

# Kava Pilot Phase 2: Allowing the commercial importation of kava

Consultation paper

23 March 2020

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### Introduction

On 11 October 2019, the Prime Minister, the Hon Scott Morrison MP, <u>announced</u> that the Australian Government is stepping up its commitment to the Pacific by launching the kava pilot program (pilot). The pilot involves the relaxation of kava related prohibited import regulations to allow Australians more access to kava and its benefits.

The pilot also supports broader efforts under the <u>Pacific Step-up</u> strategy to increase stronger cultural and economic ties between Australia and Pacific Island nations.

The purpose of the pilot is to:

- provide greater access to kava in Australia, recognising its ceremonial and cultural purposes for Australians with a Pacific Islander heritage, without compromising public health and safety in Australia
- 2. understand the social, cultural, economic and health effects of increased availability of kava across Australia to assist Government determine future kava importation requirements
- 3. ensure that the commercial importation of kava is respectful of state and territory governments' regulatory role, and
- 4. increase trade opportunities for Australia and Pacific Island countries.

The pilot consists of two phases:

- Phase 1: Increasing the amount of kava for personal importation: this phase allows passengers coming into Australia to bring up to four kilograms of kava for personal use. This is double the quantity that was previously allowed and was implemented in December 2019.
- Phase 2: Allowing the commercial importation of kava: this phase of the pilot will allow the commercial importation of unlimited amounts of kava into Australia for non-medicinal purposes, in addition to the medicinal and therapeutic purposes currently allowed under permit. This commercial importation phase will be implemented by the end of 2020.

Both phases of the pilot will run until the end of 2022. However, regulatory requirements implemented during the pilot will continue after it concludes, until the Government decides on the future requirements of kava importation into Australia.

The Government's decision on future kava importation requirements will be informed by the monitoring and evaluation conducted throughout the pilot and a final evaluation report at the conclusion of the pilot.

The Department of Health (the Department) is co-ordinating the pilot on behalf of the Government. The pilot does not impact current arrangements for the importation of kava for medicinal or therapeutic purposes.

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### Aim of this consultation paper

The Department invites interested individuals and organisations to provide feedback on the design, management, regulation and evaluation of phase two of the pilot which allows for the commercial importation of kava into Australia from the end of 2020.

Feedback could include but is not limited to:

- regulatory requirements for the commercial importation of kava into Australia, including conditions on import
- appropriate level of monitoring and evaluation during the pilot
- potential social, cultural, health and economic impacts of kava consumption on individuals and communities, and
- views on safeguards which may need to be in place to protect public health and safety without compromising the ability for Australian communities to engage in cultural practices and have access to other potential benefits of the pilot.

Additional consultation will be undertaken at a local level with those stakeholders who may be impacted by the commercial importation of kava, including Indigenous communities.

This consultation builds on the consultation for phase one of the pilot program, the importation of kava for personal use, which was undertaken in early 2019. Details of this consultation can be found on the Office of Drug Control's website.

### What is kaya?

Kava (also known as kava kava or *Piper methysticum*) is a member of the pepper family, which contains the psychoactive ingredient kavalactones. It has traditionally been cultivated by Pacific Islanders, primarily in Fiji and Vanuatu. The root of the kava plant is usually ground or chewed up and mixed with water or coconut milk to form a traditional beverage. It is generally exported as powdered product made up of ground-up dried roots. Kava is widely consumed in Pacific Island communities and is exported to other countries, including the United States and New Zealand.

Kava has long been, and continues to be, culturally, socially and economically important to Pacific Islander communities, including in Australia. As a ceremonial drink, kava has been used for formal occasions, such as weddings, festivals and family functions. More broadly, it is regularly consumed as a social and recreational beverage in countries such as New Zealand and the United States. Kava is also used internationally for medicinal and therapeutic purposes.

# Australian Government regulation of kava importation

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

The issuing of permits to commercially import kava for non-medicinal purposes was ceased in 2007. This was in response to concerns that the introduction of kava was contributing to negative health and social outcomes, including in some remote Indigenous Australian communities. The importation of kava for developing medicinal products is the only form of commercial importation of kava currently permitted.

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From 17 December 2019, an incoming passenger aged 18 years or more can import into Australia up to four kilograms of kava for personal use in their accompanied baggage, without the need for a permit.

The Department of Agriculture, Water and the Environment (DAWE) through the <u>Biosecurity Act</u> <u>2015</u>, and subordinate legislation (<u>Biosecurity (Prohibited and Conditionally Non-prohibited Goods)</u> <u>Determination 2016</u>) regulates plant and plant products that includes kava.

Kava powder is the only form of kava permitted entry into Australia under the <u>Australian Biosecurity Import Conditions (BICON) kava powder</u>.

### Other Australian Government regulation of kava

Kava used for medicinal or therapeutic purposes is regulated under the <u>Poisons Standard</u> <u>December 2019</u> and is listed as an ingredient for listed medicines in the <u>Therapeutic Goods</u> (<u>Permissible Ingredients</u>) <u>Determination</u> (No. 4) 2019.

Kava is also regulated by the Australia New Zealand Food Standard Code (the Food Standard). Standard 2.6.3 of the Food Standard states that kava and substances derived from kava may only be supplied where it is:

- a) a beverage obtained by the aqueous suspension of kava root using cold water only, and not using any organic solvent, or
- b) dried or raw kava root.

(Please note: in accordance with the Food Standard, kava, even in the forms above, cannot be supplied where incorporated into other products).

The Standard also requires that the following warning statements accompany kava when supplied:

- a) 'Use in moderation', and
- b) 'May cause drowsiness'.

In Australia, the Food Standard should be considered in conjunction with the PI Regulations and certain state and territory restrictions on the supply of kava. The inclusion of kava in the Food Standard provides an exemption so that the forms of kava listed above are not considered to be therapeutic goods.

# State and territory regulation of kava

Australian state and territory governments regulate and licence the distribution and sale of kava based on parameters in the uniform national Poison Standard and Food Standard, as well as jurisdiction-specific approaches to regulating kava, which may include conditions around, for example:

- licencing and conditions of sale
- storage and labelling
- record keeping
- possession, and
- use.

State and territory governments can impose additional requirements or exceptions relating to the distribution, sale and consumption of kava, including during the pilot.

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### Design of phase 2 of the pilot: Commercial importation

The design of the commercial importation phase of the pilot, which will allow commercial importation of kava into Australia will be finalised following this consultation process. It will include, among other things, appropriate regulation, monitoring and evaluation, and safeguards.

### The form of kava in scope for the commercial importation pilot

The only form of kava that will be included in the commercial importation pilot at this time is that which is currently outlined in the Food Standard - Standard 2.6.3 (see above). If the Food Standard does not apply, kava would be considered a therapeutic good.

Restricting the commercial importation phase of the pilot to only these forms of kava will allow for less regulatory burden on state and territory governments. The Department notes that there may be interest in the commercial importation of other forms of kava which at this stage would be considered as a therapeutic good.

### Potential changes to Australian Government regulation

This section of the consultation paper presents the two options for commercially importing kava into Australia during the commercial importation phase of the pilot. These are the only options under consideration by the Government.

Both options involve amending the PI Regulations to allow the commercial importation of kava into Australia as a food, in the forms mentioned in the previous section. The consequence of these amendments will be that the importation of kava under the pilot will be in accordance with:

- the Food Standard AND
- the <u>Biosecurity Act 2015</u>, and subordinate legislation (<u>Biosecurity (Prohibited and Conditionally Non-prohibited Goods) Determination 2016) **AND**</u>
- state and territory government regulations and restrictions on the supply and consumption of kava within their jurisdictions.

The two options for commercially importing kava into Australia are:

- Option 1: Remove kava (in the form proposed for the pilot) from the PI Regulations, making kava in the form specified in the Food Standard 2.6.3 – Kava consistent with other foods imported into Australia, such is the case with the importation of kava in New Zealand.
  - This approach means there would be no capacity for the Government to monitor the amount of kava entering Australia.
  - This option limits the ability to support state and territory requirements through controlling importation.
  - This option places the lowest regulatory burden on importers of kava.
- Option 2 (preferred): Move kava from Schedule 4 to Schedule 8 of the PI Regulations to allow commercial entities to import kava under permit (under an amended regulation 5H of the PI Regulations).
  - This option allows the Government to collect information on the quantities of kava imported into Australia and the importers, and also assist in the monitoring and evaluation component of the pilot.

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- The regulation also allows the Government to impose conditions on permits to manage concerns that have been previously raised about access to kava during the pilot. The proposed conditions are:
  - **§** the importer's custody, use, disposal and destruction of the kava must be in accordance with the laws of the states or territories in which the importer operates
  - **§** the importer must not provide kava to a person under 18 years of age
  - **§** before providing kava to a third party, the importer must be reasonably satisfied that the third party's custody, use, disposal and destruction of the kava will be in accordance with the laws of the states or territories in which the third party operates
  - **§** before providing kava to a third party, the importer must be reasonably satisfied that the third party will not provide kava to a person under 18 years of age, and
  - **§** the importer must keep records and provide as required to the Department the names, address of those the importer supplies kava to and quantity of kava supplied.

Subject to feedback received through this consultation, the Government may consider additional regulatory arrangements, including reviewing the warnings associated with the Food Standard to make the effect of kava consumption clear to consumers. For example, warnings already note that kava consumption 'may cause drowsiness' and that kava should be used 'in moderation'. Additional warnings may advise against driving a vehicle or operating heavy equipment after consuming kava.

Neither option will restrict the number of importers, nor the quantity of kava that can be imported. The average annual regulatory costs for importers are likely to be less than \$100,000. Neither option will impact on the current arrangements for the importation and use of kava for medicinal and therapeutic purposes.

### Potential changes to allow for the commercial importation of kava

Question 1: Are you supportive of the use of import permits (option 2) to allow kava importation to be controlled and monitored?

Question 2: Under option 2 what requirements or conditions do you think are responsible and necessary to be placed on commercial entities in order to allow them to import commercial qualities of kava?

Question 3: In addition to state and territory government restrictions on the supply and consumption of kava within their jurisdictions, what other restrictions should be imposed on holders of permits for importing kava into Australia?

Question 4: Should kava be sold with further warnings about potential harm, such as those in the food standards? What are your views on what these warnings should be?

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### Considerations for the pilot

### Health impacts of kava

*Kava: a review of the safety of traditional and recreational beverage consumption* (FAOUN & WHO, 2016) explores the health impacts of kava consumption.

This report cites evidence that kava consumption can result in lethargy and headaches but has been successfully used to address anxiety and increase social interaction. It presents research that shows high levels of kava consumption can result in scaly skin rash, weight loss, nausea, loss of appetite, indigestion, sore red eyes, laziness, loss of libido, general poor health and an increase in liver enzymes (which may be an early indicator of cholestasis). However, it also notes evidence that these affects are commonly reversible upon the cessation of use and that consumption of kava has no effect on the cognition of users.

The report also notes the effects of kava vary significantly between individuals, gender and communities, and kava varies significantly in its composition (i.e. levels of kavalactones). More research is required to increase understanding of the health impacts of kava consumption.

In addition to Pacific Island nations, kava is widely available in New Zealand and the United States where there is negligible evidence of negative health impacts for consumers.

### Social impacts of kava

Pacific Islander communities in Australia have identified kava use as a socially valued and culturally significant activity that may promote fellowship and companionship. Kava clubs provide opportunities to learn about and maintain culture in an environment where participants feel accepted. Despite this, there have been news reports of social harms in some communities where the kava is not consumed in a traditional manner (Clough 2009).

In Australia, leaders within some Indigenous Australian communities have expressed public concern about the negative health and social impacts in some communities in the Northern Territory. This is supported by evidence to suggest that illicit market activity in Arnhem Land has negative financial impacts on communities (Clough, Burns & Mununggurr 2000).

Outside of Indigenous Australian communities, the kava using community may also have difficulty identifying what levels of use may create harmful consequences. There is also anecdotal evidence to suggest that regular kava consumption among Pacific Islander communities could create relationship distress.

The effect of driving under the influence of kava may also need to be considered, as this is not currently regulated in Australia.

#### Additional information

Scheduling of Medicines and Poisons/Scheduling Delegates final decisions, July 2016: <u>Piper methysticum (kava)</u>

Food and Agriculture Organization of the United Nations, World Health Organisation Report: Kava: a review of the safety of traditional and recreational beverage consumption

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### Business impacts of kava

Pacific Island kava growers, processors and exporters are expected to benefit from the ability to export kava to Australia as the market for kava expands.

It is expected that a range of Australian businesses will be involved in the commercial importation and retailing of kava. These businesses may include but are not restricted to health food stores, stores focused on retailing products from the Pacific Islands, general grocery stores, businesses that specifically retail kava (commonly referred to as kava bars) or other business models that may retail kava alongside other products (such as restaurants or bars). Businesses may also retail kava online. Other businesses that may benefit from the commercial importation are importers, freight and customs brokers.

Market behaviour and kava consumption trends resulting from the commercial importation pilot may influence Government decisions concerning future requirements for regulating the importation of kava into Australia.

### Impacts of kava?

Question 5: What are your views on the potential health, social and cultural impacts of kava, and do you have any evidence to share?

Question 6: Are you concerned about any particular risks that may be caused by allowing the commercial importation of kava?

Question 7: Do you have any suggestions for how to limit any potential negative impacts or risks of using kava and / or commercially importing kava into Australia?

Question 8: What benefits may be achieved from commercially importing kava into Australia?

Question 9: What businesses may be involved in the commercial importation and supply of kava and how will kava potentially be priced, marketed and retailed?

# Monitoring and evaluation

Monitoring and evaluation are integral to this pilot.

The pilot will include an independent monitoring and evaluation capacity to capture the health, social, cultural and economic impacts of the pilot, including the development or establishment of baseline data. The effectiveness of the regulatory framework will also be analysed and reported on. This capability will be procured by tender, to ensure that a partner with relevant experience is engaged.

Monitoring and evaluation will involve the collection and analysis of data on a yearly basis, with interim evaluation reports to be provided to the Department. These reports will assist develop appropriate responses to any emerging health and social harms as they arise.

A final report will be produced at the end of the pilot that will evaluate the pilot as a whole. This report will provide input into future regulatory changes regarding kava importation into Australia.

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### Monitoring and evaluation

Question 10: What methods should be used to monitor and evaluate the success and impacts of the pilot?

Question 11: What methods should be used to monitor and evaluate the health, social, economic and regulatory impacts of kava consumption during the pilot?

Question 12: Who may be able to contribute to the monitoring and evaluation of the pilot?

Question 13: What data should be collected to effectively measure the health, social, and economic and regulatory impacts of kava?

### Your feedback

Are you interested in importing kava for commercial purposes, or are you a Pacific Islander or Indigenous community leader, health specialist, government, law enforcement or other interested party?

The Australian Government seeks your views on changes to facilitate the introduction of a pilot program to relax the restrictions on the commercial importation of kava. Your input will assist the Government address any unintended consequences and to better inform the pilot and subsequent policy regarding the commercial importation of kava into Australia.

Questions have been included in this paper to help guide your thinking on a response. You may choose to answer just one of these questions, all of them, or any combination of them.

### How to submit

The three options to submit your submission are:

- 1. Complete the online consultation submission form to upload your submission in either pdf or word format.
- Complete the consultation submission coversheet and attach to an email with your submission, in either pdf or word format, and email to <a href="mailto:dcs@health.gov.au">dcs@health.gov.au</a> with the title KAVA-Submission.
- 3. Provide a hardcopy submission with a printed coversheet which may be mailed to:

Office of Drug Control Department of Health GPO Box 9848 Canberra ACT 2601

This consultation closes on Monday, 4 May 2020.

### Next steps

All submissions provided through this consultation process will be examined in detail by the Department and will provide input in the design and implementation of the pilot and will also allow issues raised to be discussed in future stakeholder engagement processes.

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### References

Clough A (2009). Enough or too much. What is 'excessive' kava use in Arnhem Land? *Drug and Alcohol Review.* 22(1): 43-51

Clough A, Burns C, and Mununggurr N, (2000). Kava in Arnhem land: A review on Consumption and its social correlates. *Drug and Alcohol Review* 19: 319-328

Food and Agriculture Organization of the United Nations, World Health Organisation Report (2016) *Kava: a review of the safety of traditional and recreational beverage consumption* (http://www.fao.org/3/a-i5770e.pdf)

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