

CODEX ALIMENTARIUS COMMISSION



Food and Agriculture
Organization of
the United Nations

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Agenda Item 9



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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

FAO/WHO COORDINATING COMMITTEE FOR NORTH AMERICA AND THE SOUTH WEST PACIFIC

14th Session, Port Vila, Vanuatu

19 – 22 September 2016

DISCUSSION PAPER ON THE DEVELOPMENT OF A REGIONAL STANDARD FOR KAVA PRODUCT THAT CAN BE USED AS A BEVERAGE WHEN MIXED WITH WATER

Prepared by the electronic Working Group led by Vanuatu¹

Background

1. At its 11th session of the Coordinating Committee for North America and the South West Pacific (CCNASWP11) held in Tonga in 2010, the Coordinator (Tonga) presented the discussion paper on a proposal for new work on the development of a regional standard for kava and dry kava products².

2. The Coordinating Committee discussed the proposal and concluded that it still needed more scientific evidence on the safety of kava and dried kava products, more clarity on the nature of the products to be standardized and the need to determine whether the proposal is for a regional or an international standard. The members agreed to establish an electronic Working Group (eWG), led by Tonga, to revise the discussion paper, including the project document, for consideration at the next session³.

3. At CCNASWP12 held in Madang, Papua New Guinea, in 2012, the Coordinator (Tonga) presented the discussion paper on a proposal for new work on the development of an international standard for kava products. The Coordinating Committee agreed that the proposed standard will be an international standard for dry kava. An eWG was convened to provide more evidence on the safety of kava as a food. Members agreed that the Group will be led by Vanuatu.

4. At CCNASWP13 held in Kokopo, Papua New Guinea, in 2014, Vanuatu again presented the paper. The Committee agree that other risk management options such as a code of practice be explored and that the eWG would apply to only kava as a dried product that can be used as a beverage when mixed with water.

5. The eWG considered in more detail the information presented in the FAO and WHO report (Abbott, 2014), including other recent work to produce the information presented herein.

6. The current paper has taken into account the nature of the products prepared for consumption in the Pacific Island Countries and concluded that the proposal for new work on this product must be a regional standard for dried kava and other forms of kava prepared using cold water extraction and consumed as a food.

7. This discussion paper is confined to kava which is prepared fresh or dried before use.

Rationale for Development of a Standard for Kava

8. Kava (*Piper mythisticum*) is an important agricultural commodity for Pacific Island Countries (PICs), forming an integral part of cultural, economic and social life. It has been cultivated for around 3000 years⁴, and is being traded within and outside of the region in important quantities and value (Tables 1 and 2).

9. A comprehensive review of the use and safety of kava commissioned jointly by the FAO and WHO is presented (Abbott, 2014) that highlights a number of issues relating to kava safety. Kava varieties fall into two groups - those with the broad description the highly desirable 'Noble,' or medicinal kava and the less desirable varieties including 'Two day,' and *wichmannii* kava.

¹ Members of EWG: Australia, Canada, New Zealand, Solomon Islands, United States of America, IADSA, CRN,

² CX/NASWP 10/11/CRD5

³ REP11/NASWP

⁴ SPC (2001): Pacific kava: a producer's guide, p.5

10. Although the review identified a number of data gaps, there is now sufficient clinical and analytical data to delineate clearly between the two groups. This supports the preparation of a Codex-based standard that underpins the Vanuatu Kava Act⁵ which confines trade in kava to the 'Noble,' and medicinal varieties and which forms a model for the preparation of a standard that can be used more widely among the fresh and dry kava-trading nations.

11. Filling the gaps in the WHO/FAO review (Abbott, 2014) will go a long way to establishing a definitive standard that allows traders and consumers to make informed choices. This is discussed further in Paragraphs 19-25.

12. The review highlights analytical evidence (Lebot and Legendre, 2014) that there is a clear chemical difference between the two groups (Nobles and non-Nobles kava) and that this difference can be exploited to confirm freshly prepared and dry kava quality and safety as the techniques are refined and directed towards convenient, portable use.

13. The Standard prepared in the Codex format will inevitably mandate associated requirements including hygienic manufacturing practices, consistent products of the correct varieties and informed labelling that will protect consumers and traders and lessen the chances of technical barriers to trade (TBTs).

Recommendation on proposed work

14. The analytical methods for the objective confirmation of safety of kava (varieties listed in Paragraph 2 - Project Document below) have now received financial support from the New Zealand and Australian funded Pacific Horticultural and Agricultural Market Access (PHAMA) program to enable rapid determination that a product is of either the Noble kava varieties or not.

15. It is recommended to request the Codex Alimentarius Commission (CAC) to support further work to collate existing data, more recent safety assessments and analytical data as defined by the WHO/FAO (Abbott, 2014) report that will lead to the finalising a Codex Regional Standard for kava using the Vanuatu Kava Act.

16. The Committee is requested to pay good attention to the recently launched Vanuatu National Quality Standard for Kava Export, using findings from a national research, has included in the standard the mandatory analytical method that refines and simplifies quality management efficacies and which allow for mobile use by stakeholders in remote island locations where kava is grown and traded.

17. Very soon the application of the testing method will be most effectively used in the field and at the salient trading points by stakeholders who have commercial priorities. Furthermore, the importance of Good Manufacturing Practices (GMPs) supported by the testing must be disseminated throughout the industry using refined, appropriate training programmes. This is now possible using the Vanuatu Standard as the model in all the kava producing countries in the region.

18. The FAO/WHO Coordinating Committee for North America and the South West Pacific is invited to consider the project document (Appendix I) and to forward the request for new work to the Codex Alimentarius Commission for its consideration.

⁵ Kava Act No. 7 of 2002

PROJECT DOCUMENTATION

Proposal to develop a Regional Codex Standard for Kava

1. The Purpose and Scope of the Standard:

The purpose of this regional Codex standard for kava products intended for human consumption, is to protect consumers and assure its quality to promote fair trade. The scope of the standard applies to kava products as defined in (2). The standard is intended to cover kava products used as food and does not apply to products used for medicinal or any other purposes.

2. Product Definition

Kava and kava products are derived from the kava plant, *Piper methysticum* Forst.f. The products of the kava plant to be covered under the proposed standard include:

- a) Fresh and dried stumps and basal stems; and
- b) Fresh and dried roots.

2.1 Dried Kava Products

Kava plants should be cultivated using Good Agricultural Practices for at least three years growth. Dried products should have a maximum moisture content of 12% (water activity level not exceeding 0.6). The dried kava should have a minimum total kavalactones content of 10% in the roots and 5% in the rhizomes, and a minimum kavain content of 3% in the roots and 1% in the dried rhizomes. The kava drink, prepared from dry kava has been consumed in Pacific Island Countries for centuries without any reported ill-effects on the liver⁶. The roots, basal stems or rhizomes are commonly harvested, peeled, washed, dried and pounded. The powder is mixed with potable water and filtered prior to consumption.

The major feature of kava is that it is characterised by containing the physiologically active group of substances - kavalactones that are present in the native plant and survive the drying process. (Cairney *et al*, 2002). (Garner and Klinger, 1985), (LaPorte *et al*, 2011), (Russell *et al*, 1987), (Thompson *et al*, 2004).

2.2 Freshly Prepared Kava Products

Kava is also prepared fresh for consumption using part of the basal stem and roots.

3. Its Relevance and Timeliness:

Kava has been cultivated in the Pacific Region including Fiji, Federated States of Micronesia, Papua New Guinea, Samoa, Tonga and Vanuatu for many years. It is consumed as a food and traded in the Pacific Island Countries, Japan, New Zealand, Canada, China, and Europe. It has received negative publicity for over ten (10) years linking it to liver toxicity. There are no regional or international standard for the traded products of kava.

4. The Main Aspects to be covered:

The Standard for Kava will be drafted in accordance with the Codex uniform layout for food products. The proposed standard will cover fresh and dried kava from the Nobles varieties, plant parts, kava products in the fresh and dried (chips or roots), powdered and water extract, process, quality, safety, labelling in order to provide certainty and assurance to consumers.

5. An Assessment against the Criteria for the Establishment of Work Priorities:

a. Volume, Value and Pattern of Trade of Kava from the Pacific Countries

With the increasing populations of Pacific Islanders in New Zealand and the United States, export of kava products has increased to these nations in the past 30 years to ensure that their traditional drink is readily available among the diaspora. (See Tables 1 and 2). Traditionally, males are the main consumers of kava, but socially, women also partake. The inclusion of women and consumers among overseas native residents have increased exports so that dried kava has become one of the major export commodities and foreign exchange earnings for the PICs.

⁶ WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p.4

TABLE 1
EXPORTS FROM VANUATU 2012 AND 2013

Country of Exports	<i>value (in million vatu)</i>		<i>Quantity (in tons)</i>	
	2012	2013	2012	2013
New Caledonia	154	201	149	202
Fiji	200	258	199	256
United States of America	34	136	33	132
Kiribati	46	67	42	60
New Zealand	1	9	1	15
China, Peoples Republic of	-	15	-	15
Korea, Republic of	15	8	15	4
Australia	7	12	7	11
Wallis and Futuna Islands	-	-	-	-
Germany, Federal Republic of	-	5	-	5
Solomon Islands	3	-	3	-
Guam	4	6	4	6
Iceland	-	-	-	1
Ireland	-	1	-	-
Nauru	-	-	-	-
Canada	-	0	-	0
Papua New Guinea	-	-	-	-

Source: Vanuatu National Statistics
Office

Source- SPC/

TABLE 2
EXPORT OF KAVA FROM FIJI

2011 - 2013

2011	EXPORT		
COUNTRY	QUANTITY	UNIT	VALUE
CA Canada	5.0	Kg	\$238
CH Switzerland	200.0	Kg	\$5,300
CX Christmas Island (Australia)	707.0	Kg	\$21,055
GB United Kingdom	2.0	Kg	\$60
GU Guam	127.5	Kg	\$4,889
HI Hawaii	800.0	Kg	\$27,018
HN Honduras	200.0	Kg	\$6,400
JP Japan	58.5	Kg	\$2,623
KI Kiribati	56,374.3	Kg	\$1,756,130
KW Kuwait	7.0	Kg	\$1,540
MH Marshall Islands	5.5	Kg	\$5,000
NR Nauru	5,519.0	Kg	\$230,099
NZ New Zealand	104,093.0	Kg	\$1,111,215
TV Tuvalu	220.0	Kg	\$2,288
US United States	101,064.9	Kg	\$2,310,163
WF Wallis and Futuna Islands	25,778.7	Kg	\$209,911
WS Samoa	380.0	Kg	\$6,480
Total Value	in Tariff 12129910 :	295,542.3	\$5,700,409

2012

AS American Samoa	494	Kg	\$7,500
AU Australia	5,000	Kg	\$133,555
CA Canada	3,825	Kg	\$25,427
CX Christmas Island (Australia)	1,764	Kg	\$48,506
GU Guam	1,628	Kg	\$7,800
HI Hawaii	1,360	Kg	\$41,430
HK Hong Kong	340	Kg	\$6,800
IQ Iraq	98	Kg	\$4,273
IR Iran, Islamic Republic of	57	Kg	\$1,800
JP Japan	38	Kg	\$1,457
KI Kiribati	47,529	Kg	\$1,573,981
NR Nauru	8,628	Kg	\$270,560
NZ New Zealand	127,237	Kg	\$1,080,553
PF French Polynesia	5	Kg	\$100
SB Solomon Islands	225	Kg	\$8,869
TR Turkey	100	Kg	\$1,800
TV Tuvalu	410	Kg	\$13,650
US United States	85,789	Kg	\$2,456,218
WF Wallis and Futuna Islands	6,230	Kg	\$153,159
WS Samoa	459	Kg	\$10,105
Total Value	in Tariff 12129910 :	291,216	\$5,847,543

2013

		EXPORT	
AS American Samoa	5	kg	\$2,000
CA Canada	14	kg	\$13,300
CX Christmas Island (Australia)	2300	kg	\$87,444
GU Guam	663	kg	\$37,250
IQ Iraq	2	kg	\$3,000
JP Japan	4	kg	\$1,185
KI Kiribati	33239	kg	\$2,002,775
MH Marshall Islands	643	kg	\$16,056
NR Nauru	2437	kg	\$252,070
NZ New Zealand	55959	kg	\$1,272,419
PG Papua New Guinea	100	kg	\$4,500
SB Solomon Islands	1	kg	\$1,250
TV Tuvalu	258	kg	\$30,000
US United States	30,582.48	kg	\$3,000,580
WF Wallis and Futuna Islands	6489.4	kg	\$238,293
WS Samoa	4765	kg	\$55,184
ZZ From Any Other Source	4	kg	\$1,080

b. Diversity of national legislation and apparent resultant or potential impediments to international trade.

Current impediments to trade include the lack of an internationally accepted kava quality standard; the absence of relevant information on toxicological confidence on varietal differences; quality issues; and poor publicity have contributed to the decline of trade of kava products in several countries. PICs are developing national standards for kava. In 2001, the Secretariat to the Pacific Community published a Guide for Production of kava (SPC, 2001). Vanuatu enacted the Kava Act 2002 amended in 2008, with Samoa, Tonga and Fiji undergoing a similar process. In 2013 Vanuatu published the Kava Quality Manual for the export of dry kava from Vanuatu. The nation has now developed its own national quality standard for kava export using information from the research undertaken by Lebot and Legendre (2014) (FTNIR and HPTLC). The Pacific Island kava-producing Countries are committed to establishing uniform standards at national level⁷.

⁷ International Kava Executive Council (2008)

In 2005, the Australian Therapeutic Goods Administration (TGA) set kava quality standards with respect to plant part, extraction medium, and treatment modalities (TGA, 2005). In 2005, Food Safety Australia and New Zealand reported the health risk assessment of kava and the associated hepatotoxicity from commercial acetonnic or ethanolic kava extract marketed as regulated medicinal drugs rather than unregulated dietary supplements (FSANZ, 2005). This is in line with the recommendation by WHO to put in place “adequate quality control measures standardized across the producing countries with agreed quality standards and operating procedures should be instituted for growth, harvesting and processing of the kava root”.⁸

- i. Regional and International market potential, a significant amount of dried kava is being traded within the countries of the region (Tables 1 and 2). All dried kava being imported in developed countries, such as Japan, NZ, Canada, China, Europe and USA is sourced exclusively from the Pacific Island Countries. There is therefore a case for the development of a truly recognised regional standard in Codex Standard format.
- ii. Impediments to trade are the lack of uniform standardization which should eliminate the quality problems of the dry kava products considered as the concern for the safety of consumers. The standards should then be the basis of kava legislation to ensure the quality of kava products that do not threaten health, safety and trade and provide all stakeholders with the ability to make informed choices.
- iii. It is possible to standardize dried kava to some degree, because the parts of the plant used for food purposes are uniform throughout all countries. The varieties in the proposed standard are those that have been traditionally consumed in the Pacific for centuries and can be identified by standard taxonomical means.
- iv. The proposed standard will ensure consumer health protection by identifying suitable varieties of kava, parts of the plant and the process of preparation that over centuries have not shown any undesirable health effects. The standard is expected to enhance trade opportunities for the kava producing/exporting countries by providing assurance to importing countries that they will receive safe, high quality kava and products derived from it. The Codex standard will promote harmonization of national standards and thereby contribute to facilitate international trade in dry kava products.

Safety of Kava Products

The recent review commissioned by WHO/FAO (Abbott, 2014) has identified that besides the six major kavalactones (the active pharmacological components) alkaloids and flavokavins are also present. The metabolism of kavalactones is reasonably well understood and involves cytochrome P450 2D6, which has the potential for polymorphism. Kavalactones can also inhibit some P450 enzymes, raising the possibility of affecting the metabolism and toxicity of co-medications. There is little evidence for kavalactone-associated *in vitro* cytotoxicity or *in vivo* hepatotoxicity in animals. On the other hand little is known about the metabolism of the kava alkaloids or flavokavins. Evidence of significant *in vitro* cytotoxicity with alkaloids and flavokavins, as well as hepatotoxicity in animals with flavokavins, has been noted and there is a case for minimizing human exposure to these components via kava beverage. The presence of these alkaloids and flavokavins have formed the basis of differentiation between the Noble and medicinal kava varieties and the ‘Two day,’ and *wichmannii* kava varieties (Lebot and Legendre, 2014).

The analytical techniques used to establish the levels of kavalactones, flavokavins, and other hepatotoxic alkaloids - Fourier transform near infrared (FTNIR) and high performance thin layer chromatography (HPTLC) are situated in Port Vila and the equipment is cumbersome. There is a significant prospect however, that these analytical techniques capable of differentiating contents of kavalactone, alkaloids and flavokavins (i.e. the difference between Noble and medicinal varieties and Two day and *wichmannii* varieties) can be refined into a simple, portable colour test that can be used in the field. Hence rapid determinations of toxicity will be possible.

The WHO/FAO (Abbott, 2014) review is germane in setting the future direction of research. Appropriately directed research will, eventually, ensure increased safety for consumers, allow consumers to make informed decisions improve the standing of Pacific Island Countries in the kava industry and provide greater protection for trading nations against instances of imposing technical barriers to trade (TBTs). These are basic tenets of Codex.

⁸ WHO (2007): Assessment of the risk of hepatotoxicity with kava products, Geneva 2007, p.63

(c) International or regional market potential

Kava is a major source of income for thousands of small farm holders in these Pacific countries. With the increasing migration of Pacific Islanders to New Zealand, Australia and the United States, the export of kava has increased over the past 30 years, making it a major export commodity and contributes significantly to the local island economies. Table 2 shows the total volume and value of export of kava by Vanuatu, Fiji, Tonga and Samoa. However, Vanuatu produced and export an average of about 69% of total, Fiji about 27%, Tonga about 2% and Samoa about 1% of the total production and export. The value of these kava exports is also highest for Vanuatu with about the same proportion as for the volume.

The export market price of kava fluctuates from approximately US\$ 3,658 in 2002 to the highest of US\$ 14,363 in 2008. From Table 3, approximately 86% of the total kava exported are imported into countries of the region. Hence the justification of the proposal of the regional rather than the international kava standard. Recent data from the Vanuatu Statistics Office would indicate that exports from Vanuatu to Fiji (Vanuatu's largest export market) increased by almost 70% between 2009 and 2011.

Due to the increasing volumes and value of the kava products trades in the Pacific, it timely and critical to establish a standard for kava to protect consumer's health and also to ascertain its quality to promote fair trade. With a regional Codex kava standard, the confidence of consumers in the kava products is assured and the demand is projected to increase two to ten folds. The price is projected to fluctuate before stabilising, possibly increasing the earnings of farmers respectively by two to ten folds. The countries and the farmers producing of kava in the Pacific may also increase correspondingly.

(d) Amenability of the commodity to standardisation

The quality of the kava products shall be defined along the following criteria:

- a) Kava and kava products are derived from the kava plant, *Piper methysticum* Forst.f.; and
- b) The WHO/FAO review (Abbott, 2014) has clearly defined significant differences in the alkaloid profile of the Noble kava varieties and the Two day and wlichminnii varieties. Until now the origin of the kava varieties suitable for consumption in the form of freshly prepared and dried products have been used as a guide. In the meantime, the kava plant varieties among the PICs are currently selected on the traditional history of experience of safe use and by using the local vernacular languages of the country of origin. They include:
 - i. Vanuatu "Noble" varieties; *Melomelo*, *Asiyai*, *Biyaj*, *Palimet*, *Miela*, *Olitao*, *Kelai*, *Ge wiswisket*, *Ge gusug*, *Borogoru*, *Silese*, *Melmel*, *Borogu*, *Sese*, *Urukara*, *Bir Sul*, *Bir Kar*, *Palarasul*, *Palasa*, *Poivota*, *Pia*, *Ahouia*, *Leay*, *Amon*, *Puariki*, *Pualiu*, *Naga miwok*, *Ge vemea*;
 - ii. Fiji varieties; *Matakaro leka*, *Matakaro balavu*, *Loa kasa leka*, *Loa kasa balavu*, *Vula kasa leka*, *Vula kasa balavu*, *Qila leka*, *Qila balavu*, *Yalu*, *Dokobana vula*, *Dokobana loa*; *Honolulu*, *Damu*;
 - iii. Samoa varieties; *Ava Lea*, *Ava La'au*, *Ava Loa*, *Ava Tonga*;
 - iv. Tonga varieties; *Lekakula*, *Lekakula 'akau*, *Lekahina*, *Lekahina 'akau*, *kava Tea*, *kava Kula*, *kava Fulufulu*);
 - v. Solomon Islands Kava varieties (*Melomelo*);
 - vi. Federated States of Micronesia Kava varieties (*Rahmwahnger*);
 - vii. Papua New Guinea variety; (*Kau kupwe* from *Baluan Island*).

(f) Number of commodities which would need separate standards indicating whether raw, semi-processed or processed

The proposed regional kava standard will take into account various water extraction methods and techniques used to prepare kava. It will include relevant kava preparation techniques for different products of kava, including in the raw and dried forms and for different parts of the plant, namely the roots and basal stems.

(g) Work already undertaken by other international organizations in this field and/or suggested by the relevant international intergovernmental body(ies)

A huge volume of research and analysis on kava have been conducted internationally on the properties of kava considered as a drug, dietary supplement and as a food. PICs, namely Vanuatu now has its own legislation and export quality standard for kava products prepared for export, basing the quality criteria on a number of Codex Standards. Fiji will soon adopt its kava quality standard.

The information available internationally is sufficient to begin new work on a regional kava standard. Additional work support for toxicological confidence information on varietal differences can be researched to provide all required information to complete the proposed regional standard.

5. Relevance to the Codex Strategic Objectives:

The proposed standard meets the criteria outlined in Goals 1 and 2 of the Codex Strategic Plan.⁹

Strategic Goal 1: It will contribute to fulfilling goal 1 by providing a sound regulatory framework harmonized across countries of the region. As mentioned earlier, Pacific producing countries are currently at various stages of establishing national level legislation on kava to ensure fair trade in high quality kava products and to protect the health of consumers. In view of the eminent misconceptions about the quality and safety of kava and other emerging issues associated with the products of kava, harmonizing these national standards, the development of a Codex Standard for kava has been proposed by member countries to regulate the use of varieties and parts of the plant prepared for consumption in accordance with the Recommendations, Codes of Practice and Standards laid out in Codex.

Strategic Goal 2: It will promote wide and consistent application of scientific principles and risk analysis, including promoting the collection of data from developing countries and from all regions of the world so that the risk analysis is based on global conditions and requirements. The standard will be based upon findings of the recent WHO/FAO review (Abbott, 2014) and on unequivocal scientific analytical data (Lebot and Legendre, (2014).

6. Information on the Relation between the Proposal and Other Existing Codex Documents:

This proposal is an initiative of PICs to promote safe production of fresh and dried kava, as there is currently no such existing standard within Codex. It will refer as much as possible to other general Codex standards (e.g. hygiene, labelling, food additive and contaminants, etc).

7. Identification of Any Requirement for and Availability of Expert Scientific Advice:

Scientific advice is required on the following:

- i. Methods of analysis of kava lactone.
- ii. Methods that use defined parameters to show data correlation between a kava product and a particular kava variety or varieties.
- iii. Modalities of use with regards to maximum daily kavalactone dose and duration of usage.

8. Identification of Any Need for Technical Input to the Standard From External Bodies

Technical assistance by WHO and/or FAO to substantiate the scientific advice in Section 7 above as appropriate.

9. The Proposed Time-line for Completion the New Work, Including the Start Date, the Proposed Date for Adoption at Step 5, and the Proposed Date for Adoption by the Commission”

[To be determined by CCNASWP 14]

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