INITIAL ASSESSMENT REPORT

PROPOSAL P256

REVIEW OF KAVA (STANDARDS O10/2.6.3)

DEADLINE FOR PUBLIC SUBMISSIONS to the Authority in relation to this matter:
20 November 2002
(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 Federal, State and Territory governments of Australia and the New Zealand Government. It is a statutory authority under Australian Commonwealth law and an independent, expert body.

FSANZ is responsible for developing, varying and reviewing standards for food available in Australia and New Zealand including primary production and processing standards and for a range of other functions including coordinating national food surveillance and recall systems, conducting research, assessing policies about imported food and developing codes of conduct with industry.

The FSANZ Board approves new standards or variations to food standards, which are then accepted by the Australia and New Zealand Food Regulation Ministerial Council (ANZFRMC), a Ministerial Council made up of Commonwealth, State and Territory and New Zealand Health Ministers. If the Council accepts the changes made by FSANZ, the food standards are automatically adopted by reference under the food laws of Australian States and Territories and New Zealand.

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

The Authority has prepared an Initial Assessment Report of Proposal P256, which includes the identification and discussion of the key issues. The Authority invites public comment on this Initial Assessment Report for the purpose of preparing an amendment to the Food Standards Code for approval by the FSANZ Board.

Written submissions are invited from interested individuals and organisations to assist the Authority in preparing the Draft Assessment for this proposal. Submissions should, where possible, address the objectives of the Authority 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 the Authority are open to public scrutiny, and any submissions received will ordinarily be placed on the public register of the Authority and made available for inspection. If you wish any information contained in a submission to remain confidential to the Authority, you should clearly identify the sensitive information and provide justification for treating it as commercial-in-confidence. The FSANZ Act requires the Authority 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  Fax (02) 6271 2278
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PO Box 10559
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NEW ZEALAND
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Submissions should be received by the Authority by: 20 November 2002. Submissions received after this date may not be considered unless the Project Manager has given prior agreement for an extension. Submissions may also be sent electronically through the FSANZ website using the Food Standards tab and then through Documents for Public Consideration. Assessment reports are available for viewing and downloading from the FSANZ website or alternatively paper copies of reports can be requested from the Authority’s Information Officer at either of the above addresses or by emailing info@foodstandards.gov.au including other general enquiries and requests for information.

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.
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Executive Summary

Volumes 1 and 2 of the *Food Standards Code* contain a standard that regulates kava (Standards O10/2.6.3 – Kava). Kava regulation in Australia is complex: kava is permitted for traditional use in the food supply (i.e. the raw, ground or dried root) but it cannot be mixed with other foods. These regulations reflected the need to legalise the traditional use of kava while managing its supply and distribution. However, kava is not prohibited in dietary supplements in New Zealand, and as such, products can enter Australia via the Trans-Tasman Mutual Recognition Arrangement. Until recently, kava was permitted in complementary medicines in Australia.

To allow transition of the kava standard to the new joint *Food Standards Code*, a new standard (Standard 2.6.3) was established which mirrored Standard O10 with the addition of one amendment. This amendment recognised that kava could be lawfully added to foods regulated under the *New Zealand Dietary Supplement Regulations 1985* (NZDSR). This amendment was made pending a full review of the standard at a later date.

The purpose of this Initial Assessment Report is to notify stakeholders of the impending review of Standards O10/2.6.3 - Kava. The report is intended to raise issues involved in the regulation of kava in the food supply. The report is designed to assist in identifying the affected parties, to provide regulatory options, and to analyse the potential impacts of any regulatory or non-regulatory provisions. The information needed to review this proposal will include information from public submissions. Public submissions are now invited on this initial assessment report.

FSANZ’s primary objective during this review is to ensure that kava and any food that contains kava as an ingredient (which at this stage are only products regulated under the NZDSR, are safe for human consumption. Given recent reports of liver damage associated with supplement products containing kava, and the voluntary recall of complementary medicines containing kava, a review of the safety of kava, as both the raw product and standardised extract, as well as risk management options will be considered.
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 and stem of the plant *Piper methysticum* which grows throughout Melanesia, Polynesia and Micronesia.

In light of the potential health and social problems associated with kava use, an integrated national system to restrict the importation, distribution and sale of kava was instituted in Australia in 1997. This system regulated the traditional form of kava (e.g. powdered roots) in the framework of the National Code of Kava Management. The original purpose of incorporating provisions for kava within the *Food Standards Code*, was to provide a mechanism that effectively controlled its use and reduce the unregulated blackmarket of kava import and sales.

During the development of the joint *Australia New Zealand Food Standards Code*, this standard was amended to recognise the addition of kava to food type dietary supplements regulated under the NZDSR. It should be noted that kava used in dietary supplements is often a concentrated extract of the plant.

This standard will now be reviewed to consider if it effectively provides a mechanism for controlling kava in Australia, if current scientific data supports its safety in the food supply and that regulations are harmonised between the Australia and New Zealand.

2. **Regulatory Problem**

In the development of Volume 2 of the Code, Standard O10 from Volume 1 was transported into Standard 2.6.3 – Kava (Attachment 1), without a comprehensive review. This Proposal needs to be raised to formally review Standard 2.6.3 – Kava in order to fully harmonise the Australian and New Zealand food regulations under the joint *Food Standards Code*.

2.1 **Current regulations for kava**

The importation of kava and its subsequent sale and distribution within Australia is regulated in a number of ways and includes several regulatory agencies including Customs, the Therapeutic Goods Administration (TGA) and FSANZ. This strategy was designed to provide a uniform, national restriction and monitoring system for the importation of kava while targeting areas in Australia where kava abuse is a problem.

The *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 TGA. In addition to commercial importation of kava, passengers arriving in Australia can import up to two kilograms of kava for personal use without a permit.

Standards O10/2.6.3 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), which regulates the sale and distribution of kava in Australia (Attachment 2).
Standards O10/2.6.3 prohibit kava from being used as an ingredient in processed foods but recognises that kava can be present in products regulated under the NZDSR. It also imposes strict labelling requirements on the label or package of kava. The Kava Code of Management does not apply in New Zealand.

In addition, Western Australia and the Northern Territory have both introduced legislation that restricts its sale and distribution in those States.

2.1.1 Standard O10 and the development of Volume 2 of the joint Food Standards 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 Volume 2 of the Food Standards Code. However, it was agreed that the kava standard was needed in this volume 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.

2.1.2 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 from Volume 1 to Volume 2 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 P235 Review of Dietary Supplements.

3. Objective

The objective of this Proposal is to review Standard 2.6.3 – Kava to ensure it meets the FSANZ Act.

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. 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.

In particular, 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 kava, the safety of kava will also be reviewed.

4. Background

4.1 History of kava regulation in Australia and New Zealand

4.1.1 Regulation of kava by the Food Standards Code and the National Code of Kava Management (NCKM)

The original purpose of incorporating provisions for kava within the *Food Standards Code*, was to provide a mechanism that effectively controlled its use and reduced the unregulated blackmarket of kava import and sales. The management of kava in Australia has undergone many changes in the last 15 years. This is largely due to the difficulty in finding a regulatory balance for a product that has both a history of safe use (when used traditionally) and well documented pharmacological activity. A prohibition of kava would not only be inappropriate and culturally insensitive but was also previously shown to be ineffective in controlling kava importation or use in Australia. Thus a management strategy for controlling kava that did not severely impact on traditional users was developed. This scheme is detailed below and includes participation by the then ANZFA, Customs and the TGA as well as State and Territory Health Departments. A history of kava regulation in Australia is attached at Appendix 1.

Standards O10/2.6.3 – Kava together with the National Code of Kava Management, (which operates only in Australia), regulate the sale and distribution of kava in Australia and seeks to minimise any potential detrimental effects associated with kava abuse. The National Code of Kava Management essentially recognises that under the *Customs (Prohibited Imports) Regulations*, kava is a controlled substance. Accordingly, a license to import as well as a permit for each consignment is required. Both the license and permit are issued by the Therapeutic Goods Administration (TGA), which also maintains a register of all licensees.

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.

Within the *Food Standards Code*, it is generally the case that foods can be added to other foods unless specifically prohibited. The Standard for kava prohibits its use as an ingredient, that is, as a mixed food. It is noteworthy that the National Code of Kava Management was not intended nor designed to regulate kava addition to foods.
4.1.2 State and Territory regulatory action on kava

Part of the kava management strategy was to enable those states and territories to introduce more restrictive measures if it was considered necessary. Both the Northern Territory and Western Australia now have such legislation.

About the same time as the introduction of the National Code of Kava Management, the Northern Territory (NT) Kava Management Act 1998 came into effect. This was introduced after an Inquiry into state management of kava in the Northern Territory and prohibited the sale of kava without a license. This Act allows for communities to apply to the Liquor Commission to become licensed 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.

In Western Australia, kava has been regulated under the Poisons Act 1964 since 1988 which prohibits kava from being sold unless given permission for specific cultural events.

4.1.3 Regulation of kava in New Zealand

The New Zealand Food Regulations 1984 (NZFR) do not contain any provisions regulating the sale and distribution of kava within New Zealand, and it is not specifically prohibited under the NZDSR. Thus, kava is permitted in the food supply in New Zealand under both sets of regulations. When the NZFR are repealed at the end of 2002, kava addition to foods will be restricted to those foods regulated under the NZDSR only.

Standard 2.6.3 of Volume 2 recognises the addition of kava to those products permitted under the NZDSR. Thus while the NZDSR remain in effect, kava can be used in products meeting those regulations. FSANZ has initiated a review of food-type dietary supplements (Proposal P235) and it is anticipated that the NZDSR will be repealed in the future. The New Zealand Food Safety Authority intends to release a discussion paper on this matter later this year.

4.2 What is kava?

Kava (Piper methysticum) is a member of the pepper family and is primarily used to refer to a drink prepared from the fresh or dried roots and stems of that plant. It also refers to other preparations such as powdered kava for use in powdered tablets and capsules.

4.3 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 medicine in several cultures. Kava was also introduced in Aboriginal communities, predominantly in Arnhem Land in the 1980’s as an alternative to alcohol. Consumption of kava also occurs in New Zealand.

It is traditionally prepared from fresh or dried roots and stems. 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 fused in water. The degree of dilution affects the potency of the kava preparation.
4.4 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 used for calming purposes and reducing anxiety.

Commercial extracts of kava are generally prepared from the root although they can be prepared from other parts of the plant. This extract is generally standardised to contain 30% kavalactones compared to between 3-20% kavalactone content in root material. However various dosage forms with a range of indications are available. Such extracts are used primarily in complementary medicines such as in capsules, powders/teas, alcohol tinctures/liquids and in combination products that contain a variety of herbs and/or vitamins.

4.5 Pharmacological effects of kava

The active ingredients of kava are kavalactones (or kava pyrones), which are pharmacologically active compounds naturally present in the kava plant. Eighteen 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 variety and also the method of preparation. 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.

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.

4.6 Previous review of kava safety

A toxicological evaluation of kava by the 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 is generally accepted that long-term consumption of large amounts of kava (heavy use is defined as 310 - 440 g dried powder/week) can 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. 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), 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 continue to be raised.
5. **Issues Relevant to this Proposal**

5.1 **Safety of kava**

As indicated earlier, use of kava that has been prepared traditionally has not been linked to permanent and life threatening liver damage. However, this contrasts significantly with the recent reports of liver toxicity associated with the use of complementary medicines containing standardised extracts of kava. Such concern about complementary medicines has led to the (voluntary and mandatory) withdrawal of products containing kava by several countries (Australia, UK, Germany, France, Switzerland and Canada) (see section 5.5). In some countries, this withdrawal has applied to all products that contain kava, including foods.

In Australia, traditional kava use is distinguished from other forms of kava intake, whether as a complementary medicine or food-type dietary supplement. 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. The safety of the traditional use of kava as well as the safety of kava extracts will be further considered at draft assessment.

5.2 **Dietary intake of kava**

Kava, as a food (i.e. raw, ground or dried root), is not widely used in Australia except for in communities such as some Pacific Islander or Aboriginal communities. Therefore, outside of the traditional use of kava, it would be predominantly used as a complementary medicine and therefore regulated by the TGA. Any other forms of kava in foods are illegal, as it is not permitted to be added as an ingredient in foods (with the exception of dietary supplements regulated under the NZDSR).

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 Kava Code Management Group, 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.

Dietary modelling of kava consumption in Australia cannot be undertaken, as kava is not listed in the 1995 National Nutrition Survey. As an 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). It should be noted however, that the blackmarket of kava continues to be of concern, particularly in the Northern Territory. More recent data is difficult to obtain and no data was available for consumption in New Zealand.

5.3 **Kava management through the Food Standards Code**

While the *Food Standards Code* permits the sale of raw kava in Australia and New Zealand, Australian States and Territories are able to impose further conditions on its supply and sale as currently occurs with the supply and sale of alcoholic beverages.
For example, since the implementation of the National Code of Kava Management, 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 Food Standards Code. 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 introduction of the Northern Territory Kava Management Act in 1998.

In reality, control over kava import and use, more or less lies with the States and Territories, the only function that Standards O10/2.6.3 fulfil is in stipulating labelling requirements. Such labelling provisions may be more appropriately contained within other parts of the Code.

5.4 Presence of added kava in food type dietary supplements

The original standard (O10) was developed to provide a regulatory framework for the sale of kava in Australia. It was designed to regulate raw, ground or dried kava and consequently standardised extracts or dietary supplements were not considered during its development. The management of kava use in Australia was coordinated through the Food Standards Code and the National Code of Kava Management and State and Territory governments retained the flexibility to impose stricter regulations if considered necessary.

Products prepared under the NZDSR containing kava can be lawfully sold in Australia under the Trans-Tasman Mutual Recognition Agreement (TTMRA). The recognition of kava addition to dietary supplements during the development of Standard 2.6.3 of the Australia New Zealand Food Standards Code, was therefore to enable harmonised regulations for kava in both countries. It is understood, however, that there are very few food-type dietary supplements containing kava on the market in New Zealand.

In light of the recent health concerns, there will need to be a consideration of the appropriateness of a purified extract of kava being added to dietary supplements in Proposal P235 – Review of Food-Type Dietary Supplements.

5.5 Recent European concerns regarding liver damage

There are approximately 30 recently reported cases in Europe of liver damage associated with the use of kava as a medicinal herb, complementary medicine or medicinal dietary supplement. The 30 cases varied in severity from abnormal liver function to liver failure, one of which was fatal, and four requiring 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) and previous history of compromised liver function. In all of these reported cases, kava has been consumed as dietary supplements or herbal medicines.

In addition to these European reports of liver damage associated with kava use, one woman in Australia died recently after taking a herbal supplement that contained kava and two other herbs (passion flower and skullcap).

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1 Passion flower (Passiflora incarnata) and skullcap (Scutellaria lateriflora)
The woman presented with liver failure after taking the medicine containing kava for four months. The product is suspected to be the most likely cause of her illness.

Consequently, the TGA have initiated a voluntary withdrawal of all complementary medicines containing kava. The voluntary recall is a precautionary measure that will 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 will also consider if any additional regulatory action on such products needs to be taken.

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.

5.5.1 Response of other countries

Several countries have initiated either a mandatory or voluntary withdrawal of complementary medicines containing kava (Germany, France, UK, several other EU countries and Canada). 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 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 health care professionals that they be aware of and report any cases of liver or other damage associated with the use of such supplements.

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

5.5.2 Implications for FSANZ

A recall of foods containing kava was not considered necessary because no foods (i.e. food-type dietary supplements) were found in Australia. In New Zealand, a confectionery was found that contained kava extract. It was unclear whether this product is manufactured under the food regulations, the dietary supplements regulations or whether it was non-compliant with any regulation. This product was not produced in great quantities and is not exported to Australia.
5.6 Permission to manufacture in Australia food type dietary supplements that contain kava

The current standard enables food-type dietary supplements containing kava to be manufactured in (or imported into) New Zealand and subsequently exported to Australia for sale (under the TTMRA). Australian manufacturers and importers are not able to domestically produce or directly import such products into Australia other than from New Zealand. This inconsistency is not unique to food type dietary supplements that contain kava and the broader issue is being considered under Proposal P235 – Review of Food-Type Dietary Supplements.

6. Regulatory Options

Possible options are:

6.1 Maintain the status quo

6.1.1 Initial assessment

This option represents the current situation, may have public health and safety implications as well as lending itself to trans-Tasman inequity. Standard O10 was originally developed to regulate raw kava products and was amended (during the development of Standard 2.6.3 of the Joint Code) to recognise the addition of kava to dietary supplements (within the NZDSR) without full consideration of the implication of this regulation. The regulation of these products through this mechanism may not be appropriate.

Additionally, food producers in New Zealand have the ability to manufacture food-type dietary supplements containing kava, whereas Australia manufacturers cannot. As previously discussed in the review of food-type dietary supplements (Proposal P235), this results in considerable consumer and public health confusion due to inconsistencies in provisions for like products, and lack of harmonisation between Australia and New Zealand. As such, this option does meet the section 10 objectives identified in the preliminary information.

6.2 Amend Standards O10/2.6.3 – 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)

6.2.1 Initial Assessment

This option essentially reverts Standard 2.6.3 to its original version: that kava is prohibited as an ingredient in any food. Given recent concerns about the safety of kava, this option would provide a means of preventing kava use in the general food supply. In order to remove food-type dietary supplements containing kava from the market, this would also require amendment to the NZDSR to prohibit kava as an ingredient in these products, until such time that the NZDSR are repealed.

This option would cease the trans-Tasman inequity as both New Zealand or Australian manufacturers (or distributors) would not be able to make (or import) such products.
6.3 Amend Standards O10/2.6.3 – Kava, to broaden permission for kava in food

6.3.1 Initial Assessment

This option would result in harmonised regulations for kava in both countries. It would permit New Zealand and Australian manufacturers/distributors/importers to broaden the type and number of products containing kava in both countries. However, this change may not ensure a safe food supply in Australia or New Zealand given the recent concerns in Europe of liver toxicity associated with kava use and is likely to be inconsistent in maintaining public health and safety.

6.4 Remove Standards O10/2.6.3 – Kava, and incorporate mandatory labelling provisions into the appropriate labelling standard

6.4.1 Initial Assessment

This option would essentially retain the prohibition of kava as an ingredient in other foods (which may or may not include food-type dietary supplements) and retain the current labelling provisions by incorporating them within a “horizontal” standard rather than in a specific kava standard. This option recognises that in Australia, control of import, sale and use of kava has largely been implemented by the States and Territories. Similar legislative changes may be required in New Zealand.

These may not be the only regulatory options and that alternatives will be considered. FSANZ invites interested parties to submit alternative options that take into consideration the issues raised in this initial assessment report.

7. Impact Analysis

7.1 Affected parties

- those sectors of the food industry wishing to produce or market dietary supplement containing kava, particularly in New Zealand;
- importers and distributors of raw kava;
- traditional users of raw or ground dried kava;
- consumers of food type dietary supplements containing kava; and
- state, territory and New Zealand governments involved in kava management

7.2 Impact of regulatory options

In order to determine the most cost-effective and least prescriptive regulatory option for the on-going management and safe use of kava, it is necessary to consider the potential impact of each of the regulatory options described above, as reflected in the attributable costs and benefits to various stakeholder groups.

In the interest of assessing the impact of each of the above options (or any others that may be raised) FSANZ needs to determine how the stakeholder groups may be affected and what the likely costs and benefits will be. As part of this process FSANZ seeks input from stakeholders with regard to current information, quantitative where possible, that identifies the relevant costs and benefits.
Accordingly, a number of questions are raised below to stimulate discussion of this issue and assist in the impact of the above (or alternative) regulatory options.

<table>
<thead>
<tr>
<th>FSANZ seeks comment on the following questions:</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Regulation</strong></td>
</tr>
<tr>
<td>1. Is the current standard in conjunction with the NCKM providing an effective regulatory mechanism to control kava import, sale and use in Australia?</td>
</tr>
<tr>
<td>2. Is Standards O10/2.6.3 redundant now that the jurisdiction that had most concern with kava use (i.e. the Northern Territory) has now introduced its own regulatory measures to control import, sale and use in the Northern Territory?</td>
</tr>
<tr>
<td>3. Should the labelling requirements for kava be stipulated under other parts of the Code, rather than in a separate standard for kava?</td>
</tr>
<tr>
<td><strong>Safety</strong></td>
</tr>
<tr>
<td>4. Is there a distinction between use of kava that has been prepared traditionally and standardised extracts that are used in dietary supplements and complementary medicines?</td>
</tr>
<tr>
<td>5. Should kava be permitted in food type dietary supplements given concerns about its pharmacological activity, especially since very few products appear to be available?</td>
</tr>
<tr>
<td><strong>Harmonisation between New Zealand and Australia</strong></td>
</tr>
<tr>
<td>6. Do the current provisions enable equitable trading conditions for Australian and New Zealand manufacturers?</td>
</tr>
<tr>
<td>7. Are other legislative changes required in New Zealand to effectively control use of kava?</td>
</tr>
</tbody>
</table>

8. **Consultation**

FSANZ is committed to actively engaging stakeholders in the review and development of food standards. To achieve this, the following consultation processes have been/will be undertaken.

8.1 **Advisory Group**

Consistent with the development of Standard O10, FSANZ will coordinate an advisory group to discuss issues relating to kava management and permission in the food supply. In particular, those involved in the development of the original Standard (Northern Territory health and government officials, TGA, Customs, indigenous representatives, consumer advocates and industry representatives) as well as other interested parties will be targeted in the consultation. The purpose of this group will be to provide advice to FSANZ on issues of relevance to stakeholders raised by the review of kava in Australia and New Zealand. This will include consideration of:

- implications for public health and safety;
- impact on kava importers and manufacturers of dietary supplements containing kava as well as retailers, and distributors;
- implications for enforcement; and
- issues relating to harmonisation between New Zealand and Australia.
8.2 Invitation for Public Submissions

This report has raised several questions regarding kava management and permission in the food supply. These are intended to guide comment but should by no means be seen to pre-empt or restrict any views. The following points summarise the general areas of interest:

- Safety of kava use
- Management of kava and permitted food use
- Labelling of kava
- Regulatory options

Submitters’ comments will be taken into account in the development of any regulatory measures arising from this review. Furthermore, please note that comments on relevant subject matter not identified by this report are also welcome.

It is likely that targeted consultations will be conducted in both Australia and New Zealand before the preparation of the next stage of this review. If considered necessary, general stakeholder forums will also be held.

8.3 International and World Trade Organization

Australia and New Zealand are members of the World Trade Organization (WTO) and are bound as parties to WTO agreements. In Australia, an agreement developed by Coalition of Australian Governments (COAG) requires States and Territories to be bound as parties to those WTO agreements to which the Commonwealth is a signatory.

Under the Treaty between the Governments of Australia and New Zealand on joint Food Standards, FSANZ is required to ensure that food standards are consistent with the obligations of both countries as members of the WTO.

In certain circumstances Australia and New Zealand have an obligation to notify the WTO of changes to food standards to enable other member countries of the WTO to make comment. Notification is required in the case of any new or changed standards which may have a significant trade effect and which depart from the relevant international standard (or where no international standard exists).

9. Conclusion and Recommendation

This Report discusses regulatory considerations and related issues in respect of kava in the food supply. FSANZ seeks comment on these matters from all sectors of the community including consumers, health professionals, industry and governments. Submissions to this Initial Assessment will be used to further develop P256, including the preparation of draft regulatory measures, which will be circulated for public consideration within the context of the Draft Assessment Report for P256.

10. ATTACHMENTS

1. Standard 2.6.3
2. National Code of Kava Management
# Appendix 1

## History of Kava regulation in Australia

<table>
<thead>
<tr>
<th>Date</th>
<th>Action</th>
</tr>
</thead>
<tbody>
<tr>
<td>Pre-1985</td>
<td>Kava included in the old “Herbal Safe List”</td>
</tr>
<tr>
<td>March 1986</td>
<td>Aboriginal Health Section sought comment on pharmacological and toxicological aspects of kava from the Environmental Health Branch/NHMRC</td>
</tr>
<tr>
<td>April 1986</td>
<td>Kava referred to Ministerial Council on Drug Strategy (MCDS)</td>
</tr>
<tr>
<td>May 1986</td>
<td>MCDS noted that kava was used by aboriginal communities and requested a report of survey currently being conducted by NT Drug and Alcohol Bureau</td>
</tr>
<tr>
<td>April 1987</td>
<td>Noted in <em>Food Chemical News</em> that FDA would be taking no action regarding kava provided there was no evidence of toxic effects on consumers</td>
</tr>
<tr>
<td>November 1987</td>
<td>NHMRC resolution re kava stated that because of its psycho-active properties and potential for harm, use of kava should be actively discouraged.</td>
</tr>
<tr>
<td>November 1987</td>
<td>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.</td>
</tr>
<tr>
<td>March 1988</td>
<td>MCDS recommended that use of kava should be actively discouraged, education programs for health workers in NT and WA</td>
</tr>
<tr>
<td>June 1988</td>
<td>Food Science and Technology Sub committee (FST) concluded that kava was a drug</td>
</tr>
<tr>
<td>July 1988</td>
<td>Public Health Executive Committee (PHC) agreed with FST that kava is a drug and referred matter to Drugs and Poisons Scheduling Committee (DPSC).</td>
</tr>
<tr>
<td>July 1988</td>
<td>Gazetted by WA Government – kava sale and supply restricted under <em>Poisons Act 1964</em> to cultural uses and medical/scientific research.</td>
</tr>
<tr>
<td>August 1988</td>
<td>DPSC agreed that scheduling was not appropriate at this time. (No tox concerns, can be controlled under State law, e.g. WA)</td>
</tr>
<tr>
<td>September 1988</td>
<td>PHC agreed that scheduling of kava was not appropriate at this time – WA approach better</td>
</tr>
<tr>
<td>January 1990</td>
<td>NT Department of Health and Community Services requested urgent consideration of kava in scheduling context.</td>
</tr>
<tr>
<td>February 1990</td>
<td>DPSC discussion of kava scheduling deferred to May meeting with States and Territory (other than NT) encouraged to make detailed comments.</td>
</tr>
<tr>
<td>May 1990</td>
<td>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.</td>
</tr>
<tr>
<td>May 1990</td>
<td>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. <strong>Action:</strong> kava placed in Schedule 4: PHC and industry to be advised.</td>
</tr>
<tr>
<td>August 1991</td>
<td>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.</td>
</tr>
<tr>
<td>August 1991</td>
<td>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).</td>
</tr>
<tr>
<td>November 1991</td>
<td>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.</td>
</tr>
<tr>
<td>May 1992</td>
<td>NT Department of Health and Community Services advises DPSC that they have no objection to kava being removed from S4.</td>
</tr>
<tr>
<td>Date</td>
<td>Event Description</td>
</tr>
<tr>
<td>------------</td>
<td>-----------------------------------------------------------------------------------</td>
</tr>
<tr>
<td>August 1992</td>
<td>DPSC (66) kava deleted from S4</td>
</tr>
<tr>
<td>November 1992</td>
<td>NFA calls for public submission with regard to the proposed Standard for Prohibited Botanicals. (1&lt;sup&gt;st&lt;/sup&gt; round)</td>
</tr>
<tr>
<td>June 1993</td>
<td>NFA calls for public submissions with regard to the proposed Standard for Prohibited Botanicals. (2&lt;sup&gt;nd&lt;/sup&gt; round)</td>
</tr>
<tr>
<td>July 1993</td>
<td>Removal of kava from S4 effective from 14 July</td>
</tr>
<tr>
<td>August 1993</td>
<td>NFA recommends draft Standard for Prohibited Botanicals to NFSC (National Foods Standards Council).</td>
</tr>
<tr>
<td>November 1993</td>
<td>National Coordinating Committee on Therapeutic Goods (NCCTG) recommended that kava not be considered a therapeutic good.</td>
</tr>
<tr>
<td>January 1994</td>
<td>TGA inform NFA that kava will be de-listed as a therapeutic good.</td>
</tr>
<tr>
<td>March 1994</td>
<td>Kava gazetted as a Prohibited Botanicals on March 9.</td>
</tr>
<tr>
<td>February 1995</td>
<td>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.</td>
</tr>
</tbody>
</table>
| April 1995  | - NFA Board reject request from NT Health for fast-tracking under sections 36 or 37 of National Food Authority Act 1991.  
- 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 | - 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 Customs (Prohibited Imports) Regulations & 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    | Kava Management Act 1998 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 *Australia New Zealand Food Standards Code*

<table>
<thead>
<tr>
<th>Date</th>
<th>Development Event</th>
</tr>
</thead>
</table>
| October 1999 | - 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). |

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
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</thead>
</table>

## Emerging cases of liver toxicity associated with use of complementary medicines

<table>
<thead>
<tr>
<th>Date</th>
<th>Event</th>
</tr>
</thead>
</table>
| Feb 2001   | - Swiss withdraw marketing authorisation of Laitan, the acetonic 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   | - UK FSA/UK MCA issue warning to consumers; consider voluntary withdrawal of complementary medicines;  
  - 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 | - 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 |
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.

In New Zealand this Standard regulates the labelling of sale of kava, and prohibits the addition of kava to foods other than those that comply with New Zealand *Dietary Supplements Regulations (1985)*. The National Code of Kava Management is not in operation in New Zealand.

Table of Provisions

1 Interpretation
2 Prohibition
3 Labelling

1 Interpretation

In this Standard -

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

2 Prohibition

Kava must not be used as an ingredient in foods other than those products regulated under the *Dietary Supplements Regulations (1985)* in New Zealand as in force on 1 January 2000.

3 Labelling

(1) There shall be written in the label on or attached to a package containing kava, the following statements-

(a) ‘Use in moderation’; and
(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, 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.

**Editorial note:**
This Standard will be reviewed prior to the *Australia New Zealand Food Standards Code* becoming the sole *Food Standards Code* in Australia and New Zealand.
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;

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

‘sponsor’ 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 Health Ministers)
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:

   - ‘USE IN MODERATION’
   - ‘MAY CAUSE DROWSINESS’; and
   - ‘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.