codex alimentarius commission E

FOOD AND AGRICULTURE ORGANIZATION OF THE UNITED NATIONS

WORLD HEALTH ORGANIZATION

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Agenda Item **CX/NASWP 12/12/8**
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JOINT FAO/WHO FOOD STANDARDS PROGRAMME

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

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DISCUSSION PAPER ON THE DEVELOPMENT OF A STANDARD FOR KAVA PRODUCTS

(prepared by Tonga from an electronic Working Group with Australia, Canada, Fiji, Papua New Guinea, New Zealand, Samoa, Solomon Islands, USA, Vanuatu and Observers)

Background

1. At its 11th session of the Coordinating Committee for North America and the South West Pacific (CCNASWP) held in Tonga in 2010, the Coordinator (Tonga) presented the discussion paper on a proposal for new work on the development of an international standard for kava products[1].

2. The Coordinating Committee discussed the proposal and concluded that it still needs more scientific evidence on the safety of kava products, and 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, led by Tonga, to revise the discussion paper, including the project document, for consideration at it's next session[2].

3. The electronic working group was held and three members concluded that it is still premature to develop the regional kava standard, while the rest of the electronic working group supports Tonga to present the reviewed discussion paper as new work to develop a regional standard for kava products.

Rationale for development of a standard for kava

4. Kava (*Piper mythesticum*) is an important agricultural commodity for Pacific Island Countries, forming an integral part of cultural, economic and social life. It has been domesticated for around 3000 years[3], and is being traded within and outside of the region in important quantities and value.

5. The kava drink, has been consumed in Pacific Island Countries for centuries without any reported ill-effects on the liver[4], is made from a water extract of the root and/or rhizome of *Piper methysticum*. A recent WHO risk assessment concluded that "clinical trial of kava have not revealed hepatoxicity as a problem[5] suggesting that "water extracts are devoid of toxic effects"[6] and recommending that "products should be developed from water-based suspensions of kava"[7]. The safety of water based kava drinks is supported by long-term ethno-pharmacological observations[8].

[1] CX/NASWP 10/11/CRD5
[2] REP11/NASWP
[3] SPC (2001): Pacific kava: a producer's guide, p.5
[4] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p.4
[5] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 62
[6] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 59
[7] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 62
[8] Loew & Gaus (2002) in:WHO (2007):, p.11

6. The said WHO risk assessment recommended that "adequate quality control measures standardized across the producing countries with agreed standard operating procedures should be instituted for growth, harvesting and processing of the kava root or rhizome".[9]

7. Pacific producing countries are currently at various stages of establishing national level legislation[10] on kava to ensure fair trade in high quality kava products and to protect the health of consumers. In view of 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 which have been identified as a safe food for human consumption.

Recommendation on proposed work

8. It is recommended to request the Codex Alimentarius Commission to initiate work to develop a codex standard for kava.

9. The 12th Session of the FAO/WHO Coordinating Committee for North America and the South West Pacific is invited to consider the document provided in the attachment and to forward the request for new work to the 36th Session of the Codex Alimentarius Commission for its consideration.

Request for Comments

10. Governments and international organizations in Observer status with the Codex Alimentarius Commission are invited to submit comments on this discussion paper, as directed above, for further consideration by the 11th Session of the CCNASWP.

[9] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p.63
[10] Kava Act 2002, Vanuatu

PROJECT DOCUMENTATION

Proposal to develop a 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 the consumers and assure it's quality to promote fair trade. The scope of the standard applies to kava products as define in (2). This proposal intended to cover kava products used as food or food ingredient and does not apply to products used for medicinal purposes.

2. Product Definition

The roots, rhizomes and basal stems of "kava" plant *Piper methysticum* Forst. f. of the Piperaceae family, are process into kava dried products. The kava plant varieties are select based on the traditional history of experience of safe use by each Pacific country with names in local vernacular languages of the country of origin: Vanuatu "Noble" Kava 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);* Fiji Kava varieties: *(Matakaro, Matakaro balavu, Loa kasa leka, Loa kasa balavu, Vula kasa leka, Vula kasa balavu, Yaqona damu, Qila leka, Qila balavu, Yalu, Dokobana vula, Dokobana loa);* Samoa Kava varieties (*Ava Lea, Ava La'au, Ava Loa, Ava Tonga);* Tonga Kava varieties (*Lekakula, Lekakula 'akau, Lekahina, Lekahina 'akau, kava Tea, kava Kula, kava Fulufulu);* Solomon Islands Kava varieties (*Melomelo*); Federated States of Micronesia Kava varieties (*Rahmwahnger);* Papua New Guinea Kava varieties (*Kau kupwe from Baluan Island).*

2.1 Dried Kava products

Kava plants produce with Good Agricultural Practices for at least five years of growth. The kava are harvests and with Good Manufacture Practices, thoroughly cleaned with water to remove soil residues. The kava rhizomes of the main stump and basal stems including one node are removed, peeled and combine with the unpeeled lateral roots. The fresh kava products are sliced and sun dried or hot air dried or dried using other recognized methods. The kava dried products should have a maximum moisture content of 12%, and a minimum total kava lactones 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 dried kava products are then powdered and packaged.

3. Safety of kava products

The safety of kava products stems from the long-term experience of safe use by the people of the Pacific countries that defines the kava method of production, plant species, plant varieties, plant maturity, plant parts to be processed and the water extraction process. The safety of the kava products should be closely adhere to the history of safe use in the Pacific as reflected in the criteria layout in (2) and substantiated with scientific evidences. The kava species and varieties can be verified by the HPLC analysis of kava into chemotype groups, that is, the proportion of the kava's six main lactones: desmethoxyyangonin, DMY; dihydrokavain, DHK; yangonin, Y; kavain, K; dihydromethysticin; DHM; and methysticin, M (Tesche and Lebot 2011).

This will avoid misidentifications of kava species or varieties, adulterants, impurities and contaminants. The daily use of traditional kava drinks has been evaluated[11] and recommended a maximum daily intake of 250 mg kava lactones per day for not more than 4 weeks. These results are supported scientifically by SPC[12], WHO[13] and many reports[14&15] and further supported by established national legislations[16&17] and by food standards[18]. Based on available scientific information it can be inferred that kava as a traditional beverage is safe for human consumption.

[11] Teschke and Sculze (2010) Risk of Kava Hepatoxicity and the FDA consumer Advisory. J. Am. Med. Assoc. 304, 2174-2175
[12] SPC (2001). Pacific Kava. A Producer Guide
[13] WHO (2007): Assessment of the risk of hepatotoxicity with kava products,
[14] Tesche and Lebot (2011) Proposal for a Kava Quality Standardization Code. Food and Chemical Toxicology 49: 2503-2516
[15] National Botanical Research Institute. Toxicological Evaluations of Kava Drink.
[16] Vanuatu Kava Act 2002, amended 2008
[17] Therapeutic Good Administrations (2005). Australian Government.
[18] Food Safety Australia New Zealand (2005). Technical Report Nos. 30

4. 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. 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 show 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 standards.

Therefore, due to the increasing volume and value of the kava products trades in the Pacific, it quite timely and critical to establish a regional standard for kava to protect consumer's health and also to ascertain it's 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 increase and then decrease to a new equilibrium price which will also increase the earnings of farmers respectively by two to ten folds. The countries and the farmers producing of kava in the Pacific will also increase likewise.

Table 1. Total value of export of kava products from Vanuatu, Fiji, Tonga and Samoa in US dollars

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
					Value of Kava Export in US $					
Vanuatu	-	3,346,008	1,663,501	3,733,838	3,949,289	4,405,848	6,271,777	-	5,127,243	6,210,047
Fiji	5,221,103	2,402,352	886,356	845,839	1,293,357	1,692,408	2,332,303	2,626,256	3,104,500	2,233,618
Tonga	216,557	165,596	263,799	273,738	482,227	217,908	408,954	408,640	140,771	427,635
Samoa	-	-	10,256	25,435	16,925	2,083	2,726	32,538	8,613	-
Total	5,437,660	5,913,956	2,823,912	4,878,850	5,741,798	6,318,247	9,015,760	3,067,474	8,381,127	8,871,300
US$/Ton[b]	6,335	4,300	3,658	4,158	5,578	7,369	10,862	11,755	14,363	11,636

Source: Secretariat of Pacific Community Trade Statistic database (// www.pacifictradestatics.com)

[b] Calculated from the volume and value given

Table 2. Total volume of kava products exported from Vanuatu, Fiji, Tonga and Samoa in metric tons.

	2000	2001	2002	2003	2004	2005	2006	2007	2008	2009
					Volume of Export in metric tons					
Vanuatu	-	911	603	982	842	689	575	0	356	485
Fiji	836	443	138	144	143	149	203	186	197	236
Tonga	22	21	29	27	43	19	48	47	27	41
Samoa	-	-	2	21	2	0	4	28	3	-
Total	858	1,375	772	1,173	1,029	857	830	261	580	762
Area (ha)[a]	143	229	129	196	172	143	138	43	97	127

Source: Secretariat of Pacific Community Trade Statistic database (// www.pacifictradestatics.com)

[a] Estimated area from 2.5 kg dried kava/plant

Table 3. The countries and the total volume of kava products imported from 2000 to 2009

Importing Country	Amount (Tons)	Amount (%)
Fiji	2733.86	32.18
New Caledonia	1680.61	19.78
USA	1479.24	17.41
Germany	821.50	9.67
New Zealand	549.26	6.47
Australia	457.99	5.39
Kiribati	209.82	2.47
Spain	131.36	1.55
China	110.48	1.30
France	61.57	0.72
Saudi Arabia	32.03	0.38
Canada	30.76	0.36
Futuna	29.10	0.34
A Samoa	27.91	0.33

Switzerland	24.20	0.28
Tonga	19.38	0.23
Vanuatu	19.14	0.23
Samoa	12.97	0.15
Unspecified	12.78	0.15
Japan	7.73	0.09
UK	7.65	0.09
India	6.55	0.08
PNG	5.40	0.06
Tokelau	2.50	0.03
Nauru	2.09	0.02
Algeria	2.06	0.02
Ukraine	2.00	0.02
Marshal	1.87	0.02
Korea	1.87	0.02
Tuvalu	1.72	0.02
Serbia	1.38	0.02
Christmas	1.08	0.01
Cook Is	1.02	0.01
Italy	1.00	0.01
Iceland	0.87	0.01
Somalia	0.61	0.01
Indonesia	0.56	0.01
Djibouti	0.50	0.01

3. The Main Aspects to be covered:

If the CCNASWP should decide to recommend to the Codex Alimentarius Commission to consider and approve this proposal for new work, a CCNASWP Codex Standard for Kava will be drafted in accordance with the Codex uniform layout for food products. The proposed standard will cover kava varieties, plant parts, kava products in the form of frozen fresh, dried (in form of chips or roots), powdered and water extract, process, quality, safety, labeling in order to provide certainty and assurance to consumers.

4. 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 population of Pacific Islanders in Australia, New Zealand and the United States, export of kava products has increased to New Zealand, Australia and the United States has increased in the past 30 years to ensure that their traditional drink is readily available in their new country of residence. Traditionally, man is the main consumer of kava, but socially, women also partake in drinking kava too. Hence, kava has become one of the major export commodities and foreign exchange earnings for the PICs.

Since the export of kava is important to the economic development of the PICs, a major income to thousands of small farm holders, and the fact that there are known kava varieties that are not safe for direct consumption. From Table 1, there is a significant volume and pattern of trade between countries.

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

Several Pacific Island countries are developing national standards for kava. In 2001, the Secretariat to the Pacific Community published a Guide for Production of kava (SPC, 2001). Vanuatu has enacted the Kava Act 2002 amended in 2008, with Samoa, Tonga and Fiji undergoing a similar process. The Pacific Island kava producing countries have committed to establish uniform legislations/standards at national level[19] to facilitate trade and avoid trade impediments between countries.

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 hepatoxicity from commercial acetonic 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

[19] International Kava Executive Council (2008)

quality control measures standardized across the producing countries with agreed standard operating procedures should be instituted for growth, harvesting and processing of the kava root".[20]

i. Regional market potential, a significant amount of kava is being traded within the countries of the region (see above). All kava being imported in developed countries, such as Japan, NZ, Canada, China, Europe and USA is sourced exclusively from the Pacific Island Countries.

ii. Impediments to trade are the lack of uniform regional standardization which should eliminate the quality problems of the kava raw material considered as the concern for the safety of consumers. The standards should then be the basis of kava legislation to assure the quality of kava products for trade.

iii. Kava is highly amenable to standardization, because the part of the plant used for food purposes is 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 products. The codex standard will promote harmonization of national standards and thereby contribute to the facilitation of international trade in kava products.

5. Relevance to the Codex Strategic Objectives:

The proposed standard meets the criteria outlined in Goals 1, 2 and 5 of the Codex Strategic Plan.[21]

Goal 1: It will contribute 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 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.

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 Risk assessment for kava products[22].

Goal 5: It will promote maximum and effective participation of members – Pacific Island Countries are already collaborating on a regional basis through the International Kava Executive Council (IKEC) and electronic/physical working groups and this will be continued and further intensified in the development of the proposed standard.

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 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, labeling, 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. Modalities of use with regards to maximum daily kavalactone dose and duration of usage.

[20] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, Geneva 2007, p.63
[21] CODEX ALIMENTARIUS COMMISSION STRATEGIC Plan 2008–2013
[22] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, Geneva 2007

8. Identification of Any Need for Technical Input to the Standard From External Bodies so That This Can Be Planned For:

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"

Start Date: 2012

Proposed Date for Adoption at Step 5: 2014

Proposed Date for Adoption by the Commission: 2016

References

Codex Alimentarius Commission (FAO/WHO): 30th Session of CAC, ALINORM 07/30/32, Rome, Italy, 2007

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National Botanical Research Institute. Toxicological Evaluations of Kava Drink. Uttar Pradesh, India, 2008

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