means that Option 2 is not available to FSANZ in the scope of P256 despite being favoured by the majority of submitters.</p>		<p>‘The sale and distribution of kava in Australia is subject to the National Code of Kava Management’.</p>	<p>associated with consuming products containing kava extracts in NZ.</p> <ul style="list-style-type: none"> Minister of Health’s Medicines Adverse Reactions Advisory Committee (MARC) advised that kava-containing products should remain available, but products containing kava extracts should carry a label warning of the possibility of liver damage. 	<p>consultation was not suggested.</p> <ul style="list-style-type: none"> The use of kava in FTDS is so insignificant that it this should be addressed through the progression of P235. The NZ Ministry of Health has received information that the liquid prepared from fresh raw kava root had a greater intoxicating effect than dried kava root.
<p>Pacific Islands Forum Secretariat (contact: W Noel Levi CBE, Secretary General)</p>	<ul style="list-style-type: none"> Option 2 supported Option 3 could be supported as there would likely be an expansion of the market however, this is not an appropriate option at present given publicity on kava. Further scientific evidence would be need in order for this option to be effective. Option 4 would create an uncertain situation for exporters of kava. Scientific evidence supports the preferred option and the option should not be market restrictive. Concern that the Code permits the sale of kava in Australia & NZ but 	<ul style="list-style-type: none"> Extensive economic data provided which detail the loss of earnings that have occurred since the restrictions instituted in the EU (page 5 of submission) 	<ul style="list-style-type: none"> Labelling of kava should be encouraged to facilitate control measures and traceability. Labelling could include quality standards developed by Pacific Islander countries. 	<ul style="list-style-type: none"> Kava that has been traditionally prepared has not been linked to life threatening liver damage. Reports attached: “Report on kava and liver damage”, Dr Donald P Waller; and “Kava and Pacific Health Anthology Series #2”, Pacific Health Research Council 2002. Other contacts for safety reports were provided: “Herb safety review of kava”, Steven J. Dentali (sdentali@ahpa.org); and “Adverse Events Reportingly Associated with Kava” (bsporre@ahpa.org) 	<ul style="list-style-type: none"> Quality specification – individual countries have made progress in developing standards for kava. Kava Quality Standard was developed by the Institute of Applied Sciences of the University of the South Pacific to standardise and improve the quality of kava (attached) Details on action taken by the Secretariat following restrictions on kava containing products by European countries. Outcome of review should facilitate the continued safe trading of kava into the Australian

	<p>Australian states and territories are able to impose conditions on its supply and sale.</p> <ul style="list-style-type: none"> Review process should ensure that regulatory measures are standardised and comply with WTO rules. 				<p>and NZ markets.</p> <ul style="list-style-type: none"> Collaboration with the governments of the countries concerned, regional agencies and research bodies is encouraged.
<p>Republic of Vanuatu Department of Trade, Industry and Investment (contact: Mr Daniel Gay)</p>		<ul style="list-style-type: none"> Kava represented 22% of overall value of domestic exports from Vanuatu in 2001, and over past 5 years has a yearly average of 14.8% of exports. Drop in overseas exports – estimated annualized decline of 33.2% 2002. This drives down domestic prices. 			<ul style="list-style-type: none"> Support the submission made by the Vanuatu Kava Exporters Association through the Pacific Islands Forum Secretariat. Kava is defined too broadly in section 4.2 of the IAR – the distinction between ‘kava’ and ‘kava products’ should be made clear.
<p>Fiji Ministry of Commerce, Business, Development and Investment (contact: Seema Sharma)</p>	<p>Option 4 – Remove Standard & incorporate mandatory labelling provision. Current regulation is effective however, it is now redundant in NT. Regulations should be the same in Australia & NZ.</p>			<ul style="list-style-type: none"> In the absence of any strong evidence of liver damage by traditional drinking of the infusion of kava, the current deliberation should not affect the current proposal. Attached report – ‘Medicine on the Effects of Kava on the Liver’, Dr Malani of the Fiji School of Medicine. 	<ul style="list-style-type: none"> Use of FTDS should only be allowed if the inclusion of kava is of benefit to health, otherwise it should not be included in food at all.
<p>Fiji Ministry of Agriculture, Sugar and Land Settlement (contact: Permanent</p>	<p>No specified option but state: ‘in the absence of any strong evidence of liver damage associated</p>	<ul style="list-style-type: none"> Important source of livelihood for rural farmers in Fiji. Cash returns from 		<ul style="list-style-type: none"> Distinction made between traditional usage and dietary supplement usage that has been linked 	<ul style="list-style-type: none"> Rural farmers in Fiji [and other pacific countries] should be included as affected

Secretary)	with the traditional use of kava, there should be no restrictions on importation and use of kava, or at minimum, regulations should be no more restrictive than is the current practice.”	kava second behind sugar. <ul style="list-style-type: none"> • Domestic market for traditional drinking stable, F\$82 in 2001. • In 2001, Fiji exported 23.8 tonnes of dried kava worth F\$315,612 to Australia and 35.4 tonnes of dried kava to NZ worth F\$532,524 (Fiji Bureau of Statistics). 		to liver toxicity. <ul style="list-style-type: none"> • Concentrations of kavalactones in traditional beverages compared with the pharmaceutical products should be considered in assessments. 	parties of this review. <ul style="list-style-type: none"> • Regulatory response must be based on scientific risk assessments involving: multi-national clinical studies on the safety of traditional kava use in the community; and collaborative laboratory studies on toxicity of traditional kava extracts and kava based pharmaceutical products.
Government of Tonga	No option specified however, submission states that: “the import, sale and distribution of dried kava powder intended for the preparation of the ‘traditional kava extract’ or the ‘traditionally prepared kava drink’ in Australia & NZ be allowed subject to the kava standards and the National Code of Kava Management.			<ul style="list-style-type: none"> • There are significant differences in the chemical composition of the traditionally prepared kava beverage and pharmaceutical use of kava. • High concentrations of kavalactones were found in kava capsules for therapeutic use compared with the traditionally prepared beverage. • Kava glycosides (precursors to kavalactones) found in traditional beverage but not in pharmaceutical 	<ul style="list-style-type: none"> • Kava products and their intended use should be internationally classified instead of using the general term ‘kava’. A classification system has been recommended¹⁶. • Tonga has developed a Model Quality Assurance Manual and the government is taking steps to implement the manual. • Government is in the process of drafting Export Quality Regulations under the Agricultural Export Commodities Act for

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Kava Products	Intended Use
Dried kava, in form of chips or powder	For production of “traditional kava extract”, (i.e. extracted or mixed with water)
Traditional kava extract	For social drinking
Standardized kava extract	For production of pharmaceutical products

				products.	implementation. <ul style="list-style-type: none"> Tonga is in the process of drafting a National Food Standard Code and will ensure that the kava standard will be harmonised with the international kava standards including the Australia New Zealand Kava Standard.
Vanuatu Kava Exporters Association / Kava Traders (contact: Frank King, CEO Kava Traders, Chairman Kava Exporters Association of Vanuatu)	<ul style="list-style-type: none"> Regulations pertaining to kava in Australia & NZ should in some way reflect the intentions of the Vanuatu Kava Act No 1 of 2002. 				<ul style="list-style-type: none"> Vanuatu government recently passed the Kava Act No 1 of 2002 (provided as an attachment) – different varieties (chemotypes – cultivars) have been identified into 4 categories. Kava is currently used as a generic term to refer to all kava beverages, all cultivars, all organs and extracts that are added to herbal products etc - Kava Act refers to kava and kava products. Act requires labelling of kava for export – name of variety, island of origin, distinct organs and “Original Vanuatu Kava”. Submitter is available as a paid consultant.
Lita Trading Enterprises Ltd Tonga / Kavalita Pty	<ul style="list-style-type: none"> Australian regulations, which are difficult to 				<ul style="list-style-type: none"> Review should only consider kava as a food,

<p>Ltd Australia (contact: Toimoana Takataka, CEO Lita Trading Enterprises Ltd)</p>	<p>police, should be lifted and abrogated – i.e. no regulation of kava as a food in Australia or NZ (similar to option 4).</p>				<p>i.e. traditional use as a beverage.</p> <ul style="list-style-type: none"> • Kava as a food should be defined as dried, in powder or chip form made exclusively and without addition or tampering from the kava plant <i>Piper Methysticum</i>. • Traditional kava extract – kava in liquid form which has been mixed or diluted with water only – should be regarded as a food or beverage.
<p>Department of Agriculture and Livestock, Papua New Guinea</p>	<ul style="list-style-type: none"> • Preferred Option not clearly stated. However, under the heading of regulatory option 2 it is noted that “this amendment should also be welcomed to enable harmonisation of the regulations for kava in both countries and use of the kava products” which could be interpreted as support for this option. It is also suggested that Option 2 might drive the users underground, particularly the Pacific Islanders who are living in NZ. 		<ul style="list-style-type: none"> • Labelling requirements should be met through Standard 2.6.3 and these should complement horizontal labelling standards in the Code. 	<ul style="list-style-type: none"> • Distinction drawn between traditional and medicinal uses. • Scientific research to investigate liver toxicity associated with the kava extract as a complementary medicine or food supplement should be conducted. • Purified kava extraction method should be standardised. • Suggest reviewing the TTMRA. 	<ul style="list-style-type: none"> • Kava plant grows well in Papua New Guinea. • Need for data to be collected on dietary intake of kava in Australia and New Zealand. • Kava trade is encouraged for pacific islanders throughout Australia, NZ, Europe and other parts of the world.

ATTACHMENT 6

DETAILED COST-BENEFIT ANALYSIS

Option 1: Maintain the status quo

Standard 2.6.3 – Kava would be retained without modification and the NCKM would continue to apply in Australia. In New Zealand Standard 2.6.3 would apply without the NCKM. The addition of kava to other foods would continue to be prohibited however, food-type dietary supplements containing kava manufactured to the NZDSR could remain on the market in New Zealand and be imported into Australia under the TTMRA.

Traditional users of raw or ground dried kava

In Australia users are able to readily obtain kava for use as a traditional beverage so long as certain conditions are met. Restrictions on use differ between the states and territories because of the different patterns of use and different public health status, therefore, availability of kava also differs somewhat between different jurisdictions.

In New Zealand, kava is readily available to consumers without the restrictions of the NCKM.

Importers and distributors of raw kava

Importation and distribution of kava is permitted under the conditions of the NCKM in Australia. The conditions are somewhat restrictive in comparison with requirements for the general food supply. However, the restrictions are intended to minimize the detrimental impact of kava abuse.

In New Zealand the NCKM does not apply and so importation and distribution occur without the restrictions of the NCKM.

Government agencies involved in kava management and enforcement

Some Australian jurisdictions implemented more restrictive controls around kava supply and distribution because of regional public health issues associated with kava use. Because kava importation and use is not uniform across Australia some jurisdictions will have a much larger role in kava management and enforcement than others and resources allocated will reflect this. It was also raised previously that the definition of kava is insufficient to enable enforcement action. Under the NCKM, there is an avenue for a license to import to be revoked if conditions of the NCKM are breached. However, breaches of the NCKM are difficult to detect, with advertising and labelling breaches more readily noticed than selling to minors for non-signatories. Whilst there are some problems with management and enforcement, jurisdictions have indicated that overall, Standard 2.6.3 in conjunction with the NCKM have provided an effective mechanism for minimizing the widespread use of kava.

New Zealand have indicated that kava abuse is not an issue in New Zealand, that it is used responsibly by traditional users, but its use is not widespread throughout the general population. Therefore, few resources are required for kava management and enforcement.

Public health workers contributing to kava management

The regulatory framework for kava is complex, but it results in an open environment in which health professionals can work effectively. Because the use of kava is largely centred in

certain areas of the Northern Territory in Australia and amongst Pacific Islander groups in both Australia and New Zealand, public health professionals can readily reach target users. Since the use of kava is not widespread throughout the general population, the work of public health professionals is manageable and effective.

Rural farmers and agricultural sectors in Pacific Island Countries

Kava is an important source of livelihood for rural farmers in Pacific Island countries. In Fiji, cash returns for kava are second behind sugar. The domestic market for the traditional kava beverage in Fiji is stable and was worth F\$82 million in 2001.

There are opportunities for the export of kava to both Australia and New Zealand and there are many users of the traditional kava beverage. In 2001, Fiji exported 23.8 tonnes of dried kava worth F\$315,612 to Australia and 35.4 tonnes of dried kava to New Zealand worth F\$532,524. All Pacific Island countries have suffered losses of exports of kava due to the recalls of pharmaceutical products in many countries.

Food-type dietary supplement industry

Kava containing food-type dietary supplements are permitted under the NZDSR. These products can be sold in New Zealand or imported from New Zealand into Australia under the TTMRA. There have been very few products identified in either Australia or New Zealand. At the end of 2001, one non-alcoholic beverage was identified on the Australian market and an enquiry about a kava containing candy was received but this product was not sold in Australia.

Kava containing food-type dietary supplements cannot be manufactured in Australia, putting Australian industry wishing to market similar products at a disadvantage. Therefore, the current situation represents a cost for Australian industry and a benefit for New Zealand industry.

Consumers of food-type dietary supplements containing kava

As there are few, if any, food-type dietary supplements available on the market, consumers wishing to obtain these products are not able to. However, it should be noted that, since August 2002, consumers have not been able to purchase kava containing complementary medicines in Australia because of a voluntary recall issued by the Therapeutic Goods Administration following cases of liver toxicity. This situation could be seen as a perceived cost to those people wishing to consume kava containing food-type dietary supplements, but it can also be seen to be a benefit in that public health is better protected.

Summary

The existing regulatory framework for kava is effective in: containing use of kava to distinct subgroups of the population and preventing its widespread use; and restricting the health and social problems associated with kava abuse. Government enforcement agencies have indicated general support for the regulatory framework however, areas for improvement have been identified (e.g. revising the definition of kava and labelling requirements). The existing framework represents a benefit to consumers in protecting public health and government agencies in providing effective management. There are some restrictions, representing a cost for: importers and distributors of kava and exporters from Pacific Island countries; and food industry in Australia wishing to develop innovative kava products.

Option 2(a): Amend definitional and labelling aspects of Standard 2.6.3 and prohibit the use of kava extracts in Standard 1.4.1

Standard 2.6.3 – Kava, will be retained to operate in conjunction with the NCKM. The current prohibition on the mixing of kava with other foods would be retained and food-type dietary supplements containing kava manufactured to the NZDSR can continue to be produced and imported into Australia under the TTMRA. The amendments will include a new definition of kava and new labelling requirements. The use of acetone and ethanol extracts of kava will be prohibited under Standard 1.4.4 – Prohibited and Restricted Plants and Fungi.

Traditional users of raw or ground dried kava

Additional quality control will be introduced through the changes in the definition, which represents a further safeguard of the health of present users of the traditional kava beverage. This option offers significantly better protection of public health, and hence a benefit to traditional users and any potential users in the general public, through the prohibition of kava extracts, the safety of which is unclear and requires further investigation. The use of ethanol or acetone extracts of kava in food poses as significant risk to public health given the recent links to liver toxicity and the limited knowledge about the extent to which kava extracts contributed to these cases. It is necessary that this risk to public health be removed through the prohibition of the use of these extracts in food, as is the case in this regulator option.

Importers and distributors of raw kava

Importers and distributors will be largely unaffected by these amendments as the NCKM will still function in conjunction with Standard 2.6.3 and the amendments to Standard 2.6.3 are unlikely to change the cost of labelling kava.

Government agencies involved in kava management and enforcement

The amended definition of kava in combination with the prohibition of kava extracts will provide clarity to enforcement agencies and may assist in enforcement action. Greater capacity to take enforcement action may increase the public confidence in enforcement agencies. Hence this option offers a benefit to government agencies.

Public health workers contributing to kava management

This group will be largely unaffected since the regulatory framework will remain largely unchanged. It is not anticipated that the changes to the definition and labelling or the prohibition on extracts will impact on the level of use of the traditional kava beverage and as a consequence, the public health resources required to be dedicated to kava management are unlikely to change.

Rural farmers and the agricultural sector in Pacific Island countries

The quality assurances built into the definition for kava and the prohibition on kava extracts may give assist in raising the credibility of the kava producing industry, which is currently struggling under the recalls of kava-containing medicinal products around the world. In Vanuatu, the drop in exports owing to the recalls of kava containing products in several overseas markets has resulted in an estimated annualized decline of 33.2% in the value of kava exported during 2002. This reduction in value of exports during 2002 added significantly to the domestic supply of kava, reducing domestic prices. Quarterly kava earnings in Fiji fell from a high of F\$1.3 million in the 4th quarter of 2001 to F\$323,000 in the first quarter of 2002, a fall of 75%. In Tonga, exports to the US for 2000, 2001 and the first

half of 2002, which also show a loss were: T\$102,223; T\$46,125; and T\$28,052 respectively. It is not clear whether exports to Australia and New Zealand, for the traditional kava beverage, were affected by the recalls of kava-containing medicinal products.

FSANZ understands that the majority of farmers/exporters only grow and sell nobles kava and the underground parts of the plant for the traditional kava drink. Therefore, the quality factors introduced into the definition will reflect current practices and ensure a benefit to the industry in terms of public perception.

Food-type dietary supplement industry

The situation remains the same as for Option 1 and the industry is unaffected by this regulatory option in comparison with Option 1. Kava containing food-type dietary supplements can still be manufactured to the NZDSR in New Zealand or imported into New Zealand can subsequently be imported into Australia under the TTMRA. This situation represents a benefit to New Zealand and a cost to Australian industry because similar kava containing products cannot be manufactured in Australia.

Consumers of food-type dietary supplements containing kava

The situation under this regulatory option is the same as for Option 1.

Summary

Traditional users would benefit from the increased quality assurance provided through clarification of the definition of kava and prohibition of kava extracts in foods. The clarified definition for kava and the prohibition of kava extracts represents a benefit to agencies involved in kava management in addition to the benefit of retaining the overall existing regulatory framework currently supported by these agencies. The situation for public health workers is unlikely to change under this regulatory option. The credibility of the kava manufacturing industry could potentially benefit from this regulatory option in comparison with Option 1 however, it is unlikely that there will be any change to the amount of exports/imports of kava. The restrictions on kava sale and distribution which represent a cost to the food-type dietary supplement industry will be the same as with Option 1. Overall, Option 2(a) represents a benefit in comparison with Option 1.

Option 2(c): Amend Standard 2.6.3 to allow the addition of kava to other foods

Standard 2.6.3 – Kava, would be retained to operate in conjunction with the NCKM. The current prohibition on the addition of kava to other foods would be removed and as such, kava could be added to other foods and sold. Kava extracts would remain prohibited. The sale of kava in other foods would need to be subject to the NCKM in Australia, otherwise the NCKM would be made redundant if consumers could purchase intoxicating ready-to consume kava drinks without the restrictions of the NCKM.

This option would incorporate the definitional, compositional (prohibition on the use of ethanol and acetone extracts in food) and labelling changes as per in Option 2(a).

Traditional users of raw or ground kava

Consumers would benefit as per Option 2(a) due to increased quality assurance. If a premixed beverage or food containing kava contained sufficient kava to have an intoxicating effect, this could be a perceived benefit by the user, although this could also be seen as a cost in terms of public health.

There is the potential for increasing consumption and widespread use of kava given the marketability and accessibility (through availability ready made and packaged) of such a product, which in turn would be a cost to the user and community in terms of public health. While the number of kava containing foods in New Zealand is likely to increase under this regulatory option, the widespread use in Australia is unlikely because: the buyer of the product would still be required to be a signatory to the NCKM and 18 years of age or older; the manufacturer of such a kava containing product would need to abide by the NCKM; and the market is not likely to be sufficiently large to meet the manufacturing costs involved.

Importers and distributors of raw kava

Importers and distributors of kava would benefit as per Option 2a and the possibility for developing new food products provides additional benefits. These benefits are not likely to be realised to any great extent in Australia where importation and distribution is subject to the NCKM. However, this regulatory option may also be a cost to current importers and distributors since the food-type dietary supplement industry or beverage companies may be better placed financially to seize such an opportunity and in doing so, reduce the gains of the current importers and distributors.

Government agencies involved in kava management and enforcement

This regulatory option would result in a cost to government agencies due to the potentially increased number of kava containing products on the market. The benefits discussed under Option 2(a) of a refined definition and the prohibition of kava extracts may assist in enforcement action would apply however, it is likely that these benefits would be outweighed by the likely cost of additional resources needed to monitor the more liberal regulation of kava containing foods.

Public health workers contributing to kava management

This regulatory option is likely to be a cost to public health workers since the opportunity to manufacture innovative kava-containing foods may increase the exposure of the general community to kava. There is a much greater likelihood that the general community will find kava attractive if it is packaged in an accessible and marketable form. Public health workers would need additional resources to effectively monitor the use of kava and educate the community about the risks of kava abuse.

Rural farmers and the agricultural sector in Pacific Island countries

This option presents the potential for increased export sales of kava to Australia and New Zealand given the increased scope for kava use in the food supply. However, Pacific Island countries submitting with the interests of the agricultural sector in mind, have not supported broadening the scope of permissions for kava outside the traditional use because of the community uncertainty around cases of hepatotoxicity.

Food-type dietary supplement industry

This industry would have wider scope to develop new food products containing kava. These benefits are not likely to be realised to any extent in Australia where importers and distributors are tied by the NCKM.

Consumers of food-type dietary supplements

This regulatory option would provide a minor benefit to consumers however, it is unlikely that these products would be widely available to the general community in Australia because

of the restrictions of the NCKM. Some food products containing kava could potentially be manufactured in New Zealand currently under the NZDSR, so New Zealand consumers are unlikely to benefit from this regulatory option.

Summary

Consumers of kava may benefit from this option in terms of increased availability of kava however, there is also likely to be a cost to this group in terms of worsening or more widespread adverse effects of kava abuse. The potential benefits of increasing possibilities for innovation are unlikely to be realised to any great extent in Australia due to the restrictions of the NCKM. This option represents a cost to government agencies involved in kava management and enforcement and to public health workers due to the potential increase in the widespread use of kava. Kava exporting countries could potentially benefit from slightly broadened permissions however, they have generally not supported this option through submissions. Food-type dietary supplement industry in Australia may benefit slightly from this option however, there will still be some discrepancy between Australia and New Zealand. Overall, Option 2(c) is a cost in comparison with Option 2(a) and is not clearly favoured over Option 1.

Option 2(d): Amend Standard 2.6.3 to allow the addition of kava extracts in Foods

Standard 2.6.3 – Kava, would be retained to operate in conjunction with the NCKM. The sale of kava in other foods would still be subject to the NCKM in Australia. The current prohibition on the addition of kava to other foods would be removed and as such, kava could be added to other foods and sold. Kava extracts would also be permitted in food, but would not be subject to the NCKM since they are unlikely to be intoxicating to anywhere near the same extent as the traditional beverage and so do not fall within the purpose of the NCKM. In order for this option to work in a practical sense, a definition for kava extracts would be included in Standard 2.6.3 that distinguishes foods containing kava extracts with foods containing kava.

This regulatory option would harmonise trans-Tasman regulations relating to kava.

Traditional users of raw or ground dried kava

There are likely to be benefits to traditional users of kava as per Option 2(a) due to increased quality assurance of the traditional kava beverage and increased option of purchasing kava in a ready-made beverage form. This option could also be seen as providing a benefit to traditional users wishing to purchase products containing kava extracts. If total kava consumption increases for those people already consuming kava as a result of increased availability, there is a definite risk of increasing health problems including, liver abnormalities and toxicity.

Importers and distributors of raw kava

This option is likely to result in a cost for importers and distributors of the traditional kava beverage since, traditional users could switch to consuming kava in other food forms. The food-type dietary supplement industry is likely to be better placed to take advantage of this opportunity to market food products containing kava extracts.

Government agencies involved in kava management and enforcement

This regulatory option is very complex in that some kava products will be subject to the NCKM and those food products containing kava extracts will not. In addition to the

complexity of the regulatory option, there will likely be an increased number of products available. This option represents a clear cost to enforcement agencies and one that is not supported by this affected party.

This regulatory option also goes against the position taken by agencies regulating kava containing complementary medicines, including TGA, which have initiated either mandatory or voluntary recalls of all products containing kava extracts. If FSANZ, were to adopt this regulatory option, there would be significant confusion and potentially a number of consumer enquiries about the discrepancy in the regulation.

Public health workers contributing to kava management

There are significant public health consequences of a substantial increase in the number and variety of kava containing products available to consumers. The adverse effects of consumption of both the traditional kava beverage and products containing kava extracts are likely increase in those people already consuming the traditional kava beverage and are likely to become more widespread in the community. Some of the consequences of consumption of kava extracts are severe. This option is likely to represent an impossible task to public health workers who are already stretched for resources.

Rural farmers and the agricultural sector in Pacific Island countries

This option presents the potential for increased export sales of kava and kava extracts to Australia and New Zealand given the increased scope for kava use in the food supply. However, as stated under option 2(c), Pacific Island countries submitting with the interests of the agricultural sector in mind, have not supported broadening the scope of permissions for kava outside the traditional use because of the community uncertainty around cases of hepatotoxicity.

Food-type dietary supplement industry

This option represents a benefit to the food-type dietary supplement industry in Australia. In New Zealand, food-type dietary supplements containing kava extracts can already be manufactured to the NZDSR. Thus, this regulatory option would harmonise trans-Tasman regulations relating to kava.

Consumers of food-type dietary supplements

These consumers would have a greater choice of kava containing food-type dietary supplements, particularly in Australia. There are also real risks to public health of these consumers, as there have been severe adverse effects reported in association with consumption of kava extract -containing supplements.

Summary

This option is likely to pose an increased risk to public health and safety to all existing consumers of kava and the community as a whole due to the potential increase in the widespread consumption of kava. This option will cause considerable confusion and an increase in work for government agencies and public health workers. The food-type dietary supplement industry in Australia is set to benefit from this option, but Pacific Island countries exporting from kava have expressed their opposition to the use of kava extracts in food. This option goes against the position being taken by regulatory bodies throughout the world and is not consistent with the stance taken by the TGA. The risks to public health of this option far outweigh the potential benefits to the food-type dietary supplement industry in Australia.

Overall, this option is estimated to be a cost in comparison with all other options and is not favoured.

Option 3: Remove Standard 2.6.3 – Kava, and accommodate definitions and labelling requirements in other parts of the Code.

Standard 2.6.3 would be removed from the Code, as would the reference to the NCKM. The prohibition on mixing kava with other foods would also be removed. Two sub-options could be considered:

- a) prohibit the addition of ethanol and acetone extracts to foods through Standard 1.4.4; and
- b) allow the addition of ethanol and acetone extracts to foods.

The following analysis for this option addresses the first sub-option outlined (a), i.e. prohibit the addition of kava extracts to food, since the analysis of option 2(c) shows there is an unacceptable risk to public health of permitting kava extracts in food.

Traditional users of raw or ground dried kava

There would be a benefit to consumers of the traditional kava beverage as the restrictions imposed by the NCKM would be lifted and availability of kava would presumably increase. However, the risk to public health would be increased significantly due to the increased availability of kava, and the social problems associated with kava abuse would also contribute to health problems.

Government agencies involved in kava management and enforcement

The number of kava containing products on the market is likely to increase significantly placing a strain on enforcement agencies. Government agencies have indicated that they do not support this option. On the other hand it could be argued that the cost of enforcement may be reduced since agencies would no longer have to enforce strict requirements that keep a tight control on the market.

Public health workers contributing to kava management

The potential for increased health and social problems associated with increased availability of kava would make the work of public health workers increasingly difficult. There would likely be an increased number of people consuming kava without awareness of the adverse effects. The current resources of public health workers are unlikely to stretch far enough to effectively deal with the problems associated with this regulatory option.

Rural farmers and the agricultural sector in Pacific Island countries

This group could potentially benefit financially from the increased demand for kava if it is used more widely in other foods. However, submitters representing the interests of agricultural sectors have indicated that given the bad publicity associated with kava and cases of liver toxicity, it would be better to wait until conclusive scientific evidence is available before giving permission for the expanded use of kava in the food supply. Further negative publicity surrounding kava could adversely affect the industry more than at present, and the amount of negative publicity would be felt more as the number of kava containing products on the market increased.

Food-type dietary supplements industry

This option represents a benefit to the food-type dietary supplement industry in Australia. In New Zealand, food-type dietary supplements containing kava can already be manufactured to the NZDSR. Thus, this regulatory option would go some way to harmonising trans-Tasman regulations relating to kava, noting that kava extracts would not be allowed in food in Australia (on the other hand kava extracts are permitted in food-type dietary supplements in New Zealand) and so there would still be some discrepancy in permissions for kava containing foods.

Consumers of food-type dietary supplements

These consumers would have a greater choice of kava containing food-type dietary supplements, particularly in Australia. There are also risks to public health of these consumers due to the increasing availability of kava in the food supply.

Summary

This option will provide increased availability of kava to consumers, which can be seen as a benefit however, there would also likely be a cost in terms of public health due to the substantially increased availability of kava in the general community. This option will be a cost to government enforcement agencies and public health workers due to confusion, lack of knowledge about kava in the broader community, increased number of products and increased use. Importers and distributors and the food-type dietary supplement industry would benefit from this option. The option represents the breaking down of the existing regulatory framework which state and territory enforcement agencies have supported and as such (in combination with other costs), is not supported.

