



**Australian Government**

**Department of Health**  
Office of Drug Control

# Pilot program to allow the commercial importation of kava

Regulation Impact Statement

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## Executive Summary

### **Australian and Pacific Island Relations – one of Australia’s highest foreign policy priorities**

Since the launch of Australia’s 2017 Foreign Policy White Paper, the Australian Government has made a commitment to a step-change in the way it engages in the Pacific region.

The Pacific Step-up is a key foreign policy priority for the Australian Government. It recognises that more ambitious engagement by Australia, including helping to integrate Pacific countries into the Australian and New Zealand economies and our security institutions, is essential to the long-term stability and economic prospects of the region of which Australia is a member. It is supported by \$1.44 billion in development assistance to the Pacific in 2020-21, demonstrating the strength of Australia’s support to the sovereignty, stability, security and prosperity of our region.

Kava (also known as kava kava or Piper methysticum) is a member of the pepper family and contains six major kavalactones which are responsible for the plants’ pharmacological activity. Kava is an important symbol in the traditional and ceremonial lives of Pacific Islanders. It is traditionally prepared from the peeled rhizome/root of the noble kava variety which is usually ground or chewed up and mixed with water or coconut milk to form a traditional beverage. Kava is widely consumed and exported, particularly from Fiji and Vanuatu, to other countries, including the United States and New Zealand. As such kava could provide a new avenue for Australia’s commitment to strengthen cultural and economic diplomacy in the Pacific region.

The significance of the opportunity kava presents to strengthen Australia’s diplomatic relations in the Pacific itself is a function of two things. First, the domestic production industries in Pacific countries, particularly in Fiji and Vanuatu where production is sizeable. The Australian Government already advocates a number of initiatives that support the production of kava for commercial purposes, including the Market Development Facility and Pacific Horticulture and Market Access (PHAMA)<sup>1</sup> Program.

In Vanuatu, it is estimated that 30,000 households are involved in the cultivation of kava with 3,000 individuals earning an income from kava trade and retail<sup>2</sup> with annual exports of 77.7-116 million (AUD)<sup>3</sup>. In Fiji over 21,000 farms<sup>4</sup> grow kava worth an estimated 42 million (AUD) per year, with exports in 2016 valued at 12.7-23 million (AUD)<sup>5</sup>.

The market for kava is seen as a growth opportunity when considering the increasing numbers of people with Pacific Islander heritage residing in Australia. This is the second matter reflecting the opportunity kava presents for enhancing Australia’s relations in the Pacific region – that is, the significance of the Pacific diaspora residents for whom the use of kava is a symbol of ceremonial celebration. It not only strengthens our economic ties with our Pacific Island neighbours, it also deepens those ties. The 2016 national census data showed that, between 2006-2016, there was an 84% increase of persons in Australia with Pacific Island heritage to 206,673 persons<sup>6</sup> and when including the expansion of the Pacific Island workers program<sup>7</sup>, it is hoped that the opportunity for

<sup>1</sup> [www.dfat.gov.au](http://www.dfat.gov.au)

<sup>2</sup> <https://phamaplus.com.au/where-we-work/commodities/kava/>

<sup>3</sup> Department of Foreign Affairs

<sup>4</sup> [https://phamaplus.com.au/wp-content/uploads/2016/03/Kava\\_FS\\_Fiji9.pdf](https://phamaplus.com.au/wp-content/uploads/2016/03/Kava_FS_Fiji9.pdf)

<sup>5</sup> Department of Foreign Affairs

<sup>6</sup> [http://bellschool.anu.edu.au/sites/default/files/publications/attachments/2017-09/ib\\_2017\\_23\\_batley\\_revised\\_final\\_0.pdf](http://bellschool.anu.edu.au/sites/default/files/publications/attachments/2017-09/ib_2017_23_batley_revised_final_0.pdf)

<sup>7</sup> <https://www.pm.gov.au/media/pacific-islands-forum-1>

these Pacific Islander residents to celebrate significant occasions using a symbolic connection with their countries of origin will thereby identify and connect them more strongly with their new home.

These parameters mean that promoting the import of kava as a food (in addition to its already regulated status for scientific and medical use) would demonstrably serve to entwine Australia in the economies and cultural lives of the Pacific. The expectation is of a strengthening in relations with our closest neighbours.

Accordingly, during his visit to Vanuatu in January 2019, the Prime Minister announced that Australia would develop a kava pilot program, as part of the Pacific Step-up, to ease the 2007 imposed import restrictions on kava. Specifically, the Prime Minister announced:

- a doubling of the amount of kava that can be imported for personal use from 2 kg to 4 kg by the end of 2019
- the commencement of a commercial model for kava imports by the end of 2020 (this was subsequently deferred to 2021 due to the impact of COVID-19), and
- an evaluation of the pilot at the end of 2022 (deferred to 2023 due to the impact of COVID).

However, capitalising on the opportunity is not without risk – evidence from Australia’s previous kava use prior to 2007 is that it caused serious detrimental impact on public health and social cohesion of indigenous communities in Northern Australia. At the time it was estimated 70-80% of males in kava-using communities were kava drinkers<sup>8</sup>.

While mildly intoxicating when used traditionally, kava consumed in large quantities can lead to social and health issues, such as poor general health, low body weight, lethargy and dermopathy (a skin condition characterised by red, swollen skin, usually on the shins and tops of the feet).

Negative social effects were observed in Arnhem Land communities in Australia from high kava use that included decline in participation in cultural and sporting activities, neglect of supervision of children and poor hygiene.

Reflecting on this history there is also a risk that the use of kava as a food in Australia will spread to the broader community with the potential to cause occupational health issues, such as impacts on driving and using large machinery, the effect on mixing with alcohol and the use of kava by minors.

The objectives of the Government action take these competing considerations into account.

### **The objectives of the Government action**

The objectives of the Government’s ‘kava’ action are to:

- with other measures included in the Pacific Step-up:
  - strengthen economic development and cultural ties with the Pacific, significantly contributing to the new chapter in relations with our Pacific family
  - increase access to kava for ceremonial and traditional use in Australia and
- (simultaneously) protect public health and safety through measures to ameliorate the risk of an adverse outcome and by the collection of data on the size of the kava market in Australia. The data would be used with the proposed monitoring programme of the effect on the health of the community, especially indigenous communities, noting

history's lesson of serious adverse impacts on the health of indigenous communities in Northern Australia.

### Choosing the appropriate response

Having regard to these objectives there are three potential options explored in this Regulation Impact Statement as set out in Table 1 below.

**Table 1: Key options explored in this Regulation Impact Statement**

Option numbers and element explored

Option	Element
1	Maintain the status quo where kava continues to be allowed for importation for medical and scientific purposes; it may not be imported as a food (no change)
2	As a time-limited (two-years) pilot program, remove kava altogether from the <i>Customs (Prohibited Imports) Regulations 1956</i> (the PI Regulations) with only domestic (state and territory) controls regulating kava as a food. The <i>Imported Food Control Act 1992</i> (the IFC Act) and the <i>Biosecurity Act 2015</i> (the Biosecurity Act) would continue to apply.
3	As a time-limited (two-years) pilot program, amend the PI Regulations to allow for import permission, for which applicant eligibility may be specified and to which conditions may be attached, to be granted for the commercial import of kava as a food (additional to the current permission for medical and scientific purposes); domestic (state and territory) controls on regulation of kava as a food would continue to apply. This option is option 2 augmented by the proposed controls under the PI Regulations.

The appropriate regulatory response to deliver on the Government's objectives reflects the tension created by simultaneously delivering on the increased opportunities for engagement in the Pacific region and managing any increased public health risk it presents.

### Recommended Option

Option 1, the status quo, does not deliver on the Pacific Step-up goals of the Government; it does not allow for the use kava to increase export opportunities for our Pacific neighbours nor does it include a measure to increase the sense of connection to Australia for the Pacific diaspora including seasonal workers. Option 1 does, however, continue to allow for kava to be imported for medical and scientific purposes and provides for 4 kg of kava to be brought into Australia by travellers for personal use. It meets concerns, informed by Australia's pre-2007 stance, that the increased import of kava could have detrimental public health consequences on vulnerable communities.

Option 2 contributes to the Government's goals in the Pacific as well as providing for the lowest regulatory burden on importers. Like other imported foods, kava would be required to comply with biosecurity requirements under the Biosecurity Act and be available for sale and supply in accordance with the Australia New Zealand Food Standard Code as provided for by the IFC Act. However, this Commonwealth legislation does not provide a tool by which the Commonwealth may manage the public health risk to the community, for example, by restrictions on eligibility to apply for a permit or by the imposition of conditions on a permit. There are also no means of monitoring commercial importation of kava in Australia, a critical informant of a robust evaluation of the pilot program to be carried out by the National Drug and Alcohol Research Centre (NDARC)

and Ninti One Limited. Persons importing kava under Option 2 are not limited to commercial importers only and the Government would not be able to rapidly respond, with a swift change to the lever (the import permission), should an adverse event occur.

Option 3 delivers on all the Government's objectives. In supplementing option 2 with the additional regulatory tool of the PI Regulations, option 3 not only creates a new supply pathway but also facilitates the management of risk to public health (additional to the biosecurity requirements). The PI Regulations would facilitate the imposition of restrictions on applicants' eligibility and the imposition of conditions including obligations to report (including on quantities) as well as, should an adverse event occur, an immediate response by way of suspension of permissions. The opportunity to import is, by giving weight to the need to manage the public health risk, appropriately balanced with the reasonably low regulatory burden of the requirement to apply for import permission for each consignment. A comprehensive evaluation, informed by the commercial importation data, of the pilot program will inform recommendations to the Government regarding the longer-term regulatory settings for kava use in Australia.

On balance, providing for a new supply pathway for kava as a food combined with the ability to restrict eligibility, condition permits and suspend them along with being able to track quantities of kava imported into Australia as a food makes Option 3 the preferred option. This option takes account of the regulatory burden of applying for import permission for each kava consignment. This is appropriate in the context of a pilot program and facilitates the collection of information on the use of kava to inform any future regulatory settings which could include additional controls or a reduction in controls. A comprehensive evaluation of the pilot program will, under this option, include more information, both from reports from permit holders and analysis by the Department, to form the basis of recommendations to the Government regarding the longer-term regulatory settings for kava use in Australia.



## 1. Background

### What is kava?

Kava (also known as kava kava or *Piper methysticum*) is a member of the pepper family and contains six major kavalactones which are responsible for the plants' pharmacological activity.

Traditionally kava is prepared from the noble variety, however another variety of kava known as two-day (tudei) is higher in kavalactones than noble kava and has a stronger psychotropic effect as well as the presence of higher levels of flavokavins which can produce a toxic effect<sup>9</sup>.

Kava is an important part of traditional and ceremonial use by Pacific Island countries. It is traditionally prepared by Pacific Islanders from the peeled rhizome/root of the noble kava variety which is usually ground or chewed up and mixed with water or coconut milk to form a traditional beverage. Kava is widely consumed in Fiji and Vanuatu and exported to other countries, including the United States and New Zealand.

In Vanuatu, it is estimated that 30,000 households are involved in the cultivation of kava with 3,000 individuals earning an income from kava trade and retail<sup>10</sup> with annual exports of 77.7-116 million (AUD)<sup>11</sup>. In Fiji over 21,000 farms<sup>12</sup> grow kava worth an estimated 42 million (AUD) per year, with exports in 2016 valued at 12.7-23 million (AUD)<sup>13</sup>. Kava is exported to other Pacific Island countries and to New Zealand, New Caledonia and the United States. The trade primarily relates to the use of kava as beverage, although there is trade for kava in pharmaceutical products, such as to Australia.

### Effects caused by kava consumption

The effects of kava are described as feelings of sociability, reduction in stress and anxiety and a positive mood. As kava intoxication increases, consumers can develop numb mouth, sedation, sense of muscle weakness and fatigue<sup>14</sup>.

There is limited documented evidence on harms caused by traditional consumption of kava. The World Health Organization (WHO) and the Food and Agricultural Organisation (FAO) concluded that the overall potential of harm from kava is low. Harmful effects from kava appear to be focused on heavy drinking and chronic use<sup>15</sup>.

Studies in New Zealand indicate that kava intoxication could slow thinking and decision making which could affect how safely people drive<sup>16</sup>.

Interaction of kava with other drugs, such as central nervous system depressants (e.g. alcohol and benzodiazepines) may also be of concern.

A safety assessment conducted by Food Standards Australia New Zealand (FSANZ) in 2004 indicated there is sufficient evidence to suggest that excessive consumption of kava extracts (prepared using organic solvent extraction, primarily ethanol or acetone) pose a significant risk to

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<sup>9</sup> [https://phamaplus.com.au/wp-content/uploads/2016/05/Kava\\_FS\\_Overview9.pdf](https://phamaplus.com.au/wp-content/uploads/2016/05/Kava_FS_Overview9.pdf)

<sup>10</sup> <https://phamaplus.com.au/where-we-work/commodities/kava/>

<sup>11</sup> Department of Foreign Affairs

<sup>12</sup> [https://phamaplus.com.au/wp-content/uploads/2016/03/Kava\\_FS\\_Fiji9.pdf](https://phamaplus.com.au/wp-content/uploads/2016/03/Kava_FS_Fiji9.pdf)

<sup>13</sup> Department of Foreign Affairs

<sup>14</sup> <https://healthbulletin.org.au/wp-content/uploads/2019/04/kava-bulletin-web.pdf>

<sup>15</sup> Food and Agricultural Organization of the United Nations, Kava: A Review of the Safety of Traditional and Recreational Beverage Consumption, 2016, FAO/WHO

<sup>16</sup> Kava and Driving – Its About Respect – Apo S. Aporosa, Health Research Council of New Zealand

public health when compared to kavalactones developed through traditional water-based methods.

Kava drink consumption initially causes a positive relaxed mood and reduces stress and anxiety while retaining clear thinking. Increasing levels of intoxication can lead to a skin irritation, numb mouth, sedation, muscle weakness, loss of control and coordination, and fatigue. At high doses kava can lead to increased levels of harm such as liver toxicity.

Adverse social and economic effects could occur in communities with excessive kava consumption. In Australia, leaders within some Indigenous Australian communities have expressed public concern about the negative health and social impacts associated with kava use in some communities in the Northern Territory.

### Impacts of kava use on Arnhem Land Communities

Between 1989 and 2002 some kava consumption exceeded 400g per week per person and consumption was in excess of the level at which harms are thought to occur<sup>17</sup> by 70-80% of males. Excessive kava consumption lead to reports of poor general health, low body weight, lethargy and dermatopathy.

Due to the high prevalence of kava consumption at the time, negative social effects were observed. They include decline in participation in cultural and sporting activities, neglect of supervision of children and poor hygiene<sup>18</sup>.

### Kava Regulation in Australia<sup>19,20</sup>

Kava has had a turbulent regulatory history in Australia. Kava itself first emerged in several areas of Arnhem Land in 1982 following a visit by a group of people from the Yirrkala to Fiji to examine community management, where they were introduced to kava<sup>21</sup>. Consumption quickly became common in Arnhem land by 1984, where its use was encouraged as an alternative to alcohol.

In 1988, Western Australia (WA) became concerned about the introduction of kava into the Kimberly and banned sale and supply under its poisons legislation.

Kava was scheduled as a prescription only medicine in 1990 by the Drugs and Poisons Schedule Committee (DPSC), at the request of the Northern Territory Government due to the rising community and government concerns of the effects and misuse of kava, despite special state-run programs to curb use. The Northern Territory invoked its consumer protection legislation to prohibit the sale of kava and kava was restricted to 50 grams per person per day, available to persons 18 years or older and sold by the local council under licence.

The DPSC recommended the deletion of the Schedule 4 entry for kava from the Poisons Standard in August 1992. This followed reports from the Northern Territory that other controls were now in

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<sup>17</sup> <https://healthbulletin.org.au/wp-content/uploads/2019/04/kava-bulletin-web.pdf>

<sup>18</sup> Butt, J. (2013). *Kava usage in Aboriginal and Pacific Islander communities in Australia*. Perth: National Drug Research Institute.

<sup>19</sup> Butt, J. (2019). Review of kava use among Aboriginal and Torres Strait Islander people. *Australian Indigenous HealthBulletin*, 19(2)

<sup>20</sup> Butt, J. (2013). *Kava usage in Aboriginal and Pacific Islander communities in Australia*. Perth: National Drug Research Institute.

<sup>21</sup> <https://healthbulletin.org.au/articles/review-of-the-misuse-of-kava-among-indigenous-people/>

place for the substance, and that the other states did not deem it necessary to schedule kava. Kava was removed from Schedule 4 in the December 1993 version of the Poisons Standard.

In 1993, the Therapeutic Goods Administration (TGA) declared kava not to be a therapeutic good; the effect of which was for the regulation of kava to be left solely in the hands of states and territories.

The Food Standards Council gazetted kava as a prohibited plant in 1994, which stopped importation of kava. The Northern Territory Government revoked all kava licences in line with the Commonwealth prohibition on importation.

The Commonwealth developed the National Code of Kava Management, which was endorsed by Federal and State Territory Ministers, in 1997. The Code promoted the responsible sale and distribution of kava. The PI Regulations and food regulations were amended to facilitate the Code allowance for the responsible sale of kava and for travellers into Australia to bring up to 2 kg of kava.

Sales of kava recommenced in licensed areas of the Northern Territory in 2002.

The National Drugs and Poisons Scheduling Committee (NDPSC) recommended kava be placed back into Schedule 4 in February 2004, in response to concerns of liver toxicity associated with kava-containing medicines, the need to regulate extracts of kava supplied for extemporaneous compounding, and a TGA-initiated voluntary recall of medicines containing kava. Following an independent evaluation of the safety of kava products, a number of controls were suggested including a recommendation that the substance be scheduled. The new Schedule 4 entry was confirmed in October 2004 and amended in October 2005 to remove ambiguity and include reference to the *Required Advisory Statements for Medicine Labels* for the existing exemptions.

In 2007, the Australian Government, as part of the Northern Territory Emergency Response enforced border controls on kava, effectively banning non-medical supply in Australia and importation of kava as a food became unlawful. This was in response to concerns that the free importation of kava as a food allowed for its abuse and contribution to negative health and social outcomes in some Indigenous communities

Concerns regarding the diversion of raw forms of kava for illegitimate use/abuse prompted the NDPSC, in October 2007, to amend the Schedule 4, entry to exempt only specified products listed on the ARTG, with supply of any other forms occurring only via registered medical practitioners. This was further amended in February 2008 to remove the exemption for whole or peeled rhizome, for similar reasons to the October 2007 amendment.

Kava, remained in the *Food Standard 2.6.3 – Kava*<sup>22</sup>, but with import prohibitions, other than the 2 kg traveller allowance, its availability as a food in Australia was limited.

In 2016, the Poisons Standard was amended to allow for kava to be used in listed medicines, in addition to being a prescription only medicine. The WA Government removed the kava prohibition in 2017 to allow access to medical kava<sup>23</sup>.

Currently, as a practical matter, kava is available as a pharmacy only medicine (there is no kava product regulated as a prescription only medicine under the Poisons Standard) and recreationally from the small quantities brought into Australia by travellers. Kava access remains limited to 2 kg in

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<sup>22</sup> <https://www.legislation.gov.au/Details/F2021C00673>

<sup>23</sup> <https://www.tga.gov.au/book-page/45-piper-methysticum-kava>

the Northern Territory with a prohibition on sales without a licence under the Northern Territory *Kava Management Act 1998*<sup>24</sup>.

### History of Australian Kava Imports

Kava is imported in accordance with regulation 5 of the PI Regulations, that is, for medical and scientific use only. There is presently no means by which kava may be imported commercially for supply as a food. Australia's decision in 2007 to impose this restriction on the importation of kava has been, since that time, an ongoing concern for Pacific Island countries.

Import data on kava is available for the years prior to the commercial import prohibition:

#### **Kava imported into Australia between the years 2000 and 2007**

Kava imports per year measured by weight in tonnes and by value in Australian dollars.

Year	Tonnes	AUD
2000	47.4	535,000
2001	68.2	666,000
2002	80.1	795,000
2003	67.3	585,000
2004	58.7	682,000
2005	81.3	979,000
2006	73.2	1,159,000
2007	18.3	436,000

After 2007, kava for food use was imported via travellers and no data is collected on the quantities of kava entering Australia by this method.

### Kava as a food and medicine in Australia

Australian state and territory governments currently regulate and licence the distribution and sale of kava for medical or scientific use based on entries in the schedules in the Poisons Standard<sup>25</sup>. Kava is also regulated as a food under the Australian New Zealand Food Standards Code<sup>26</sup> (the Food Standard).

<sup>24</sup> <https://legislation.nt.gov.au/en/Legislation/KAVA-MANAGEMENT-ACT-1998>

<sup>25</sup> <https://www.legislation.gov.au/Details/F2021L00650>

<sup>26</sup> <https://www.legislation.gov.au/Details/F2021C00673>

There are similarities between medicines and food<sup>27</sup>: both can be consumed orally; they can support your health; and they may also contain the same ingredients. Kava is a therapeutic good if the product makes health claims which might bring it under the *Therapeutic Goods Act 1989*<sup>28</sup>.

Only those kava products which meet the Food Standard may be supplied in Australia for food purposes, which includes for traditional and cultural use. Despite there being no kava imported into Australia for food use, the Food Standard for kava remains in effect, which allows kava which meets the standard to be sold and supplied domestically.

In addition to the Food Standard, the Northern Territory *Kava Management Act 1998* remains in force and the sale and supply of kava may only occur under licence. Licences may be issued for retail or wholesale.

Prior to 2020, exemptions were required in the Australian Capital Territory (ACT) to consume kava for traditional purposes and public events. WA permitted access to kava in 2017 following the scheduling changes to the Poisons Standard in 2016 (to which reference was made earlier).

### Australian regulation of kava

Kava which is imported for medical and scientific use, or as a foodstuff, is subject to the following standards and controls:

<p><b>National Standards</b></p> <p>The Food Standard and the Poisons Standard, which apply to kava, are made under Commonwealth Legislation. States and territories then adopt these standards into their respective legislation.</p>
<ul style="list-style-type: none"> <li>• <b>Food Standard</b></li> </ul> <p>Kava is regulated under the Food Standard 2.6.3 which provides that kava and substances derived from kava may only be supplied where it is:</p> <ol style="list-style-type: none"> <li>a. a beverage obtained by the aqueous suspension of kava root using cold water only, and not using any organic solvent, or</li> <li>b. dried or raw kava root.</li> </ol> <p>It should be noted that kava, even in the above forms, cannot be supplied where incorporated into other products.</p> <p>The Food Standard also requires that the following warning statements accompany kava when supplied:</p> <ol style="list-style-type: none"> <li>a. 'Use in moderation', and</li> <li>b. 'May cause drowsiness'</li> </ol>
<ul style="list-style-type: none"> <li>• <b>Poisons Standard</b></li> </ul> <p>The Poisons Standard is a legislative instrument for the purposes of the <i>Legislation Act 2003</i>. The Poisons Standard consists of decisions regarding the classification of</p>

<sup>27</sup> <https://www.tga.gov.au/blogs/tga-topics/let-medicine-be-thy-medicine-and-food-thy-food>

<sup>28</sup> <https://www.tga.gov.au/what-are-therapeutic-goods>

medicines and poisons into Schedules for inclusion in the relevant legislation of the States and Territories. The Poisons Standard also includes model provisions about containers and labels, a list of products recommended to be exempt from these provisions, and recommendations about other controls on drugs and poisons.

The Poisons Standard has been presented with a view to promoting uniform scheduling of substances and uniform labelling and packaging requirements throughout Australia. For kava the Poisons Standard specifies:

**Schedule 4:**

PIPER METHYSTICUM (kava) in preparations for human use except when included on the Australian Register of Therapeutic Goods in preparations:

a) for oral use when present in tablet, capsule or teabag form that is labelled with a recommended maximum daily dose of 250 mg or less of kavalactones and:

i) the tablet or capsule form contains 125 mg or less of kavalactones per tablet or capsule, or

ii) the amount of dried whole or peeled rhizome and/or root in the teabag does not exceed 3 g

and, where containing more than 25 mg of kavalactones per dose, compliant with the requirements of the Required Advisory Statements for Medicine Labels

b) in topical preparations for use on the rectum, vagina or throat containing dried whole or peeled rhizome and/or root or containing aqueous dispersions or aqueous extracts of whole or peeled rhizome and/or root, or

c) in dermal preparations.

There are sixteen medicines containing kava listed on the Australian Register of Therapeutic Goods (ARTG).

**Commonwealth Legislation**

The Commonwealth legislation, which applies to kava, are enforced at the border before entering the domestic supply chain. The legislation covers biosecurity, food quality and border controls on controlled substances.

- ***Biosecurity Act 2015***

Imports of kava (*Piper methysticum*) plants and plant products are regulated by the Department of Agriculture, Water and the Environment (DAWE) under the *Biosecurity Act 2015* (the Biosecurity Act). The Biosecurity Act aims to manage biosecurity risk. Biosecurity risk refers to the likelihood of a pest or disease entering or establishing itself in Australia, which has the potential to cause harm to human, animal or plant health, the environment or the economy.

Section 174 of the Biosecurity Act provides that the Director of Biosecurity and the Director of Human Biosecurity may jointly determine that certain goods or classes of goods that are brought into Australian territory or imported, are prohibited absolutely (prohibited goods) or are prohibited unless certain conditions are satisfied (conditionally non-prohibited goods).

Division 1 of the *Biosecurity (Conditionally Non-prohibited Goods) Determination 2021* (the Goods Determination) specifies that live plants (including roots and tubers) and plant products (including goods containing or made of plants) are conditionally non-prohibited goods. Section 12 of the Goods Determination provides that goods included in a class of goods covered by the determination must not be brought or imported into Australian territory unless the goods are covered by an import permit; or if alternative conditions for bringing or importing the goods into Australian territory are specified in the determination – the alternative conditions are complied with.

For the purposes of the Goods Determination, kava powder and kava beverages are considered to be processed plant products. There are alternative conditions listed in the Goods Determination for processed plant products (see section 23 (2) item 1 of table). This means that kava powder and kava beverages may be brought or imported into Australia without an import permit provided that the alternative conditions have been complied with. The alternative conditions require the kava to be processed so that it is not viable and there is no risk of contamination or infection from a disease or plant pathogen. Other forms of kava (such as live plants, dried or fresh whole roots) currently do not have alternative conditions listed in the Goods Determination. This means that this material can only be brought or imported into Australian territory under an import permit.

Section 177 of the Biosecurity Act provides that a person may apply for an import permit to import conditionally non-prohibited goods such live plants, dried or fresh whole roots. In assessing an import permit application for this material, a biosecurity risk assessment is required to determine the level of the biosecurity risk posed by the goods and what conditions or measures may be required to reduce these risks to an acceptable level.

- ***Imported Food Control Act 1992***

The *Imported Food Control Act 1992* (the IFC Act) provides for an at-border risk-based border inspection system – the Imported Food Inspection Scheme (IFIS) – to verify imported food is safe and complies with Australia’s food standards, including the Food Standard.

Kava is currently a prohibited good under Schedule 4 of the PI Regulations. The IFC Act does not apply to food the importation of which is prohibited under the *Customs Act 1901*. Should the PI Regulations be amended to permit commercial importation of kava, kava for human consumption will be automatically classified as a surveillance food under the IFC. Consignments of surveillance food are randomly referred to the Scheme at the rate of 5%.

To inform a review of the risk management of commercial imports of kava, the Department has requested risk advice from Food Standards Australia New Zealand to determine if kava presents a potential medium or high risk to public health. If the advice identifies a medium or high risk, the Department will amend the

<p>Imported Food Control Order 2019 to classify kava as a risk food. Risk food is referred to the Scheme at a rate based on the food's history of compliance, starting at 100% of consignments. As kava does not have a unique tariff classification, to target the food under the Scheme a Community Protection Question can be placed on relevant tariff classifications to require importers to declare whether the food is kava.</p>
<ul style="list-style-type: none"> <li> <p><b>Customs (Prohibited Imports) Regulations 1956</b></p> <p>Kava is currently classified as a drug under the PI Regulations and requires permission to be imported commercially into Australia for medical (e.g. listed medicines) or scientific purposes. Importers must meet a fit and proper test to obtain a licence to import and demonstrate they have the appropriate state/territory licence to use or supply kava. The Australian Border Force enforces the laws relating to the importation of kava under the PI Regulations.</p> </li> </ul>
<ul style="list-style-type: none"> <li> <p><b>Trans-Tasman Mutual Recognition Arrangement</b></p> <p>In relation to food imported from New Zealand, the Trans-Tasman Mutual Recognition Arrangement is a non-treaty arrangement between New Zealand and Australian Commonwealth, state and territory governments, which allows for goods (excluding therapeutic goods) legally sold in New Zealand to be sold in Australia. This means that foods that are compliant with the regulation in NZ can legally enter Australia.</p> </li> </ul>

## 2. What is the policy problem?

Australia is supporting Pacific Islands' integration into the Australian and New Zealand economies through the Pacific Step-up<sup>29</sup> which is essential to the long-term stability and economic prospects of the Pacific. Australia has contributed \$1.44 billion in developmental assistance to the Pacific in 2020-21 to support the sovereignty, stability, security and prosperity of the region.

Kava is an important part of the Pacific Island culture and tradition.

However, while there is a recognition of the economic and cultural importance of kava, the ban on the commercial import of kava in 2007 has affected Australia's bilateral relationships with Pacific Island countries.

Fiji and Vanuatu are the two main kava growing countries and derive significant economic benefit from its production as highlighted earlier. Exports are largely to other Pacific Island countries, as well as to New Caledonia, New Zealand, and the United States (where there are large Pacific Island communities). While these exports are primarily for consumption of kava as a beverage, kava is also used in some pharmaceuticals, given its relaxing effects.

The 2016 national census data showed that, between 2006-2016, there was an 84% increase of persons in Australia with Pacific Island heritage to 206,673 persons<sup>30</sup> and when including the expansion of the Pacific Island workers program<sup>31</sup>, any lifting of the restrictions on the commercial importation of kava presents a significant commercial opportunity for importers and for the

<sup>29</sup> <https://www.dfat.gov.au/geo/pacific>

<sup>30</sup> [http://bellschool.anu.edu.au/sites/default/files/publications/attachments/2017-09/ib\\_2017\\_23\\_batley\\_revised\\_final\\_0.pdf](http://bellschool.anu.edu.au/sites/default/files/publications/attachments/2017-09/ib_2017_23_batley_revised_final_0.pdf)

<sup>31</sup> <https://www.pm.gov.au/media/pacific-islands-forum-1>



exporting nations. It is also hoped that the opportunity for Pacific Islander residents in Australia to celebrate significant occasions using a symbolic connection with their countries of origin will assist them to identify and connect more strongly with their new home.

The impact of COVID-19 has also resulted in kava becoming increasingly scarce in Australia throughout 2020 and 2021 due to travel and border restrictions. The shortage of kava supply in Australia from the import ban and border closures has driven up the cost of kava significantly. While the price for a kilogram of kava had previously been \$50, prices of up to \$500 a kilogram have more recently been reported<sup>32</sup>.

The shortage of kava supply has had an impact on the Pacific Island diaspora's cultural engagement including on important ceremonies like births, funerals and weddings at which kava is an important traditional component. The lack of supply of kava may also create an incentive to use of more harmful substances such as alcohol. Major Australian industry stakeholders engaged in Australia's Pacific labour mobility initiatives have nominated kava access as a concern as their anecdotal reports indicate a rise in alcohol abuse by Pacific workers, a substance with which they are generally not familiar, in the absence of access to kava.

Australia stands to generate significant goodwill through recommencing the commercial import of kava as a food. This action would alleviate an irritant in our relationship with Pacific neighbours, while helping support economies particularly impacted by the COVID-19 pandemic on restriction of tourism, and better connecting Australia with the culture of the Pacific. The expectation is of a strengthening in economic and cultural relations, and an improvement in our overall engagement with the Pacific.

Accordingly, during his visit to Vanuatu in January 2019, the Prime Minister announced that Australia would develop a kava pilot program, as part of the Pacific Step-up, to ease import restrictions on kava.

However, capitalising on this opportunity is not without risk – evidence from Australia's previous kava use prior to 2007 is that it caused serious detrimental impact on public health and social cohesion of indigenous communities in Northern Australia.

Reflecting on this history there is also a risk that the use of kava as a food in Australia will spread to the broader community, with the potential to cause occupational health issues, potential impacts on driving and using large machinery, the effect on mixing with alcohol and the use of kava by minors.

This Regulation Impact Statement considers options to better align Australia's regulatory settings to support the Pacific Step-up and the diaspora in Australia, in line with the Prime Minister's announcement in 2019 whilst appropriately managing any potential risk to public health, particularly in communities for which there is a history of negative impact.

### **3. Why Government action is needed?**

The Australian Government advocates a number of initiatives that support the production of kava for commercial purposes, including the Market Development Facility and Pacific Horticulture and Market Access (PHAMA)<sup>33</sup> Program.

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<sup>32</sup> [Australian Pacific Islanders struggle to find kava amid international border closures - ABC News](#)

<sup>33</sup> [www.dfat.gov.au](http://www.dfat.gov.au)

PHAMA provides practical and targeted assistance to help Pacific Island countries manage regulatory aspects associated with exploring primary and value added products to export markets around the world.

To further complement these initiatives, the Australian Government is working with its Pacific Island partners to provide additional export opportunities that will maximise the growth potential of the economies in the Pacific region, including easing import restrictions on kava through its Pacific Step-up program.

Estimating the value of Australia's market for kava exports is a task for which being precise is difficult because exports to Australia have been non-existent since 2007. There are, however, factors that point towards growth in the potential size of the Australian kava market since 2007. These include:

- increase in the size of Pacific communities in Australia
- increase in the number of seasonal workers from the Pacific, through Australia's labour mobility program—currently at the highest levels ever in Australia at any one time
- development of kava markets in New Zealand and USA, and
- industry development in kava producing countries, which has led to an increased ability to meet quality standards.

The increase in supply may place downward pressure on the purchase price of kava. The kava pilot will mean Pacific communities in Australia will have better access to kava through commercial imports, relieving any financial burden caused by prices inflated by the 2007 imposed and the additional COVID-19 restrictions.

Pacific workers residing in Australia under the Government's labour mobility schemes (the Seasonal Worker Programme and the Pacific Labour Scheme) will also benefit from having their traditional beverage available to them. All Australian industry stakeholders engaged in Australia's Pacific labour mobility initiatives have nominated existing restricted access to kava as a concern, noting anecdotally a rise in alcohol use by Pacific workers because access to kava is limited or non-existent. Industry stakeholders have raised welfare concerns in this respect and are keen to see better access to kava as a critical support measure for the Pacific workers they employ.

Nevertheless, noting that the 2007 ban for commercial kava imports was motivated to remove the harm from kava use the proposed greater access to kava requires that its use is effectively monitored. This would be so as to ascertain the impact of kava on the Australian community.

The monitoring of the pilot is integral to the action to inform how access to kava in Australia will be in the future and what, if any, impact or harms might occur during the pilot.

To realise these actions, Government action is required – regulations will need to be amended to provide for the commercial importation of kava as a food. States and territories, which are responsible for food regulation, must also matters such as community impacts from kava, the potential for burden on an already stressed health system and possible interventions and support needed for affected communities. The Commonwealth regulations, where possible, should assist the states and territories regulatory role regarding domestic supply and use of kava, such as by applying conditions on imports, such as reporting obligations, and sharing data on importers and quantities of kava imported.

#### 4. What policy options are being considered?

The policy options being considered, and the recommended regulatory response, are appropriately measured by reference to the Government's commitment to a two-year pilot (a pilot because of the public health risks demonstrated by the effect kava had on Arnhem Land communities prior to 2007). The recommended regulatory response needs to be able to deliver on this commitment. That is, the recommended option needs to generate relevant data on access and use so as to inform a report to Government. This report will inform further Government decisions, post the two-year pilot, on kava access and the regulatory stance which will support it. It is expected that the pilot will continue until such decisions are made, unless evidence supports discontinuation due to harms.

In summary, the recommended response must address the following criteria:

1. Contribute to the Pacific Step-up by opening a new market in Australia for kava.
2. Make available kava for traditional and cultural use of Pacific Island diaspora and seasonal workers.
3. Minimise the regulatory burden on importers.
4. Provide proportionate risk based regulatory tools to address any emerging adverse health impacts on vulnerable communities including Indigenous communities
5. Monitor the use of kava in Australia and the effect on the community.

Whatever that regulatory response, each (excluding the status quo) will necessarily include a monitoring arm.

#### Monitoring the Pilot

The FAO reviewed kava in 2016 and concluded that *there was little documented evidence of adverse health effects associated with moderate consumption*, and that while there was clear evidence of issues associated with heavy kava use that *on balance, the weight-of-evidence from both a long history of use of kava beverage and from the more recent research findings indicates that it is possible for kava beverage to be consumed with an acceptably low level of health risk*.

The FAO report also concluded that further studies are needed to define the parameters necessary to ensure safe use of kava beverage.

In order to gather data in the Australian context and whether the issues prior to 2007 will again occur, the Department has commissioned NDARC<sup>34</sup> at the University of New South Wales and Ninti One Limited<sup>35</sup>, an Indigenous owned organisation, to undertake the evaluation of the pilot.

The evaluation will assess the health, social, cultural and economic effects of the pilot on the Australian community, particularly Aboriginal and Torres Strait Islander and Pacific Islander communities. A mixed methods evaluation approach will be utilised, including a literature review examining kava use and its harms and economic implications; community surveys and focus groups; interviews with key stakeholders; analysis of routinely collected data; and health economic methods. Data on quantities of kava imported which can be obtained from import permissions, should they be selected as the preferred option, will provide context in the evaluation on community impact.

<sup>34</sup> <https://ndarc.med.unsw.edu.au/>

<sup>35</sup> <https://www.nintione.com.au/>

The evaluation is aimed at addressing the following eight evaluation questions using a mixed methods evaluation approach:

- Was the pilot implemented as expected?
- Were the expected outcomes achieved?
- What have been the health, cultural, social and economic outcomes on Pacific Islander communities, Aboriginal and Torres Strait Islander communities and the broader Australian population?
- Has the pilot increased commercial supply and distribution?
- Has the pilot increased supply and use in high-risk communities?
- Has the regulatory framework protected public health?
- What are the cost implications?
- Were there unintended consequences?

Consultation with key stakeholders will occur at all stages of the evaluation. For the initial planning phase, consultation has already begun with the Australian, state and territory governments and Indigenous stakeholders. This will inform the final design of the evaluation plan and instruments, development of data collection tools, scoping of Indigenous communities, and identification of stakeholders for surveys, focus groups and interviews.

The evaluation approach will be highly collaborative to ensure all stakeholders are confident that the relevant groups have been consulted with, and systematic to ensure clarity and replicability in the engagement process. Indigenous communities, Pacific Islander communities and stakeholders responsible for the development and implementation of the kava importation pilot will be consulted with via community surveys and focus groups. Other key informants including state/territory governments, regional councils, community representatives and commercial importers of kava will be consulted via semi-structured interviews.

NDARC and Ninti One will consult with the following groups to identify and ensure all relevant participants are engaged in the data collection phase: Australian Government representatives, state/territory government representatives, regional councils, community representatives and community-based professionals (e.g. police, health centres, local councils), commercial importers of kava, representatives of Pacific Island governments and PHAMA.

Data collection will commence on implementation of the pilot; data collection or engagement with Indigenous communities will not commence until ethics approval has been granted. Stakeholder feedback has indicated a need for the pilot to be regularly reviewed and reported on. This will be supported by NDARC and NINTI One providing formal progress reports to the Department on a six monthly basis, in addition to a final report due by the end of 2023. These reports will provide summaries of all data collected and analysed at the point of submission.

What effect kava will have on the Australian community during the pilot is unknown. Therefore the option chosen must be that which gives the pilot the greatest chance to succeed and ensuring the appropriate level regulatory tools are in place to manage the risk of adverse public health outcomes and to gather the information necessary for an informed decision, following the pilot, on the future of kava use in Australia.

Each of the three options under consideration follows.

## Option 1: Status quo

Access to kava for personal or cultural traditional use will continue to be limited to the personal traveller limit, which was increased from 2 kg to 4 kg in 2019<sup>36</sup>. Persons (18 years or older) may only bring kava into Australia as a food if in the accompanying baggage.

The limited supply prevents commercial availability of kava for food use in Australia and concentrates kava use to those persons who can travel regularly to obtain supplies. It is unlikely that the traveller limit provides sufficient kava to support broad diaspora traditional and ceremonial use or be sufficient for use by seasonal workers.

The status quo completely fails to address the goals of the Government to strengthen economic development and cultural ties with Pacific Island countries since there would be little or no increase in kava exports to Australia. Nor will Option 1 increase the sense of connection to Australia of the Pacific Island nations.

## Option 2: Remove kava from regulation under the Customs (Prohibited Imports) Regulations 1956

For a period of at least two years, kava will be imported in a manner consistent with other imported foods into Australia.

The PI Regulations do not presently allow kava to be imported into Australia for use as a food and they restrict import to medical and scientific use, so an amendment to the regulations would be required. The amendment would remove border controls for the importation of kava, which would also remove licence and permit to import requirements for kava used in medicinal and scientific purposes. This approach is similar to the control of kava in New Zealand.

Imported kava would be in the form specified in the Food Standard<sup>37</sup> and comply with the IFC Act and Biosecurity Act. Domestic sale and supply of foods, including kava, would continue to be regulated under state and territory legislation.

At any time during the pilot, the Government may decide to amend the PI Regulations to reinstate the ban on the commercial import of kava.

The use of kava will be monitored and the impact of kava being lawfully imported as a food in Australia evaluated. This option, however, will not generate data on imported quantities which would assist the evaluation. The evaluation would therefore be missing critical data which would otherwise usefully inform an evaluation carried out by Government to for the purpose of assessing and deciding on the future of kava use in Australia. It would, at the least, inform an assessment of whether importation of kava as a food would continue to be a viable proposition. A reporting obligation imposed on importers could also usefully inform on and respond to any emerging public health risk.

Additionally, Option 2 has the least regulatory burden on Australian business (and removes the current burden on importers of kava for medical and scientific use) and meets the part of the objectives to increase commercial access of kava into Australia. However, there is no tool by which the Commonwealth can manage public health risk by limiting applicant eligibility and imposing appropriate conditions including to oblige particular reporting as well as suspending or cancelling

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<sup>36</sup> <https://www.legislation.gov.au/Details/F2019L01616>

<sup>37</sup> <https://www.legislation.gov.au/Details/F2021C00673>

a permission to import. Unlike Option 3, importers would not be limited to commercial only, thereby opening up imports to the general public.

### **Option 3: Create a new import regulation**

Option 3 augments option 2 - for the two year pilot period with a requirement for commercial importers of kava as a food to apply for permission to import. No changes to the current import arrangements for medical or scientific purposes will be required. The existing biosecurity and food legislation would be maintained and state and territory regulation would continue to apply to domestic supply and sale.

The PI Regulations presently limit the use of kava imported into Australia to medical and scientific purposes only. Consequently, an amendment to the regulations would be required to allow kava to be imported as a food.

Persons who are able to demonstrate they intend to import kava for supply as a food for the purpose of conducting business would be eligible to apply for import permission under the PI Regulations. Imported kava would be in the form specified in the Food Standard<sup>38</sup> and comply with the IFC Act and Biosecurity Act. Domestic sale and supply of foods, including kava, would continue to be regulated under state and territory legislation. Supply of kava would only be permitted for commercial food purposes (e.g. personal imports would not be permitted) and import permissions may be conditioned, such as reporting obligations. Travellers may still bring up to the 4 kg into Australia.

The form of kava to be imported would be required to meet biosecurity requirements (currently dried and raw kava root require a separate permission under the Biosecurity Act) and the Food Standard.

Since the impact kava will have on the public is unclear the two-year pilot will be monitored and a report provided on the impact of kava as a food in Australia. It would include a recommendation to Government on the future of kava use in Australia. Should that decision be to reimpose the import ban, amendments would be made to the PI Regulations. Kava would continue to be available until a decision it made.

Option 3 delivers on all of the Government objectives. A new supply pathway and regulatory tool, under the PI Regulations, would allow for quantities of kava being imported to be tracked and should an adverse event occur, allow for permission to import to be suspended.

## **5. What are the net benefits of each option?**

### **Option 1 – Status quo**

Option 1 supports the Government's objective to limit the potential for harm of kava use on the Australian community. However, this option does not address the main objective to support economic development and recovery for Pacific Island countries. The sense of an irritant to Pacific Islands, in the form of the maintenance of the restriction on commercial import of kava for food, will persist. There will be a failure to seize an opportunity to increase the sense of connection to Australia with the Pacific diaspora and seasonal workers.

The benefit of Option 1 is that the protections put in place to limit quantities of kava in Australia via the 2007 import ban remain. Specifically, supplies of kava for food are limited to the 4 kg traveller exemption and may not enter the country via other means such as post. The limitation on

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<sup>38</sup> <https://www.legislation.gov.au/Details/F2021C00673>

supply reduces the likelihood of kava entering communities which could lead to kava abuse, with the related health effects, and social effects (decline in participation in cultural and sporting activities, neglect of supervision of children and poor hygiene).

### **Net benefit**

The status quo directly addresses the concerns of jurisdictions, raised during public consultation and subsequent meetings, of the harms which may occur based on experience prior to 2007 when kava was prohibited for import.

Option 1 has no change to the regulatory burden on existing kava importers or other entities, such as social and health providers, that may be affected by the increased use of services due to kava abuse.

### **Option 2 – Remove kava from the Customs (Prohibited Imports) Regulations 1956**

This option meets the Government's objective to increase the availability of kava in Australia, strengthening economic development and cultural ties with Pacific Island countries as well as increasing the sense of connection to Australia of the Pacific diaspora and seasonal workers.

Like the approach taken by New Zealand, kava would be recognised as a food and would meet biosecurity and food quality requirements under the Biosecurity Act and IFC Act. Unlike Option 3, which is limited to commercial importers, under Option 2 any person would be eligible to import kava.

Option 2 also removes the separate import requirement for the import of kava for medical and scientific use<sup>39</sup>, bringing it into alignment with many other ingredients imported for complementary medicines in Australia. A consequence of removing kava from the PI regulations is that the 4 kg of kava limit on travellers would also be removed allowing increased amounts of kava to be brought into Australia by travellers.

However Option 2 does not create an opportunity for Commonwealth regulatory consistency with existing state and territory controls for kava, such as through the restriction of applicant eligibility, the application of import conditions, such as reporting obligations, and data sharing. There would, without amendment to the PI Regulations, be no capacity for the Commonwealth to suspend imports in response to an adverse event (i.e. abuse of kava in indigenous communities, harms to minors, kava, mixing with alcohol or driving while intoxicated). Separate, likely urgent, amendments to the PI Regulations would be required.

Option 2 also does not provide data on quantities of kava imported which provides valuable context to the evaluation of the pilot.

In the absence of consistency of regulation at the border and domestically, there is also a risk that Australian jurisdictions may, unilaterally, in the face real or perceived crystallisation of public health risks, move to restrict supply of kava as a food thereby undermining any intended effect of Option 2, the increase in the domestic availability of kava as a food. The imposition of such restrictions would not only threaten the proposed strengthening of relationships with our Pacific neighbours, it would also potentially create the perverse outcome that kava may become a highly sought after commodity lending itself to lucrative illegal supply within Australia. In turn, this would require law enforcement intervention. Like other foods, appropriate risk based regulation of import and domestic supply of kava is required for the Government's objectives to succeed.

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<sup>39</sup> [www.odc.gov.au](http://www.odc.gov.au)

It is unclear as to the market opportunities that exist in Australia in the broader community. Overseas use of kava seems to be primarily by persons of Pacific Island heritage. The monitoring component of the pilot would provide much needed data on the demand for kava in the Australian community.

With the removal of kava from the PI Regulations, an average annual saving on the current imports of kava for medical purposes of \$900 is possible. This is based on currently seven importers of kava for medical use and an average time spent to apply for seven import permits per year.

The labour cost formula was used to determine these administrative compliance costs: price x quantity (or in its more expanded version: (time required x labour cost) x (times performed x number of businesses or community organisations x number of staff)).

The ABS publishes 'Average Weekly Earnings' semi-annually. As at May 2021, the latest dataset is November 2020. Given that applicants for licences and permits could be based in any state/territory, the national ('All Industries') dataset was used.

For November 2020, the figure for average weekly earnings is \$1,711.60. To determine the average hourly cost, this figure is divided by the average number of total hours worked (includes overtime) for full-time non-managerial employees (the 'All Industries' category has been used) (39.40 hours).

In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the non-wage labour on-costs and overhead costs. The arising calculation is shown below.

Average total weekly earnings (Average total weekly earnings (November 2020) for the All Industries sector (from ABS) / Average hours (total) worked (May 2018) for full-time non managerial employees (from ABS)) \* On-cost and overheads multiplier (from OBPR) = Average Hourly Cost ( $\$1,711.60/39.40$ )\*1.75 = \$76.02

There is no impact on individuals (as opposed to businesses) arising from the regulatory changes being quantified and therefore the non-work-related labour costs has not been used in the regulatory costing model.

Importers will no longer be required to complete and submit an online application for an annual licence and permit each consignment. Applications for a permit should take approximately 10 minutes which equates to approximately \$12.67 per permit, and 30 minutes to apply for an annual licence which equates to approximately \$38.

## Regulatory burden estimate table for option 2

Average annual regulatory savings from business as usual for option 2

Change in costs (\$ million)	Business	Community organisations	Individuals	Total change in cost
<b>Total, by sector</b>	\$0.0009	\$0	\$0	\$0.0009

Option 2 would reduce the impact on current importers of kava for medical and scientific use by removing the licence and permit requirements. Importers of kava for commercial food purposes would not need import approval.



## Net benefit

Option 2 has the benefit of contributing to the Government's goals in Pacific by providing a new export opportunity and increasing a sense of connection to Australia for Pacific diaspora and Pacific workers from the availability of kava under this option.

The import of kava is treated in the same manner as other imported foods, with compliance to biosecurity requirements and food quality and safety. Additional import permits under the PI regulations are not required, thereby simplifying trade with Australia.

With the removal of import controls under the PI regulation, the regulatory burden is also reduced for the import of kava for medical and scientific purposes by removing the current import licence and permit requirements.

## Option 3 – Create a new import regulation

*Option 3 delivers the Government's objectives*

Of the three options presented, Option 3 delivers on all the Government's objectives. This option:

1. increases the availability of kava in Australia
2. strengthens the economic development and cultural ties with Pacific Island countries
3. by the requirement for a permission to import, provides appropriate risk based regulatory options to deal with the emergence of any public health risks
4. with the ability to collect real time data, supports the monitoring of the potential harms of kava use in Australia.

Data on the quantities of kava imported into Australia will be collected through the issue of permits under the PI Regulations.

Kava will be recognised as a food and would meet biosecurity and food quality requirements under the Biosecurity Act and IFC Act.

Kava grown domestically in Australia is not part of the pilot as it does not support the Pacific Step-up objective.

Under Option 3 the Government can impose conditions on permits issued under the PI Regulations such as

- the importer's custody, use, disposal and destruction of the kava must be in accordance with the laws of the states and territories in which the importer operates
- the importer must not provide kava to a person under 18 years of age
- the use, disposal and destruction of the kava will be in accordance with the laws of the states and territories, and
- the importer must keep records and provide as required to the Department.

Option 3 has no effect on existing importers of kava for medical use and retains the personal traveller exemption. Persons intending to import kava as a food would be required to obtain import permission under the PI Regulations.

Option 3 imposes regulatory burden on the importation of kava as a food, noting that such import is not presently lawful (other than in the small personal quantities earlier noted). Commercial importers of kava for use as a food will need to obtain a permit from the ODC prior to importing the product.

As information on potential importers is relatively unknown, the amendments to the PI Regulations will improve the data collection on commercial imports and will help inform the pilot outcomes enabling the Government to know who is importing kava, and how much they are importing.

There are several matters of concern to jurisdictions, raised during public consultation and subsequent meetings, as abuse of kava in the community, the effect on minors from consuming kava, mixing with alcohol and driving while intoxicated. Option 3 can assist jurisdictions by collecting data on import volumes to assist the monitoring program and stopping imports where importers are in contravention of Commonwealth, state or territory law.

In the absence of consistency of regulation at the border and domestically, there is also a risk that Australian jurisdictions may, unilaterally, in the face real or perceived crystallisation of public health risks, move to restrict supply of kava as a food thereby undermining any intended effect of Option 3, the increase in the domestic availability of kava as a food and the export opportunity provided to the Pacific. The imposition of such restrictions would not only threaten the proposed strengthening of relationships with our Pacific neighbours, it would also potentially create the perverse outcome that kava may become a highly sought after commodity lending itself to lucrative illegal supply within Australia. In turn, this would require law enforcement intervention. Like other foods, appropriate risk based regulation of import and domestic supply of kava is required for the Government's objectives to succeed.

#### *Option 3 would meet anticipated Pacific Island community demand for kava*

Given the geographic distribution and transient nature of some Pacific Island communities in Australia, it is difficult to determine exactly how the commercial import market will operate. Standard market forces would allow for the appropriate supply and distribution to meet the demand for kava. It is anticipated that kava products may be stocked and available for sale in some health food stores, supermarkets, and shops which focus on goods associated with Pacific Island communities and certainly in locations associated with clustering of Pacific Island communities and periodic movements associated with the Seasonal Worker Programme and Pacific Labour Scheme. Even without such a geographic push for the supply of product, Australian businesses could position themselves to supply by the use of online platforms. Indeed, a number of peak organisations representing Pacific Island communities have already indicated their interest in supporting the supply of kava within their state or territory, either through local businesses or applying for permits themselves. These initiatives will assist with supply channels to local communities and overcome any negative effect created by the particularly concentrated geographic or transient nature of those partaking in the abovementioned schemes.

While it is understood that standard market forces will allow for adequate levels of kava to be supplied to interested Pacific Islander consumers, it is unclear as to the existing or likely demand for kava as a food in the broader Australian community. Overseas use of kava seems to be primarily by persons of Pacific Island heritage. The monitoring component of the pilot should provide much needed data on the demand for kava in the Australian community.

#### *Regulatory impact of Option 3*

The two-year pilot will assist in further informing the quantification of the regulatory impact. An estimate average annual regulatory costs (from business as usual) of \$1,300 for all affected stakeholders has been made. This is based on consultation submissions and the number of industry representatives that have lobbied for the commercial importation of kava into Australia, it is predicted 100 businesses may apply for a permit in the first year.

There is no fee associated with the applying for the permit. However, importers will incur the administrative costs associated with familiarising themselves with the regulatory scheme and

making the application for a permit to import kava as a food for commercial purposes into Australia.

The labour cost formula was used to determine these administrative compliance costs: price x quantity (or in its more expanded version: (time required x labour cost) x (times performed x number of businesses or community organisations x number of staff)).

The ABS publishes 'Average Weekly Earnings' semi-annually. As at May 2021, the latest dataset is November 2020. Given that applicants for licences and permits could be based in any state/territory, the national ('All Industries') dataset was used.

For November 2020, the figure for average weekly earnings is \$1,711.60. To determine the average hourly cost, this figure is divided by the average number of total hours worked (includes overtime) for full-time non-managerial employees (the 'All Industries' category has been used) (39.40 hours).

In accordance with OBPR guidance, a multiplier of 1.75 was used to account for the non-wage labour on-costs and overhead costs. The arising calculation is shown below.

Average total weekly earnings (Average total weekly earnings (November 2020) for the All Industries sector (from ABS) / Average hours (total) worked (May 2018) for full-time non managerial employees (from ABS)) \* On-cost and overheads multiplier (from OBPR) = Average Hourly Cost (\$1,711.60/39.40)\*1.75 = \$76.02

There is no impact on individuals (as opposed to businesses) arising from the regulatory changes being quantified and therefore the non-work-related labour costs has not been used in the regulatory costing model.

Importers will be required to complete and submit an online application for each consignment that should take approximately 10 minutes which equates to approximately \$12.67 per permit.

### Regulatory burden estimate table for option 3

Average annual regulatory costs from business as usual for option 3

Change in costs (\$ million)	Business	Community organisations	Individuals	Total change in cost
Total, by sector	<b>\$.0013</b>	<b>\$0</b>	<b>\$0</b>	<b>\$.0013</b>

Option 3 does not restrict the number of importers, nor the quantity of kava that can be imported.

Importers of kava for commercial food use are required to apply for an import permit under the PI Regulations for each consignment of kava.

### Net benefit

Option 3 delivers on all the Governments objectives by providing a new export opportunity for the Pacific, increasing a sense of connection to Australia for Pacific diaspora and pacific workers and placing an additional import permit requirement under the PI Regulations to allow the collection of data to support the monitoring and evaluation of the pilot, including intervention with imports at the border should an adverse incident occur.

Despite the additional import requirements under the PI Regulations, kava is treated in the same manner as other imported foods, with compliance to biosecurity requirements and food quality and safety. Importers of kava for medical or scientific purposes are unaffected by amendments made to the PI regulations under Option 3.

## 6. Who was consulted and how was their feedback incorporated?

A public consultation paper was released in March 2020 and was open for comment until 31 May 2020. The consultation was advertised via social media and the ODC website. The Department of Foreign Affairs and Trade assisted with notification to relevant High Commissions. State and territory jurisdictions were invited directly to comment on the consultation paper.

Overall 53 submissions were received:

### Number of submissions measured by demographic

The number of submissions received from each population demographic

Demographic	Number of Submissions
Pacific Island Government Agencies	5
Commonwealth Agencies	1
Australian residents (mostly with ties to the Pacific Islands)	18
International residents (Pacific Islands and New Zealand)	3
Australian Community Organisations representing the Pacific Island diaspora	4
Businesses	19
Other	3
Total number of submissions received	<b>53</b>

Submissions received in response to the consultation showed overall stakeholder support for the implementation of Option 3 (the use of import permits).

Those not in favour of Option 3 viewed it as too restrictive and preferred either Option 2, or a model based on the New Zealand system.

The main concerns raised by stakeholders were:

- financial gains for individuals and businesses being preferred over the cultural and social benefits of kava
- excessive use resulting in health problems, and
- introduction to Indigenous populations.

There were no, or limited, submissions from some potential stakeholders' groups, including Indigenous Australians, large businesses and health and welfare bodies within states and territories. The monitoring component of the pilot will provide data on some of the areas not addressed by the consultation.

### Summary of stakeholder views

The submissions were supportive of import permits being used to control and monitor kava importation (Option 3), though some enterprises expressed concerns that this may place too many restrictions on importers.

The submissions also supported the use of requirements or import conditions. Suggested requirements and conditions were predominantly to ensure biosecurity and quality of product, and assurance that importers would be monitored. It is important to note that quality of product was not considered in the consultation paper.

The majority of submissions supported additional restrictions in order to balance the protection of the kava consumer with the commercial viability of the import. Restrictions on bulk and online purchases to mitigate concerns around trafficking were the most common suggestion. The submissions were also largely supportive of the inclusion of warnings of potential harm when consuming kava. The predominant view was that warnings should be similar to, but no more stringent than, those in place for alcohol products. However, some consumers and industry bodies opposed additional warnings, citing the lack of research on the negative health impacts of kava, and how it has been proven to be less destructive than alcohol.

Public health from the use of kava, including warnings will be an important consideration to the suitability of the Food Standard as it applies to kava during the pilot.

The submissions highlighted the positive social and cultural impacts of kava, including improved family relationships and cultural perpetuation. Many submissions cited evidence of positive medicinal uses improving mental health conditions such as anxiety, depression, insomnia and PTSD.

Some submissions warned of mild negative health impacts such as dry skin and lack of motivation, however all noted the cessation of symptoms upon ceasing consumption.

Approximately half of the submissions had no concerns about particular risks of allowing commercial kava importation. The other half had concerns regarding poor quality or contaminated kava, financial benefits being viewed as more important than the positive cultural impact, excessive use leading to health problems and the introduction to Indigenous populations. The monitoring and evaluation program are expected to consider these issues during the pilot.

Some submissions expressed the view that the commercial importation of kava into Australia would result in significant economic, commercial, social and cultural benefits.

Additionally, suggested positive health ramifications included improved mental health, reduction in domestic violence (as less people turn to alcohol or other drugs as a substitute), and the potential to minimise the use of other illicit drugs within Indigenous populations.

Australian growers and retailers, commercial importation businesses, and exporters were the most commonly suggested businesses that may be involved in the importation and supply of kava.

In terms of monitoring and evaluation, the submissions indicated that frequent review and reporting of a diverse demographic including importers, retailers, consumers and community members should be put in place. Additionally, the majority of stakeholders who responded expressed interest in contributing to the monitoring and evaluation of the pilot, and recommended a broad representation of government officials, consumers, importers, retailers, and community members.

### **Summary of Jurisdiction views**

Additional consultation was undertaken with the states and territories in August 2020, following the close of the public consultation. Jurisdictions were invited to provide an additional submission by 10 September 2020.

State and territory jurisdictions identified several issues, including:

- mixing of kava with alcohol and other drugs
- concerns over the introduction of a psychoactive substance
- use of kava by minors
- whether the Food Standard for kava was fit for purpose
- introduction of kava into the broader community
- the types of kava to be made available (e.g. pre-mixes)
- impacts on Indigenous communities
- health warnings and harms
- driving under the influence of kava
- quality of kava imported
- health effects of non-traditional use of kava
- content labelling and warnings
- advertising
- consistency of regulation across jurisdictions; and
- regulatory costs incurred by jurisdictions.

Of note was the oft mentioned concern over the use of kava by the broader community and whether, to deal with any risk, kava could be exclusively available for cultural use. While this might be a means of ensuring the exclusive traditional use of kava, it would have additional, not necessarily desirable, consequences. By limiting access to kava to select population groups the Pacific Step-up objective of promoting an Australian market for kava would be undermined and such a measure would also likely be considered discriminatory. It is blunt instrument to deal with a problem which may or may not materialise.

The concerns raised by the Jurisdictions are important factors in the increase in supply of kava to the Australian community. However, because there is limited evidence available it is difficult to hazard an evidenced based response to these issues. The monitoring and evaluation of the pilot will gather data and provide an opportunity to monitor the situation as kava enters the Australian community during the two-year period, through six-monthly progress reports, prepared by NDARC and Ninti One on the evaluation. Although sale and supply of kava is regulated by the states and territories in accordance with the Food Standard, impacts will be monitored during the pilot with recommendations at the end of the pilot on the future of kava in Australia.

The Department's consultation with jurisdictions and Government agencies will continue throughout the pilot design phase to ensure the pilot aligns with whole of Government objectives.

## 7. Recommended option

Option 3 is the preferred option to meet the Government's objectives.

Option 1, the status quo, does not support the Pacific Step-up by increasing export opportunities for our Pacific neighbours, nor does this option create a sense of connection to Australia of the Pacific diaspora seasonal workers through increased availability of kava. Option 1 does, continues to allow kava to be brought into Australia by travellers and addresses concerns raised by jurisdictions on the potential harms kava might cause to the broader community. Adopting Option 1 would mean that kava remains a point of contention with the Pacific Island Nations to the detriment of bilateral relations.

Option 2 contributes to the Government's goals in the Pacific as well as providing for the lowest regulatory burden on importers. By removing import controls and using existing food legislation,

kava availability will increase in Australia, and the Pacific Island Nations will have a new market for kava, which meets the objective of the Pacific Step-up. However, Option 2 will not enable the collection of data imported quantities of kava (information which is valuable for the evaluation of the pilot to be carried out by NDARC and Ninti One Limited). Option 2 will also not assist states and territories controlling or managing the public health risk to the community, for example, by restrictions on eligibility to apply for a permit or by the imposition of conditions on a permit.

Option 2 is similar to the model used in New Zealand, which has had some experience with the use of kava in the community. Unlike Option 3, kava imports are not limited to commercial importers, which as a result the quantity of kava imported would likely to be higher under Option 2.

Option 3 delivers on all the Government's objectives. In supplementing option 2 with the additional regulatory tool of the PI Regulations, option 3 not only creates a new supply pathway it facilitates the management of risk to public health (additional to the biosecurity requirements). The PI Regulations would facilitate the imposition of restrictions on applicants' eligibility and the imposition of conditions including obligations to report (including on quantities) as well as, should an adverse event occur, an immediate response by way of suspension of permissions. The opportunity to import is, by giving weight to the need to manage the public health risk, appropriately balanced with the reasonably low regulatory burden of the requirement to apply for import permission for each consignment. A comprehensive evaluation, informed by the commercial importation data, of the pilot program will inform recommendations to the Government regarding the longer-term regulatory settings for kava use in Australia.

Import permits will incur a regulatory burden of around \$1300 per year during the pilot, but this is considered acceptable with the ability to track quantities and provide an intervention should it be required.

On balance the ability to track quantities imported kava into Australia as a food and the ability to suspend kava imports should an adverse event occur makes Option 3 the preferred option, despite the regulatory burden of applying for import permission for each kava consignment.

## **8. How will the chosen option be implemented and evaluated?**

A comprehensive qualitative and quantitative evaluation of both the personal importation and commercial importation elements of the pilot is necessary in light of concerns that there may be negative health and social effects as a result of more ready access to kava through the changes in importation arrangements.

Following Executive Council approval of the amendments to the PI Regulations, the ODC will publish guidelines and application forms to allow persons to apply for commercial importation.

Any kava to be imported will need to comply with existing biosecurity and food controls. Supply of kava in the jurisdictions is in accordance with local food legislation.

Data collection will commence upon implementation of the pilot, data collection or engagement with Indigenous communities will not commence until ethics approval has been granted. Formal progress reports will be provided on a six-monthly basis with a final report due at the end of the pilot (mid-2023).

Following the preparation of the report, a recommendation to Government will be made on whether to apply additional import controls to those implemented under the pilot, relax further the import controls or return the current status quo.

Although import controls can be amended, the sale and supply of kava is under the jurisdiction of state and territory governments. Controls initiated by jurisdictions have the potential to disrupt supply of kava which could undermine the purpose of the action. It will be important that data collected during the pilot provide a clear indicator on the impact of kava use in Australia in order to inform any necessary regulatory actions in the future.