African, Caribbean and Pacific Group of States

"Scientific and Legal assistance for the Development of a Quality and Safety Standard for Kava Production and Trade in the Pacific Region"

"ACP-EU TBT PROGRAMME"

(REG/FED/022-667)

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Final Report

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FRATINIVERGANO
EUROPEAN LAWYERS

TBT Programme implemented by AESA • Avenue de Tervuren 32, box 31 • 1040 Brussels • Belgium
Tel: +32-2 739 00 00 • Fax: +32-2 739 00 09 • e-mail: contact@acp-eu-tbt.org • www.acp-eu-tbt.org

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1. INTRODUCTION

The following report is the Final Report, drafted and submitted as mandated under the Terms of Reference (hereinafter, ToRs) of the contract: "*Scientific and Legal assistance for the Development of a Quality and Safety Standard for Kava Production and Trade in the Pacific Region*" of the ACP-EU TBT PROGRAMME (REG/FED/022-667), Project code: 042/14.

Kava is an important crop of the South Pacific Island Countries. Due to the calming and relaxing properties of certain active ingredients of the plant, kava extracts have been used for the development of herbal medicinal products for the treatment of mostly situational anxiety, in particular in Europe, where kava was exported.

In the second half of the 1990s, kava exports climbed sharply, and the supply of kava roots became a challenge. This situation led to the organisation of a controlled cultivation project in Vanuatu, preceded by a screening of kava varieties. The variety selected for cultivation was the '*two-day*' type *Palisi*, which for the contractor of the cultivation had the unique advantage of featuring high contents of kavalactones (the active constituents responsible for the relaxing effect), a high biomass upon harvesting of the roots, and the possibility of harvesting already after one year from plantation, whereas '*noble*' kava varieties normally stay in the ground for at least two to three years.

'*Two-day*' kava is a designation of kava varieties with unpleasant effects, causing nausea, headaches and flashbacks, with such effects lasting for two days. As a consequence of the economic advantages of growing '*two-day*' kava, *Palisi* is by now the most far-spread '*two-day*" variety in Vanuatu. There are, however, more varieties deemed unsuitable for daily kava drinking, varieties not necessarily classified as '*two-day*' kava, such as '*wild-type*' kava (*Piper wichmanii*) or medicinal kavas. Within this report these kava types including '*two-day*' kava are generally classified as '*non-noble*' kava.

Kava products containing extracts manufactured from '*two-day*' kava came to the Swiss market in 1999, and in the following twelve months a series of nine case reports of liver toxicity was observed, all related to the intake of said kava preparations. It has as yet not been formally proven that '*two-day*' kava was in fact the causative factor of the case reports. There are circumstantial indications for further deviations from the usually consumed quality of kava in traditional kava drinking with a potential on safety, especially the use of stem peelings. Stem peelings would not be considered "*kava*" in the kava-producing countries, but to date, kava stem peelings from Vanuatu serve as a cheap source of kavalactones for international markets. Their export is banned under the Vanuatu Kava Act[1], but quite obviously this has not stopped its trade. The reasons identified during the 2012 ACP-MTS Project were problems with the enforcement of the legislation (*inter alia*, due to a lack of analytical capacities and applicable standards), but also with the legal loopholes in the Vanuatu Kava Act through the permission of exports of '*non-noble*' material on explicit demand of the customer[2].

On the basis of the alleged liver toxicity of kava, marketing authorisations of kava-extract containing

[1] Republic of Vanuatu. Kava Act No. 7 of 2002; amended by Act No.6 of 2015.

[2] Bovoro T., Draft National Kava Strategy Vanuatu 2015-2025. IFS Pacific, 2015.

products were suspended and withdrawn in Germany through four decisions, the first issued in June 2002 and the most recent one issued in 2012, of the Bundesinstitut für Arzneimittel und Medizinprodukte (the German Federal Institute for Drugs and Medical Devices, hereinafter, "*BfArM*"), the German regulatory authority responsible for the monitoring of risks related to medicinal products. These decisions severely affected the ability of kava-exporting Pacific Islands Countries to export kava to the European Union (hereinafter, the "*EU*"). A number of other European countries, in fact, followed Germany and imposed similar measures. As a consequence of the EU measures against kava, the worldwide markets severely suffered from the tainted reputation of kava.

In 2011/2012, the EU-funded ACP MTS Project "*Establishment of health and safety standards for the production and export of kava-based products (Ref: 9 ACP RPR 140-039/11)*" (hereinafter, the 2012 ACP-MTS Project) was carried out by *FratiniVergano – European Lawyers* (hereinafter, FratiniVergano) with Dr. Mathias Schmidt and Mr. Paolo Vergano as two of the key experts. As a result of this project, it was established that quality standards of kava needed to be defined, standards allowing the differentiation between '*noble*' kava and '*two-day*' kava, in order to reconcile the practice of kava use and exports with the traditional experience of the accepted safety of '*noble*' kava. In March 2012, a "*High Level Conference*" on kava took place in Port Vila, Vanuatu. A decision was made for the definition of a regional standard for kava as a beverage in *Codex Alimentarius*. This regional standard should result in an internationally accepted definition of kava (*e.g.*, the definition of roots and peeled root stumps, but not of stem peelings), and define parameters for the analytical differentiation of '*noble*' versus '*two-day*' kava.

The regulatory decision of a withdrawal of marketing authorisations of kava-extract containing medicinal products in Germany was recently declared invalid through two court decisions of the Administrative Court of Cologne of June 2014[3] and of the Higher Administrative Court of Münster of 25 February 2014[4], which upheld the Cologne ruling (see Annex 1). The second ruling came into definitive effect on 10 April 2015, (*i.e.*, corresponding to the last day of the appeal period, with no appeal filed by the German regulatory authority). This development makes the task of defining quality specifications of '*noble*' kava more timely.

In order to understand the significance of the German court rulings, one must take a closer look at the formal chain of arguments used by the German authorities in the ban of kava. In a nutshell, the argument was not based on toxicity, but on an assumed lack of efficacy – not of kava as a traditional drink in the South Pacific, but of medications specifically authorised for the treatment of anxiety disorders. When the problem with potential toxicity was first observed, the German BfArM re-examined the existing proofs of efficacy (in the form of published clinical studies) in the light of the most recent guidelines for the performance of clinical trials. Their conclusion was that there was not a single clinical trial, which would today be deemed acceptable as a pivotal proof of the efficacy of kava medications in a marketing authorisation procedure. With efficacy thus declared unproven, BfArM even said that kava products were not efficacious against anxiety. With efficacy balanced against a potential risk in marketing authorisation procedures, the assumed non-existing efficacy would automatically tip the balance towards a heavier

[3] Administrative Court of Cologne: Court ruling VG 7K 6969/11.
[4] Higher Administrative Court of Münster: Court ruling 13A 1374/14 / 7K 6972/11 Köln.

weight of the risk, as in such a case any risk would outweigh the benefit. As a consequence, the kava ban was not issued because of a relevant risk, but rather because of an assumed negative benefit-to-risk ratio. This was, however, not what was communicated to the public, as in the mediatic discussion of kava only the risk side was perceived and blown up to enormous proportions, which were not supported by facts and scientific evidence.

Both German courts ruled that the BfArM's approach was inappropriate and not covered by German law. In particular, the Higher Administrative Court of Münster did not accept the conclusion of a lack of efficacy of kava extract as an anxiolytic medication. Both courts also found the evidence of risk rather non-convincing, and in the light of exposure data quite irrelevant. The court rulings re-established the status of the marketing authorisations of kava-extract containing products to their status in 2002.

Although the court rulings thus lifted the ban of the German kava products, the corresponding medications are still far from coming back to the markets. The reasons for the delay are again regulatory issues about the kind of warnings and precautionary measures to be applied, and questions related to the quality of kava, which still remain open. Whereas since 1999 (the year of the first occurrence of liver case reports) the discussion of questions of kava quality had always been avoided by BfArM, the court rulings now brought the issue back. Kava quality, especially the definition of '*noble*' kava, is therefore currently the most important obstacle for a return of kava products to the German market. Germany may never have been a noteworthy importer of kava roots in comparison with other international markets, but the devastating signal coming from Germany in 2001/2002 through the drug safety protocol caused huge damage to the South Pacific economies. Likewise, the signal of the German measures against kava being lifted by the courts is already inspiring new kava production activities in the South Pacific.

Against this background, this consultancy has been conceived with the overall objective of enhancing the participation of kava-producing Pacific countries in international trade and of addressing current technical barriers to trade in order to improve exports. The purpose is to address the specific technical barriers to trade faced by kava producers, processors and exporters by means of improving the quality and safety of kava and kava-based products. The results to be achieved by this consultancy (as mandated by the ToRs) were two-fold:

- On the scientific and quality/safety side, to complete the scientific sampling of all trade-relevant kava cultivars and ensure that kava is produced and processed according to good agricultural practices, and recognised by FAO/WHO Codex regional and international standards; and
- On the legal and regulatory side, to contribute to the definition and preparation of the draft kava regional/international standard, based on the results achieved through the scientific assessment, for it to be put forward for adoption within the FAO/WHO Codex regional process, more specifically in the Codex Coordination Committee North America South West Pacific (hereinafter, "*CCNASWP*").

The **specific activities** (as defined by the ToRs) to be conducted in implementing this project were:

- **The collection and classification of all relevant kava cultivars for sampling and scientific assessment**: This activity required the conduct of documental analysis, consultations with stakeholders and field missions to five Pacific Countries (*i.e.*, Fiji, Samoa, Solomon Islands, Tonga and Vanuatu). Hawaii was added to this list for practical considerations. The mission to Hawaii has been factored-in the Inception Report and was approved by the PMU and the Beneficiary;
- **Scientific assessment and analysis of the samples of kava cultivars**: This activity included home-based scientific analysis, and the assessments and sampling by the scientific expert and the laboratory expert in a specialised and GMP-certified laboratory, in order to draft the scientific report with the required toxicological profile, hepatotoxicity implications, cultivar identification and technical specifications to be reflected in the FAO/WHO Codex kava standard;
- **Stakeholders' meetings** with kava growers, kava exporters, trade and farming associations, scientist working on kava quality and kava standard projects, and governmental authorities. The aim of these meetings was to disseminate the message about the importance of a kava standard and kava quality, and to find support for the submission of a kava standard to *Codex Alimentarius*; and
- **Drafting the appropriate legislative and regulatory language**. This activity was carried-out for purposes of defining the regional/international FAO/WHO Codex kava standard, to be proposed to the FAO/WHO CCNASWP for its consideration, and of assisting Pacific Island Governments in the definition, adoption and implementation of parallel national standards or technical regulations. This activity took due note of the 2014 WHO report "*Kava: A review of the safety of traditional and recreational beverage consumption*", which in a general way defines a dual approach through analytical parameters for the identification of '*noble*' kava, and through agricultural harvesting and processing protocols. The drafting of the Codex standard based on the scientific assessment under the project needs, after the finalisation of the project, to be submitted to the EWG on kava, to develop the discussion paper and to be prepared ahead of the next (the fourteenth) session of the CCNASWP, which is going to be held in September 2016.

All these expected results and activities were conducted in constant coordination among the experts, the Pacific stakeholders (public and private), the Beneficiary (particularly Vanuatu's Embassy to the EU) and the TBT Programme Management Unit (hereinafter, the "*PMU*"), aiming at ensuring that the project be a successful and meaningful step forward in the Pacific Countries' struggle to regain full trading opportunities for quality kava. The timeline for the implementation of this work was of seven months, from March to October 2015.

Section 1 of this final report provides an introduction to the consultancy.

Section 2 describes which activities were carried-out in line with the methodology (*i.e.,* documental analysis; collection of relevant kava cultivars; stakeholders' meetings and consultations).

The kava sample analysis is described in **Section 3** of this report and its corresponding annexes, with the respective results.

Section 4 of this final report addresses the draft FAO/WHO Codex standard for submission to the CCNASWP, i.e.:

- Background;
- FAO/WHO Codex kava standard;
- History of a kava standard in Codex: work undertaken in the CCNASWP;
- Kava: food or drug?;
- Applicable general Codex standards and examples of other standards;
- Further regulations to be considered; and
- Next steps in relation to the development of a Codex standard for kava).

Section 4 provides, in particular, a draft proposal for a Regional Standard for Kava and Kava Products taking into consideration the analytical results.

Finally, the main conclusions are given in **Section** 5.

2. IMPLEMENTATION

FratiniVergano and its international experts have been conducting the relevant activities in line with the following outline **methodology**, taking full account of the ToRs, the "*Organisation and Methodology*" submitted in FratiniVergano's bid and of the Inception Report approved by the PMU and the Beneficiary.

2.1. Methodology

FratiniVergano implemented the project by means of a flexible approach that was largely based on four phases and that was meant to guarantee the full attainment of all stated objectives and expected results.

1) A **first phase** (March 2015), during which the briefing meeting with the PMU and Beneficiary was held at the PMU's office in Brussels (17th March 2015), the work-plan was defined and the Inception Report was submitted (29th March 2015), and the required coordination among the three key experts was achieved.

2) A **second phase** (end-March to end-May 2015), divided into two sub-phases:

   2a) In the first part of the second phase, home-based preliminary research was conducted and sampling organised and streamlined in order to increase the efficiency and the outcome of the sampling process in the South Pacific kava producing countries. Documental analysis and the evaluation of recent scientific publications was started immediately after the Inception Report and carried out on a rolling basis during the process of compilation of data from the laboratory analyses.

   2b) The second part of the second phase included a mission of the Scientific Expert (KE1) in Vanuatu, followed by other four Pacific Countries (*i.e.*, Fiji, Tonga, Samoa and Solomon Islands) and Hawaii, USA. The mission to Hawaii gained even more importance as the situation after the cyclone Pam made the gathering of many otherwise important cultivars in Vanuatu highly difficult. Many of these cultivars, which originally came from Vanuatu, can be found in collections and cultivations in Hawaii. The missions to the different locations included visits to the growing sites for the identification of the varieties, on-the-ground meetings, the collection of local information and kava samples, and the coordination with all stakeholders. The samples collected and documented during this phase were directly transferred to the laboratories involved in the analyses.

3) A **third phase** (mid-May to end of September 2015), during which the bulk of the scientific analysis and assessments mandated under Section 4.2 of the ToRs (Activity 1.2) were conducted, largely in a highly specialised laboratory, by the Laboratory Expert (KE2) working in close coordination with KE1. The scientific expert provided a framework of analytical specifications to be included in a quality definition of kava in a draft regional/international FAO/WHO Codex kava standard. Based on the technical specifications evolving through the

scientific assessments, the Legal Expert (KE3) started to draft the legislative and regulatory language for purposes of defining the regional/international FAO/WHO Codex kava standard and assisting the Pacific Islands Governments in the definition, adoption and implementation of parallel national standards and technical regulations. Following the drafting of the Interim Report, a second coordinating meeting among Key Experts was held.

4) A **fourth and final phase** (October 2015), during which the results of the consultancy were compiled and the Final Report was drafted for formal submission by FratiniVergano to the beneficiary and the TBT PMU, with all activities brought to a conclusion.

2.2. Introduction

The 13-year old "*de facto ban*" of kava products in Germany was just legally overcome through court decisions of 14 June 2014[5] and 25 February 2015[6] – decisions achieved, *inter alia*, by the active participation of KE1 as a scientific expert in the litigations[7,8,9,10,11]. The court ruling became final, when the deadline for a possible appeal by the German Institute for Drugs and Medical Devices ("*Bundesinstitut für Arzneimittel und Medizinprodukte*", BfArM) expired on 10 April 2015.

The return of kava in the German market is moving the question of kava quality to the centre of attention. It is now important that an international kava standard differentiating between '*noble*' and '*non-noble*' kava be defined. The results of the current project must, therefore, also serve for the information of the health authorities of the importing countries (including Germany) on the available options of kava quality determination. The lack of a standard is already creating new obstacles, which KE1 has already discussed in scientific circles on different occasions[12,13,14,15].

[5] *Supra*. See also: Burkhard Sträter, The risk benefit assessment of kava-kava is at least not negative when compared with benzodiazepines. Pharma R (9), 1-7; 2014.
[6] *Supra*.
[7] OVG Münster: Widerruf der Zulassung von Kava-Kava-Arzneimitteln rechtswidrig. Press release of the Higher Administrative Court, 25 February 2015.
[8] J. Ziegler, Vorinstanz bestätigt – Kava-Kava-Widerruf war rechtswidrig. DAZ Online 25 February 2015.
[9] M. Schmidt, German court ruling reverses kava ban; German regulatory authority appeals decision. HerbalGram 103: 38-43 (2013).
[10] K. Kraft, Verwaltungsgericht Köln kippt das Kavaverbot. Z Phytother 35(4): 186-189; 2013.
[11] K.Kuchta, M. Schmidt, A. Nahrstedt, German kava ban lifted by court: The alleged hepatotoxicity of kava (Piper methysticum) as a case of ill-defined herbal drug identity, lacking quality control, and misaimed regulatory politics. Planta Med., accepted for publication (2015).
[12] M. Schmidt, Defining a standard for kava roots (Piper methysticum) used in beverages. KavaCon 2015 – International Conference on Kava. Honolulu, Hawaii, 25 July 2015.
[13] M. Schmidt, Kava: Nutzen-Risikobewertung und deren Konsequenzen. Wissenschaftliches Symposium der Zeller AG: Die Leber als Zielorgan von Phytopharmaka. Romanshorn (Switzerland), 4 September 2015.
[14] M. Schmidt, Kava: Vom Haltesignal zum Licht am Ende des Tunnels. Phytokongress 2015, Gesellschaft für Phytotherapie. Warnemünde (Germany), 9 October 2015. Abstract published in Z Phytother 36(Suppl. 1):S18; 2015.
[15] M. Schmidt, Second German court ruling on kava: Government's ban again declared void. A detailed account of the assessment and regulation of kava in Germany. HerbalGram, submitted; 2015.

2.3 Documental Analysis

The next submission of a draft standard to CCNASWP should cover data on the safety and quality of kava. The call for safety data is most likely based on the widespread belief that the ban of kava-containing medicinal products in Germany was caused by safety concerns. In fact, it was not, as became clear in the German litigation with court rulings declaring the ban illegal[5,6], and the subsequent publications explaining the mechanisms by which the risk-benefit profile of kava medications had been declared negative by the German drug regulatory authority[9,10,11]. This mechanism was predominantly based on declaring kava-containing medicinal products the equivalent of a new and unknown chemical entity, thus applying the requirement of efficacy of the latest standard to drugs for which the efficacy had been demonstrated in older studies. No efficacy studies according to latest standards automatically meant an unproven efficacy, which, combined with the more or less completely undiscussed possibility of adverse effect, resulted in a negative risk-benefit profile and hence the mandatory revocation of marketing authorisations.

This mechanism had already been described in the introduction to the 2012 ACP-MTS report "*Establishment of health and safety standards for the production and export of kava-based products (Ref: 9 ACP RPR 140-039/11)*". The same report also discussed at length the safety data on kava, with the result that there was no relevant risk known for the consumption of '*noble*' kava in usual quantities.

For this consultancy, the literature published between 2011 and 2015 was screened for new data on the quality and safety of kava. The search in the scientific literature database PubMed resulted in 123 hits, which were then hand-searched for potentially relevant publications in the context of botany, pharmacology, pharmacokinetics, toxicology and clinical studies. Special attention was given to *in vivo* studies.

2.3.1 Kava Quality and Harvesting Protocols

As will be discussed in the section describing the field missions, Vanuatu, Fiji and Hawaii have already worked out detailed descriptions of their local varieties. Tonga is currently re-activating an HACCP protocol, introduced shortly before the ban of kava in Europe. Harvesting and processing protocols are also planned for Vanuatu, Fiji and Samoa, but it will take some time for them to be established.

2.3.2 Pharmacology

Pharmacological studies with kava preparations may serve for drawing conclusions with respect to safety, especially when kava or isolated constituents are applied in animal studies. Although these studies are not formal toxicological studies, the fact that the animals tolerated a given dose over a certain period of time is an important information.

Johnson et al. (2011) examined the tumour-preventive effects of kava and flavokavins in mice[16]. Commercial kava at 10 mg/g of diet (during 22 weeks) was effective, so were the flavokavins. The latter, however, were less effective than their abundance in the kava sample, which led the authors to the conclusion that other constituents in kava must participate in the effect. The liver and liver function tests were monitored in this study, with no hints to liver toxicity.

Li et al. (2012) demonstrated cancer-preventive effects of kava and flavokavin in mice[17]. The kava used in this study was a commercial preparation, for which the analysis points to a '*non-noble*' kava material. Whereas the treatment with flavokavin B at an intraperitoneal dose of 200 mg/kg for 28 days did not induce toxicity, the corresponding kava extract at an oral dose of 6 g/kg for 18 days led to some changes in liver histology, which points to a yet unknown other constituent of kava as a potential (albeit rather weak) hepatotoxin in this '*non-noble*' kava material.

Triolet et al. (2012) examined cancer-preventive effects of kava ethanol extract and its polar and non-polar fractions. This was a 14 week study in rats with oral exposure. No hepatic lesions were found in the animals at the end of the study, suggesting that kava is safe to consume[18].

Abu et al. (2013) reviewed the pharmacological properties of flavokavins, mainly their anti-inflammatory and anti-cancer effects[19]. They also examined the toxicological effects of flavokavins, but cannot confirm toxicity of flavokavin B.

Liu et al. (2013) demonstrated cancer-preventive effects of flavokavin A in mice in a 318-day study with exposure to 6 mg flavokavin A per gram of food[20]. No noticeable toxicity was observed.

Leitzman et al. (2014) attributed cancer-preventive effects in mice to the fraction of kavalactones[21]. The applied dose was 5 mg/g of diet, with no toxicity observed.

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[16] Johnson TE, Hermanson D, Wang L, Kassie F, Upadhyaya P, O'Sullivan MG, Hecht SS, Lu J, Xing C., Lung tumorigenesis suppressing effects of a commercial kava extract and its selected compounds in A/J mice. Am J Chin Med 39(4): 727-42; 2011.

[17] Li X, Liu Z, Xu X, Blair CA, Sun Z, Xie J, Lilly MB, Zi X., Kava components down-regulate expression of AR and AR splice variants and reduce growth in patient-derived prostate cancer xenografts in mice. PLoS One 7(2): e31213; 2012.

[18] Triolet J, Shaik AA, Gallaher DD, O'Sullivan MG, Xing C., Reduction in colon cancer risk by consumption of kava or kava fractions in carcinogen-treated rats. Nutr Cancer 64(6): 838-46; 2012.

[19] Abu N, Ho WY, Yeap SK, Akhtar MN, Abdullah MP, Omar AR, Alitheen NB, The flavokawains: uprising medicinal chalcones. Cancer Cell Int. 13(1): 102; 2013.

[20] Liu Z, Xu X, Li X, Liu S, Simoneau AR, He F, Wu XR, Zi X., Kava chalcone, flavokawain A, inhibits urothelial tumorigenesis in the UPII-SV40T transgenic mouse model. Cancer Prev Res 6(12): 1365-75; 2013.

[21] Leitzman P, Narayanapillai SC, Balbo S, Zhou B, Upadhyaya P, Shaik AA, O'Sullivan MG, Hecht SS, Lu J, Xing C., Kava blocks 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone-induced lung tumorigenesis in association with reducing O6-methylguanine DNA adduct in A/J mice. Cancer Prev Res 7(1): 86-96; 2014.

Narayanapillai et al. (2014) demonstrated antitumor-effects of the kavalactone dihydromethysticin in mice fed with a diet containing 0.05 mg DHM per gram of diet[22]. No toxicity was observed.

Tawfiq et al. (2014) found beneficial effects of 100 and 200 mg/kg of an aqueous kava extract in mice treated with benzodiazepines[23]. The seven-day treatment did not cause toxicity or impairment of motor coordination – kava even improved the reduced motor coordination induced by diazepam. Furthermore, kava ameliorated changes in liver function tests induced by diazepam. No impact on liver transaminases was found despite of the rather high dose of kava extract.

Abu et al. (2015) reported anti-tumour effects of flavokavin A in mice[24]. This observation fits to epidemiological observations of a lower cancer incidence with the consumption of kava.

The same group also examined anti-tumour effects of synthetic flavokavin B in mice[25]. 50 mg/kg daily for 28 days did apparently not cause toxicity, which contradicts other reports cited in the 2012 ACP-MTS report.

Abu et a. (2015) also examined flavokavins through *in vitro* assays on cytotoxicity, next to their anti-inflammatory effects in mice[26]. Neither flavokavin A nor flavokavin B caused mortality, and all mice were observed as behaving normally after the period of treatment.

2.3.3 Pharmacokinetics

Pharmacokinetic interactions (*i.e.*, an influence of kava on the metabolisation of other medications) have been proposed as potential causes of liver toxicity. Corresponding studies are, therefore, important for the discussion. The studies published between 2011 and 2015 demonstrate the possibility of such an effect, however, the metabolic systems with Cytochrome P450 isoforms 1A and 2E are only minor pathways in drug metabolisation, and a potential effect of kava on this level could not serve as an explanation for the case reports observed in Switzerland and Germany.

Li et al. (2011) found an activation of the metabolic system Cytochrome P450 1A1 through the kavalactone methysticin *in vitro*, which the authors think is one of the mechanisms of the anti-cancer effect of kava[27].

Zadoyan and Fuhr (2012) and Wanwimolruk et al. (2014) reviewed the data on interactions of kava on the

[22] Narayanapillai SC, Balbo S, Leitzman P, Grill AE, Upadhyaya P, Shaik AA, Zhou B, O'Sullivan MG, Peterson LA, Lu J, Hecht SS, Xing C. Dihydromethysticin from kava blocks tobacco carcinogen 4-(methylnitrosamino)-1-(3-pyridyl)-1-butanone-induced lung tumorigenesis and differentially reduces DNA damage in A/J mice. Carcinogenesis 35(10): 2365-72; 2014.

[23] Tawfiq RA, Nassar NN, El-Eraky WI, El-Denshary ES, Enhanced efficacy and reduced side effects of diazepam by kava combination. J Adv Res 5(5): 587-94; 2014.

[24] Abu N, Mohamed NE, Yeap SK, Lim KL, Akhtar MN, Zulfadli AJ, Kee BB, Abdullah MP, Omar AR, Alitheen NB, In vivo anti-tumor effects of flavokawain A in 4T1 breast cancer cell-challenged mice. Anticancer Agents Med Chem 15(7): 905-15; 2015.

[25] Abu N, Mohamed NE, Yeap SK, Lim KL, Akhtar MN, Zulfadli AJ, Kee BB, Abdullah MP, Omar AR, Alitheen NB. In vivo antitumor and antimetastatic effects of flavokawain B in 4T1 breast cancer cell-challenged mice. Drug Des Devel Ther 9: 1401-17; 2015.

[26] Abu N, Mohameda NE, Tangarajoo N, Yeap SK, Akhtar MN, Abdullah MP, Omar AR, Alitheen NB. In vitro Toxicity and in vivo Immunomodulatory Effects of Flavokawain A and Flavokawain B in Balb/C Mice. Nat Prod Commun 10(7): 1199-202; 2015*Ibid.*

[27] Li Y, Mei H, Wu Q, Zhang S, Fang JL, Shi L, Guo L, Methysticin and 7,8-dihydromethysticin are two major kavalactones in kava extract to induce CYP1A1. Toxicol Sci 124(2): 388-99; 2011.

level of cytochrome P450 enzymes. They advise caution with co-medication metabolized via cytochrome P450 isoforms 1A2 and 2E1[28,29].

Zenger et al. (2015) examined the metabolism of flavokavins A-C by human liver microsomes[30]. There is no immediate relation with toxicology, but the knowledge of metabolic pathways may become important in the debate of the potential toxicity of higher doses of flavokavin B.

2.3.4 Toxicology

A number of studies published between 2011 and 2015 explicitly examined toxicological aspects of kava and isolated constituents. None of the studies gave convincing evidence for the existence of kava toxicity. The few studies suggesting toxicity were potentially related to flavokavin B, but the '*nobility*' of the kava used in the studies remains doubtful. In addition, flavokavin B does not appear to have relevant toxicity in dose ranges achievable with kava.

Chen et al. (2011) in a review attribute liver toxicity by kava to a depletion of glutathione in the liver[31]. This hypothesis would, however, not explain why there were not much more case reports, as this would be a mandatory and dose-dependent mechanism.

Olsen et al. (2011) reviewed the proposals for mechanisms of kava-induced liver toxicity, but cannot find convincing evidence for any of the proposals (direct toxicity of kavalactones, inhibition of induction of major metabolizing enzymes, formation of reactive metabolites). They concluded that to date, there remains no indisputable reason for the increased prevalence of kava-induced hepatotoxicity in Western countries[32].

Rowe et al. (2011) reviewed potential mechanisms of kava-induced liver toxicity[33]. The authors do, however, assume that all reported cases were in fact caused by kava, which is highly doubtful (see publications of Teschke et al.).

Teschke et al. (2011) called for a return to the basics of kava use (*i.e.*, the use of '*noble*' kava roots and peeled rhizomes only, a minimum plant age of five years, and the preferential use of water as an extraction

[28] Zadoyan G, Fuhr U, Phenotyping studies to assess the effects of phytopharmaceuticals on in vivo activity of main human cytochrome p450 enzymes. Planta Med 78(13):1428-57; 2012.
[29] Wanwimolruk S, Phopin K, Prachayasittikul V, Cytochrome P450 enzyme mediated herbal drug interactions (Part 2). EXCLI J 13: 869-96; 2014.
[30] Zenger K, Agnolet S, Schneider B, Kraus B, Biotransformation of Flavokawains A, B, and C, Chalcones from Kava (Piper methysticum), by Human Liver Microsomes. J Agric Food Chem 63(28): 6376-85; 2015.
[31] Chen XW, Serag ES, Sneed KB, Zhou SF, Herbal bioactivation, molecular targets and the toxicity relevance. Chem Biol Interact 192(3): 161-76; 2011.
[32] Olsen LR, Grillo MP, Skonberg C, Constituents in kava extracts potentially involved in hepatotoxicity: a review. Chem Res Toxicol 24(7): 992-1002; 2011.
[33] Rowe A, Zhang LY, Ramzan I, Toxicokinetics of kava. Adv Pharmacol Sci 2011: 326724; 2011.

solvent)[34,35,36]. The authors also pointed out that mould toxins may have played a crucial role, next to non-'*noble*' varieties with a high content of flavokavin B[37].

Vignier et al. (2011) reported an association between kava use and suicidal ideation in Kanak youth, whereas no such ideation was found in the non-Kanak population[38]. The authors do, however, not report the differences in suicidal ideation in non-kava drinking Kanak youths, and also fail to examine the question whether kava drinking was the consequence or the cause of depressed mood and suicidal ideations.

Yang and Salminen (2011) found a potentiation of acetaminophen-induced liver toxicity by kava extract in primary rat hepatocytes *in vitro*. The observations seem to suggest a depletion of glutathione as a mechanism of action[39]. Again, with this mechanism a much higher incidence rate of hepatotoxicity would have to be expected, as this would be a mandatory and dose-dependent toxicity.

Bodkin et al. (2012) reported a case of rhabdomyolysis in the context of the ingestion of a high dose of kava. The authors state that it is not clear whether the observation was due to kava or possibly an adulterant in the product[40].

Freshour et al. (2012) reported a case of a deep vein thrombosis and pulmonary embolism in a patient who took herbal preparations with at least 15 different herbal extracts, among them kava. The authors assumed an anticoagulant effect through the herbal remedies and suspected the plant coltsfoot, but would not exclude kava either because of assumed "*estrogenic effects*"[41]. This is the kind of report that creates more confusion than addition to knowledge through unsubstantiated hypotheses.

Teschke et al. (2012) reviewed case reports of liver toxicity associated with kava from the South Pacific, and compare these cases with the European case reports with kava extracts. They point out that the "*Pacific paradox*" stating that liver toxicity was entirely a European issue is not correct. There are also cases in the South Pacific and, as in Europe, they seem to be related to poor kava quality, such as adulterants, impurities and mould contaminants[42].

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[34] Teschke R, Sarris J, Glass X, Schulze J, Kava, the anxiolytic herb: back to basics to prevent liver injury? Br J Clin Pharmacol 71(3): 445-8; 2011.

[35] Teschke R, Lebot V, Proposal for a kava quality standardization code. Food Chem Toxicol 49(10): 2503-16; 2011.

[36] Teschke R, Qiu SX, Xuan TD, Lebot V, Kava and kava hepatotoxicity: requirements for novel experimental, ethnobotanical and clinical studies based on a review of the evidence. Phytother Res 25(9): 1263-74; 2011.

[37] Teschke R, Qiu SX, Lebot V, Herbal hepatotoxicity by kava: update on pipermethystine, flavokavain B, and mould hepatotoxins as primarily assumed culprits. Dig Liver Dis 43(9): 676-81; 2011.

[38] Vignier N, Lert F, Salomon C, Hamelin C, Kava drinking associated with suicidal behaviour among young Kanaks using kava in New Caledonia. Aust N Z J Public Health 35(5): 427-33; 2011.

[39] Yang X, Salminen WF, Kava extract, an herbal alternative for anxiety relief, potentiates acetaminophen-induced cytotoxicity in rat hepatic cells. Phytomedicine 18(7): 592-600; 2011.

[40] Bodkin R, Schneider S, Rekkerth D, Spillane L, Kamali M, Rhabdomyolysis associated with kava ingestion. Am J Emerg Med 30(4): 635; 2012.

[41] Freshour JE, Odle B, Rikhye S, Stewart DW, Coltsfoot as a potential cause of deep vein thrombosis and pulmonary embolism in a patient also consuming kava and blue vervain. J Diet Suppl 9(3): 149-54; 2012.

[42] Teschke R, Sarris J, Schweitzer I, Kava hepatotoxicity in traditional and modern use: the presumed Pacific kava paradox hypothesis revisited. Br J Clin Pharmacol 73(2): 170-4; 2012.

Askeroglu et al. (2013) counted kava among the pharmaceutical and herbal preparations that may contribute to dry eyes[43].

Xia et al. (2012) examined the generation of free radicals through ultraviolet radiation in the presence of kavalactones, with 5,6-dehydrokavain (a minor kavalactone) and yangonin inducing a low level of lipid peroxidation by free radicals. From these *in vitro* results, the authors drew the conclusion that kava may be phototoxic and photogenotoxic[44]. However, such a conclusions seems premature from an *in vitro* model without correlation to clinical observations.

Zhang et al. (2012) studied the influence of macrophage depletion on kavalactone damage in the perfused rat liver. The kavalactone concentration used for triggering hepatotoxicity in this model was 43.5 µM, slightly lower than the threshold for cytotoxicity. Damage to the liver is to be expected under such conditions. It was not the aim of this study to test whether liver toxicity can be induced by kava, but rather to examine the cellular mechanism of action. Destruction of liver cell macrophages reduced the toxic effects to a certain degree, which points to a participation of macrophages in the development of liver toxicity[45]. The kavalactones used in this study were racemic kavain and methysticin, not the naturally occurring compounds.

Bunchrontavakul et al. (2013) reviewed hepatotoxicity induced by herbal preparations, among them kava. They cannot identify a clear pattern of hepatotoxicity, and refer to the studies of Teschke pointing to potential quality issues and contaminations[46].

Dunnick and Nyska (2013) published the results of the NTP toxicity study[47], as already detailed from the NTP research reports in the 2012 ACP-MTS report[48,49]. The results did not indicate liver toxicity, and the material used for the study was not a regular kava extract, but a highly unusual preparation manufactured with supercritical carbon dioxide as an extraction solvent, where the lipophilic kava constituents are enriched.

Sarris et al. (2013) performed a randomized, placebo- and reference-controlled double-blind study to examine the effects of kava extract with 180 mg kavalactones on the ability do drive. The study was designed as a three-way cross-over trial with one week of wash-out between applications. Kava had no impairing effect on driving abilities when compared with kava, whereas the reference oxazepam (30 mg)

[43] Askeroglu U, Alleyne B, Guyuron B, Pharmaceutical and herbal products that may contribute to dry eyes. Plast Reconstr Surg 131(1): 159-67; 2013.
[44] Xia Q, Chiang HM, Zhou YT, Yin JJ, Liu F, Wang C, Guo L, Fu PP, Phototoxicity of kava - formation of reactive oxygen species leading to lipid peroxidation and DNA damage. Am J Chin Med 40(6): 1271-88; 2012.
[45] Zhang L, Rowe A, Braet F, Ramzan I,. Macrophage depletion ameliorates kavalactone damage in the isolated perfused rat liver. J Toxicol Sci 37(2): 447-53; 2013.
[46] Bunchorntavakul C, Reddy KR, Review article: herbal and dietary supplement hepatotoxicity. Liver Int 32(10):1543-56; 2013.
[47] Dunnick JK, Nyska A, The toxicity and pathology of selected dietary herbal medicines. Toxicol Pathol 41(2): 374-86; 2013.
[48] National Toxicology Program, Toxicology and carcinogenesis studies of kava kava extract (CAS No. 9000-38-8) in F344/N rats and B6C3F1 mice (Gavage Studies). Natl Toxicol Program Tech Rep Ser (571):1-186; 2012.
[49] Behl M, Nyska A, Chhabra RS, Travlos GS, Fomby LM, Sparrow BR, Hejtmancik MR, Chan PC. Liver toxicity and carcinogenicity in F344/N rats and B6C3F1 mice exposed to Kava Kava. Food Chem Toxicol 49(11): 2820-9; 2011.

showed some impairment[50].

Teschke et al. (2013) made a re-evaluation of case reports of liver toxicity with different plants, among them kava. They demonstrated that the *ad hoc* assessment procedure applied by the German regulatory authority is unsuitable for the assessment of liver toxicity, as in a high percentage of cases, potential alternative causes were evident[51].

Teschke et al. (2013) assume that mould formation and corresponding toxicity by aflatoxins was the trigger for liver toxicity in some case reports with kava. They call for better quality control, the use of roots and peeled rhizomes only, and the use of '*noble*' kava varieties only[52]. The culpability of mould toxins was subsequently put in doubt by Rowe and Ramzan (2012), who think that there is little similarity between kava hepatotoxicity and aflatoxicosis, and that in addition there is insufficient evidence for mould hepatotoxins[53]. There is, however, in fact, evidence for mouldy kava having been exported to Europe at the time of the kava case reports. Mould and aflatoxins could, therefore, still be a causal factor in some of the cases. However, it must be said that the number of cases where a causality by kava is to a certain degree possible or likely, is very low, and too low to draw valid conclusions as there is no emerging pattern.

Toohey et al. (2013) reported two cases of potential interactions of kava with psychotropic medication. In the first case, the patient experienced cardiac problems similar to an overdose of haloperidol prescribed for the treatment of bipolar affective disorder. In the second case, the patient had used kava together with ropinolole, which caused hallucinations. In both cases, the authors suggest an inhibition of cytochrome P450 metabolizing enzymes such as 1A2[54].

Hannam et al. (2014) examine the scaling of the skin in heavy kava drinkers called "*kava dermatopathy*". They propose an involvement of cytochrome P 450 enzymes in the development of skin scaling, but also mention that this condition is not considered a disease in kava-consuming countries[55].

Huynh et al (2014) reported a case of reversible sebotropic skin eruption observed after three weeks of kava ingestion in unknown quantities[56]. Skin eruptions following chronic use of elevated doses of kava are well known and thus not surprising. They are dose-dependent.

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[50] Sarris J, Laporte E, Scholey A, King R, Pipingas A, Schweitzer I, Stough C, Does a medicinal dose of kava impair driving? A randomized, placebo-controlled, double-blind study. Traffic Inj Prev 14(1):13-7; 2013.

[51] Teschke R, Schulze J, Schwarzenboeck A, Eickhoff A, Frenzel C, Herbal hepatotoxicity: suspected cases assessed for alternative causes. Eur J Gastroenterol Hepatol 25(9): 1093-8; 2013.

[52] Teschke R, Sarris J, Lebot V, Contaminant hepatotoxins as culprits for kava hepatotoxicity--fact or fiction? Phytother Res 27(3): 472-4; 2013.

[53] Rowe A, Ramzan I, Are mould hepatotoxins responsible for kava hepatotoxicity? Phytother Res 26(11): 1768-70; 2012.

[54] Toohey TP, Lu BY, Wada C, Toxic effects of psychotropics related to possible p450 enzyme inhibition by kava: report of 2 cases. Prim Care Companion CNS Disord 15(5); 2013.

[55] Hannam S, Murray M, Romani L, Tuicakau M, J Whitfeld M, Kava dermopathy in Fiji: an acquired ichthyosis? Int J Dermatol 53(12): 1490-4; 2014.

[56] Huynh JC, Asgari MM, Moore MM, Sebotropic eruption associated with use of oral kava kava supplement. Clin Exp Dermatol 39(7): 816-8; 2014.

Li et al. (2014) examined the oral toxicity of flavokavin A (6g/kg food) and commercial kava extract (same dose) for three weeks in mice. Whereas flavokavin A was non-toxic, slight effects of the kava preparation were seen in spleens, thymus, testis and liver (induced nodular proliferation)[57]. The composition of the kava extract used in this study was not stated. Hence, no conclusions can be drawn on the nobility of kava.

Martin et al. (2014) reported increasing quantities of kava imported to the US, with at least 4,504 metric tonnes exported to international markets in the years 2008 to 2013. A screening of 25 kava samples did not show *in vitro* cytotoxicity up to 500 µg/ml, and a moderate association of the observed cytotoxicity with flavokavin contents. The analysis showed that the assortment of commercially available kava products varies widely in chemical composition and cytotoxicity level, which led to the call for analytical specifications for the distinction between '*noble*' and '*non-noble*' varieties [58].

Narayanpillai et al. (2014) examined hepatotoxicity of kava in the model of potentiation of acetaminophen-induced liver toxicity in mice. Kava alone was not liver toxic even with doses of 500 mg per kg body weight for 14 days. A three-day pre-treatment with kava did, however, potentiate acetaminophen-induced liver toxicity. Whereas the kavalactone dihydromethysticin (37.5 mg/kg) did not have this effect, a toxicological synergism with acetaminophen was found with flavokavin B (11.5 mg/kg)[59]. The abundance of flavokavin B with 2.3 % in the product would seem to indicate a '*non-noble*' kava variety used for this study.

Parker et al. (2014) attributed the diagnosis of hepatitis A to the shared use of kava bowls by infected consumers[60]. This report would give reason for caution with shared drinking vessels, but not with kava as such.

Aghdassi et al. (2015) re-examined four patients, who stated that kava caused fulminant liver toxicity. No detailed descriptions are given, and the cases are most likely referring to case reports published in 2001. All four patients had taken kava for the treatment of mild depression, and in all patients kava was said to have been the only identifiable risk factor. Three of the four patients had no co-medication, one was using piretanide and etilefrine. All had developed liver dysfunction with jaundice, encephalopathy and marked elevations of liver transaminases, and three of the four ultimately needed liver transplants. Based on the examination of genetic polymorphism in the UDP glucuronyltransferase UGT1A7 gene, the authors postulate that polymorphism in this gene might represent a risk factor[61].

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[57] Li X, Xu X, Ji T, Liu Z, Gu M, Hoang BH, Zi X, Dietary feeding of Flavokawain A, a Kava chalcone, exhibits a satisfactory safety profile and its association with enhancement of phase II enzymes in mice. Toxicol Rep 1: 2-11; 2014.

[58] Martin AC, Johnston E, Xing C, Hegeman AD, Measuring the chemical and cytotoxic variability of commercially available kava (Piper methysticum G. Forster). PLoS One. 9(11): e111572; 2014.

[59] Narayanapillai SC, Leitzman P, O'Sullivan MG, Xing C, Flavokawains A and B in kava, not dihydromethysticin, potentiate acetaminophen-induced hepatotoxicity in C57BL/6 mice. Chem Res Toxicol 27(10): 1871-6; 2014.

[60] Parker JA, Kurien TT, Huppatz C, Hepatitis A outbreak associated with kava drinking. Commun Dis Intell Q Rep 38(1): E26-8; 2014.

[61] Aghdassi AA, Kraft M, Domschke W, Lerch MM, Weiss FU, Genetic polymorphisms in the UDP-glucuronosyltransferase UGT1A7 gene in patients with acute liver failure after kava-kava consumption. Arch Tox; 2015.

Ketola et al. (2015) reported a fatal case of suicidal poisoning, where the victim had apparently applied unknown doses of an intravenously injected kavalactone preparation in combination with alcohol[62]. The available information does not allow drawing conclusions on the composition of the preparation, the applied dose and the cause of death, however, intravenous use of kava preparations must be considered off-label use and is, therefore, not relevant for the debate of the toxicity of kava as a drink.

2.3.5 Clinical studies

Clinical studies do not only potentially strengthen the benefit side of the benefit-to-risk-ratio, but also allow drawing conclusions on safety under controlled conditions. No hints to liver toxicity were observed during the time under examination.

Sarris et al. (2012) reviewed treatment options against anxiety, with efficacy attributed to kava based on the clinical evidence [63].

Sarris et al. (2012) presented a pharmacodynamic study, where kava (180 mg/day), oxazepam (30 mg(day) and placebo were administered as an acute dose with a wash-out phase of one week between treatment arms. The study design was randomized and double-blind. 22 subjects with moderate anxiety were included. Oxazepam significantly reduced anxiety, but also cognitive functions. Kava did not lead to a change of pre-post anxiety values, but did not impact cognitive functions. With placebo, the anxiety increased[64].

Sarris et al. (2013) presented the results of a randomized, placebo-controlled six-week clinical double-blind trial on the treatment of generalized anxiety with kava. 58 patients were included after a one-week placebo run-in phase. The study medication was an aqueous extract standardised to 120 mg kavalactones per day. The dose was increased to 240 mg in non-responders after three weeks. The dose increase was made in n = 13 participants of the kava group (45%) and n = 16 participants of the placebo group (55%). A significant difference to placebo was found for anxiolytic activity. Kava was well tolerated, there were no important adverse effects and specifically no deviations from the norm in the liver function tests performed as safety parameters[65,66].

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[62] Ketola RA, Viinamäki J, Rasanen I, Pelander A, Goebeler S, Fatal kavalactone intoxication by suicidal intravenous injection. Forensic Sci Int 249: e7-11; 2015.

[63] Sarris J, Moylan S, Camfield DA, Pase MP, Mischoulon D, Berk M, Jacka FN, Schweitzer I, Complementary medicine, exercise, meditation, diet, and lifestyle modification for anxiety disorders: a review of current evidence. Evid Based Complement Alt Med 2012:809653;2012.

[64] Sarris J, Scholey A, Schweitzer I, Bousman C, Laporte E, Ng C, Murray G, Stough C,. The acute effects of kava and oxazepam on anxiety, mood, neurocognition; and genetic correlates: a randomized, placebo-controlled, double-blind study. Hum Psychopharmacol 27(3): 262-9; 2012.

[65] Sarris J, Stough C, Bousman CA, Wahid ZT, Murray G, Teschke R, Savage KM, Dowell A, Ng C, Schweitzer I, Kava in the treatment of generalized anxiety disorder: a double-blind, randomized, placebo-controlled study. J Clin Psychopharmacol 33(5): 643-8; 2013.

[66] Sarris J, Stough C, Teschke R, Wahid ZT, Bousman CA, Murray G, Savage KM, Mouatt P, Ng C, Schweitzer I, Kava for the treatment of generalized anxiety disorder RCT: analysis of adverse reactions, liver function, addiction, and sexual effects. Phytother Res 27(11): 1723-8; 2013.

Shi et al. (2014) reviewed medicinal plants useful for the treatment of insomnia[67]. They consider the benefit-risk ratio of kava preparations as positive, even as high in comparison with other drugs used to treat anxiety.

2.4 Collection of Relevant Kava Cultivars

Between 14 April and 14 May 2015, the collection of relevant kava cultivars was organised in Vanuatu, Fiji, Hawaii, Samoa, Solomon Islands and Tonga. Details of the travel schedule and activities are given in Annex 2. The identified varieties are displayed in Annex 3.

2.4.1 Vanuatu

The mission to Vanuatu was performed from Tuesday 14 to Friday 17 April 2015, and from Tuesday 12 to Thursday 14 May 2015.

Whereas sample collection went according to plans in all beneficiary countries, the sampling in Vanuatu was complicated and delayed by several external circumstances. Vanuatu was just recovering from the aftermath of tropical cyclone "*Pam*" in March 2015, and access to many kava growing sites was still restricted or impossible. Consequently, sampling was focused on the island of Espiritu Santo, which fortunately was mostly spared by the storm.

As it turned out, the variety collection of the Vanuatu Agricultural Research and Technical Centre (hereinafter, *VARTC*) in Luganville, Santo, was not in a good state, and sampling needed scouting of the terrain and good preparation. Kava sampling was, therefore, also organised on private farms in *Kona* and *Fanafo*, securing a number of important varieties, including '*noble*' and '*two-day*' types:

- *Borogu* short ring ('noble' kava);
- *Borogu* long ring ('*noble*' kava);
- *Borogu* Big Han ('*noble*' kava)
- *Melo melo* ('*noble*' kava);
- *Melo melo* yellow leaf (a recent mutant of *Melo melo*)
- *Palarasul* ('*noble*' kava);
- *Bir Fok* ('*two-day*' kava);
- *Palisi* ('*two-day*' kava);
- *Ambae* (no information yet on the status); and
- *Sese* ('*noble kava*').

In each case samples of roots, peeled chips (the peeled and cut root stump) and stem peelings (the bark of the three lowest internodes) were collected. In addition, roots and chips from Pentecost were obtained from a kava exporter. These samples were, however, seized by the French customs authorities when they reached France for re-drying in a specialised facility. Despite urgent interventions by the PMU and

[67] Shi Y, Dong JW, Zhao JH, Tang LN, Zhang JJ, Herbal Insomnia Medications that Target GABAergic Systems: A Review of the Psychopharmacological Evidence. Curr Neuropharmacol 12(3):289-302; 2014.

Vanuatu's Ambassador to the EU and to France, H.E. Roy Mickey Joy, the samples remained irretrievable and had to be considered a total loss. A re-sampling had to be organised, but was delayed due to unexpected bad weather conditions, which prevented harvesting and drying. At the time of finalization of this Final Report the new batch of samples had not yet reached the laboratory. Therefore, its analysis and scientific assessment had to be abandoned. Despite this setback, the sample of Vanuatu cultivars collected and scientifically assessed can be considered as wide enough to be characterised as "*relevant to trade*", in line with the mandate and scope under the ToRs.

As an alternative source, further varieties were collected from the collection of the *VARTC* in Luganville, including some varieties specifically collected on the island of *Ambae* for this project. In each case the sampling included roots, chips and stem peelings:

- *Borogu* ('*noble kava*');
- *Kelai* ('*noble kava*');
- *Melo melo* ('*noble kava*');
- *Palarasul* ('*noble kava*');
- *Palisi* ('*two-day kava*');
- *Pia* ('*noble kava*' from *Ambae*);
- *Puariki* ('*noble kava*' from *Ambae*);
- *Sese* ('*noble kava*');
- *Silese* ('*noble kava*'); and
- *Two-day* ('*two-day kava*').

In total, thirty samples of ten important and commercially relevant kava varieties were available for analysis.

The samples of the 2012 ACP project could also be used for the comparison or results, as the same analytical method was applied for this report. This added data from 20 samples for roots, peeled chips, stem peelings and peeled stems for the following five varieties:

- *Bir Fok* ('*two-day kava*');
- *Borogu* ('*noble kava*');
- *Kelai* ('*noble kava*');
- *Palisi* ('*two-day kava*'); and
- *Sinibo* ('*Piper wichmannii-type kava*').

Bir Fok, *Borogu*, *Kelai* and *Palisi* were thus present in duplicate, allowing an internal comparison of results between laboratories. The outcome of the analyses was highly reproducible, thus giving additional weight to the results.

In total, eleven kava varieties of Vanuatu were tested, covering eight different '*noble*' varieties and three '*non-noble*' kava types. The '*non-noble*' types give a rather complete picture of the situation in Vanautu. Through sampling of the most important single '*two-day*' variety still exported in huge quantities (*Palisi*), the results could be verified and confirmed for different and independent origins. The eight '*noble*' types include the most favoured kava types for daily drinking and exports.

The still open testing of the yet to arrive delivery of kava samples would add additional variations of *Borogu* and *Melo melo* – the most important kava varieties grown for exporting, and possibly another '*noble*' variety. However, the timing and the exhaustion of the available resources made this impossible. It may be left to future scientific undertakings.

2.4.2 Fiji

The mission to Fiji was performed on Monday 4 to Tuesday 5 May 2015, and Sunday 10 to Monday 11 May 2015.

Fiji features thirteen different varieties of kava, all of which are considered 'noble'.

PHAMA (Pacific Horticultural and Agricultural Market Access, an NGO) had already conducted a survey in Fiji, describing the morphology of the kava types together with their kavalactone composition in "*Development of a yaqona quality manual: Survey of varieties of yaqona grown in Fiji*" (URS Report, Pacific Horticultural and Agricultural Market Access Program, APAC, 29. September 2014). It covers details for morphology and vernacular names on the varieties

- *Damu*;
- *Dokabana loa*;
- *Dokobana vula*;
- *Loa kasa balavu*;
- *Loa kasa leka*;
- *Matakara balavu*;
- *Matakaro leka*;
- *Qila balavu*;
- *Qila leka*;
- *Vula kasa balavu*;
- *Vula kasa leka*;
- *Yalu*; and
- *Yonolulu*.

The names of kava varieties are subject to regional changes and are, therefore, not always a reliable indicator for the type of kava harvested. Not all Fijian kava varieties are equally important for trading. Three varieties (*i.e.*, *Matakaro leka*, *Dokabano vula* and *Vula kasa leka*) cover approximately 34% of the total market. An important outcome of the survey was the finding that kava growers would not give priority to the aspect of drinking quality of kava, but rather to the aspect of productivity. Kava in Fiji has a uniform price. For the farmers it is, therefore, more profitable to grow more productive varieties.

As during this programme all Fijian varieties were already sampled, it was possible to retrieve separate samples of roots and chips for eleven of the thirteen varieties – the two missing (*i.e.*, *Loa kasa balavu* and *Vula kasa balavu*) are not regularly planted, as the "*leka*" varieties of *Loa* and *Vula* are favoured over the "*balavu*" types.

From a practical point of view, the mission, therefore, covered 100% of the Fijian varieties and gives a complete picture of the Fijian market and exports from local sources.

In Fiji, there are also abundant quantities of '*false kava*', locally called '*Tongan kava*' (*Piper auritum*) – an invasive species probably identical to the '*Hawaiian kava*' found in Tonga. This material can sometimes be found as an adulteration of kava. It has no kavalactones and no kava effects. A root sample of this plant was also taken.

2.4.3 Samoa

The mission to Samoa was performed from Friday 24 to Tuesday 28 April 2015.

Samoa has four varieties, only two of which are practically exclusively grown due to the recommendation of the Samoan Association of Manufacturers and Exporters (*SAME*) to kava growers. The other two varieties are meanwhile hard to find and do not play a role for kava exports. All four cultivated varieties are considered 'noble', with the two exported considered especially well-suited for kava drinking.

Varieties secured from Samoa are:

- *Ava la'au*; and
- *Ava lea*.

These samples cover 100% of the kava consuming and trading practice in Samoa.

2.4.4 Solomon Islands

Kava cultivation and exportation is not a major issue in the Solomon Islands. With the predominant habit of chewing betel pepper, there is practically no tradition of kava drinking, although there are still kava plants to be found in remote places. In the past years, kava cultivation was re-established for export purposes on the island of Santa Isabel, with two varieties for which the planting material was imported from Vanuatu. The original names of the varieties were lost, and the two kava types were simply called "*Feo*" and "*Tahu*", meaning '*heavy*' and '*light*'.

Both kava types could be sampled and in both cases samples of roots and chips were obtained. Through the analytical results, the variety '*Tahu*' could be identified as identical to the Vanuatu '*two-day*' variety '*Palisi*', whereas '*Feo*' corresponded to the 'noble' Vanuatu variety '*Borogu*'.

Sampling covered 100% of the current kava trading practice in the Solomon Islands.

2.4.5 Tonga

The mission to Tonga was performed from Saturday 18 to Thursday 23 April 2015.

Tonga has seven varieties, one of them being very rare and difficult to find. This variety does not play a role for kava exports, and was, therefore, not sampled. All six cultivated and exported varieties are considered 'noble'.

Varieties secured from Tonga (directly from a kava farm on the island of *Eua*) are:

- *Hina Akau*;
- *Kata Kofe*;
- *Kula Akau*;
- *Leka Hina*;
- *Leka Kula*; and
- *Valu*.

Therefore, the sampling covered 100% of the Tongan kava varieties relevant for consumption and exports.

2.4.6 Hawaii

The mission to Hawaii was performed from Tuesday 28 April to Sunday 3 May 2015.

Hawaii is the only non-ACP kava-producing country growing noteworthy quantities. It was included into the sampling process because a regulation of kava quality standards needs to take the realities of Hawaii into account.

According to Ed Johnston and Helen Rogers "*Hawaiian 'Awa: Views of an ethnobotanical treasure*" (Association for Hawaiian 'Awa,Hilo, Hawaii 2006), there are thirteen native varieties in Hawaii, which have been described with analytical data and must all be considered as '*noble*':

- *Hanakapi'ai*;
- *Hiwa*;
- *Honokane iki*;
- *Kumakua*;
- *Mahakea*;
- *Mapulehu*;
- *Mo'i*;
- *Nene*;
- *'Opihikao*;
- *Pana'ewa*;
- *Papa ele'ele pu'upu'u*;
- *Papa 'ele'ele*; and
- *Papakea*.

In addition, there are several varieties introduced from other sources. Of these varieties, only "*Isa*" is not '*noble*':

- *Ava La'au* from Samoa;
- *Rahmdel* from the Federal States of Micronesia;
- *Rahmwanger from the Federal States of Micronesia;*
- *Isa* from Papua New Guinea;
- *Gilbert Islands* from Gilbert Islands, originally from the Fijian island of *Rotuma* (possibly the Fijian variety *Dokubana vula*); and
- *Hina Tonga*, presumably from Tonga.

For the project, the following samples (eight of the thirteen '*classical*' Hawaiian varieties) were secured:

- *Hanakapi'ai* root + chip powder;
- *Honokane iki* roots, peeled chips and stump peelings;
- *Mahakea* roots, peeled chips and stump peelings;
- *Mapulehu* roots and peeled chips;
- *Mo'i* roots, peeled chips and stump peelings;
- *Nene* roots, peeled chips and stump peelings;
- *Opihikao* root + chip powder; and
- *Panaewa* root + chip powder.

In addition, samples of four of the six recently introduced varieties were obtained:

- *Isa* roots + chips (two-day kava);
- *Rahmdel* roots and peeled chips;
- *Hina Tonga* roots and peeled chips (could correspond to the Tongan variety *Hina 'Akau*); and
- *Gilbert Island* roots and peeled chips (could correspond to the Fijian variety *Dokubana vula*).

Av La'au was already part of the Samoan samples and is, therefore, part of the overall analysis.

Overall, the project covered 74% of all varieties currently grown in Hawaii, with a good representation of varieties relevant for trading.

2.5 Stakeholders' Meetings

Stakeholders' meetings took place in all beneficiary countries, plus in Hawaii. Pictures of stakeholders' meetings and activities are displayed in Annex 4. Press releases on the project are collected in Annex 5.

In all stakeholders' meetings, the background of the ACP project and the most recent developments in Germany – especially the lifting of the so-called '*kava ban*' – were explained. With the German situation just evolving out of 15 years of complete legal uncertainty, there is now an urgent need for the definition of '*noble*' kava, which coincides with the aim of defining a regional kava standard in the South Pacific kava producing countries.

Obstacles may be expected from Hawaii, as Hawaii falls under US legislation. The US is represented in the CCNASWP, and could therefore question an ACP-defined regional kava standard for the Pacific. This situation calls for an early integration of US stakeholders into the process of regional standardisation. For instance, Hawaiian and US mainland delegates could be invited to attend the validation workshop being organised or the preparatory meetings of the scientific authorities from the Pacific that will be tabling the proposed kava standard within FAO Codex in 2016.

2.6 Codex Standard for '*Noble*' Kava

The 2014 WHO report on "*Kava: A review of the safety of traditional and recreational beverage consumption*" was drafted in reaction to the first presentation of the standard proposal to FAO/Codex in 2012. It points out the gaps in knowledge on kava in general, and states that a full understanding of the potential for consumption of kava beverage to impact on health of consumers is not possible in the absence of the additional data filling the gaps in knowledge. However, the WHO report concludes that a risk minimisation strategy to minimise any harm associated with moderate to high kava beverage consumption should include:

- Using only '*noble*' kava for beverage preparation;
- Restricting the plant material for kava beverage preparation to peeled rhizomes and root; and
- Monitoring kava storage conditions and employing surveillance for contaminants, in particular, aflatoxins.

The WHO report concludes that these issues must be fully covered by the intended kava standard, including a definition of '*noble kava*'.

In the stakeholders' meetings, it was regularly discussed that the regional kava standard in Codex Alimentarius would be a standard for a beverage, not for a medicinal product, or, more explicitly, for kava extracts manufactured with ethanol. This, however, is not an obstacle, as (in the absence of a definition of a starting material for the manufacture of herbal medicinal products or their active ingredients in the European Pharmacopoeia), the EU would fully accept a Codex Alimentarius standard. This was the case

with ginseng, before the Codex standard for ginseng[68] was adapted for inclusion into the European Pharmacopoeia, with little changes. A standard for an extract in the Pharmacopoeia would require the definition of the starting material as a precondition. Therefore, the first step would clearly have to be the definition of quality of '*noble*' kava roots.

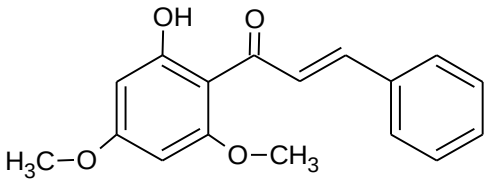
It is, however, important that the standard is not made based on a positive list of names recognised as '*noble*' kava. With names changing for the very same variety from location to location, with new varieties constantly being created (in the course of this project alone, we could witness two new varieties being placed on the market, one in Santo/Vanuatu and one in Hilo/Hawaii), a list of names may create confusion and no legal certainty. In addition, the control of variety names is difficult in the absence of a proper system for the traceability of origins. Kava growers mostly do not grow a single variety, and the varieties on site are often not sorted by type. The shrubs ready for harvesting must be identified individually, this being an almost non-controllable source of error when it comes to labelling. There is a risk that collections labelled with a given variety name are not 100% pure. However, this should not pose a problem as long as the harvested varieties are '*noble*'.

Our recommendation is, therefore, to formulate the standard in a way that '*noble*' kava be defined as a group, not individually for each variety. The parameters for the definition should be selected in a way that their application allows the identification of a kava harvest as '*noble*', even if the names of the varieties are not known. This approach corresponds to the usual definitions in Codex Alimentarius, and in the European Pharmacopoeia.

Another recommendation is that the parameters for the distinction between '*noble*' and '*non-noble*' kava must be clearly defined as quality parameters, not safety parameters. To date, the relation between '*non-noble*' kava, liver toxicity and the level of flavokavins is only circumstantial. Not much is known about further constituents of kava beyond the kavalactones, and even though this project is aimed on verifying the suitability of flavokavin B as a marker for the nobility of kava, is was not necessarily the triggering agent for liver toxicity. Relating flavokavin B to toxicity might create new obstacles, as then the EU regulations on food and medicinal products would call for toxicological examinations of the "*No Adverse Effect Level*" (*NOAEL*). In the absence of toxicological data, a worst case approach would be taken, and safety factors would be applied. Experience shows that in such cases the resulting levels would be the equivalent to a new ban. A typical example is the current debate on pulegone contents in medicinal plants, with proposed limits so low that peppermint might no longer be marketed as a medicinal plant[69]. This kind of approach would not differentiate between the properties of flavokavin B as an isolated substance and the properties of kava containing, among many other ingredients, flavokavin B. Defining flavokavin B as a safety marker would therefore not help re-opening the markets, it might have the opposite effect.

[68] Codex Regional Standard for Ginseng Products (Codex STAN 295-2009; attached as Annex 9) (now superseded by a global Codex Standard on Ginseng (Codex STAN 321-2015; attached as Annex 10).

[69] EMA/HMPC/138386/2005/Rev. 1: Draft Public Statement on the use of herbal medicinal products containing pulegone and menthofuran.



Flavokavin B

Flavokavin B could, however, be used as a quality marker in the distinction between '*noble*' and '*non-noble*' kava. There is no immediate implication of safety with the use of a quality marker. '*Noble*' kava is not free of flavokavin B, but it can be shown to contain substantially less flavokavin B than '*non-noble*' kava. There is general agreement that '*noble*' kava is safe, although '*noble*' kava still contains certain levels of flavokavin B. As an implicit consequence, the level of flavokavin B in '*noble*' kava is acceptable, and the definition of maximum levels of flavokavin B would be made as a parameter to control the quality, and explicitly not based on safety considerations.

As a matter for fact, there is already good progress in the discussions of the kava Codex standard. There is a kava working group at work in all Pacific kava growing countries visited to date, mostly under the control of *PHAMA*, the Pacific Horticultural and Agricultural Market Access programme. Vanuatu, Fiji, Tonga and Samoa have drafts of a local standard to be developed into the regional standard. The Vanuatu *PHAMA* group, with Dr. Vincent Lebot as the chief scientist, has recently presented a quick test applicable to routine work in kava exports. New parameters developed through the results of this project must, therefore, be channelled into the existing efforts of standard creation. A parallel approach might cause delays, but joining forces should speed up the process.

A standard alone will not solve all problems: means of efficient market control and perhaps conformity assessments by Government inspection facilities or accredited laboratories are needed.

2.7 The Kava Production Level

The kava growers and kava exporters were informed about the urgent need for full traceability of kava and of agricultural harvesting and processing protocols. This requirement is also stressed by the WHO position paper of 2014 on the consequences of the 2012 ACP report on the quality of kava, and the approach to defining a regional quality standard through Codex Alimentarius.

Practically all of the stakeholders were fully aware that the focus should be turned to the growing of '*noble*' kava. Commitments were already made to this respect. There seems to be a deficit in communication between kava traders and growers, as the growers need more information and training in matters of growing and harvesting the right varieties.

Fiji and Vanuatu have manuals for kava growers[70,71], clearly explaining what and how to grow.

Tonga and Samoa are actively pursuing the implementation of *HACCP* protocols[72] and an accreditation

[70] Australian Aid, Kava quality manual for the export of kava from Vanuatu. Commonwealth of Australia, 2013.

[71] URS Report: Development of a yaqona quality manual: Survey of varieties of yaqona grown in Fiji. Pacific Horticultural and Agricultural Market Access (PHAMA) program; 26. September 2014.

[72] International Border Systems and Training Pty Ltd, Quality Assurance Manual for Tongan kava exporters, 2001.

scheme for growers and exporters. According to information received in Samoa, a resolution has recently been passed for the establishment of the *International Kava Executive Council* (*IKEC*) as the organisation responsible for the accreditation of growers and exporters.

The requirement for agricultural protocols such as *HACCP* documentation is also stressed by the fact that already today, data on Good Agricultural and Collection Practice (*GACP*)[73] documentation is a precondition for exports of any plant material to Europe. One of the pillars of *GACP* is documentation of the origins of plant materials and their traceability. The documentation of traceability is part of EU food legislation[74,75] and is also applicable to supplies of starting materials for herbal medicinal products[76]. *GACP* documentation means documenting the origin and identity of the material, the specifics of growing (*i.e.*, the use of fertilizers or pesticides), the conditions of transport, and the conditions of processing and storage. It also includes the documentation of treatments such as fumigation. The presentation of such documentation is mandatory and applies to kava. The *HACCP* protocol approach by Tonga and Samoa would fully cover the documentation requirements of *GACP*.

2.7.1 Vanuatu

Vanuatu is the kava growing country with the highest number of varieties, with '*noble*' and '*non-noble*' kava types. Vanuatu has momentarily lost a part of its ability for exporting kava through the devastating effects of the cyclone Pam hitting the country on 14 March 2015. Although this was a humanitarian catastrophe of the highest possible level, the aftermath of the cyclone damage offers some chances for the restructuring of the kava market. This is the moment when farmers have to be convinced to replant 'noble' kava varieties, and this would be the chance for the departments of the Ministry of Agriculture to offer active support in replanting through nurseries, as it is done in Samoa.

The members of the kava working group are working on programmes to educate growers on the different kava varieties and encourage the use of '*noble*' kava varieties. There has been slight progress through the activities of the Chamber of Commerce and of *PHAMA*, which both strongly advocate the growing of '*noble*' kava forms. Vanuatu issues manuals and educational material[70] for the growing and harvesting of kava, all directed towards an improvement of kava quality.

However, progress is undermined by the activities of foreign importers: Whereas exports of '*two-day*' kava and of peelings are prohibited by the Vanuatu Kava Act[77], the legislation allows exports of '*two-day*' kava

[73] World Health Organisation, WHO Guidelines on Good Agricultural and Collection Practices (GACP) for Medicinal Plants. Geneva (Switzerland), 2003.
[74] Regulation (EC) No. 178/2002 (as amended) of the European Parliament and of the Council of 28 February 2002 laying down the general principles of foodlaw, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.
[75] Regulation (EC) No. 852/2004 (as amended) of the European Parliament and of the Council of 29 April 2004 on the hygiene of foodstuffs, OJ L 139, 30.4.2004, p. 1–54.
[76] EMEA/HMPC/246816/2005, Guideline on Good Agricultural and Collection Practice (GACP) for starting materials of herbal origin.
[77] Republic of Vanuatu. Kava Act No. 7 of 2002; amended by Act No.6 of 2015.

in cases where the client specifically demands such material. This loophole is extensively used, and there is considerable doubt that the customers really know about the quality that they are ordering. There are also indications that the exporters are actively suggesting the explicit order or '*two-day*' kava to their clients.

It is, therefore, paramount to increase awareness about kava quality through workshops and the development of conformity assessment and accreditation schemes.

According to information obtained from Vanuatu Biosecurity (part of the Quarantine administration), Vanuatu has currently decided to put all exports to the EU temporarily on hold until the situation with '*two-day*' kava is cleared. With trading to Europe practically non-existing, this measure is unlikely to change the situation: '*Two-day*' kava is reportedly exported in huge quantities to New Caledonia, the US and Asia.

During the mission to Vanuatu, KE1 was informed by a kava exporter that the US customs authorities recently increased their awareness with respect to '*two-day*' kava. Apparently, there were cases of shipments seized by the US customs authorities and the US *Food and Drug Administration* (*FDA*) based on alleged contents of '*two-day*' kava. KE1 could not confirm this through contacts to US organisations involved in the testing of kava and surveillance of trade activities (namely Dr. Gary Stoner from T.K. Group Labs and the organisation "*TrueKava.com*"). Such reports still show that there is an urgent need to define kava quality, also from this point of view.

The visit to Vanuatu allowed covering a large part of the stakeholders.

a) Meetings with the Government of Vanuatu

A meeting with the Deputy Prime Minister Ham Lini Vanuaroroa (responsible for Trade, Industries and Tourism) served for explaining the situation. A major focus was given to the concern that the already existing shortage of kava might give the growers the idea of planting more '*two-day*' kava. The Deputy PM seemed well aware of this threat. The most important message, though, was the fact that Vanuatu will, in the near future, still be the number one kava producing country.

b) Meetings with the Kava Working Group and *PHAMA*

The major members of the Kava Working Group of Port Vila attended the meetings, as well as stakeholders composed of kava exporters and authorities dealing with kava exports, namely:

- Leith Veremaito (*PHAMA*) – who organised the meeting;
- James Wasi (Acting Director Agriculture; Government of Vanuatu);
- Tekon Timothy Tumukon (Director Biosecurity of Vanuatu);
- Sidney Suma (*PHAMA*);
- Vincent Lebot (*CIRAD*);
- John Aruhuri (Kava exporter);
- Frank King Jnr (Kava exporter);
- Peniana Patrick (Vanuatu Chamber of Commerce and Industries);

- Michael Louzé (Kava exporter); and
- Rosemary Leona (Kava exporter).

c) Meetings with kava exporters and the Vanuatu Commodity Marketing Board

In the absence of an association, meetings with kava exporters covered individual exporters:

- Rosemarie Leona (Kava store, Port Vila);
- Michel Louzé (Port Vila);
- Leong Mansan (Kava exporter);
- Peter Colmar's secretaries (Kava exporter);
- Asinate Pikiane (Kava exporter); and
- Roger Kee (General Manager, Vanuatu Commodities Marketing Board - *VCMB*).

d) Meetings with kava growers

Meetings with individual kava growers were held in the process of securing the sampling of varieties:

- Michel Kalorib;
- John Boy (Kona, Santo); and
- David Wilson.

e) Field missions for the identification of cultivars and trading structures

Visits were made to the:

- *VARTC* in Luganville (Vanuatu Agricultural Research and Technical Centre);
- Fields of kava growers in two different locations in *Kona* and *Fanafo* (John Boy and Michel Kalorib);
- Market in Port Vila; and
- A drying facility.

Kava is locally traded at the market in Port Vila. This market had been closed as a consequence of cyclone damage, and had just been re-opened on 11 May 2015. Kava was not yet on display, but people selling kava could be found and interviewed.

There was re-assuring information for some of the major centres of kava cultivation in Vanuatu:

- The island of *Efate* was strongly affected by the cyclone, but the kava cultivations in the inner island were largely unaffected;
- The island of *Tanna* was practically razed by the cyclone, but this will not have a major impact on the capabilities of Vanuatu to trade with kava: A few years back, *Tanna* ceased to be a major kava supplier due to setbacks caused by the "*die-back*" disease destroying the kava plants;
- *Pentecost* was also fully hit by the cyclone, but the kava cultivations behind the mountain crest were spared the worst. *Pentecost* is still a major source of kava in Vanuatu; and
- The fact that the island of *Santo* was unaffected was observed by KE1 in the course of the field mission.

Consequently, kava trading is still a major source of income for the local population.

However, the infrastructure on *Efate* has been severely damaged by the storm, with drying and storage facilities partly destroyed and slowly being re-built. As a consequence, kava trading has temporarily suffered from the non-availability of processing infrastructures and from the lasting poor weather conditions still interfering with kava drying many weeks after the cyclone.

2.7.2 Fiji

The visit to Fiji covered the most important stakeholders.

a) Meetings with *PHAMA*

Participants of *PHAMA* meetings were:

- Losalini Leweniqila: National Market Access Coordinator for Fiji;
- Guy Redding: Team Leader, *PHAMA*;
- Sam Nelson: Agricultural Adviser; and
- Bronwyn Wiseman: Deputy Team Leader, *PHAMA*.

PHAMA is already working on a Fijian kava standard. *PHAMA* already did a complete survey of all Fijian varieties, but the analyses were not yet available. As *PHAMA* handed over samples of all varieties, results could be exchanged. Through these results, it could be confirmed that all Fijian varieties are in fact '*noble*'. Fiji is, however, a major re-exporter of '*two-day*' kava from Vanuatu, frequently mislabelled as "*Fijian kava*", and *PHAMA* is aware that this practice must be stopped. Fiji is currently preparing legislation against the importation of kava peelings.

There is also an *HACCP* protocol in preparation in *Ovalau*. The idea of *HACCP* certification is already taking shape.

b) Meetings with the kava exporters at the Government of Fiji

A meeting with the kava exporters had been organised through *PHAMA* at the Ministry of Agriculture. Participants were:

- Nacanieli Bola: Managing Director Marine Fuel Services (Chairman of the meeting);
- Kelvin Vinod: Director of Kell Investment Fiji Ltd.;
- Anukar Dayal: Dayal's Spice and Kava Ltd.;
- Vinesh Reginald Chandra: Managing Director Date Line Kava Pounding & Exports;
- Ravneel Chand: Director Twins Kava Dealers (Suva Kava market);
- Bridget Middenway Blümel: Sales and Marketing Director Lami Kava; and
- Donny Jason Yee: Managing Director Lami Kava.

The major messages given in this session were:

- Do not mix and re-label kava material from different sources; and
- Do not use skins.

The meeting at the government was followed by further encounters with government officials. One of these encounters was with Pauliasi Tuilao (Principal Economist, Policy Department of Agriculture, Ministry

of Primary Industries), who is also growing kava in the island of *Rotuma*.

Furthermore, there were separate meetings with Abhishek Sapra, a kava exporter from *Taveuni*.

c) Meeting at the University of the South Pacific

The *University of the South Pacific* (*USP*) is testing the *PHAMA* samples on kavalactones. A meeting was arranged with the scientist responsible for the analytical part, Dr. Usaia Dolodolotawake, who delivered the samples of twelve of the thirteen Fijian varieties.

d) Field missions for the identification of varieties

The field missions included:

- A visit to a kava farm near Suva;
- A visit to kava growing regions and a village processing kava in central Viti Levu. Kava quality issues and potential improvements were discussed directly with the village chiefs;
- A visit to the Suva kava market, where we met and interviewed Sakiusa Sorovi (Sorovi Kava Co. Ltd.) from the island of Kadavu; and
- Specific attention was given to kava bars.

2.7.3 Samoa

Kava exporters in Samoa are organised through the *Samoan Association of Manufacturers and Exporters* (*SAME*). *SAME* organised the project work in Samoa.

a) Meetings with *PHAMA* and governmental authorities

Meetings with *PHAMA* included a discussion with Asuao Kititi Puono (*PHAMA* representative in Samoa).

Governmental meetings held included:

- A visit to the agricultural development station of the Ministry of Agriculture and Fisheries (MAF), where a meeting with Parate Matalavea (Head of Crops Division) and Pueata Tanieli (Principal Crops Division Officer, MAF) took place. Kava is part of the CCCK-priority protocol of MAF, together with cocoa, coffee and coconut. The MAF is advising the growers on the material to plant and the corresponding techniques. The MAF had previously been advised by SAME that preferentially the varieties Ava La'au or Ava Lea should be grown, and MAF adopted this advice by creating planting materials from these two varieties for the use by the growers.
- A meeting with Lemamea Ropati, the Minister of Agriculture, in his office;
- A brief encounter with Tolofua Leiataua, the Minister of Women and Rural Affairs;
- A brief encounter with Dr. Faale Tumalii, the Minister of MNRE/SROS (Scientific Research Organisation of Samoa) and with David Hunter, the CRO of SROS; and
- A meeting with the Prime Minister of Samoa, Sailele Tuila'epa Malielegaoi.

SROS (*Scientific Research Organisation of Samoa*) was visited, a governmental research organisation helping the farmers improving their crops, and doing testing of standard parameters for food materials

such as heavy metals by AAS, pesticides by GC, microbiology and residual humidity. The laboratories are well equipped any technology required for testing kava was present. *SROS* is even ISO-certified and acknowledged by New Zealand and Australia. The CEO is Tilafono Leatiogie David Joseph Hunter, with whom a more detailed discussion was possible on this occasion. Also present was the Technical Services Division Manager Pousui Dr. Fiame Leo. Dr. Leo presented the laboratories. *SROS* could easily become the central testing point for testing of kava samples before plant material being exported. It was discussed how the current project could help *SROS* setting up the required analytical methods and parameters, based on the analytical findings of the TBT programme.

A Codex group meeting with the participation of observers from WHO and FAO took place. The plans for a Codex Alimentarius standard were discussed, including potential obstacles from Pacific Countries opposed to kava trading. Such obstacles might be expected from New Zealand and, mainly, from Australia, where kava consume is made responsible for the poor social situation of the Aborigines. Establishing a kava standard might be regarded as a contradiction to the proposals of a zero-tolerance politics suggested by some politicians.

A press conference took place after the Codex meeting, followed by a media event with the Prime Minister. This, in turn, led to a TV interview.

b) Kava exporters

Kava exporters are organised through *SAME*. There were regular meetings with *SAME* and their members, including the participation in a board meeting and a *SAME*-organised press conference.

c) Kava growers

A meeting was held with Afamasaga Toleafoa, the chairman of the Samoan Farmers Association.

d) Field missions for the identification of cultivars

A field mission was performed in *Tagaloa*, the centre of the Samoan kava production. The kava samples used in the process were obtained from there.

2.7.4 Solomon Islands

Due to logistical problems, the growing sites of kava on the island of *Isabel* could not be visited. Instead, the time was used for stakeholder meetings.

a) Meetings with *PHAMA*

- Dale Hamilton (Technical Advisor); and
- Andrew Sale (National Market Access Coordinator Solomon Islands).

b) Meeting with the only kava exporter of Solomon Islands

- Dudley Langemai: The exports from Solomon Islands amount to around 500 kg per week.

c) Meeting with governmental bodies

Meeting at the Ministry of Foreign Affairs and External Trade:

- Jack O'oi (Deputy Director); and
- George Tuti (CTO/EIF-NIU Coordinator).

Meeting at the Ministry of Agriculture:

- Francis Tsatsia (Head of Biosecurity);
- Helen Tsatsia (Research Department);
- Max Kolubalona (Biosecurity);
- Crispus Fanai (Biosecurity);
- Roy Timothy (Extension); and
- Irene Nanau (Biosecurity).

There are as yet no advances towards harvesting/processing protocols for kava, but then it must be taken into consideration that kava is only a less relevant crop. It is only planted on *Isabel* in quantities not exceeding 500 kg of harvest per week, and is exclusively exported to New Caledonia and the US. There is only a single exporter (Dudley Langemai). From an economic point of view, kava was not considered a promising crop, because of the volatile demands. The growers want guarantees for selling their harvest, but of course, such guarantees cannot be given.

In addition, there is no longer an established tradition for kava drinking in large parts of the Solomon Islands. The reason for this is the abundant availability and use of betel pepper. Betel chewing is cheaper and easier accessible than kava drinking, and it has stronger cognitive effects.

2.7.5 Tonga

Kava growers in Tonga are organised through the *Tongan Kava Growers' Association*, which organised the project work in Tonga.

a) Meetings with *PHAMA* and governmental authorities

A joint meeting with authorities, experts responsible for Codex and *PHAMA* was held. Participants included:

- Tsutomu Nakao II (Coordinator, *PHAMA* Tonga);
- Siosaia Ma'asi (Protocol Officer for Export Commodities, Ministry of Agriculture, Forestry and Fisheries);
- Emmanuel Moale (Head of Extension Division, Ministry of Agriculture);
- Viliami T Manu (Coordinator Kava-Standard Working Group Tonga);
- Siutoni Tupou;
- Viliami Kami;
- Pousima Afeaki (Manager, *Tinopai* Farm);
- Elsie Fukofuka;
- Minouru Nishi (Managing Director, Nishi Trading); and
- To'imoana Takataka (Chairman, Growers' Federation of Tonga).

A meeting with *Ministry of Agriculture, Forestry and Fisheries* (*MAFF*) was held on the island of *Eua*.

b) Kava exporters

A dedicated meeting took place with all members of the *Kava Grower's Association*. All agree that the way forward will be the establishment of an *HACCP* (Hazard Analysis and Critical Control Point) protocol and bringing the Codex Standard to the implementation.

A press conference was held on the premises of the *Kava Grower's Association*.

c) Kava growers

The meeting with twelve kava growers took place on the island of *Eua*, the centre of Tongan kava production. It was chaired by the local department of the *MAFF*, with five representatives of *MAFF* and one of the *Kava Grower's Association*. The kava growers were briefed on the intentions of *MAFF* to introduce an *HACCP* standard.

d) Field missions for the identification of cultivars

A field mission was performed to the heart of kava production in Tonga: the island of *Eua*. All sampled varieties were ready for inspection and were clearly labelled.

2.7.6 Hawaii

Meetings took place with kava growers and scientists in *Hilo* (Big Island) and on *Oahu*. On these occasions, the kava varieties of Hawaii could be inspected and documented. The contact to the scientists as opinion leaders in the US was especially valuable.

The meetings were followed up by a participation in the *KavaCon 2015* in Honolulu on 25-26 July 2015[12], where the current situation around kava was discussed at length with international kava experts present.

The kava issues were mainly discussed with:

- Edward Johnston (kava scientist and kava grower seated on *Big Island*);
- Chris Allen (kava grower on *Big Island*);
- Jonathan Yee (kava grower on *Oahu*);
- Prof. Dr. H.C. Bittenbender (College of Tropical Agriculture and Human Resources, University of Honolulu);
- Prof. Dr. JD Baker (Department of Anthropology, University of Hawaii);
- Prof. Dr. Helen Turner (Division of Natural Sciences and Mathematics, Chaminade University of Honolulu);
- Garry Stoner (T.K. Group Labs, Slater, USA, specialist in kava analyses and chairman of *TrueKava.com*);
- Prof. Dr. Jerome Sarris (Department of Psychiatry, University of Melbourne, Australia; invited guest speaker on kava at the *KavaCon2015*); and
- Dr. Vincent Lebot (*CIRAD*, Port Vila, Vanuatu; invited guest speaker on kava quality at the *KavaCon2015*).

As it turned out, the growers and scientists are already well aware of the difference between '*noble*' and '*non-noble*' kava. Hawaii grows one '*non-noble*' variety (*Isa*, a *Piper wichmannii*-type originally from Papua New Guinea), which accidentally made its way to Hawaii and has been used for rather strong kava drinks ever since. *Isa* is known to cause hangover, headache and nausea, and kava drinkers in the US became aware of such '*two-day*' effects. This was outlined in the presentation of Chris Allen at the *KavaCON 2015*, who had collected feedback from customers clearly demonstrating that not only there are distinct adverse effects from drinking *Isa*, but also questions from the consumers about how to avoid '*two-day*' kava. With very few exceptions, the scientists agreed that '*two-day*' kava should be avoided or, if used, only consumed diluted and in moderate quantities.

2.8 Conclusions from the Stakeholders' Meetings

The stakeholders' meetings led to the following conclusions:

1) The WHO report of 2014 calls for both, additional data for the justification of the proposed standard and harvesting/processing protocols for ('*noble*') kava. Only the former would go into the actual Codex standard, whereas the latter would have to be established in the individual countries;

2) The Codex standard should be as simple as possible. It should not be specific on variety names. Variety names can and do change constantly. The goal of the standard should be making sure that 'noble' kava can be safely recognised, but the name or exact type of the variety would not matter;

3) The traceability of the kava and potentially also the harvested variety must be provided through harvesting and processing protocols. An *HACCP* protocol would do perfectly. These protocols can also address regional differences (*e.g.*, in the drying technology);

4) Establishing a system of traceability can be used for marketing through regional branding. Such an approach should lead to added value and could allow quality payment to farmers according to the kava quality they deliver. The current system of a uniform price per kilogram regardless of traceability or variety is inadequate and does not give an incentive for improvements in kava growing;

5) Samoa and Tonga are already working towards harvesting and processing protocols. Fiji has just started the process, while Vanuatu still appears to have a long way to go;

6) The lifting of the '*kava ban*' in Germany will probably lead to a shortage of kava on the export markets once the message that parts of Europe are again open for kava filters through, for the following reasons:

   - Vanuatu has suffered damages from the cyclone "*Pam*" in March 2015;
   - Fiji is a net importer and cannot provide sufficient quantities for increased export demands;
   - Tonga does not have the quantities and is currently facing a draught, which is aggravating the situation;
   - Samoa will need years to regrow the quantities that the country once had (having downsized from 3,000 to 300 acres since 2002); and
   - Solomon Islands are only exporting very small quantities, half of them '*two-day*' kava.

   This situation calls for additional awareness, as farmers might now favour the faster growing '*two-day*' varieties for reasons of profitability. The situation with the exports of '*two-day*' kava is in Fiji (already now) felt as an unjust competition, with '*two-day*' kava from Vanuatu underbidding the price of '*noble*' kava from Fiji. An unfortunate, but economically rather logical conclusion, might be the introduction of '*two-day*' kava cultivation in other countries as well, which must be prevented at any cost;

7) The observations within this project made clear that the focus on the five ACP countries (*i.e.*, Fiji, Samoa, Solomon Islands, Tonga and Vanuatu) is insufficient. The States of Micronesia also grow kava, and Papua New Guinea (hereinafter, PNG) seems to be envisaging kava growing for exports

as well. PNG does have '*two-day*' and '*wild-type*' kava varieties, but no screening has been made there;

8) A screening is also recommended for the Solomon Islands. There are much more than just two varieties in these islands, although only two are systematically grown, harvested and exported through one single exporter. One variety of which turned out to be a '*two-day*' kava variety. It must be anticipated that others will likely come into play when the demands for kava start increasing. For such a case, it would be important to know what to expect from other local varieties. The sampling of such varieties was not possible within the scope of this consultancy and its TORs: it would take considerably more time than just the three working days foreseen in the programme;

9) The US should be involved more deeply in the question of quality control, in view of the Hawaiian growers being solicited by international markets. At some point, the FDA should be informed and involved;

10) The future accreditation of growers and/or exporters requires a certification and conformity assessment system. There are corresponding bodies in Australia and in the EU;

11) The analytical examination of the sampled varieties provides sufficient information for the justification of the selection of parameters for the definition of '*noble*' kava in the standard. The methodology used has been formally validated according to the rules laid down for drug regulation[78]. These rules call for a validation of analytical methods in order to assure the reproducibility or results. The validation under *GMP* (*Good Manufacturing Practices*) conditions would, therefore, be entirely acceptable for the Codex Alimentarius; and

12) The implementation of the analytical proposals in Codex Alimentarius must necessarily be organised in close cooperation with *PHAMA* and the Kava Working Group. Approaching Codex Alimentarius in parallel to the already existing communication of *PHAMA* and the *eWG* (*electronic Working Group*) would likely cause irritation or confusion and it might even cause the opposite of the desired effect. It is highly likely that a duplicate approach will cause the rejection of the standard already in the early phases of its negotiation, due to differing ideas with respect to the approach. The necessary contacts were made in the course of this project.

[78] CPMP/ICH/381/95. ICH Topic Q2 (R1). Note for Guidance on Validation of Analytical Procedures: Text and Methodology.

3. KAVA SAMPLE ANALYSIS

3.1. Background

The 2012 ACP-MTS project "*Establishment of health and safety standards for the production and export of kava-based products (Ref: 9 ACP RPR 140-039/11)*" made a tentative proposal for a regional standard for '*noble*' kava as a potential solution to regulating kava quality. The proposal was based on five representative kava varieties from Vanuatu, two '*noble*' kavas, two '*two-day*' types and one '*wild-type*' kava (*Piper wichmanii*). Whereas the analytical examination had shown distinct differences between '*noble*' and '*non-noble*' kavas, the number of tested varieties was not deemed sufficient for a standard covering the entire variability between kava growing countries. This gap was to be filled by the current project.

3.2. Sampling

The task to fulfil within this project was to provide sufficiently representative data for the creation of a regional standard for '*noble*' kava in Codex Alimentarius. The existing drafts for the Codex Standard, as already submitted at the regional FAO Conference (*i.e.*, the CCNASWP) in Madang, PNG, in 2012, foresee that only roots and peeled root stumps (= chips) of kava may be used – other plant parts such as stem peelings cannot be regarded as "*kava*", regardless of their origin from '*noble*' or '*non-noble*' varieties. The focus of this project was, therefore, primarily on roots and chips. As peelings and in some cases also peeled stems are in fact traded, such samples were also gathered for comparisons.

An unexpected finding was, however, that "*peelings*" were used for trading exclusively in Vanuatu – the other beneficiary countries have no history of use of peelings, which led to confusion in the sampling process. In fact, the samples obtained in the collection process were frequently not stem peelings, but rather stump peelings – the rejects from peeling the chips. The preparation of such material is highly time-consuming and does not deliver noteworthy biomass (*e.g.*, the typical sample size was 200g of roots, 500g of chips, but only 20g of stump peelings). The farmers given the task of providing the peelings had associated the material with the process of peeling the stumps, not the stems – in all countries except Vanuatu the stems were never used in kava processing.

Despite the misunderstanding with respect to the nature of the "*peelings*", the stump peelings provided valuable information on the traditional habit of peeling the root stumps. Peeling is usually made to improve the taste and agreeability of kava drinks, as the stump bark adds a pungent and earthy taste to kava. The analytical results now show that there is a distinct difference between root stumps and their bark, the tendency being a shift of analytical results towards indicators of '*non-nobility*' (see below).

Another complication was predominantly encountered in Fiji, where the peeling of the root stumps is no longer performed for kava exports. Comparisons were made between peeled and unpeeled stumps within this project, which allowed drawing conclusions of the effect of peeling the roots stumps on the overall quality of kava.

Following the scope of the programme defined by the TORs, **148 samples** of a **total of 45 kava varieties** relevant for exportation were gathered in the kava growing countries Vanuatu, Fiji, Samoa, Solomon

Islands and Samoa. Samples were differentiated according to plant part: roots, stumps and partly also other plant parts such as stump peelings or stem peelings.

The coverage of kava varieties by the selection process by far exceeded the expectations, with a 100% coverage of all varieties from Samoa, the Solomon Islands and Tonga, a practically full coverage of Fiji (with the exception of two varieties not frequently cultivated) and an excellent coverage of relevant varieties for Vanuatu and Hawaii. Some specifically important samples were obtained from different locations, thus providing the possibility to compare results with respect to age of the plant or its origin.

Varieties collected (entries marked in red are traditionally considered '*non-noble*' kava varieties):

Vanuatu	**Fiji**	**Samoa**	**Solomon Islands**	**Tonga**	**Hawaii**
Bir Fok *Borogu* *Kelai* *Melo melo* *Palarasul* *Palisi* *Pia* *Puariki* *Sese* *Silese* *Sinibo* *Two-day*	*Damu* *Dokobana loa* *Dokobana vula* *Loa kasa leka* *Matakaro balavu* *Matakaro leka* *Qila balavu* *Qila leka* *Vula kasa leka* *Yalu* *Yonolulu* *False kava**	*Ava la'au* *Ava lea*	*Feo* *Tahu*	*Hina 'akau* *Kata kofe* *Kula 'akau* *Leka hina* *Leka kula* *Valu*	*Gilbert Island* *Hanakapi'ai* *Hina tonga* *Honokane iki* *Isa* *Mahakea* *Mapulehu* *Mo'i* *Nene* *Opihikao* *Panaewa* *Rahmdel*
12 varieties	11+1 varieties	2 varieties	2 varieties	6 varieties	12 varieties
51 samples	42 samples	6 samples	4 samples	18 samples	27 samples

* False kava (*Piper auritum*) is not a variety of kava (*Piper methysticum*), but can be found as an adulterant in kava collected for exports.

Plant parts collected (entries marked in red are traditionally considered '*non-noble*' varieties):

Variety	**Roots**	**Chips**	**Stump peelings**	**Stem peelings**	**Peeled stems**
Vanuatu					
Bir Fok	1	1		1	1
Borogu	2	2		2	1
Kelai	2	2		1	1
Melo melo	1	1		1	
Palarasul	1	1		1	
Palisi	2	2		2	1
Pia	1	1		1	

Variety	Roots	Chips	Stump peelings	Stem peelings	Peeled stems
Puariki	1	1		1	
Sese	1	1		1	
Silese	1	1		1	
Sinibo	1	1		1	1
Two-day	1	1		1	
Commercial sample				1	
Total Vanuatu	**15**	**15**	**0**	**16**	**5**
Fiji					
Damu	2	2			
Dokobana loa	2	2			
Dokobana vula	2	2	1		
Loa kasa leka	4	4	2		
Matakaro balavu	1	1			
Matakaro leka	1	1			
Qila balavu	1	1			
Qila leka	2	1			
Vula kasa leka	2	2	1		
Yalu	1	1			
Yonolulu	1	1			
False Kava	1				
Total Fiji	**19+1**	**18**	**4**	**0**	**0**
Samoa					
Ava la'au	1	1	1		
Ava lea	1	1	1		
Total Samoa	**2**	**2**	**2**		

Variety	Roots	Chips	Stump peelings	Stem peelings	Peeled stems
Solomon Islands					
Feo	1	1			
Tahu	1	1			
Total Solomon Islands	**2**	**2**	**0**	**0**	**0**
Tonga					
Hina 'akau	1	1			1
Kata kofe	1	1			1
Kula 'akau	1	1			1
Leka hina	1	1			1
Leka kula	1	1			1
Valu	1	1			1
Total Tonga	**6**	**6**	**0**	**0**	**6**
Hawaii					
Gilbert Island	1	1			
Hanakapi'ai	1				
Hina Tonga	1	1			
Honokane iki	1	1	1		
Isa	2	1			
Mahakea	1	1	1		
Mapulehu	1	1			
Mo'i	2	1	1		
Nene	1	1	1		
Opihikao	1				
Panaewa	1				
Rahmdel	1	1			
Total Hawaii	**14**	**9**	**4**	**0**	**0**

3.3. Analytical Methodology

For the analyses, the same analytical approach was made as presented in the report of the 2012 ACP-MTS project. The analyses were made by *Berghof Analytik*[79] using *High-Performance Liquid Chromatography* (*HPLC*), applying the method published by Meissner and Häberlein[80] (for detailed results see Annex 6). This method allows the quantification of the six major kavalactones next to the fraction of flavokavins. The determination of the latter fraction was important, as the 2012 ACP-MTS project had already shown that flavokavin B (FKB) could be regarded as a parameter indicating the '*nobility*' of kava: '*non-noble*' kava contained distinctly more FKB than '*noble*' kava. This association was fully confirmed in this survey.

3.4. Validation

Reproducibility of analytical results requires a validation of the method used for the quantification. Comparison of results, especially of absolute figures, depends on the laboratory method used. Validation of the method serves for an evaluation of the methods:

- Specificity: Excluding signals, which could wrongly be interpreted as belonging to the fraction of kavalactones or flavokavins;
- Linearity: Assuring that the quantification of small quantities is as exact as the quantification of larger quantifies;
- Limit of Detection: Determination of the lowest possible quantity still visible in the chromatograms;
- Limit of Quantification: Determination of the lowest possible quantity correctly quantifiable by the method;
- Range: Assuring that the highest quantity present in the samples would still be correctly quantified by the method;
- Repeatability: Different runs with the same samples must yield the same result (within acceptable and defined error margins);
- Precision: The method must not yield different results if performed by another scientist or on different work day; and
- Robustness: The method must not yield different results if performed with small variations, e.g. with small variations of the extraction time or the HPLC solvent.

The validation report as attached as Annex 7.

The method was fully validated according to analytical standards applicable to medicinal products in the EU[78].

[79] Berghof Analytik GmbH & Co. KG, Ob dem Himmelreich 9, 72072 Tübingen.

[80] Meissner O, Häberlein H, HPLC analysis of flavokavins and kavapyrones from Piper methysticum Forst. J Chromatogr B Analyt Technol Biomed Life Sci 826(1-2): 49-49; 2005.

3.5. Results

The first approach was correlating variety names with known associations to nobility. This association between name, chemotype and traditional expectations for nobility have been published in the books and scientific papers of Dr. Vicent Lebot[81,82,83,84,85,86,87] (*CIRAD*, Vanuatu). Further information on associations between kava variety and nobility can be derived from the "*Hawaiian 'Awa*"[88], the Vanuatu growers' manual[70] (Vanuatu) and the Fijian *PHAMA* report[71].

The analytical results obtained with the collected samples were compared with the corresponding data taken from these literature sources. Absolute quantities are for orientation only, as with differing methods the absolute findings may vary to a certain degree. The kavalactone fingerprints (signatures) are, however, not dramatically influenced by the method, and can still be used for comparisons. Likewise, the calculation of ratios with relative values should be largely transferable.

The results from the actual measurements by variety and – where applicable – their comparison with data from other sources are detailed in Annex 6.

The following abbreviations are used in the tables:

KL Kavalactones:
- DMY Desmethoxyyangonin
- DHK Dihydrokavain
- Y Yangonin
- K Kavain
- DHM Dihydromethysticin
- M Methysticin

FK Flavokavins:
- FKA Flavokavin A
- FKB Flavokavin B

The kavalactone signature refers to the sequence of elution from the HPLC column in the original method used by Dr. Lebot at the time of this screenings, and indicates the quantities of the six kavalactones in

[81] Lebot V, Levesque J, The origin and distribution of Kava (Piper methysticum Forst. f., Piperaceae): A phytochemical approach. Allertonia 5(2): 223-281; 1989.

[82] Lebot V, Aradhya MK, Manshardt RM, Geographic survey of genetic variation in Kava (Piper methysticum Forst. f. and P. wichmannii C. DC.). Pacific Sci 45(2): 169-185; 1991.

[83] Lebot V, Merlin M, Lindstrom L, Kava, the Pacific elixir. Yale University Press, New Haven; 1992.

[84] Lebot V, Levesque J, Genetic control of kavalactone chemotypes in Piper methysticum cultivars. Phytochem 43(2): 397-403; 1996.

[85] Lebot V, Levesque J, Evidence for conspecifity of Piper methysticum Forst. f. and Piper wichmannii C. DC. Biochem Syst Ecol 24(7-8): 775-782; 1996.

[86] Siméoni P, Lebot V, Identification of factors determining kavalactone content and chemotype in Kava (Piper methysticum Forst. f.). Biochem Syst Ecol 30: 413-424; 2002.

[87] Siméoni P, Lebot V, Buveurs de Kava. Géoconsulte, Port Vila (Vanuatu); 2014.

[88] Johnston E, Rogers H (Eds.), Hawaiian 'awa: Views of an ethanobotanical treasure. Association for Hawaiian 'Awa. Hilo (Hawaii); 2006.

descending order. A signature starting with "*4*" would be a kava type where kavain is the most prominent kavalactone. For signatures starting with "*2*", the major kavalactone is dihydrokavain, etc.

The total kavalactones and flavokavins can slightly deviate from the sum of the individual compounds, because there may be further minor peaks contributing to the overall sum or because of rounding differences.

Through a close examination of the data and discussions with scientists such as Dr. Gary Stoner or Dr. Vincent Lebot, there were three potential parameters emerging for the distinction of '*noble*' and '*two-day*' kava. The suggestion for a standard made in 2012 in the ACP-MTS-project based on five representative varieties was therefore slightly changed and simplified.

3.5.1 Flavokavins A and B

In the 2012 ATC-MTS report, it was presented that '*non-noble*' kava has distinctly higher contents of flavokavins, namely FKB. This finding was confirmed in this study, although it seems that FKB as a stand-alone parameter might not always be an unambiguous parameter for the differentiation between noble and '*non-noble*' kava.

As a result of the sampling and testing of kava varieties, a value of < 0.15 % is suggested for FKB. This limit can be shown to be sufficiently robust for a differentiation between '*noble*' and '*non-noble*' kava when used together with the FKB/K-ratio, the K/(KL-K)-ratio and the K/DHM-ratio, and would include all '*noble*' varieties.

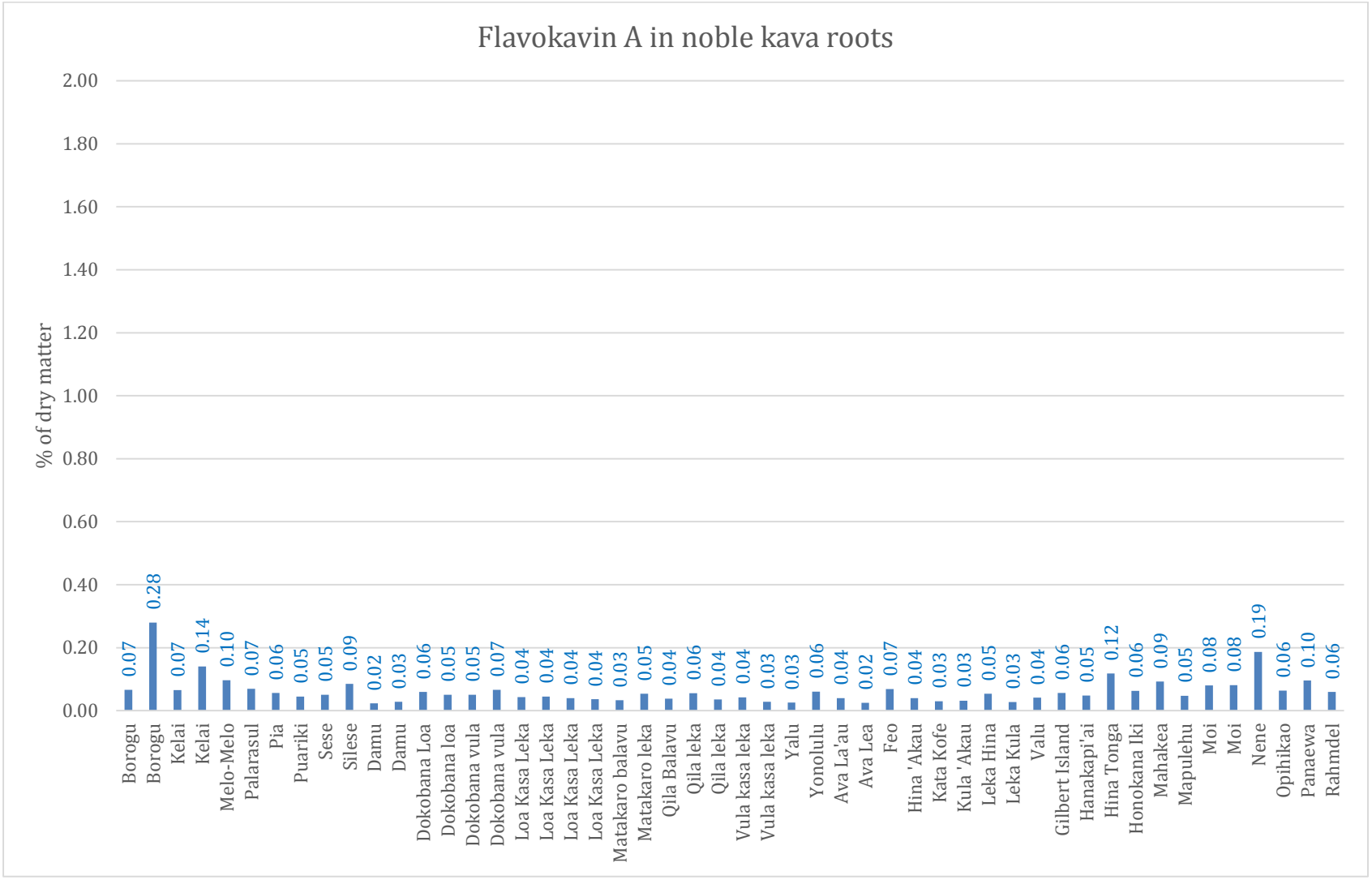
For direct comparisons, the graphs in the following subsections are adjusted to the same scale.

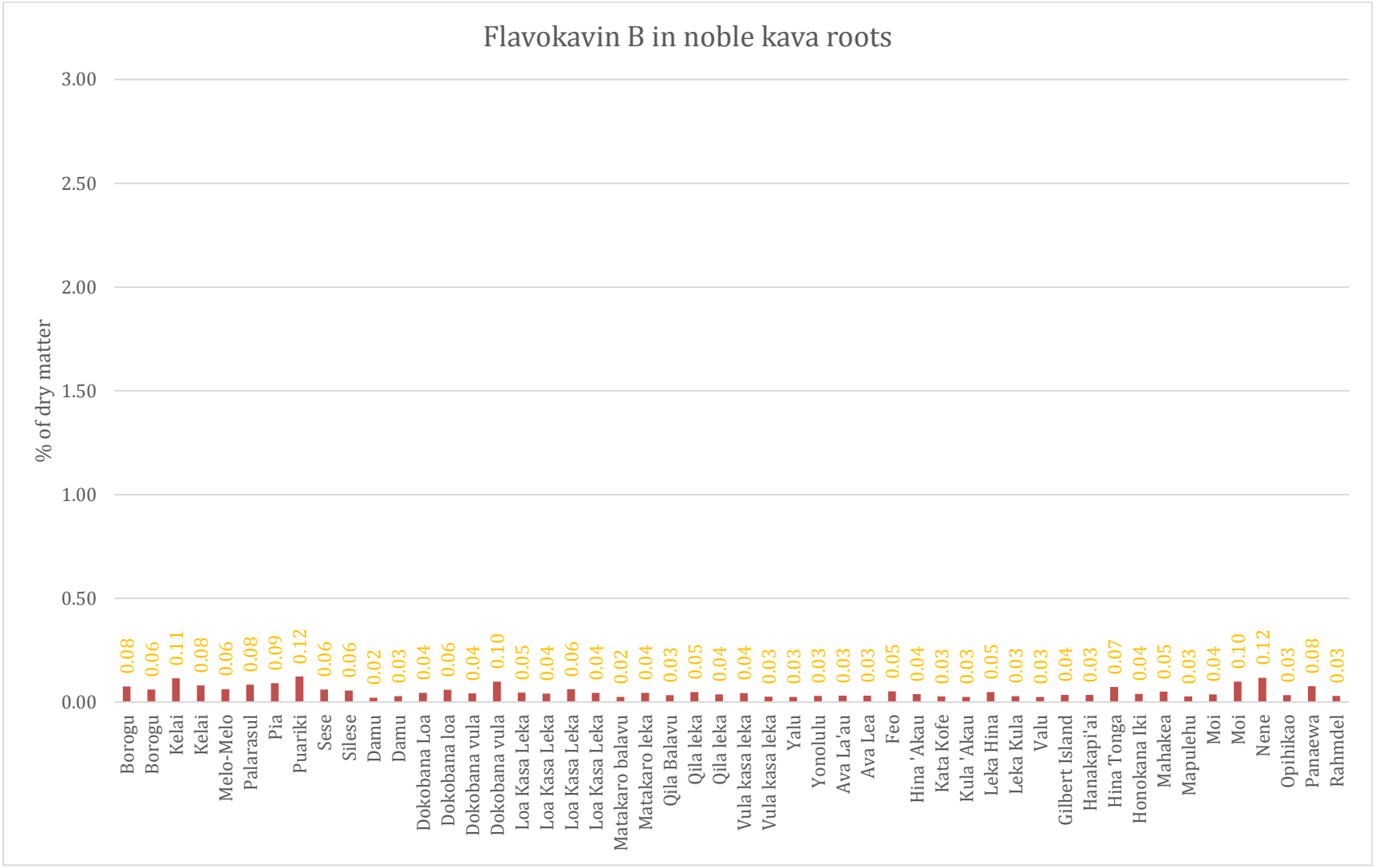
a) Roots

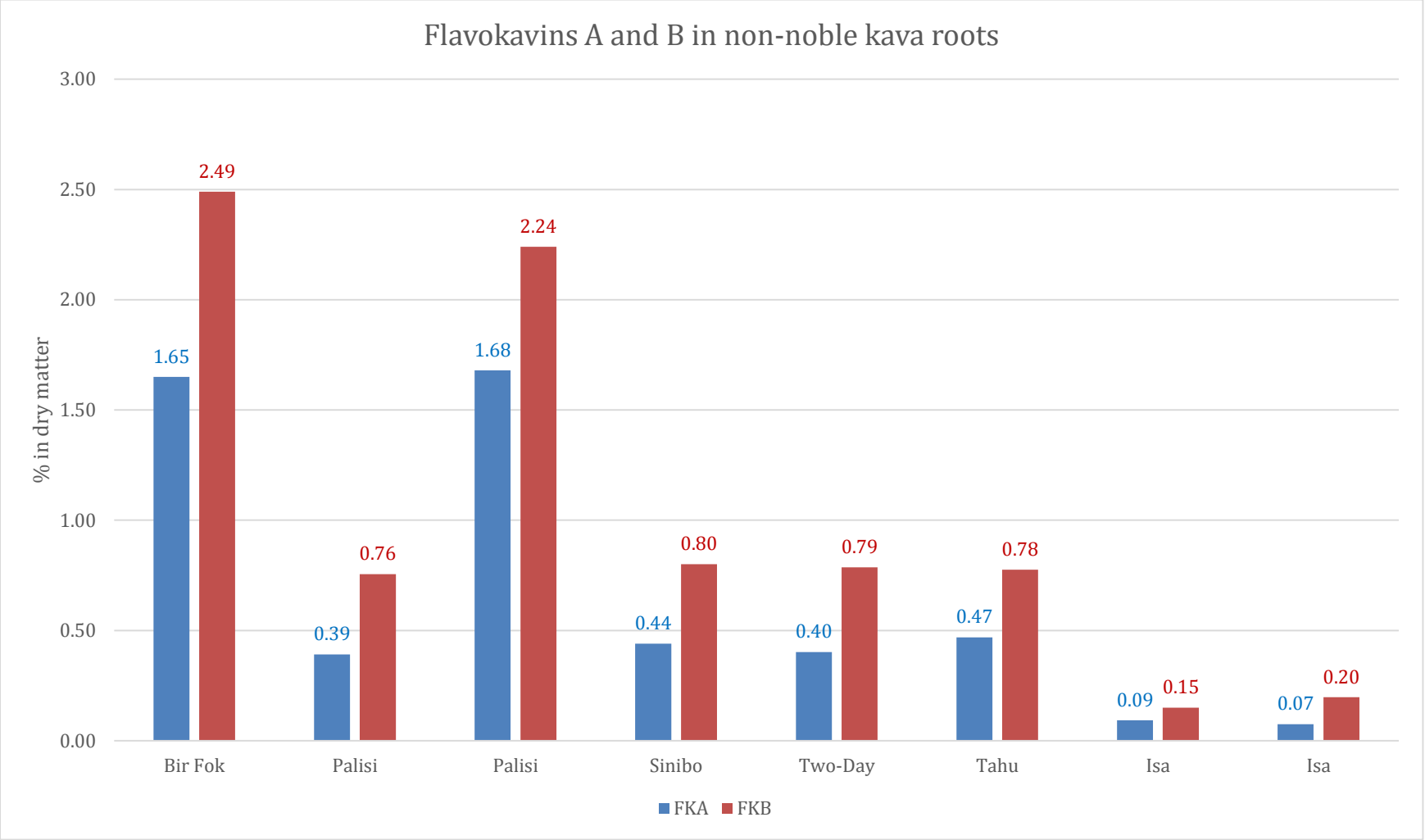
FKA ranged from 0.02 to 0.28% in the dry matter of '*noble*' kava roots, and from 0.07 to 1.68% in '*non-noble*' varieties, with the highest values found in the variety *Bir Fok*.

FKB ranged from 0.02 to 0.12% in the dry matter of '*noble'* kava roots, and from 0.15 to 2.49% in '*non-noble*' varieties, with the highest values found in the variety *Bir Fok*.

All root samples of '*noble*' kava remained below 0.15% of FKB, all root samples of '*non-noble*' varieties showed contents ≥ 0.15% FKB.


Flavokavin A in noble kava roots
% of dry matter
2.00
1.80
1.60
1.40
1.20
1.00
0.80
0.60
0.40
0.20
0.00
0.07 0.28 0.07 0.14 0.10 0.07 0.06 0.05 0.05 0.09 0.02 0.03 0.06 0.05 0.05 0.07 0.04 0.04 0.04 0.04 0.03 0.05 0.04 0.06 0.04 0.04 0.03 0.03 0.06 0.04 0.02 0.07 0.04 0.03 0.03 0.05 0.03 0.04 0.06 0.05 0.12 0.06 0.09 0.05 0.08 0.08 0.19 0.06 0.10 0.06
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana vula
Dokobana vula
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila Balavu
Qila leka
Qila leka
Vula kasa leka
Vula kasa leka
Yalu
Yonolulu
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Gilbert Island
Hanakapi'ai
Hina Tonga
Honokana Iki
Mahakea
Mapulehu
Moi
Moi
Nene
Opihikao
Panaewa
Rahmdel


Flavokavin B in noble kava roots
% of dry matter
3.00
2.50
2.00
1.50
1.00
0.50
0.00
0.08 Borogu
0.06 Borogu
0.11 Kelai
0.08 Kelai
0.06 Melo-Melo
0.08 Palarasul
0.09 Pia
0.12 Puariki
0.06 Sese
0.06 Silese
0.02 Damu
0.03 Damu
0.04 Dokobana Loa
0.06 Dokobana loa
0.04 Dokobana vula
0.10 Dokobana vula
0.05 Loa Kasa Leka
0.04 Loa Kasa Leka
0.06 Loa Kasa Leka
0.04 Loa Kasa Leka
0.02 Matakaro balavu
0.04 Matakaro leka
0.03 Qila Balavu
0.05 Qila leka
0.04 Qila leka
0.04 Vula kasa leka
0.03 Vula kasa leka
0.03 Yalu
0.03 Yonolulu
0.03 Ava La'au
0.03 Ava Lea
0.05 Feo
0.04 Hina 'Akau
0.03 Kata Kofe
0.03 Kula 'Akau
0.05 Leka Hina
0.03 Leka Kula
0.03 Valu
0.04 Gilbert Island
0.03 Hanakapi'ai
0.07 Hina Tonga
0.04 Honokana Iki
0.05 Mahakea
0.03 Mapulehu
0.04 Moi
0.10 Moi
0.12 Nene
0.03 Opihikao
0.08 Panaewa
0.03 Rahmdel


Flavokavins A and B in non-noble kava roots
% in dry matter
3.00
2.50
2.00
1.50
1.00
0.50
0.00
1.65
2.49
0.39
0.76
1.68
2.24
0.44
0.80
0.40
0.79
0.47
0.78
0.09
0.15
0.07
0.20
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa
Isa
FKA
FKB

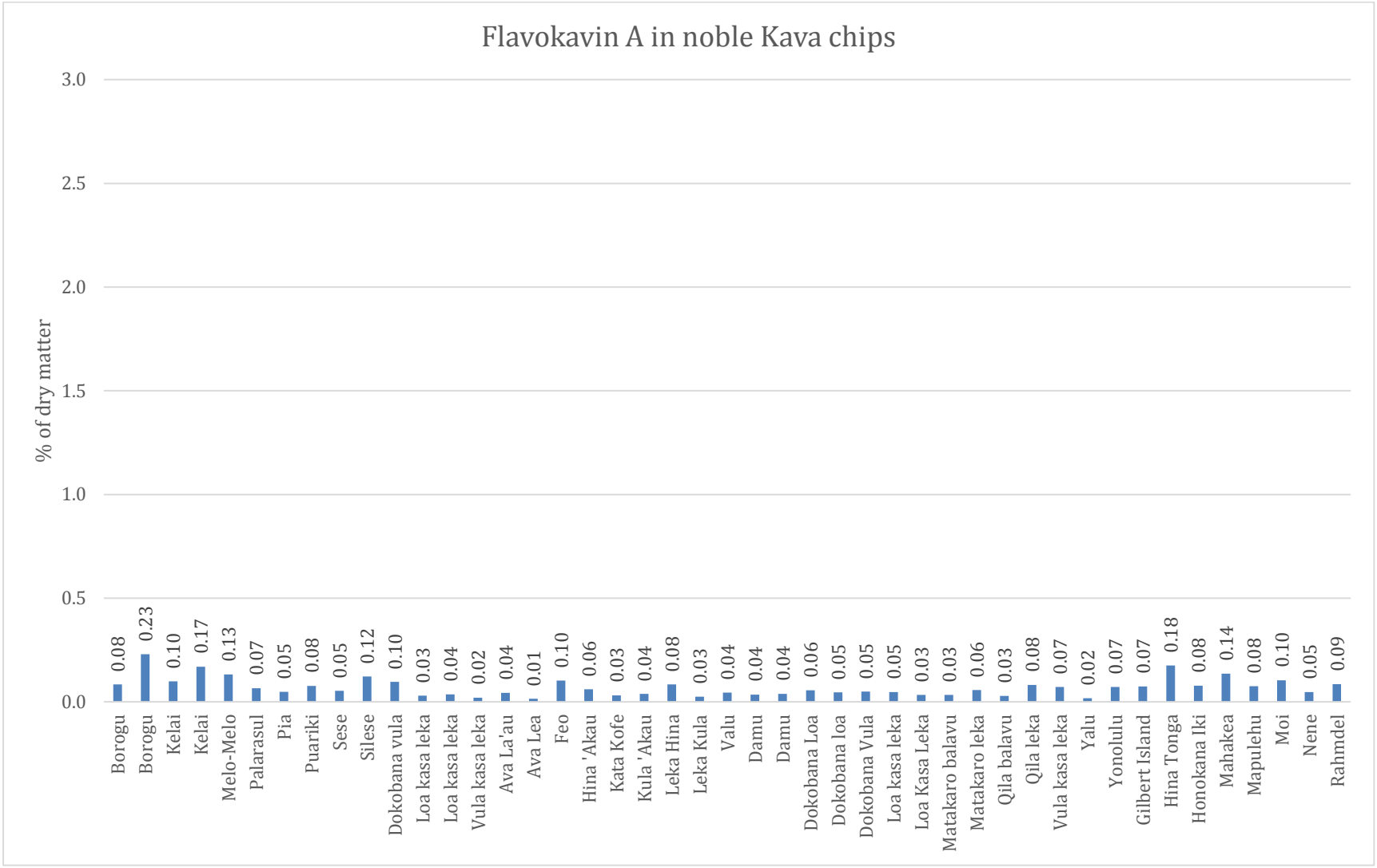
b) Chips

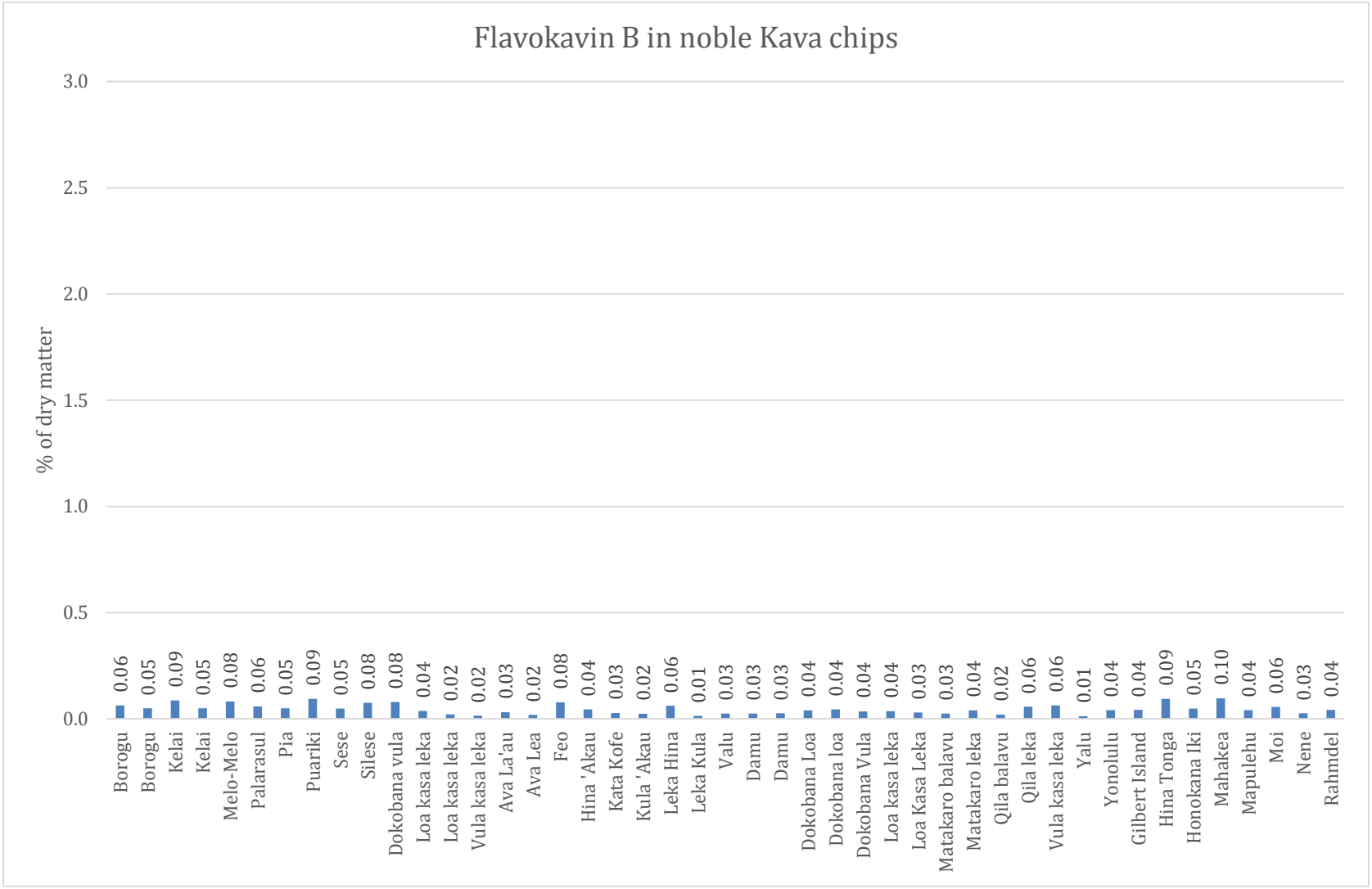
FKA ranged from 0.01 to 0.23% in the dry matter of '*noble*' chips, and from 0.06 to 0.99% in '*non-noble*' varieties, with the highest values found in the variety *Palisi*.

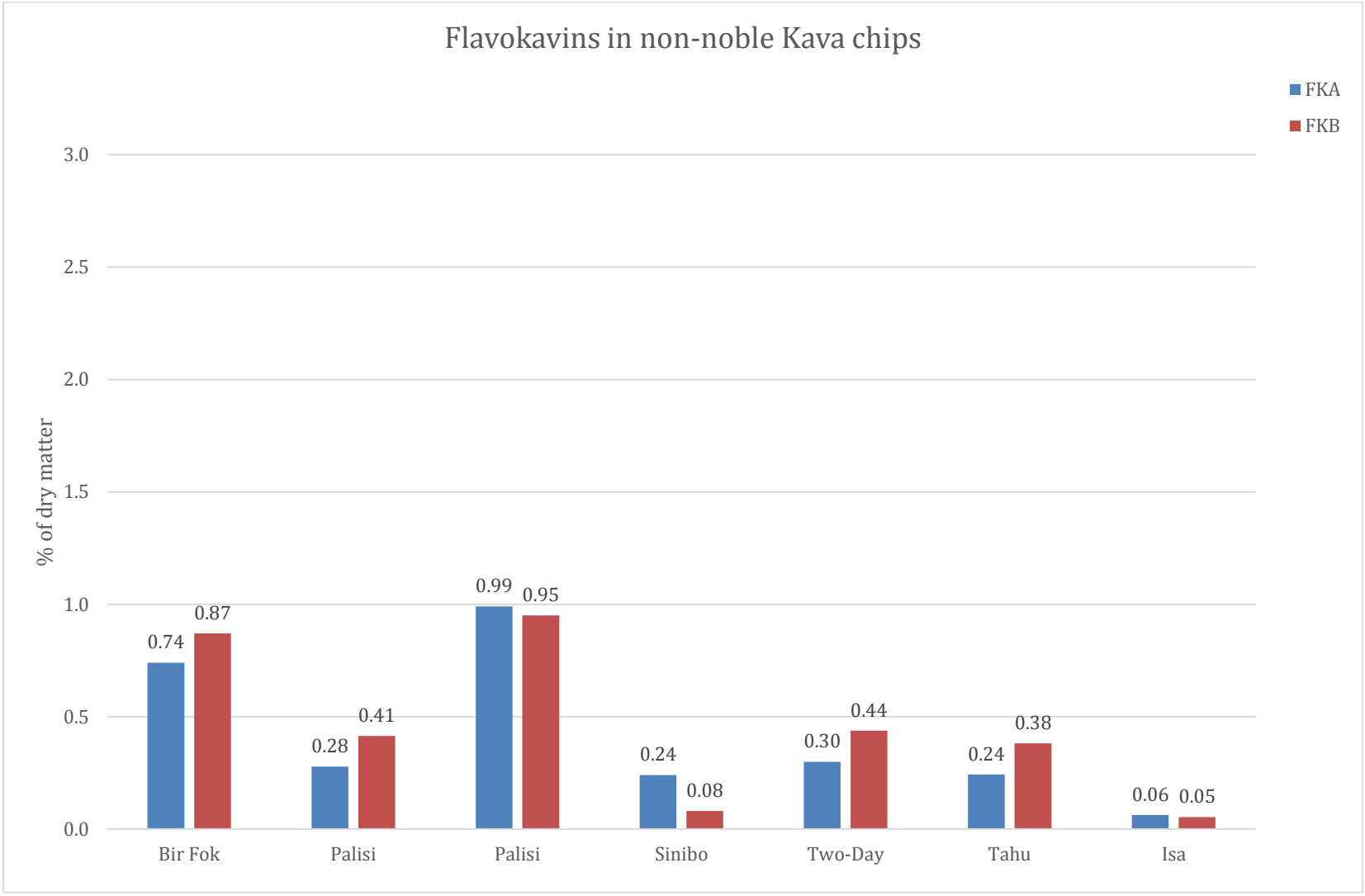
FKB ranged from 0.01 to 0.10% in the dry matter of '*noble*' kava chips, and from 0.05 to 0.95% in '*non-noble*' varieties, with the highest values again found in the variety *Palisi*.

All chips samples of '*noble*' kava remained below 0.15% of FKB, all but two chips samples of '*non-noble*' varieties showed contents ≥ 1.5% FKB.

The exceptions were *Sinibo* with 0.08% FKB and *Isa* with 0.05%. Both clearly indicated '*non-noble*' when submitted to the calculation of the K/FKB-ratio, the K(/KL-K)-ratio and the /DHM ratio (see below).


Flavokavin A in noble Kava chips
% of dry matter
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Borogu 0.08
Borogu 0.23
Kelai 0.10
Kelai 0.17
Melo-Melo 0.13
Palarasul 0.07
Pia 0.05
Puariki 0.08
Sese 0.05
Silese 0.12
Dokobana vula 0.10
Loa kasa leka 0.03
Loa kasa leka 0.04
Vula kasa leka 0.02
Ava La'au 0.04
Ava Lea 0.01
Feo 0.10
Hina 'Akau 0.06
Kata Kofe 0.03
Kula 'Akau 0.04
Leka Hina 0.08
Leka Kula 0.03
Valu 0.04
Damu 0.04
Damu 0.04
Dokobana Loa 0.06
Dokobana loa 0.05
Dokobana Vula 0.05
Loa kasa leka 0.05
Loa Kasa Leka 0.03
Matakaro balavu 0.03
Matakaro leka 0.06
Qila balavu 0.03
Qila leka 0.08
Vula kasa leka 0.07
Yalu 0.02
Yonolulu 0.07
Gilbert Island 0.07
Hina Tonga 0.18
Honokana Iki 0.08
Mahakea 0.14
Mapulehu 0.08
Moi 0.10
Nene 0.05
Rahmdel 0.09

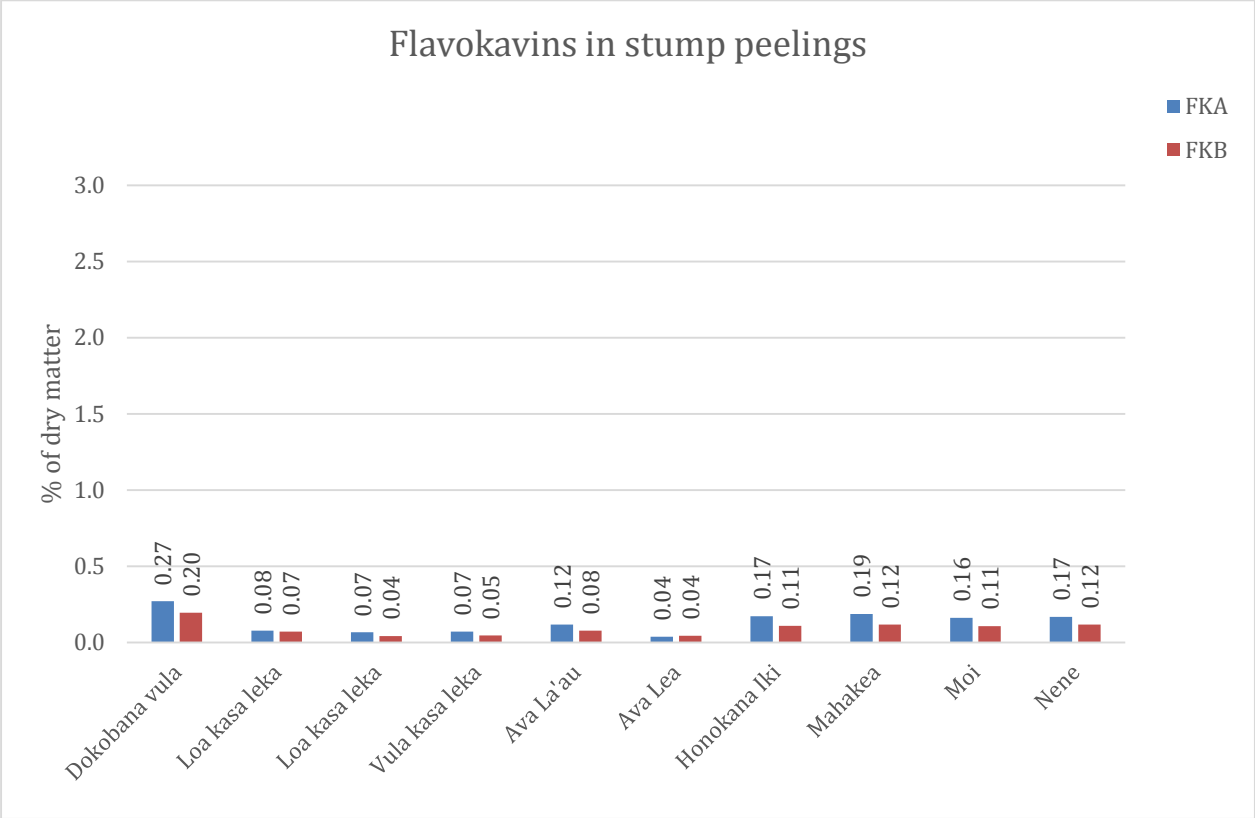

Flavokavin B in noble Kava chips
% of dry matter
3.0
2.5
2.0
1.5
1.0
0.5
0.0
Borogu 0.06
Borogu 0.05
Kelai 0.09
Kelai 0.05
Melo-Melo 0.08
Palarasul 0.06
Pia 0.05
Puariki 0.09
Sese 0.05
Silese 0.08
Dokobana vula 0.08
Loa kasa leka 0.04
Loa kasa leka 0.02
Vula kasa leka 0.02
Ava La'au 0.03
Ava Lea 0.02
Feo 0.08
Hina 'Akau 0.04
Kata Kofe 0.03
Kula 'Akau 0.02
Leka Hina 0.06
Leka Kula 0.01
Valu 0.03
Damu 0.03
Damu 0.03
Dokobana Loa 0.04
Dokobana loa 0.04
Dokobana Vula 0.04
Loa kasa leka 0.04
Loa Kasa Leka 0.03
Matakaro balavu 0.03
Matakaro leka 0.04
Qila balavu 0.02
Qila leka 0.06
Vula kasa leka 0.06
Yalu 0.01
Yonolulu 0.04
Gilbert Island 0.04
Hina Tonga 0.09
Honokana Iki 0.05
Mahakea 0.10
Mapulehu 0.04
Moi 0.06
Nene 0.03
Rahmdel 0.04


Flavokavins in non-noble Kava chips
FKA
FKB
% of dry matter
3.0
2.5
2.0
1.5
1.0
0.5
0.0
0.74
0.87
0.28
0.41
0.99
0.95
0.24
0.08
0.30
0.44
0.24
0.38
0.06
0.05
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa

c) Stump peelings

FKA ranged from 0.04 to 0.27%, FKB from 0.04 to 0.20%. One sample (*Dokobana vula*) was above the defined threshold of ≤ 0.15% of FKB (0.20%).

There were no samples of stump peelings of '*non-noble*' varieties, hence no comparison can be made. However, the testing of the stump peelings was only made out of scientific interest, as the standard proposal clearly defines roots and peeled stumps as materials of kava. Stump peelings, the left overs from stump peeling, would in no case be considered acceptable kava materials.

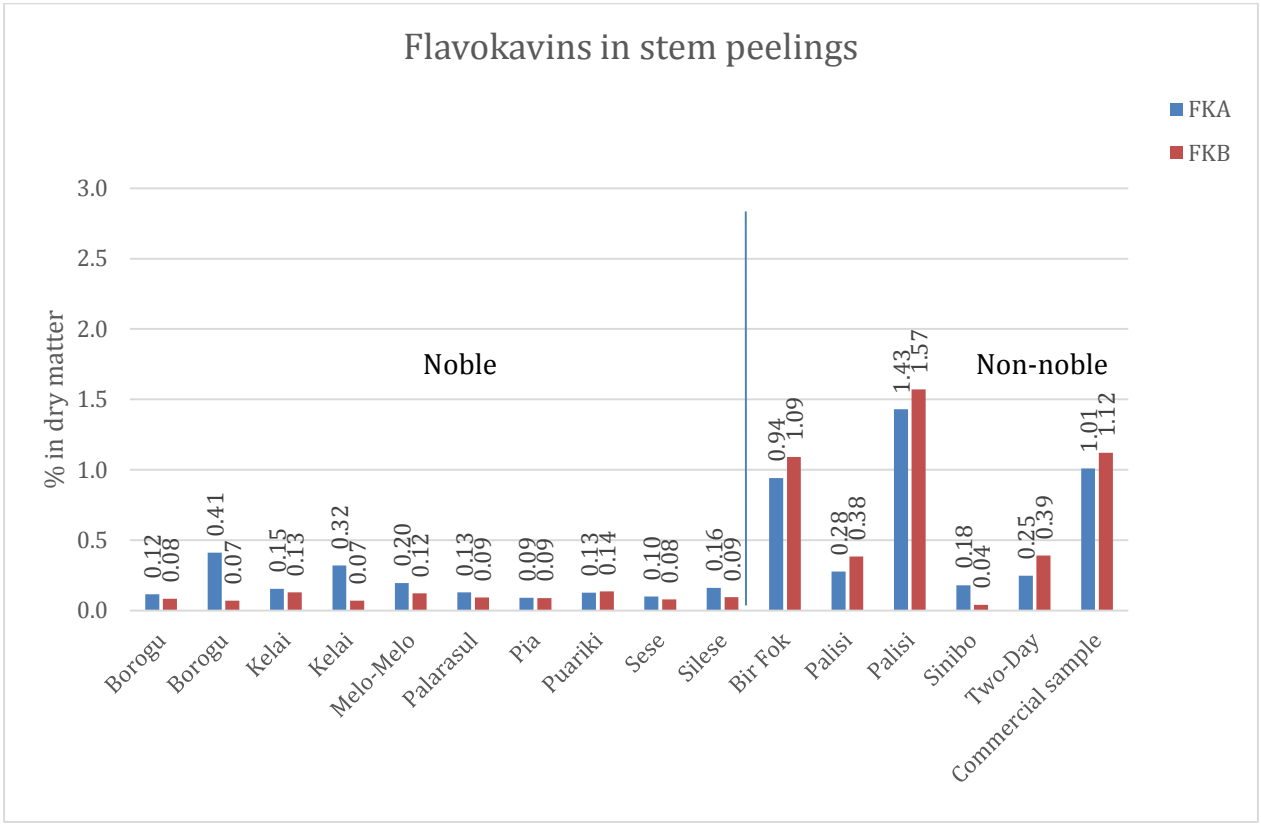


d) Stem peelings

In stem peelings of '*noble*' kava varieties, FKA ranged from 0.09 to 0.41%, FKB from 0.07 to 0.15%.

In stem peelings of '*non-noble*' varieties, FKA ranged from 0.18 to 1.43%; FKB from 0.04 to 1.57%. The only variety with FKB values lower than 0.15% was *Sinibo* (0.04 %). *Sinibo* would, however, have been correctly identified using the ratios FKB:K, K/(KL-K) and K/DHM.

Stem peelings can in no case be accepted as trading material of kava. Peelings of '*non-noble*' varieties can be recognised with an excellent error margin.

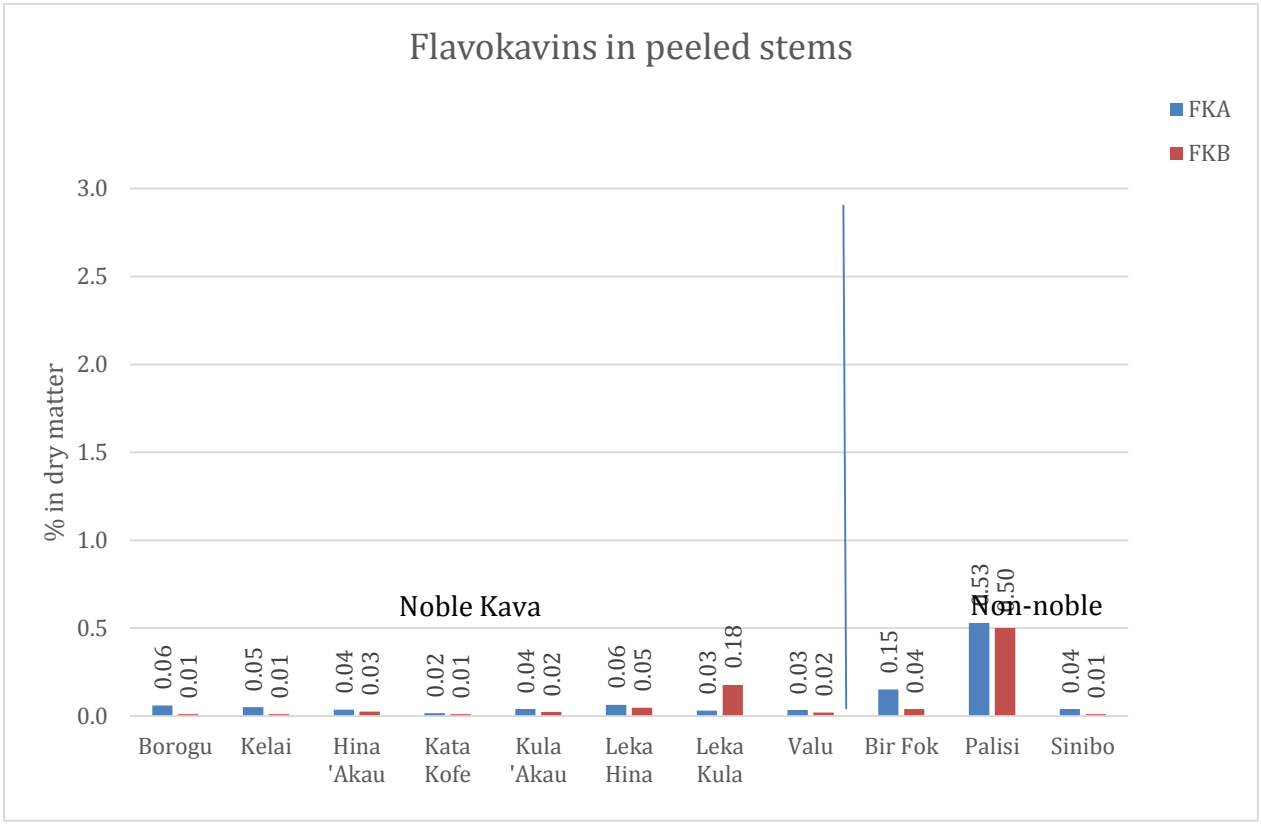


e) Peeled stems

In peeled stems of '*noble*' kava varieties, FKA ranged from 0.02 to 0.06%, FKB from 0.01 to 0.18%. Only one '*noble*' variety (*Leka kula* from Tonga) exceeded the threshold of 0.15% FKB with a value of 0.18%.

In stem peelings of non-noble varieties, FKA ranged from 0.04 to 0.53%; FKB from 0.01 to 0.50%. The only variety with FKB values lower than 0.15% was *Sinibo* (0.01 %). *Sinibo* would, however, have been correctly identified using the ratios FKB:K, K/(KL-K) and K/DHM.

Peeled kava stems do not fall under the definition of "*kava*" in the standard proposal, they would have to be regulated separately. Kava stems would not be in high demand by importers because of their extremely low kavalactone content.



3.5.2 Ratio Flavokavin B/Kavain

In all kava varieties perceived as '*noble*', kavain is one of the most predominant kavalactones, if not the highest kavalactone (as in the kava varieties from Samoa).

At the same time, a consistently low content of flavokavin B parallels the high values of kavain: as a rule of thumb, flavokavin B is lower than the kavain content. Generally, the flavokavin B content of '*noble*' kava is below 0.1%. This observation is, however, not sufficiently robust for a differentiation between '*noble*' and '*non-noble*' varieties. Even some '*noble*' varieties have FKB contents approaching (or in some cases even slightly exceeding) 0.1%.

The calculation of the factor FKB divided by K (multiplied by 100 for a better visualisation) turned out a highly reliable indicator of nobility.

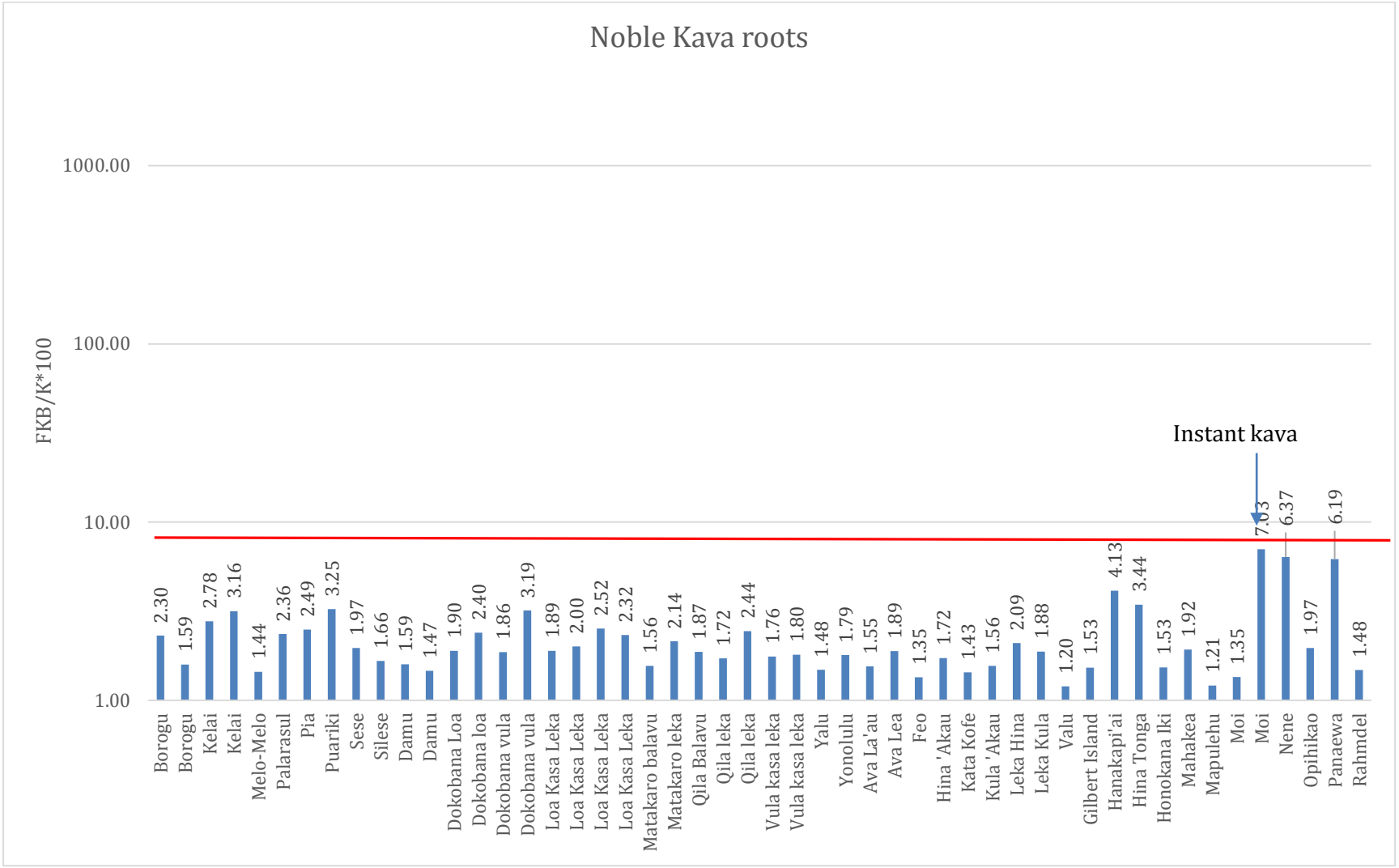
As a result of the sampling and testing of kava varieties, a value of 8.5 is suggested as the upper limit of the ratio FKB/K*100. This limit can be shown to be sufficiently robust for a differentiation between '*noble*' and '*non-noble*' kava, and would include all '*noble*' varieties.

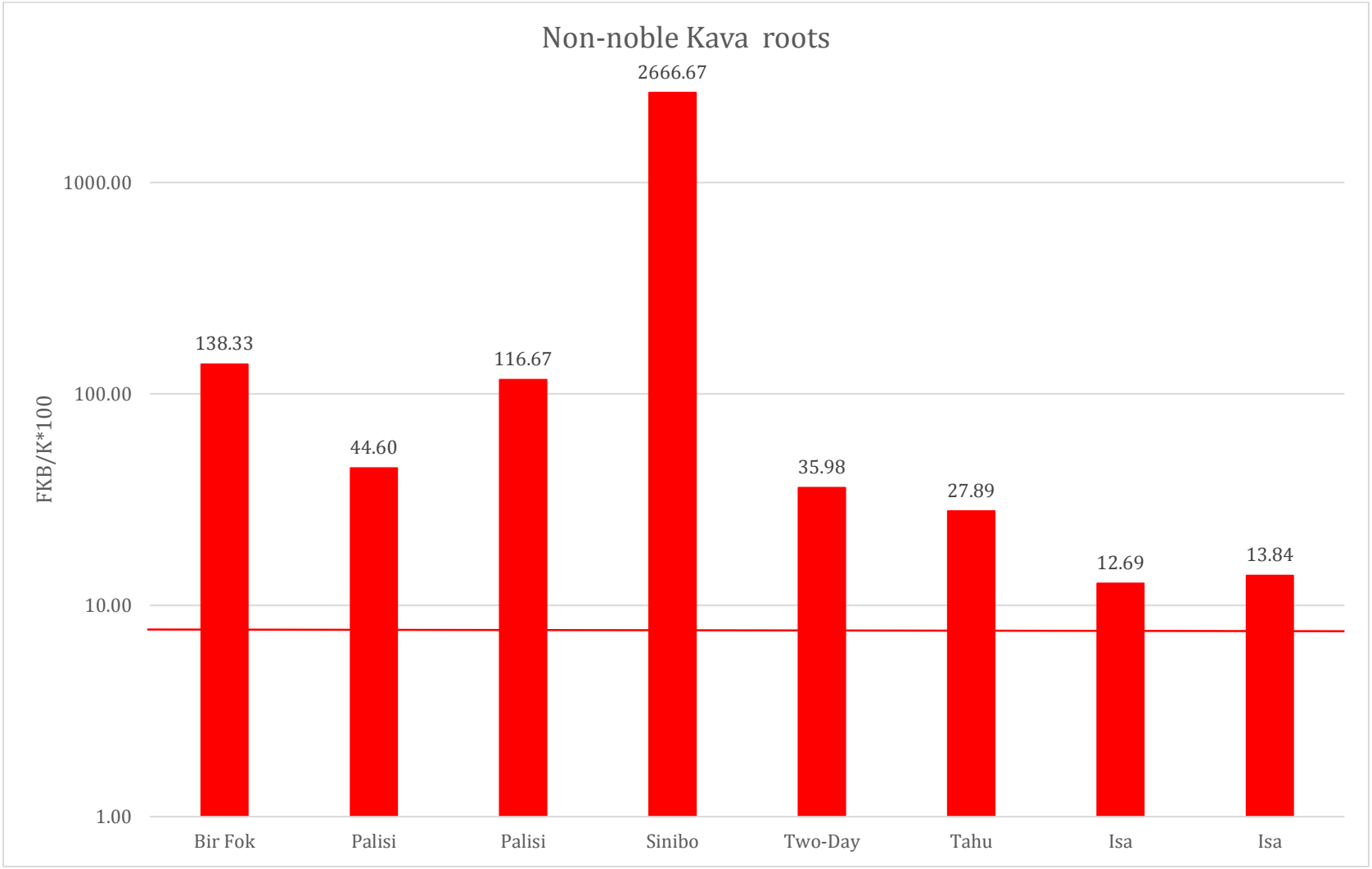
a) Roots

FKB:K-ratios ranged from 1.2 to to 4.1 for '*noble*' kava roots, and 12 to 140 for '*non-noble*' varieties, with '*wild-type*' kava showing values >2000.

Values above 5 were only detected in three out of 50 samples of '*noble*' kava, all from Hawaii: *Nene* with 6.37, *Panaewa* with 6.19, and *Mo'i* with 7.03.

- In the case of *Nene*, additional samples showed a very low FKB:K-ratio (sample 21: FKB:K-ratio of 1.21 in peeled chips), confirming the traditional classification of *Nene* as '*noble*' kava. The measured value is an outlier and difficult to explain. In any case would the proposed limit of 8.5 not interfere with electability of *Nene* for kava exports according to the proposed standard;
- The sample of *Mo'i* with an FKB:K-ratio was not a root powder, but an instant kava powder ready for drinking. Due to the processing, some shifts in the kavalactone composition must be expected and can be observed. Instant powder preparation leads to losses in kavalactones by roughly 50%, whereas FKB remained unchanged. Testing with the roots showed a FKB:K-ratio of 1.35 and thus clearly indicated '*noble*' kava. The proposed limit would strictly spoken not be applicable to *Mo'i* extracts such as the instant powder tested here. The results were still within the proposed standard limit of 8.5; and
- The sample of *Panaewa* was a powder sample consisting of roots and chips mixed together in an unknown ratio. Due to the additional content of chips powder, and the chips usually showing slightly higher FKB:K-ratios than the roots, the measured result of 6.2 would not necessarily be representative for '*noble*' kava roots. There was no pure root samples available for testing, but literature data indicated nobility for *Panaewa*, as did the K:DHM-ratio for the powder mix. Again, an FKB:K ratio of 6.2 would be acceptable within the limit proposal of 8.5 for the Codex standard.


Noble Kava roots
1000.00
100.00
10.00
1.00
F'KB/K*100
Instant kava
Borogu 2.30
Borogu 1.59
Kelai 2.78
Kelai 3.16
Melo-Melo 1.44
Palarasul 2.36
Pia 2.49
Puariki 3.25
Sese 1.97
Silese 1.66
Damu 1.59
Damu 1.47
Dokobana Loa 1.90
Dokobana loa 2.40
Dokobana vula 1.86
Dokobana vula 3.19
Loa Kasa Leka 1.89
Loa Kasa Leka 2.00
Loa Kasa Leka 2.52
Loa Kasa Leka 2.32
Matakaro balavu 1.56
Matakaro leka 2.14
Qila Balavu 1.87
Qila leka 1.72
Qila leka 2.44
Vula kasa leka 1.76
Vula kasa leka 1.80
Yalu 1.48
Yonolulu 1.79
Ava La'au 1.55
Ava Lea 1.89
Feo 1.35
Hina 'Akau 1.72
Kata Kofe 1.43
Kula 'Akau 1.56
Leka Hina 2.09
Leka Kula 1.88
Valu 1.20
Gilbert Island 1.53
Hanakapi'ai 4.13
Hina Tonga 3.44
Honokana Iki 1.53
Mahakea 1.92
Mapulehu 1.21
Moi 1.35
Moi 7.03
Nene 6.37
Opihikao 1.97
Panaewa 6.19
Rahmdel 1.48


Non-noble Kava roots
FKB/K*100
1000.00
100.00
10.00
1.00
138.33
44.60
116.67
2666.67
35.98
27.89
12.69
13.84
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa
Isa

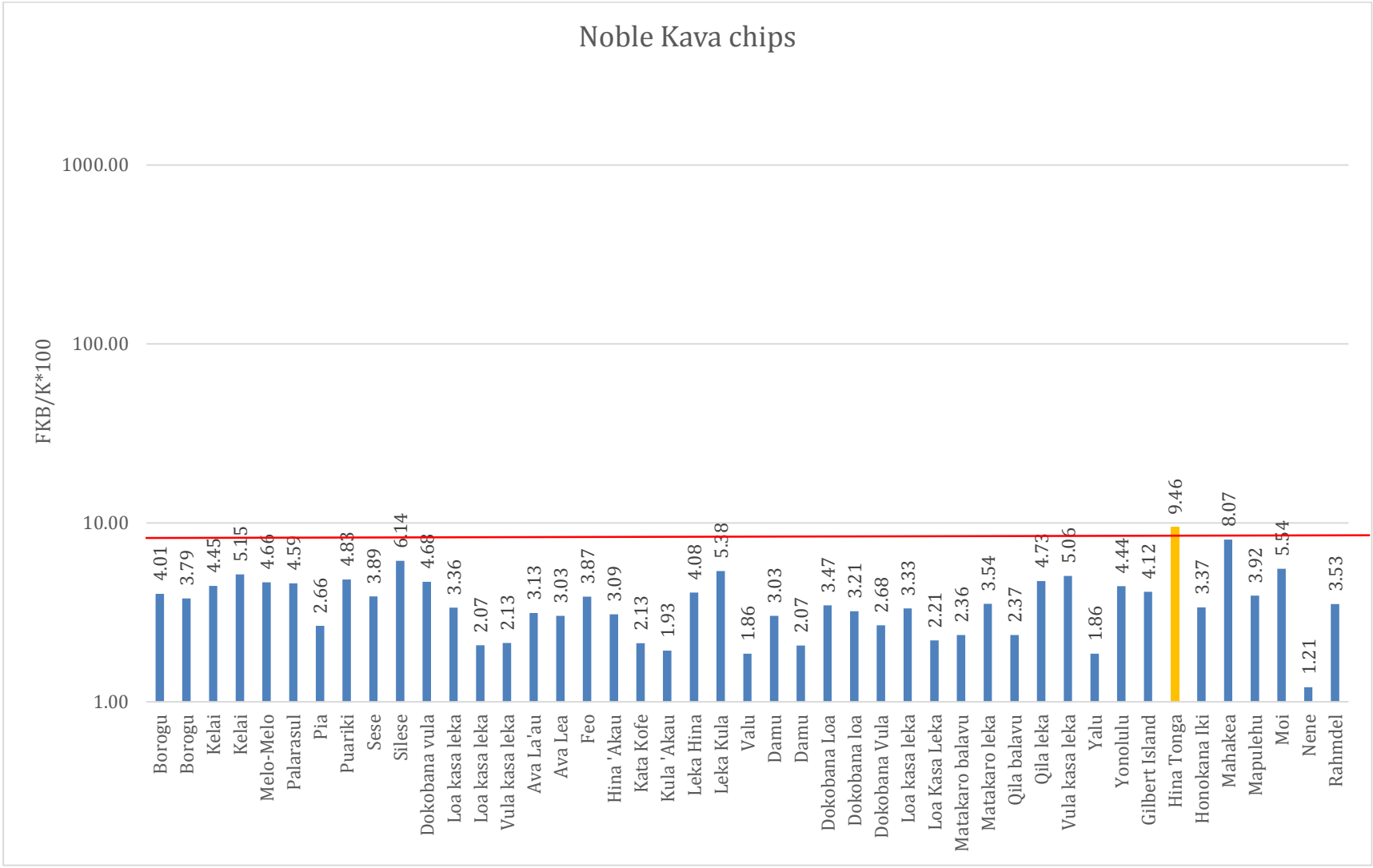
b) Chips

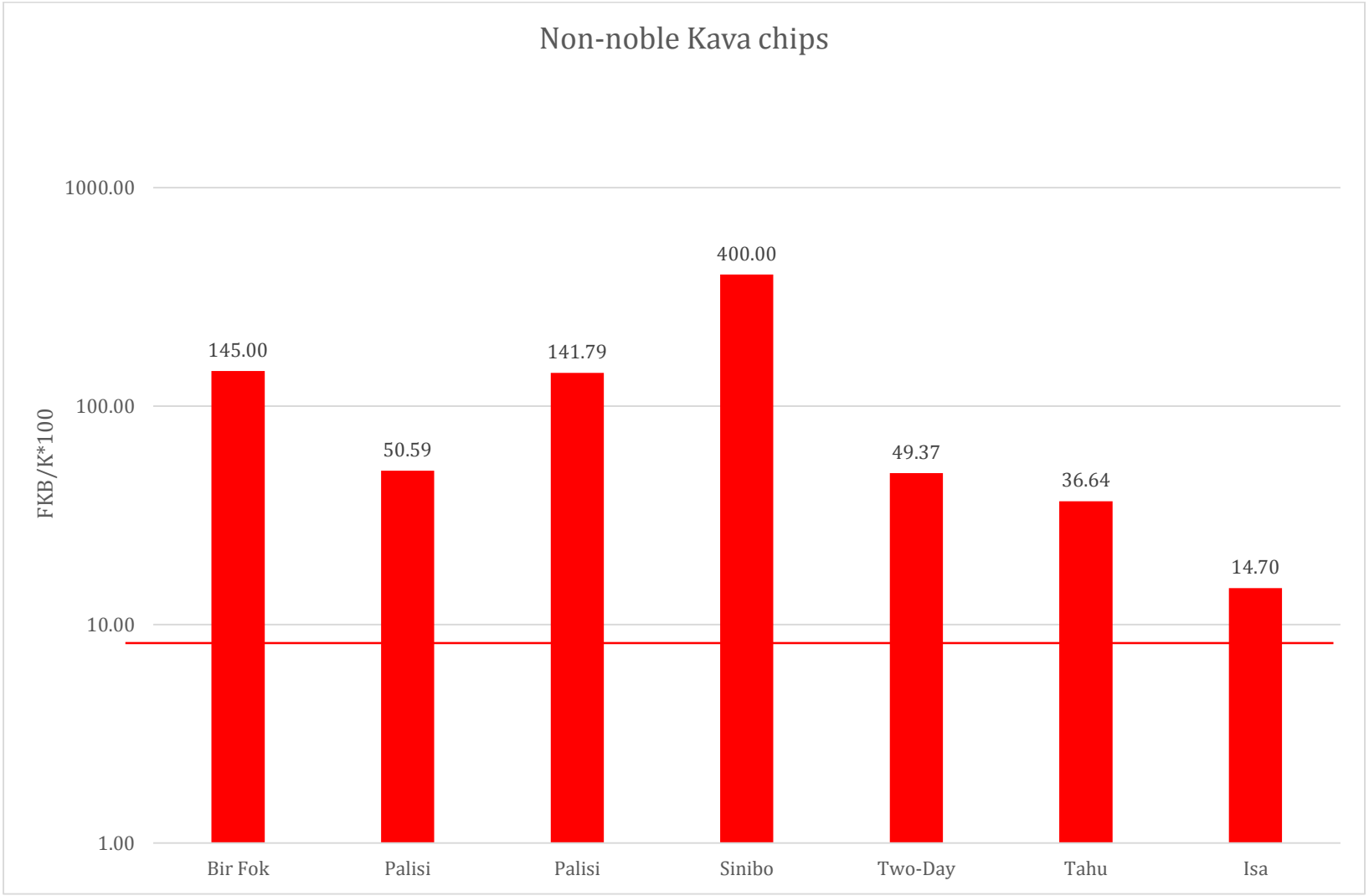
FKB:K-ratios ranged from 1.2 to 6.1 for '*noble*' kava roots, and 14 to 145 for non-noble varieties, with '*wild-type*' kava showing values >2000.

Values above 6.1 were only detected in two out of 43 samples of '*noble*' kava, both from Hawaii: *Hina* Tonga with 9.46 and *Mahakea* with 8.07.

- In the case of *Mahakea* (FKB:K-ratio of 8.07 in the peeled chips), the roots had shown a very low ratio of 1.92. The finding of 8.07 seems high, but in the absence of additional samples, cannot be discussed. *Mahakea* is clearly a '*noble*' kava with respect to traditional use. The definition of the upper limit of 8.5 would still allow inclusion of this sample into exports; and
- *Hina* Tonga is a different topic: According to the measurements, the FKB:K-ratio of 9.46 would clearly exceed the suggested limit. *Hina* Tonga is not a traditional Hawaiian variety, and there is no reference data available from published analyses. The FKB:K-ratio of 3.44 for the roots is already relatively high in comparison with other noble varieties (although clearly not '*non-noble*'). Growing *Hina* Tonga for export purposes might not be advisable.

In conclusion, all '*noble*' kava chips samples, with one exception (*Hina Tonga*), were found below the proposed FKB:K ratio of 8.5. The reason for the result with the Hawaiian variety *Hina Tonga* is as yet unclear.

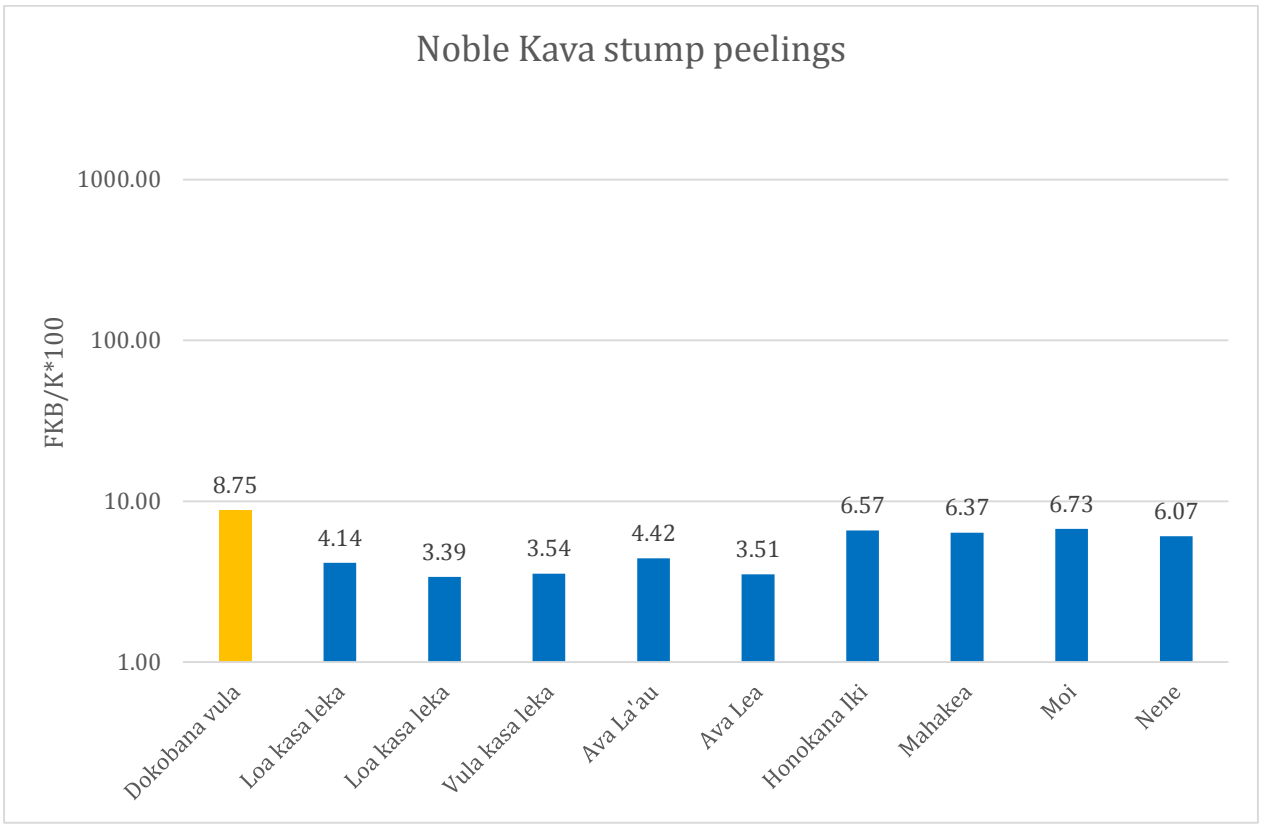

Noble Kava chips
FKB/K*100
1000.00
100.00
10.00
1.00
4.01
3.79
4.45
5.15
4.66
4.59
2.66
4.83
3.89
6.14
4.68
3.36
2.07
2.13
3.13
3.03
3.87
3.09
2.13
1.93
4.08
5.38
1.86
3.03
2.07
3.47
3.21
2.68
3.33
2.21
2.36
3.54
2.37
4.73
5.06
1.86
4.44
4.12
9.46
3.37
8.07
3.92
5.54
1.21
3.53
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Dokobana vula
Loa kasa leka
Loa kasa leka
Vula kasa leka
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana Vula
Loa kasa leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila balavu
Qila leka
Vula kasa leka
Yalu
Yonolulu
Gilbert Island
Hina Tonga
Honokana lki
Mahakea
Mapulehu
Moi
Nene
Rahmdel


Non-noble Kava chips
1000.00
100.00
10.00
1.00
FKB/K*100
145.00
50.59
141.79
400.00
49.37
36.64
14.70
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa

c) Stump peelings

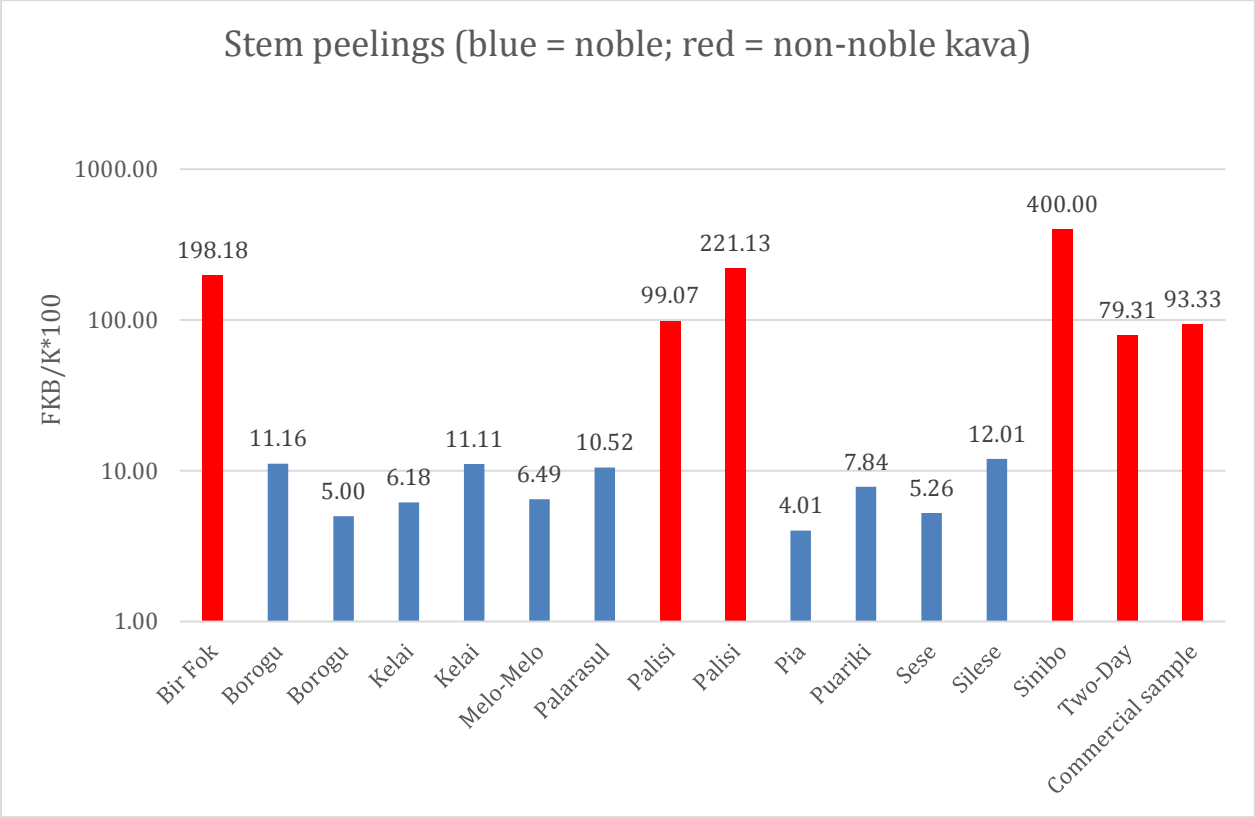
FKB:K-ratios ranged from 3.39 to 8.75 for '*noble*' kava stump peelings, with a single Fijian variety (*Dokobana vula* from *Rotuma*) slightly exceeding the defined limit of 8.5, whereas all other samples were well below this limit. There were no samples of stump peelings of '*non-noble*' varieties, hence no comparison can be made. However, the testing of the stump peelings was only made out of scientific interest, as the standard proposal clearly defines roots and peeled stumps as materials of kava. Stump peelings, the leftovers from stump peeling, would in no case be considered acceptable kava materials.

The analyses still highlighted an interesting aspect: even if '*noble*' kava is not peeled, the testing would not be expected to falsely indicate '*non-noble*' kava.



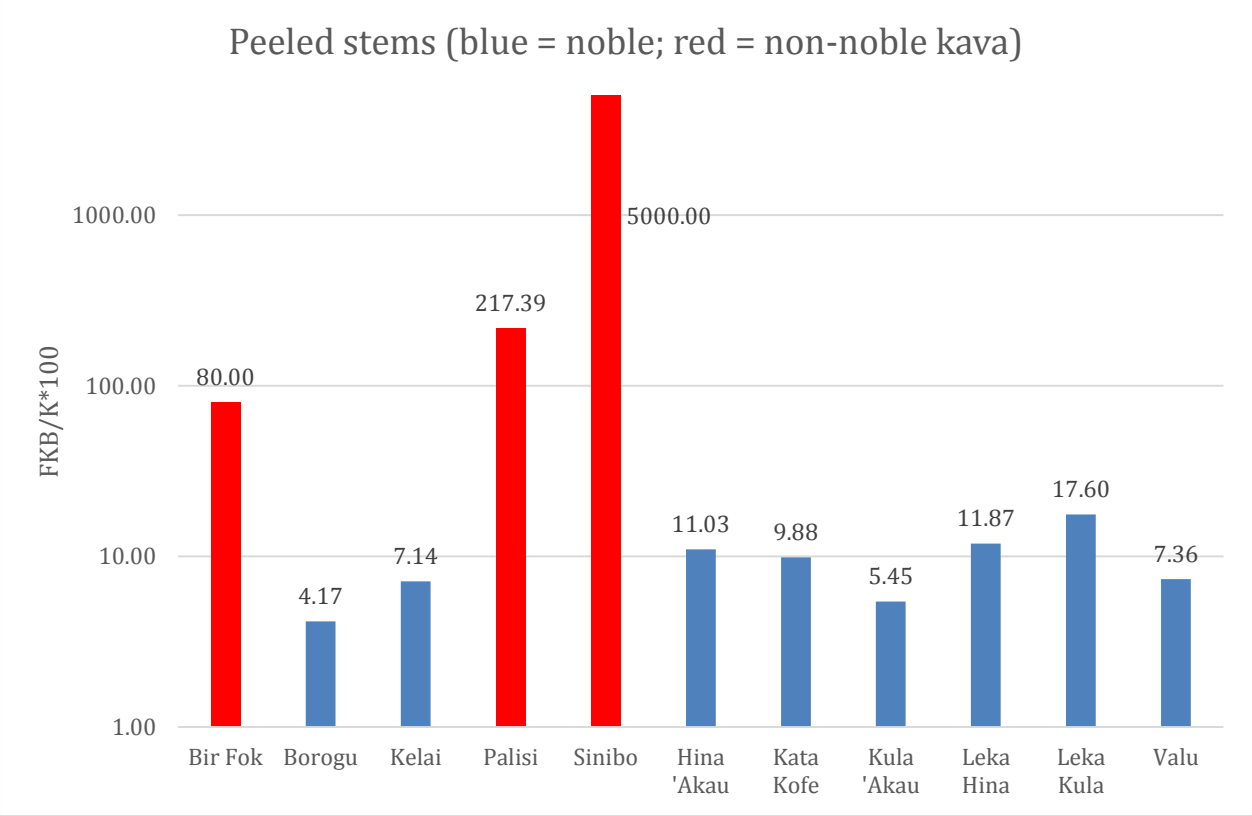
d) Stem peelings

FKB:K-ratios ranged from 4.0 to 12.0 for '*noble*' kava stem peelings, and from 79 to 400 for '*non-noble*' kava. Stem peelings can in no case be accepted as trading material of kava. Even the most favoured '*noble*' kava varieties such as *Borogu*, *Kelai*, *Palarasul* or *Silese* indicate '*non-noble*' when tested on their FKB:K-ratios. Peelings of '*non-noble*' varieties can be recognised with an excellent error margin.



e) Peeled stems

FKB:K-ratios ranged from 4.2 to 17.6 for '*noble*' kava peeled stems, and from 80 to 5000 for '*non-noble*' kava. The ratio could be applied to kava stems as well, but only with an adjusted limit. Peeled kava stems do not fall under the definition of "*kava*" in the standard proposal, they would have to be regulated separately. Kava stems would not be in high demand by importers because of their extremely low kavalactone content.



3.5.3 Ratio Kavain to Total Kavalactones minus Kavain

The calculation of K:(KL-K)*100 can serve for an estimation of nobility even when the flavokavins have not been measured. '*Noble*' kava typically shows values ≥ 25, non-noble varieties typically show lower ratios.

The ratio is, however, not 100% reliable, as single noble varieties would not be recognised as '*noble*', being analysed with values < 25, whereas single '*two-day*' varieties would falsely be recognised as '*noble*'.

As a result of the sampling and testing of kava varieties, a value of 25 is suggested as the lower limit of the ratio K/(KL-K)*100.

The overall impression is that this test reacts sensitive to differences in the age of the plant at harvesting. This hypothesis would require closer examination. With different samples of the Fijian variety "*Loa Kasa Leka*" sampled with plant ages from 2.5 to 3.5 years, the effect of plant maturity on the K:(KL-K)-ratio shows a tendency towards higher values with increasing age.

Most interestingly, '*nobility*' was correctly assigned in all but two cases where the age of the sample was known to be at least 3 years. There would have been only one false positive attribution to *noble* kava ('*two-day*' from Vanuatu) with samples having a documented age of three years.

a) Roots

K:(KL-K)-ratios ranged from 19.9 to to 79.6 for '*noble*' kava roots, and from 1.1 to 33.5 for '*non-noble*' varieties, with '*wild-type*' kava showing the lowest values.

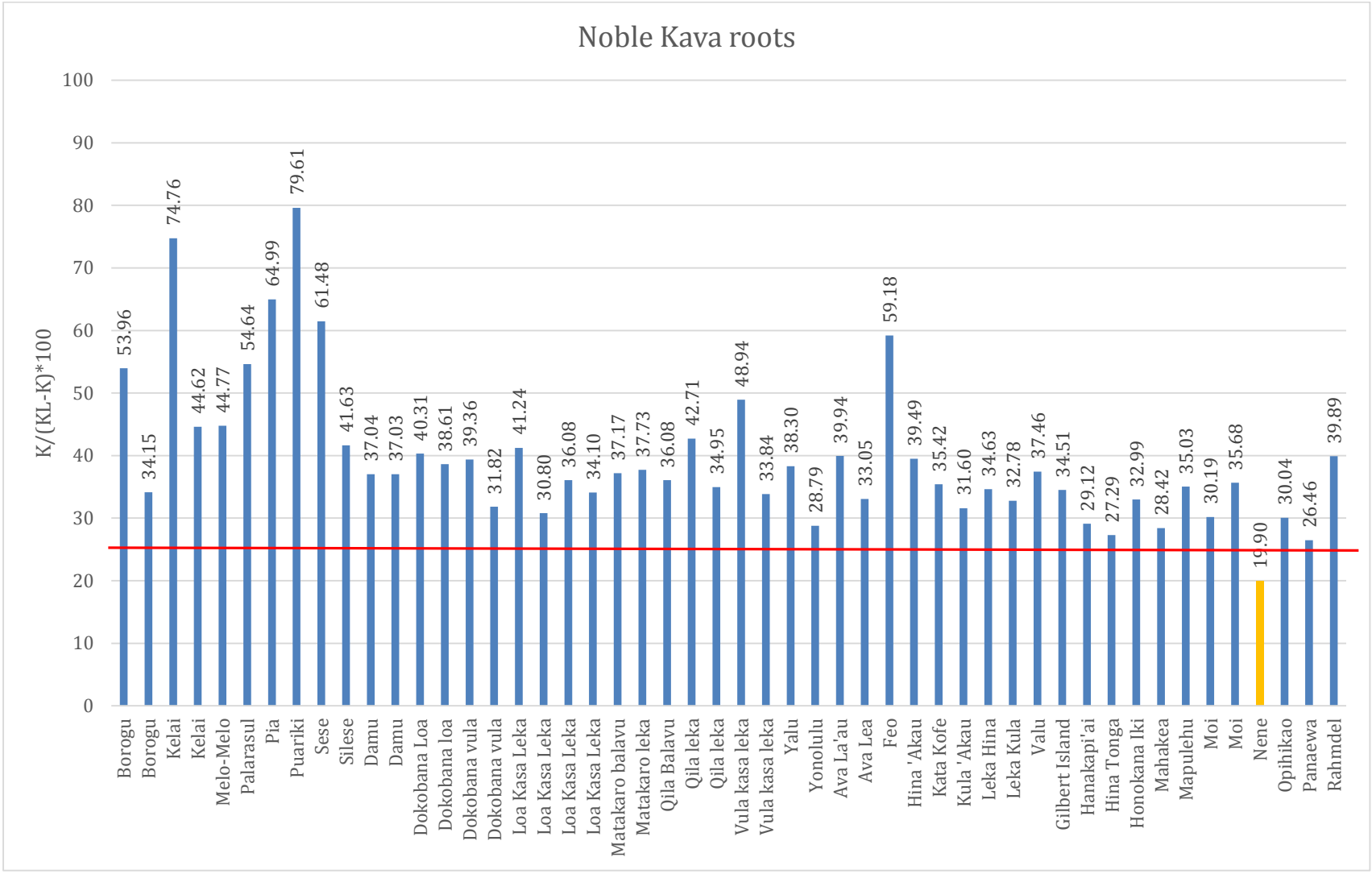
'*Noble*' kava values < 25 (false positive on '*non-noble*' kava) were detected in:

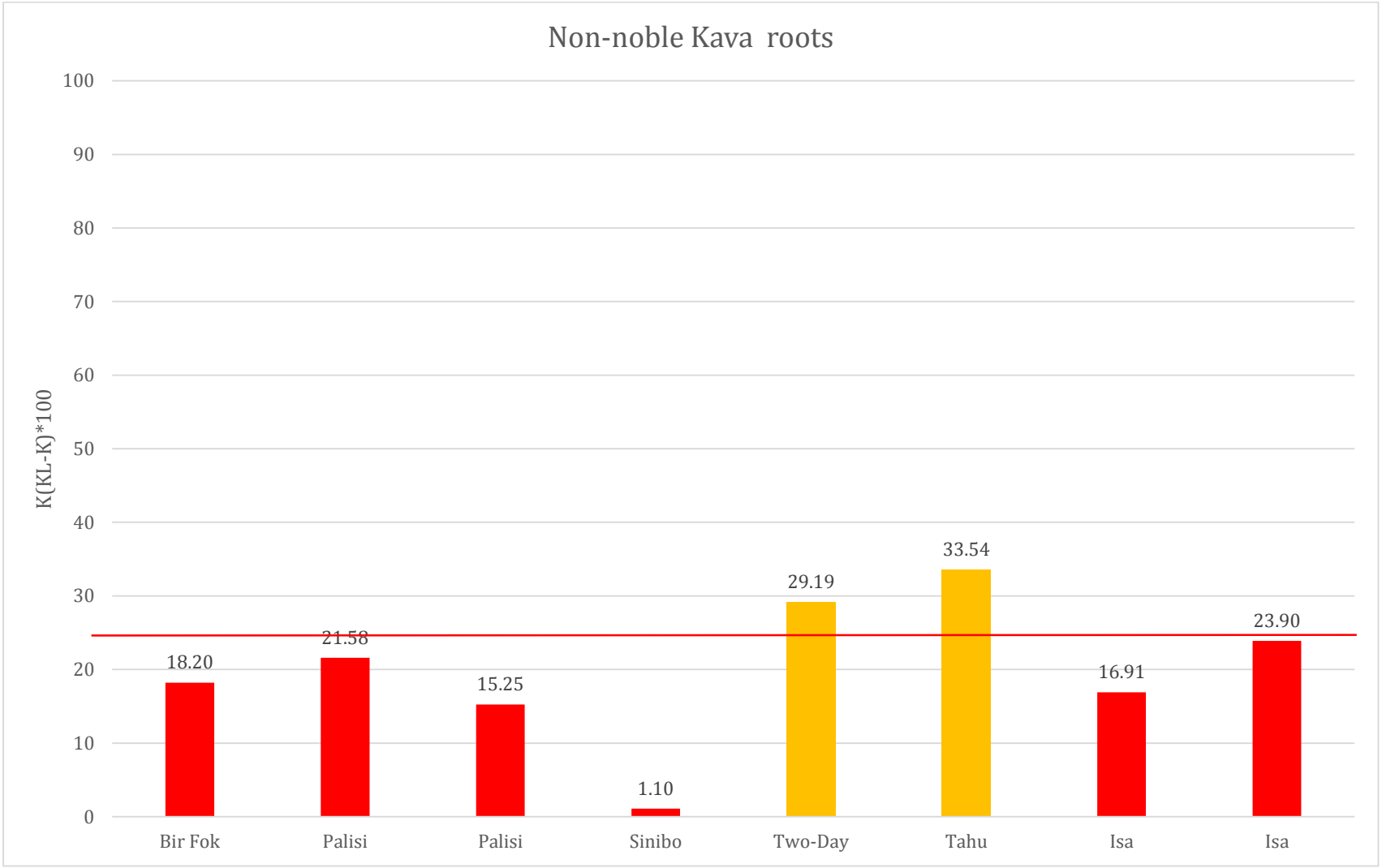
- One root sample of the Hawaiian '*noble*' variety Nene (19.9), but not in the sample of the peeled chips (35.0) or in published analyses (see Annex 6 in the entry for *Nene* in the Hawaiian samples). The deviation seems unusual and may have been related to the specific sample. The same sample also showed a K:DHM-ratio < 1, which again would in an unknown sample lead to the conclusion of '*non-noble*' material. The finding is not in line with published data (see Annex 6) or the values given in the collection of analyses presented by *www.TrueKava.com*.

'*Non-noble*' values > 25 (false negative on '*non-noble*' kava) were detected in:

- A root sample of the Vanuatu variety '*Two-Day*' (ratio = 29.2). In the peeled chips of the same variety the ratio was already 21.6 and thus below the limit. The variety '*two-day*' would not be recognised using the K:DHM ratio as an additional measure, but would clearly be identified using the K:FKB ratio; and
- A root sample of the variety "*Tahu*" from Solomon Islands. Again, the application of the K:DHM ratio would not allow a safe recognition of this variety as '*non-noble*', but the proposed FKB:K-ratio would.

In conclusion, setting the limit of the K:(KL-K)-ratio to 25 gives a good impression, but not 100% safety for the distinction between '*noble*' from '*non-noble*' roots.


Noble Kava roots
K/(KL-K)*100
100
90
80
70
60
50
40
30
20
10
0
53.96
34.15
74.76
44.62
44.77
54.64
64.99
79.61
61.48
41.63
37.04
37.03
40.31
38.61
39.36
31.82
41.24
30.80
36.08
34.10
37.17
37.73
36.08
42.71
34.95
48.94
33.84
38.30
28.79
39.94
33.05
59.18
39.49
35.42
31.60
34.63
32.78
37.46
34.51
29.12
27.29
32.99
28.42
35.03
30.19
35.68
19.90
30.04
26.46
39.89
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana vula
Dokobana vula
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila Balavu
Qila leka
Qila leka
Vula kasa leka
Vula kasa leka
Yalu
Yonolulu
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Gilbert Island
Hanakapi'ai
Hina Tonga
Honokana Iki
Mahakea
Mapulehu
Moi
Moi
Nene
Opihikao
Panaewa
Rahmdel


Non-noble Kava roots
K(KL-K)*100
100
90
80
70
60
50
40
30
20
10
0
18.20
21.58
15.25
1.10
29.19
33.54
16.91
23.90
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa
Isa

b) Chips

K:(KL-K)-ratios ranged from 19.6 to 55.8 for '*noble*' kava chips, and 1.2 to 26.7 for '*non-noble*' varieties.

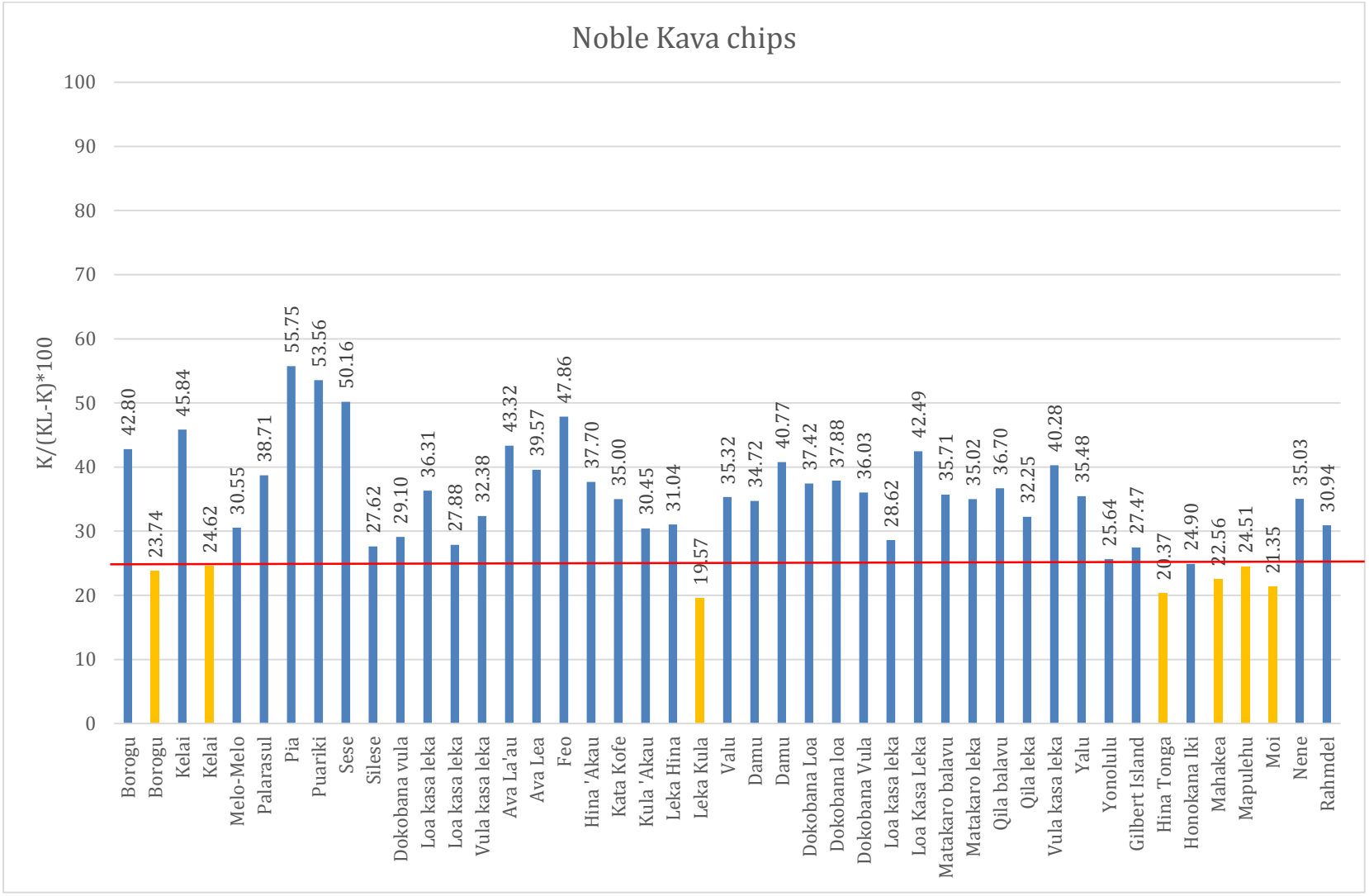
'*Noble kava*' values < 25 (false positive on '*non-noble*' kava) were detected in:

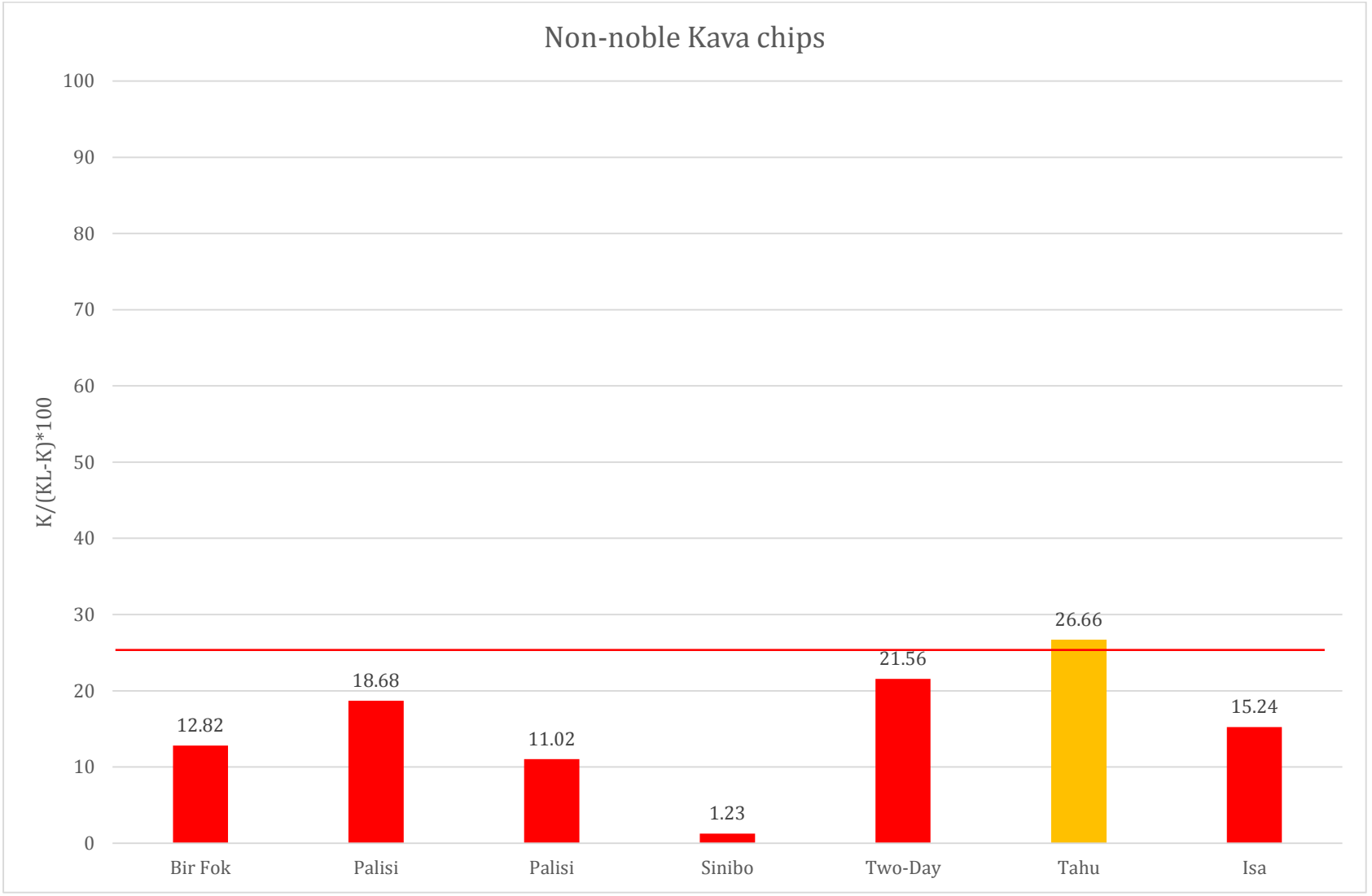
- One root sample of the Vanuatu '*noble*' variety "*Borogu*" (23.7): An independently collected sample showed a ratio of 42.8 and thus indicated nobility as clearly as the literature data identified in the research for this project. It is possible that the deviating sample was not fully mature, which may explain the low ratio;
- A chips sample of the Vanuatu '*noble*' variety "*Kelai*" barely missed the defined limit (24.6), but an independently collected sample clearly indicated '*nobility*' with a ratio of 45.8. It is possible that the deviating sample was not fully mature, which may explain the low ratio;
- A chips sample of the Tongan '*noble*' variety "*Leka Kula*" had a rather low ratio of 19.6. It would also have been falsely labelled '*non-noble*' with the use of the K:DHM ratio, but not with the FKB:K-ratio;
- A chips sample of the Hawaiian '*noble*' variety "*Honokane Iki*", which just barely missed the limit with a ratio of 24.9. The FKB:K-ratio and the K:DHM ratio both correctly recognised this variety as '*noble*';
- A chips sample of the Hawaiian '*noble*' variety "*Mapulehu*", which again just barely missed the limit with a ratio of 24.5. The FKB:K-ratio and the K:DHM ratio both correctly recognised this variety as '*noble*';
- A chips sample of the Hawaiian '*noble*' variety "*Mo'i*", with a ratio of 21.4. The FKB:K-ratio correctly identified this variety as '*noble*', whereas the K:DHM-ratio just barely indicated '*nobility*';
- A chips sample of the Hawaiian variety "*Hina Tonga*", with a ratio of 20.4. This sample would have been recognised as '*non-noble*' under all conditions. As already mentioned in section 3.5.1, there is no sufficient traditional experience with "*Hina Tonga*" in Hawaii to rely on, and cultivation may not be advisable; and
- A chips sample of the Hawaiian '*noble*' variety "*Mahakea*", with a ratio of 22.6. This sample was borderline '*noble*' in the FKB:K-ratio and the K:DHM-ratio, but has clearly been recognised as '*noble*' in published analyses and in an independent sample of a mixed root&chips powder.

"*Non-noble*" values > 25 (false negative on "*non-noble*" kava) were detected in:

- A chips sample of the variety "*Tahu*" from Solomon Islands. Again, the application of the K:DHM ratio would not have allowed a safe recognition of this variety as '*non-noble*', but the proposed FKB:K-ratio would.

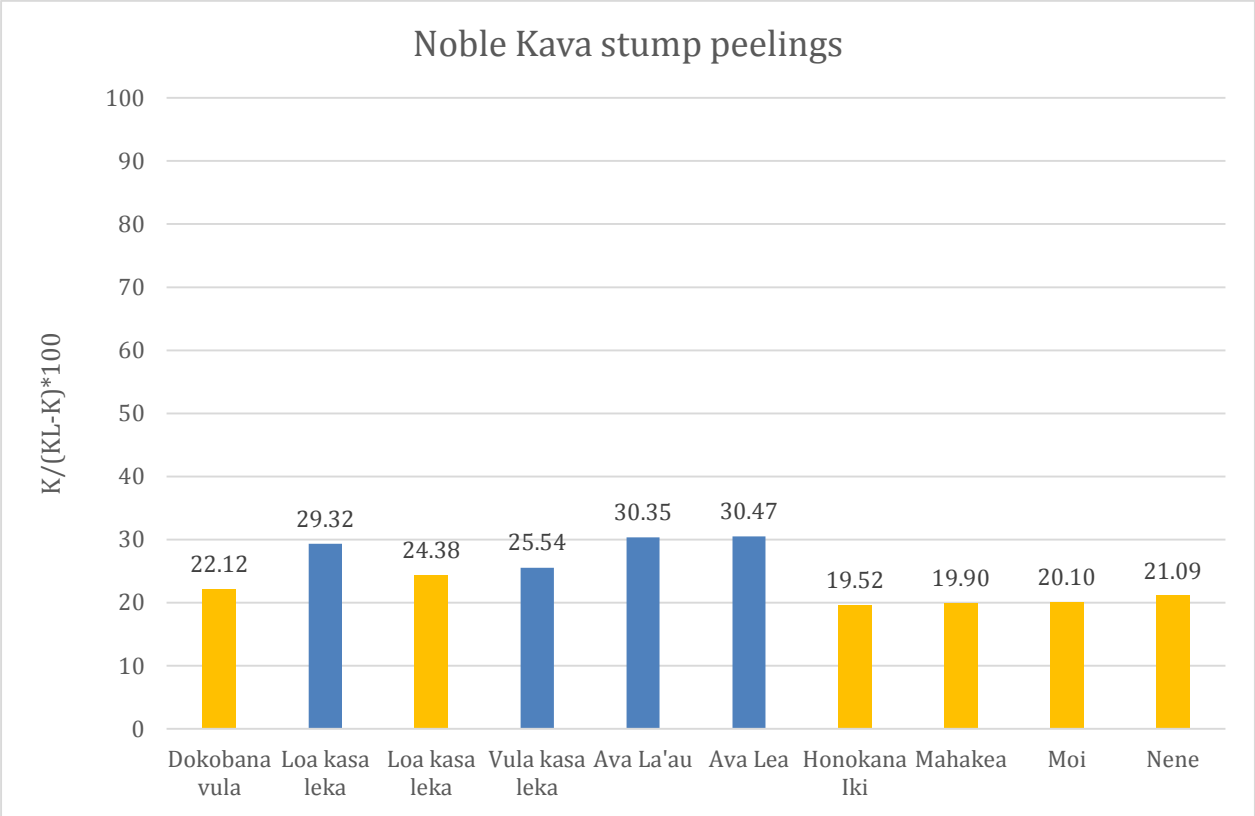
In conclusion, setting the limit of the K:(KL-K)-ratio to 25 gives a good impression, but not 100% safety for the distinction of '*noble*' from '*non-noble*' roots. As stated above, the seemingly high number of false attributions within this project may have been related to the age of the plant upon harvesting. It is recommended that the standard should define a minimum age of three years.


Noble Kava chips
K/(KL-K)*100
100
90
80
70
60
50
40
30
20
10
0
42.80
23.74
45.84
24.62
30.55
38.71
55.75
53.56
50.16
27.62
29.10
36.31
27.88
32.38
43.32
39.57
47.86
37.70
35.00
30.45
31.04
19.57
35.32
34.72
40.77
37.42
37.88
36.03
28.62
42.49
35.71
35.02
36.70
32.25
40.28
35.48
25.64
27.47
20.37
24.90
22.56
24.51
21.35
35.03
30.94
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Dokobana vula
Loa kasa leka
Loa kasa leka
Vula kasa leka
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana Vula
Loa kasa leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila balavu
Qila leka
Vula kasa leka
Yalu
Yonolulu
Gilbert Island
Hina Tonga
Honokana Iki
Mahakea
Mapulehu
Moi
Nene
Rahmdel


Non-noble Kava chips
K/(KL-K)*100
100
90
80
70
60
50
40
30
20
10
0
12.82
18.68
11.02
1.23
21.56
26.66
15.24
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa

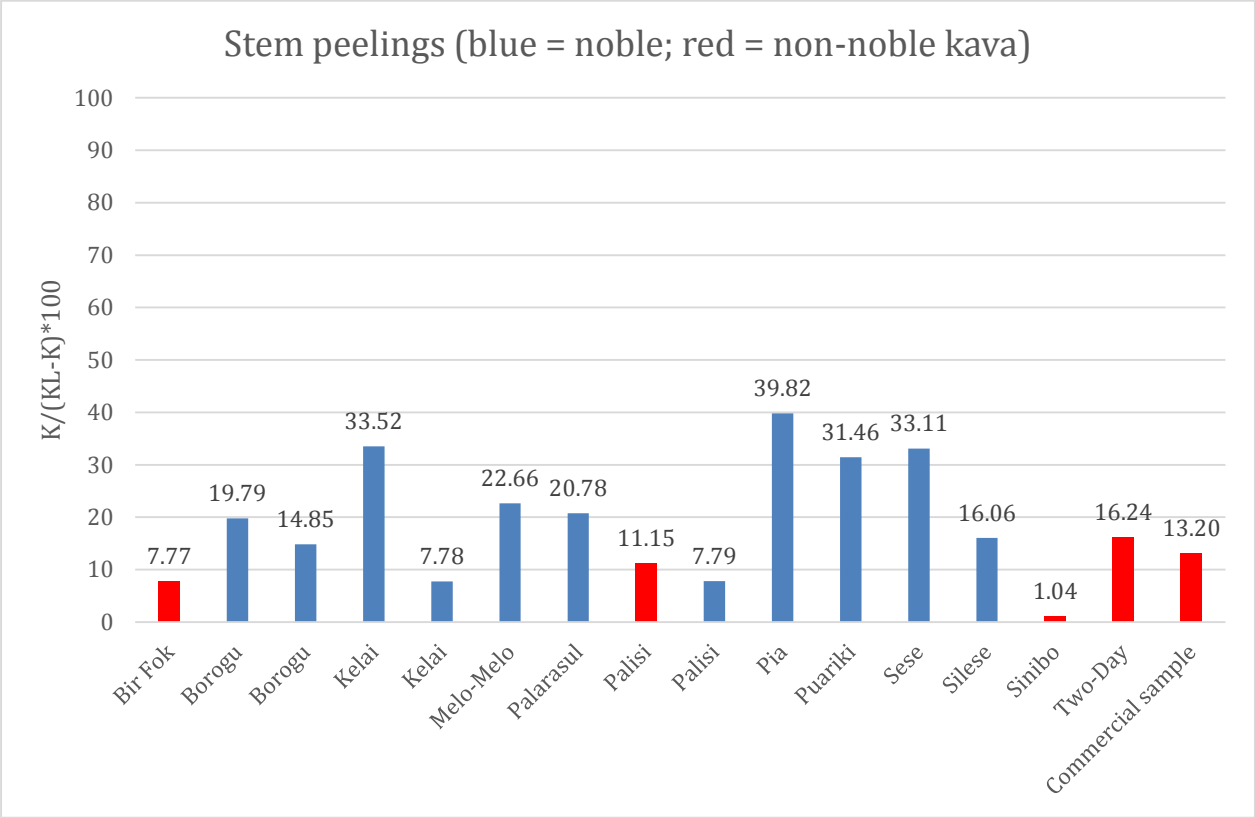
c) Stump peelings

K:(KL-K)-ratios ranged from 19.52 to 30.47 for '*noble*' kava stump peelings, with 70% of all samples below the limit value of 25. In all cases the findings were considerably lower than in the parallel samples with roots or chips of the same variety. There were no samples of stump peelings of '*non-noble*' varieties, hence no comparison can be made. In the case of '*non-noble*' varieties, stem peelings had been produced to reflect trading realities – this is, however, only the case for Vanautu, whereas in the other kava-producing Island Countries the conception of stem peelings is completely unknown. The demand for peelings was misunderstood, and the leftovers from stump peeling were delivered. During the testing, it was found that this accidental sampling of stump peelings still gives highly interesting findings, because the comparison between peeled stumps and stump peelings may help explaining why peeling should be performed on the stumps. The standard proposal clearly defines roots and peeled stumps as materials of kava. Stump peelings, the left overs from stump peeling, would in no case be considered acceptable kava materials.



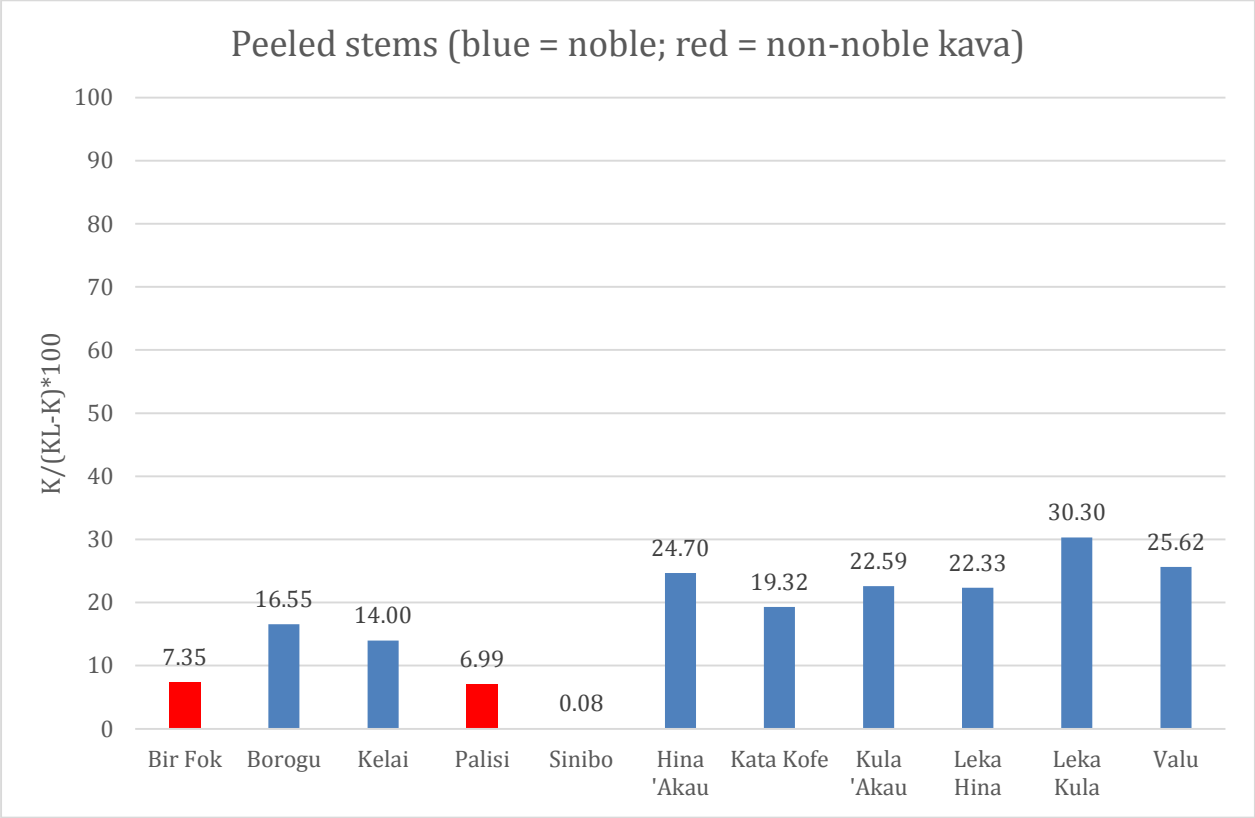
d) Stem peelings

K:(KL-K)-ratios ranged from 7.8 to 39.8 for '*noble*' kava stem peelings, and from 1.0 to 16.2 for '*non-noble*' kava. Whereas all '*non-noble*' kava varieties were correctly recognised as such, the number of false attributions in the noble group was 60 %. This means that even with '*noble*' kava stem peelings would stand a high probability for being rejected by testing using the K:(KL-K)-ratio. Stem peelings can in no case be accepted as trading material of kava.



e) Peeled stems

K:(KL-K)-ratios ranged from 14.0 to 30.3 for '*noble*' kava peeled stems, and from 0.1 to 7.4 for '*non-noble*' kava. The ratio is not applicable to kava stems: whereas all '*non-noble*' samples were correctly recognised as '*non-noble*', 75% of the '*noble*' kava stem samples would also have been recognised as '*non-noble*'. Peeled kava stems do not fall under the definition of "*kava*" in the standard proposal, they would have to be regulated separately. Kava stems would not be in high demand by importers because of their extremely low kavalactone content.



3.5.4 Ratio Kavain to Dihydromethysticin

The calculation of the ratio K:DHM can also serve for an estimation of '*nobility*' when the flavokavins have not been measured. This parameter is suggested by www.TrueKava.com. '*Noble*' kava typically shows values ≥ 1, '*non-noble*' varieties typically show values < 1.

With the methodology used in this project, the proposed ratio of 1 would have led to a recognition of '*non-noble*' kava roots as '*noble*' in 75% of kava roots and 43% of kava chips. In contrast, in one case (*Nene* roots) the '*noble*' variety would have falsely been recognised as 'non-noble' (2%).

Similarly, 43% of '*non-noble*' chips samples would have been accepted as '*noble*', and 4.7% of '*noble*' kava varieties would have wrongly been identified as '*non-noble*'.

If, however, a limit of 2.5 (the upper limit of values found in '*non-noble*' kava) is defined, there would have been no false positive results with roots and chips (*i.e.*, '*non-noble*' kava interpreted as '*noble*'), but instead 36% of false negative findings with the roots and 70% with the chips (*i.e.*, '*noble*' kava interpreted as '*non-noble*').

Again, the application of this ratio might mirror the effect of the plant age – the younger the plant on harvesting, the lower the K:DHM-ratio. It seems that the application of this ratio would only make sense with mature plants. In addition, chips have generally lower K:DHM ratios as their root counterparts. A mix of roots and chips (*e.g.*, in a powder sample, could therefore easily be mistaken for a borderline '*noble*' or '*non-noble*' material).

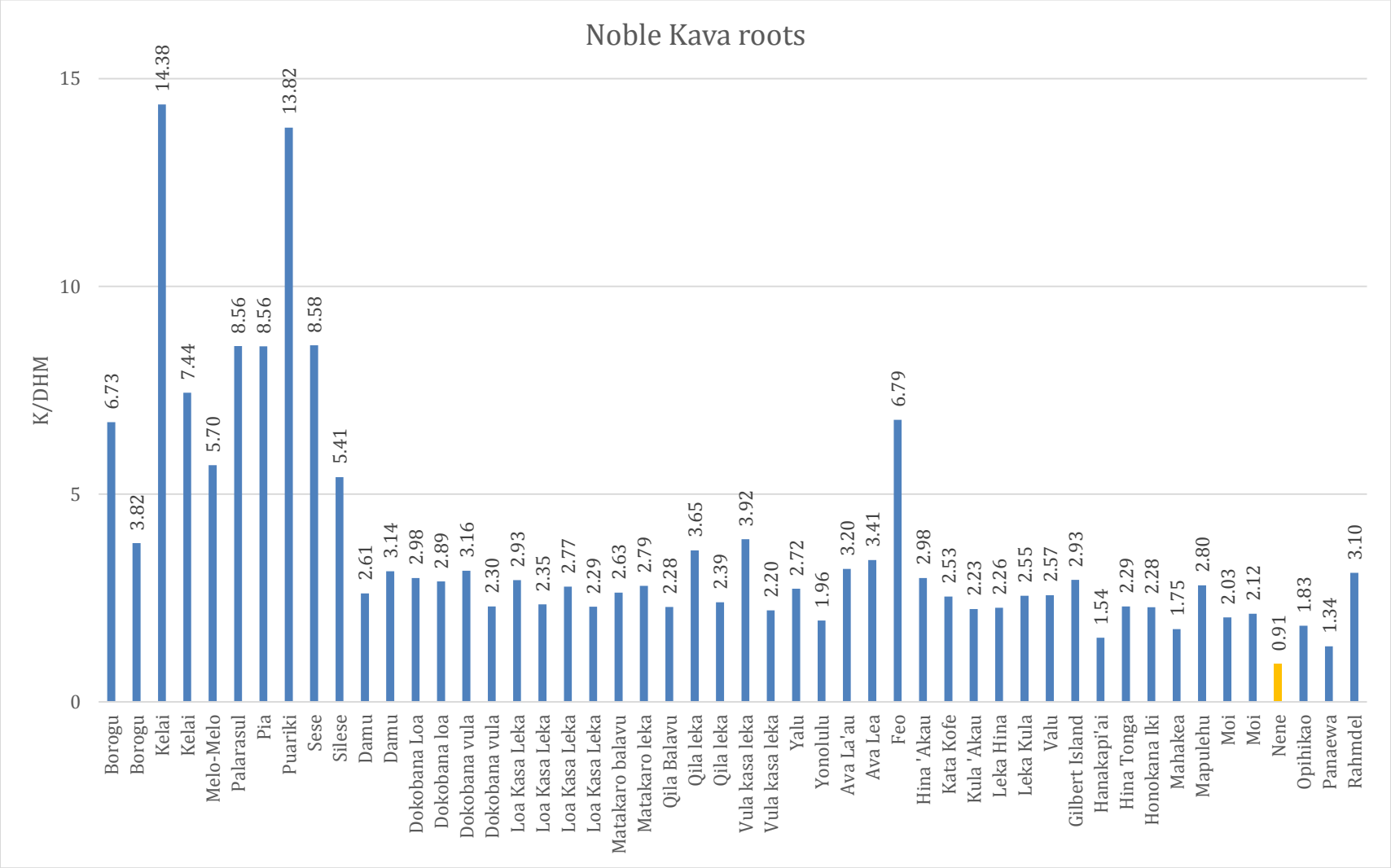
As a result of the sampling and testing of kava varieties, no recommendation can be given for the K:DHM ratio, without more systematic comparisons with plants of different age. The plant age cannot be controlled at the export level, even though the risk of false attribution of '*noble*' kava to '*non-noble*"'material might have an educational effect with respect to the harvesting date.

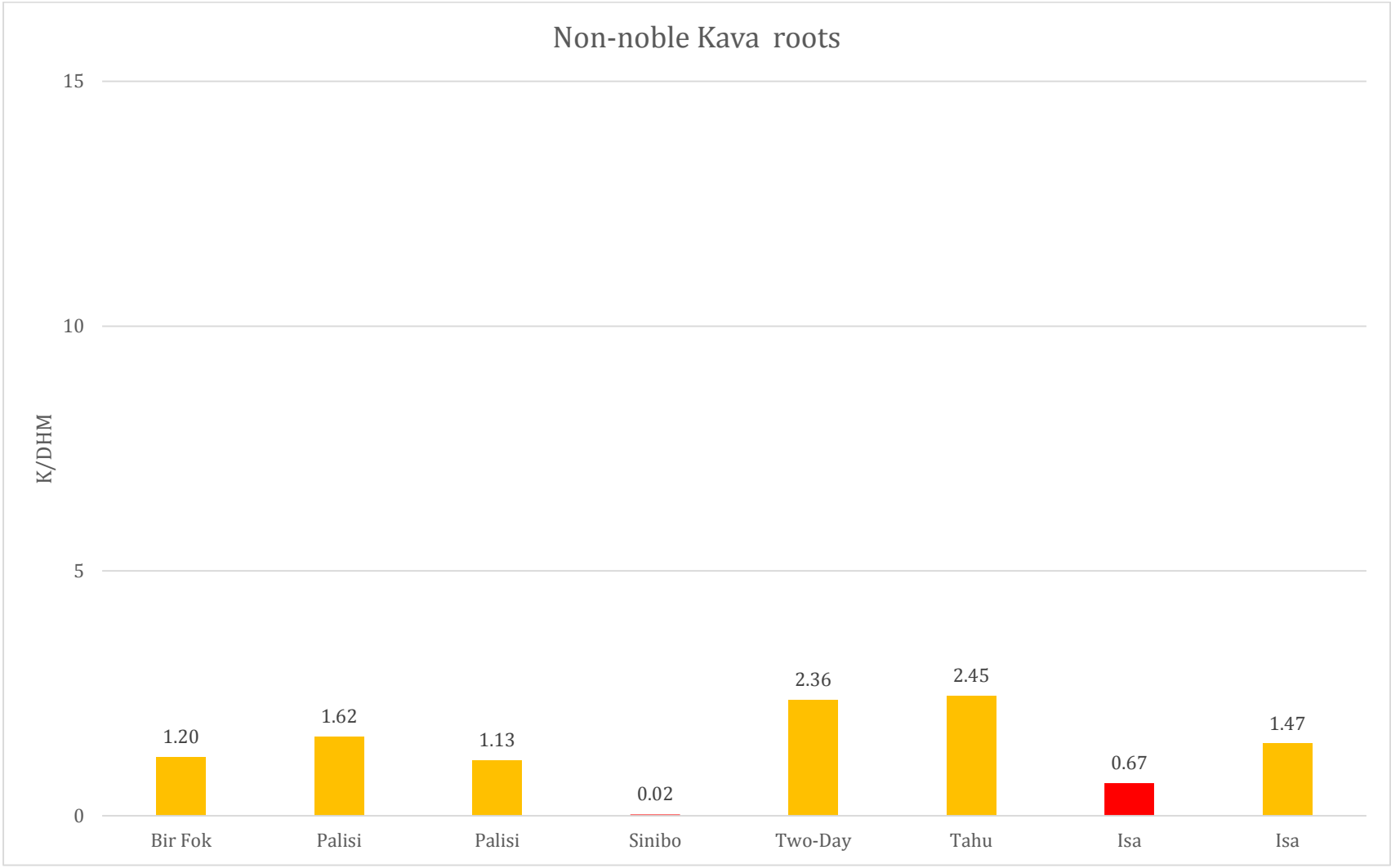
It can, however, clearly be stated that – using the methodology of this programme, any K:DHM ratio ≥ 2.5 would truly indicate '*noble*' kava.

a) Roots

K:DHM-ratios ranged from 0.9 to to 14.4 for '*noble*' kava roots, and from 0.02 to 2.45 for '*non-noble*' varieties, with '*wild-type*' kava showing the lowest values.

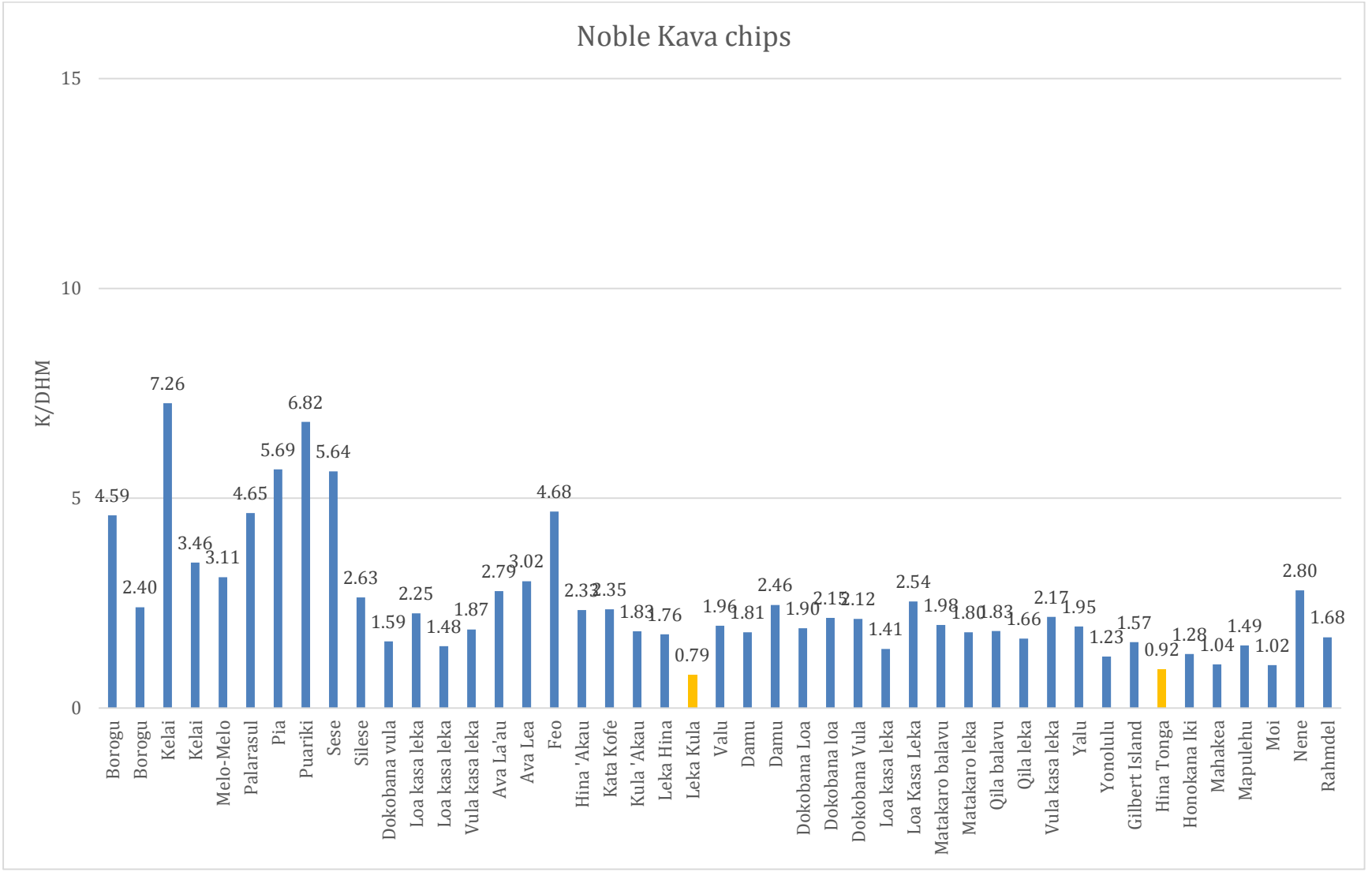
Due to the large variability of the results, no detailed discussion is provided here.

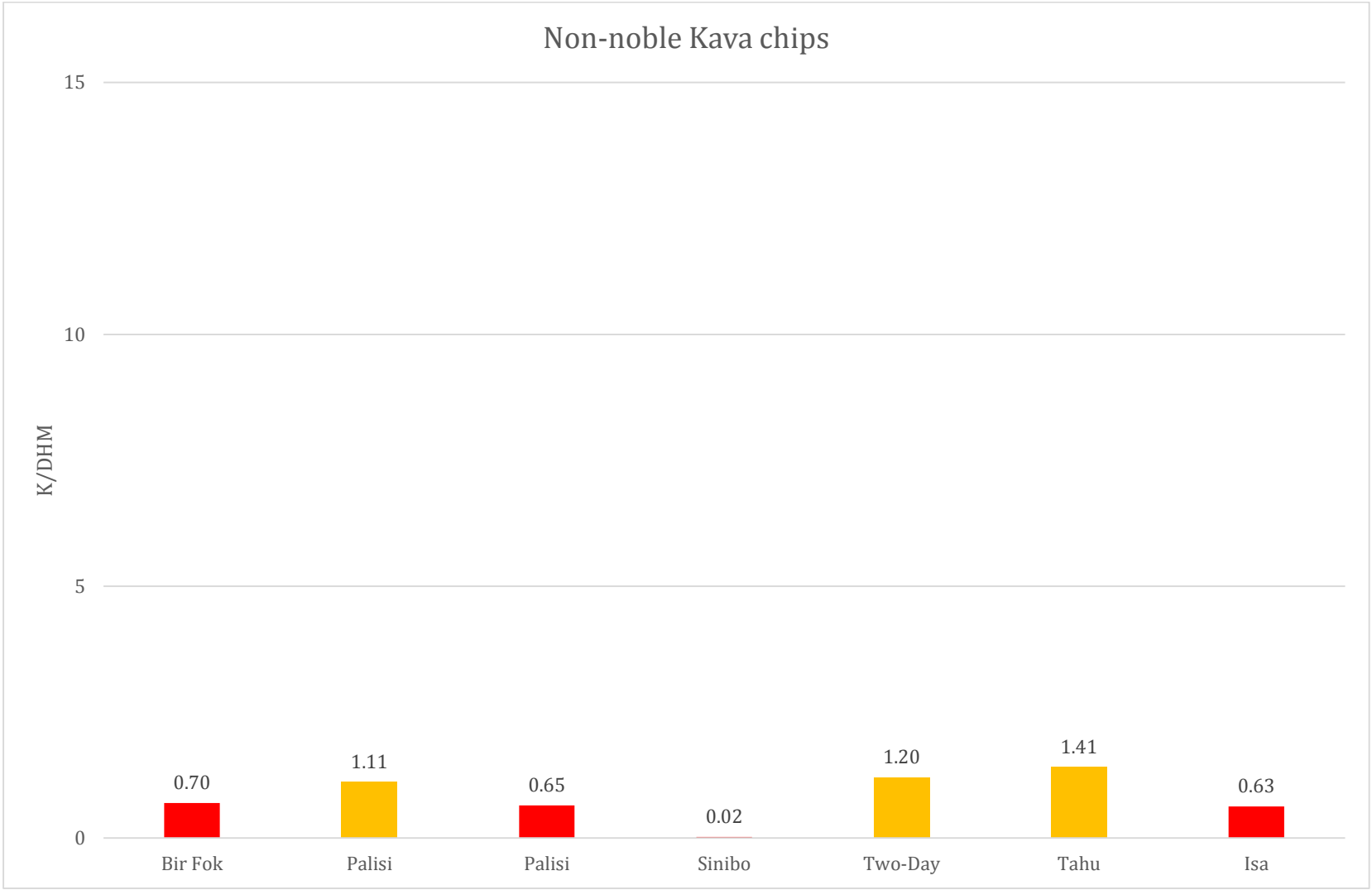

Noble Kava roots
K/DHM
15
10
5
0
6.73
3.82
14.38
7.44
5.70
8.56
8.56
13.82
8.58
5.41
2.61
3.14
2.98
2.89
3.16
2.30
2.93
2.35
2.77
2.29
2.63
2.79
2.28
3.65
2.39
3.92
2.20
2.72
1.96
3.20
3.41
6.79
2.98
2.53
2.23
2.26
2.55
2.57
2.93
1.54
2.29
2.28
1.75
2.80
2.03
2.12
0.91
1.83
1.34
3.10
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana vula
Dokobana vula
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila Balavu
Qila leka
Qila leka
Vula kasa leka
Vula kasa leka
Yalu
Yonolulu
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Gilbert Island
Hanakapi'ai
Hina Tonga
Honokana Iki
Mahakea
Mapulehu
Moi
Moi
Nene
Opihikao
Panaewa
Rahmdel


Non-noble Kava roots
15
10
5
0
K/DHM
1.20
1.62
1.13
0.02
2.36
2.45
0.67
1.47
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa
Isa

b) Chips

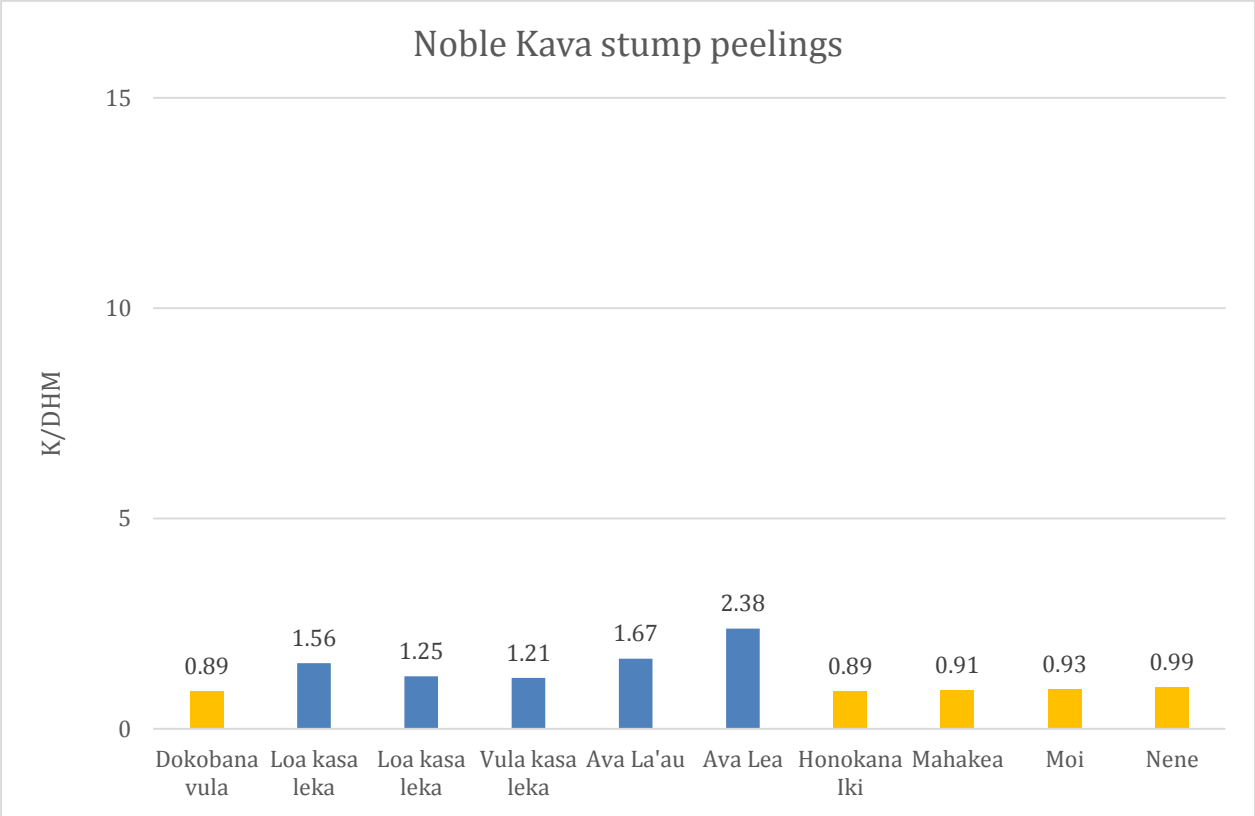
K:DHM-ratios ranged from 0.79 to 7.26 for '*noble*' kava chips, and 0.02 to 1.41 for '*non-noble*' varieties. Again, the overlap of values was too distinct to allow safe interpretation of unknown samples.


Noble Kava chips
K/DHM
15
10
5
0
4.59
2.40
7.26
3.46
3.11
4.65
5.69
6.82
5.64
2.63
1.59
2.25
1.48
1.87
2.79
3.02
4.68
2.33
2.35
1.83
1.76
0.79
1.96
1.81
2.46
1.90
2.15
2.12
1.41
2.54
1.98
1.80
1.83
1.66
2.17
1.95
1.23
1.57
0.92
1.28
1.04
1.49
1.02
2.80
1.68
Borogu
Borogu
Kelai
Kelai
Melo-Melo
Palarasul
Pia
Puariki
Sese
Silese
Dokobana vula
Loa kasa leka
Loa kasa leka
Vula kasa leka
Ava La'au
Ava Lea
Feo
Hina 'Akau
Kata Kofe
Kula 'Akau
Leka Hina
Leka Kula
Valu
Damu
Damu
Dokobana Loa
Dokobana loa
Dokobana Vula
Loa kasa leka
Loa Kasa Leka
Matakaro balavu
Matakaro leka
Qila balavu
Qila leka
Vula kasa leka
Yalu
Yonolulu
Gilbert Island
Hina Tonga
Honokana Iki
Mahakea
Mapulehu
Moi
Nene
Rahmdel


Non-noble Kava chips
15
10
5
0
K/DHM
0.70
1.11
0.65
0.02
1.20
1.41
0.63
Bir Fok
Palisi
Palisi
Sinibo
Two-Day
Tahu
Isa

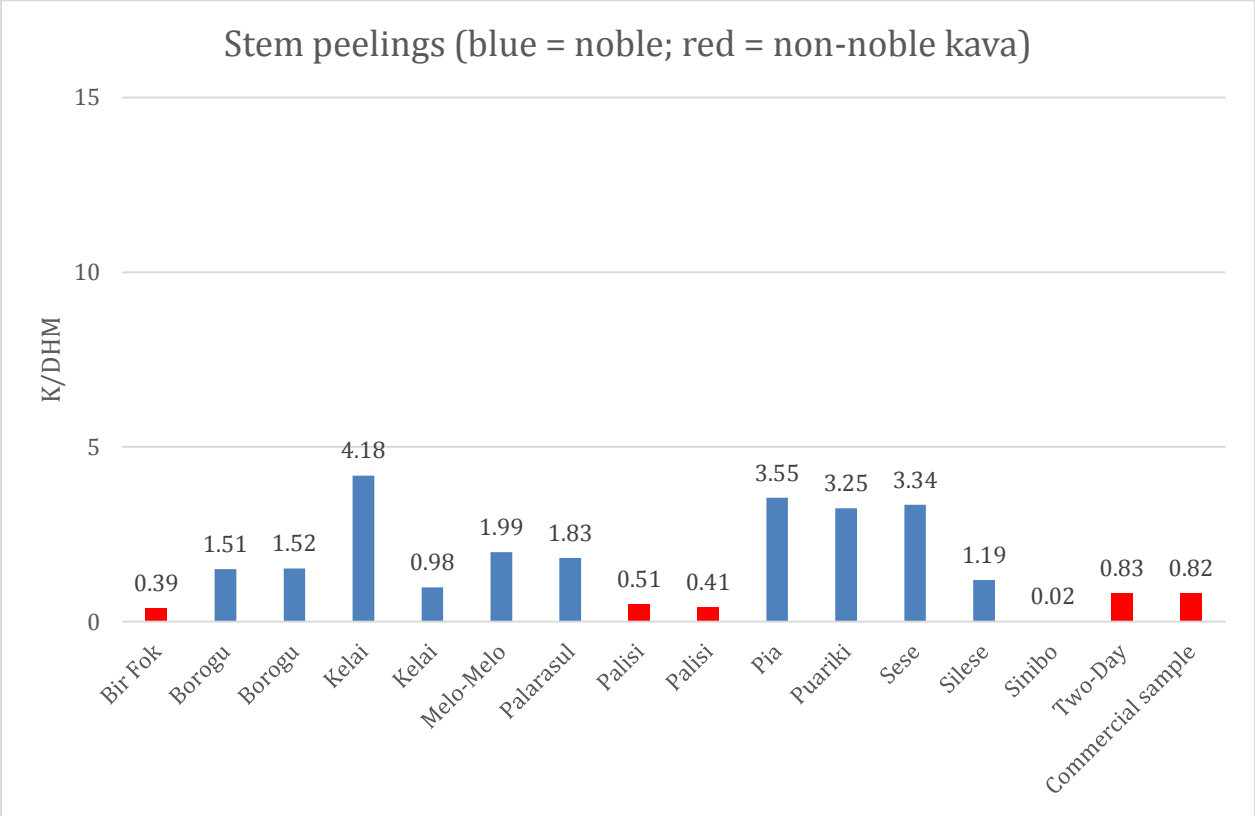
c) Stump peelings

K:DHM-ratios ranged from 0.89 to 2.38 for '*noble*' kava stump peelings, with 50% of all samples below the limit value of 1. In all cases the findings were considerably lower than in the parallel samples with roots or chips of the same variety. There were no samples of stump peelings of '*non-noble*' varieties, hence no comparison can be made. In the case of non-noble varieties, stem peelings had been produced to reflect trading realities – this is, however, only the case for Vanautu, whereas in the other kava-producing island states the conception of stem peelings is completely unknown. The demand for peelings was misunderstood, and the leftovers from stump peeling were delivered. During the testing, it was found that this accidental sampling of stump peelings still gives highly interesting findings, because the comparison between peeled stumps and stump peelings may help explaining why peeling should be performed on the stumps. The standard proposal clearly defines roots and peeled stumps as materials of kava. Stump peelings, the left overs from stump peeling, would in no case be considered acceptable kava materials.



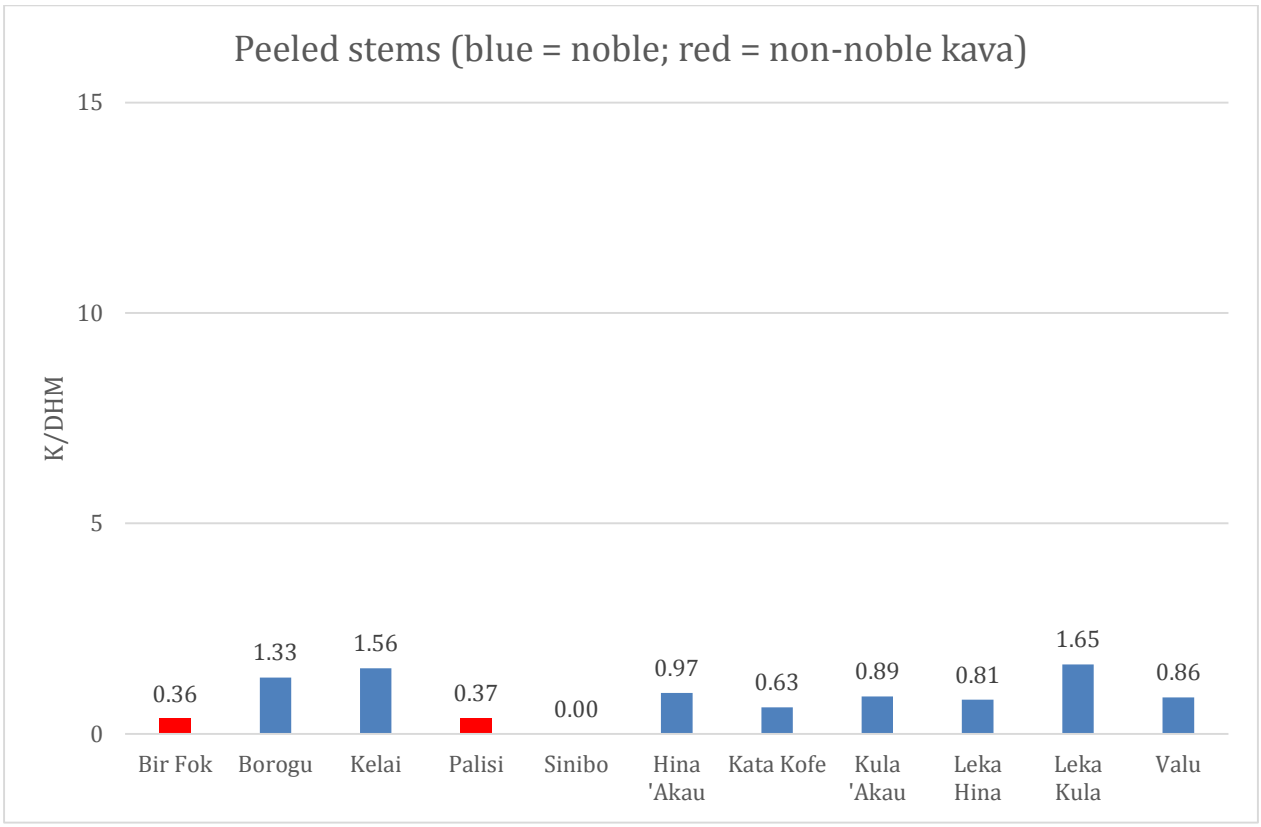
d) Stem peelings

K:DHM-ratios ranged from 1.0 to 4.2 for '*noble*' kava stem peelings, and from 0.02 to 0.8 for '*non-noble*' kava. With the stem peelings, all samples would have been correctly identified, however, stem peelings can in no case be accepted as trading material of kava.



e) Peeled stems

K:DHM-ratios ranged from 0.6 to 1.7 for '*noble*' kava peeled stems, and from 0.0 to 0.4 for '*non-noble*' kava. The ratio is not applicable to kava stems: whereas all noble samples were correctly recognised as '*non-noble*', 50% of the '*noble*' kava stem samples would also have been recognised as '*non-noble*'. Peeled kava stems do not fall under the definition of "*kava*" in the standard proposal, they would have to be regulated separately. Kava stems would not be in high demand by importers because of their extremely low kavalactone content.



3.5.5 Tabulated Results

	Roots		Peeled chips		Unpeeled chips	
	Noble	**Non-noble**	**Noble**	**Non-noble**	**Noble**	**Non-noble**
N	**50**	**8**	**31**	**6**	**14**	**1**
FKA						
Range	0.02-0.28	0.07-1-68	0.01-0.23	0.24-0.99	0.02-0.08	0.06
Average ± SD	0.06 ± 0.04	0.65 ± 0.64	0.08 ± 0.05	0.46 ± 0.32	0.05 ± 0.02	0.06
Median	0.05	0.42	0.08	0.29	0.05	0.06
FKB						
Range	0.02-0.12	0.15-2.49	0.01-0.10	0.08-0.95	0.01-0.06	0.05
Average ± SD	0.05 ± 0.03	1.02 ± 0.87	0.05 ± 0.02	0.52 ±0.33	0.04 ± 0.01	0.05
Median	0.04	0.78	0.05	0.43	0.04	0.05
FKB/K*100						
Range	1.20-7.03	12.69-2267	1.21-9.46	36.64-400	1.86-5.06	14.70
Average ± SD	2.27 ± 1.25	382 ± 924	4.01 ± 1.75	137.2 ±137.46	3.17 ± 1.01	14.70
Median	1.88	40.29	3.89	96.19	3.12	14.70
K/(KL-K)*100						
Range	19.90-79.61	1.10-33.54	19.57-15.75	1.23-26.66	25.64-42.49	15.24

Average ± SD	39.45 ± 11.77	19.96 ± 9.84	33.74 ± 9.88	15.33 ± 8.97	35.64 ± 4.53	15.24
Median	36.56	19.89	31.04	15.75	35.87	15.24
K/DHM						
Range	0.91-14.38	0.02-2.45	0.79-7.26	0.02-1.51	1.23-2.54	0.63
Average ± SD	3.77 ± 2.84	1.36 ± 0.81	2.80 ± 1.75	0.85 ± 0.50	1.93 ± 0.36	0.63
Median	2.78	1.33	2.22	0.90	1.92	0.63

	Stump peelings		**Stem peelings**		**Peeled stems**	
	Noble	**Non-noble**	**Noble**	**Non-noble**	**Noble**	**Non-noble**
n	**10**	**0**	**10**	**6**	**8**	**3**
FKA						
Range	0.04-0.27		0-09-0.41	0.18-1.43	0.02-0.06	0.04-0.53
Average ± SD	0.13 ± 0.07		7.96 ± 2.98	0.68 ± 0.52	0.04 ± 0.02	0.24 ± 0.262
Median	0.14		7.16	0.61	0.04	0.15
FKB						
Range	0.04-0.20		0.07-0.14	0.04-1.57	0.01-0.18	0.01-0.50
Average ± SD	0.09 ± 0.05		0.10 ± 0.02	0.77 ± 0.58	0.04 ± 0.06	0.18 ± 0.27

Median	0.09		0.09	0.74	0.02	0.04
FKB/K*100						
Range	3.39-8.75		4.01-12.01	79-400	4.17-17.60	80-5000
Average ± SD	5.35 ± 1.80		7.96 ± 2.98	181 ± 122	9.31 ± 4.28	1766 ± 2802
Median	5.24		7.16	148.63	8.62	217.39
K/(KL-K)*100						
Range	19.52-30.475		7.78-39.82	1.04-16.24	14.00-30.30	0.08-7.35
Average ± SD	24.28 ± 4.43		23.98 ± 10.11	9.53 ± 5.28	21.93 ± 5.22	4.81 ± 4.10
Median	23.25		21.72	9.47	22.46	6.99
K/DHM						
Range	0.89-2.38		0.98-4.18	0.02-0.83	0.63-1.65	0.00-0.37
Average ± SD	1.27 ± 0.48		2.33 ± 1.13	0.49 ± 0.30	1.09 ± 0.38	0.24 ± 0.21
Median	1.10		1.91	0.46	0.93	0.36

3.5.6 General conclusion of the scientific testing for consideration in the draft Codex standard

For consideration of the draft Codes standard, the results of the scientific testing are that:

- the content of flavokavin B must not exceed 0.15% of the dry matter;
- the ratio of Kavain [% of dry matter]: (Total Kavalactones [% of dry matter] – Kavain [% of dry matter]) should be ≥ 25; and
- the ratio of Flavokavin B [% of dry matter]: Kavain [% of dry matter] * 100 must not exceed 8.5.

4. DRAFT FAO/WHO CODEX STANDARD FOR SUBMISSION TO THE CCNASWP

4.1. Background

In line with the methodology, taking full account of the ToRs, the "*Organisation and Methodology*" submitted in *FratiniVergano*'s bid and of the Inception Report approved by the PMU and the Beneficiary, *FratiniVergano* and its international experts drafted a FAO/WHO Codex kava standard for submission to the *CCNASWP*.

Based on the technical specifications evolving through the scientific assessment, the experts have drafted the legislative and regulatory language for purposes of defining the regional/international FAO/WHO Codex kava standard and assisting the Pacific Islands Governments in the definition, adoption and implementation of parallel national standards and technical regulations.

Imports of plant materials to the EU are regulated by generic requirements (*e.g.*, for residues of heavy metals, pesticides, aflatoxins and microbiological purity). Such parameters would also be part of a kava standard and do not need to be addressed within this project, as the corresponding specifications are not specific for kava. What is, however, specific for kava is a marker for unambiguously demonstrating the difference between '*noble*' and '*non-noble*' kava. Such a marker has been established within the 2012 ACP-MTS Project, and has been verified on a large scale base within this project.

A defined standard would create a framework for analyses and acceptance criteria within the recipient (importing) countries, where there is no traditional knowledge about kava. Most recipient countries have the advantage of laboratory capacities for quality control, which is mandatory in each case where there is a defined standard. The programme is, therefore, not so much focussed on the task that only '*noble*' kava must be exported by the kava producing countries, but rather on the issue that only '*noble*' kava must be imported by other nations. A defined standard thus provides a self-regulating system with ultimately improved quality in the producing countries.

The first step in the approach of defining a kava standard was the identification of the relevant kava cultivars. Relevant are those kava cultivars used for exports. There are clearly more kava cultivars, especially in Vanuatu, than could be sampled for this project – many of them would only be used for medicinal or ceremonial purposes, but not be exported. If possible, these cultivars have been collected to enlarge the framework of the database required for the substantiation of the kava standard parameters for Codex Alimentarius.

The consequences of a standard created on the foundation of this framework would also cover kava trading in regions outside Melanesia. Hawaii has established itself as a non-Melanesian centre for kava planting and trading, with the downside that at least one cultivar used nowadays in Hawaii is a '*non-noble*' variety originating from a *Piper wichmanii*-variety (*Isa*, originally from Papua New Guinea and traditionally not considered kava material good for drinking) is regularly consumed. A regulation of kava quality must necessarily also involve the qualities traded outside Melanesia and Polynesia: it would not make sense to

have the Pacific exports regulated when at the same time a major market competitor would remain unaffected. The kava standard should contribute to avoiding trade with unacceptable kava qualities. Any future concerns with '*non-noble*' kava originating in Hawaiian trade would automatically cause damage to the Melanesian and Polynesian economies, and *vice versa*.

Sampling for the establishment of a standard required the inclusion of '*non-noble*' cultivars next to the '*noble*' varieties: defining standards must be based on reference values, which means that both, good and unacceptable varieties must be tested in order to clearly differentiate between the two groups.

The outcome of a FAO/WHO Codex standard would be equivalent to a positive list: the characteristics defined therein will be generically applicable to all '*noble*' kava cultivars, thus implicitly excluding '*non-noble*' cultivars not meeting the standards. Any additional cultivar not tested within this project, which in the future might be traded, would automatically be acceptable, if it meets the standards. This approach avoids regular updates of lists of kava cultivars included by name.

The identification of the relevant kava cultivars has been made through the identification of local stakeholders in the Pacific kava producing Countries. These stakeholders were contacted in the first phase of the project, and local kava sampling, drying and labelling was organised through them for later inspection, documentation (including the documentation of the plants) and pick-up or organisation of shipment during the field missions.

A documental analysis has been carried-out by the scientific expert to provide an update on the 2012 ACP-MTS Project. This report supports the application for a kava standard at FAO/WHO Codex by providing supplementary material on the relationship of kava quality and safety, and on differences between '*noble*' and '*non-noble*' cultivars.

4.2. FAO/WHO Codex Kava Standard

In view of a FAO/WHO Codex kava standard and seeking its approval by "*Codex Alimentarius*", a comprehensive research and legal analysis is necessary of the applicable and/or relevant (from a comparative perspective) "*Codex Alimentarius*" standards and SPS/TBT requirements vis-à-vis kava production and consumption.

This section of the Final Report addresses the objective of "*drafting the legislative and regulatory language for purposes of defining the regional/international FAO/WHO Codex kava standard*". The development of Codex Alimentarius standards and their approval requires following an established procedure, as described in this section of the report.

This section gives a brief overview on the relevance of Codex Alimentarius Standards within the context of the WTO SPS Agreement. It describes the General Principles of the Codex Alimentarius and describes the procedures for the elaboration of Codex Standards and related texts and addresses issues like who proposes new work and '*develops*' a standard, the format for Codex commodity standards, and the role of science in the Codex decision making progress.

4.2.1 The Codex Alimentarius and the SPS Agreement

The Agreement on the Application of Sanitary and Phytosanitary Measures (hereinafter, the "*SPS Agreement*") concerns the application of food safety and animal and plant health regulations. The SPS Agreement allows countries to set their own standards. However, it also specifies that regulations must be based on scientific findings and should be applied only to the extent that they are necessary to protect human, animal or plant life or health; they should not unjustifiably discriminate between countries where similar conditions exist. WTO Member Countries are encouraged to use the standards developed by the relevant international bodies whenever they exist. The SPS Agreement encourages governments to "*harmonise*" or base their national measures on the international standards, guidelines and recommendations developed in other international organisations. In relation to food safety, the relevant organisation is the joint FAO/WHO Codex Alimentarius Commission.

In particular, the SPS Agreement provides that "*desiring to further the use of harmonized sanitary and phytosanitary measures between Members, on the basis of international standards, guidelines and recommendations developed by the relevant international organizations, including the Codex Alimentarius Commission, the International Office of Epizootics, and the relevant international and regional organizations operating within the framework of the International Plant Protection Convention, without requiring Members to change their appropriate level of protection of human, animal or plant life or health*."

Article 3 of the SPS Agreement concerns the issue of harmonization of sanitary and phytosanitary measures:

> *"1. To harmonize sanitary and phytosanitary measures on as wide a basis as possible, Members shall base their sanitary or phytosanitary measures on international standards, guidelines or recommendations, where they exist, except as otherwise provided for in this Agreement, and in particular in paragraph 3.*
>
> *2. Sanitary or phytosanitary measures which conform to international standards, guidelines or recommendations shall be deemed to be necessary to protect human, animal or plant life or health, and presumed to be consistent with the relevant provisions of this Agreement and of GATT 1994.*
>
> *3. Members may introduce or maintain sanitary or phytosanitary measures which result in a higher level of sanitary or phytosanitary protection than would be achieved by measures based on the relevant international standards, guidelines or recommendations, if there is a scientific justification, or as a consequence of the level of sanitary or phytosanitary protection a Member determines to be appropriate in accordance with the relevant provisions of paragraphs 1 through 8 of Article 5.[89] Notwithstanding the above, all measures which result in a level of sanitary or phytosanitary protection different from that which would be achieved*

[89] (footnote original of the text) For the purposes of paragraph 3 of Article 3, there is a scientific justification if, on the basis of an examination and evaluation of available scientific information in conformity with the relevant provisions of this Agreement, a Member determines that the relevant international standards, guidelines or recommendations are not sufficient to achieve its appropriate level of sanitary or phytosanitary protection.

by measures based on international standards, guidelines or recommendations shall not be inconsistent with any other provision of this Agreement."

As to the interpretation of the phrase "*international standards … where they exist*", the Panel on EC - Hormones noted as follows:

> *"Article 3.1 unambiguously prescribes that '… Members shall base their sanitary … measures on international standards … where they exist …'. Paragraph 3 of Annex A of the SPS Agreement states equally clearly that the international standards mentioned in Article 3:1 are 'for food safety, the standards … established by the Codex Alimentarius Commission …"*[90]

The development of a Codex Alimentarius standard for kava, so that Pacific Countries could then produce, harvest, dry, store and export (with all the related steps) according to internationally-recognised quality and safety standards, is important. Trade restrictive SPS measures should not be imposed on products that comply with such standard. WTO rules can then be used to shift the burden of proving that possible other standards required by importing countries are scientifically justified, if not based on or conforming to the FAO Codex Standard.

4.2.2 General Principles of the Codex Alimentarius

The *Codex Alimentarius Commission* (CAC) is an intergovernmental body with over 170 members, within the framework of the Joint Food Standards Programme established by the Food and Agriculture Organization of the United Nations (FAO) and the World Health Organization (WHO). The purpose of the Codex Alimentarius is to protect the health of consumers and to ensure fair practices in the food trade, promoting coordination of all food standards work undertaken by international governmental and non-governmental organizations. The Codex Alimentarius is the result of the *CAC*'s work: a collection of internationally adopted food standards, guidelines, codes of practice and other recommendations. The *CAC*, as a risk management body, does not undertake scientific evaluations per se but relies on the opinions of scientific expert bodies convened by FAO and WHO on specific issues[91].

Further to the establishment and harmonisation of food standards and ensuring their global implementation, the Codex Alimentarius also allows the development of codes governing hygienic processing practices and recommendations relating to compliance with those standards. Some of these Codex Alimentarius texts are very general, and some are very specific. Some deal with detailed requirements related to a food or group of foods; others deal with the operation and management of production processes or the operation of government regulatory systems for food safety and consumer protection.

Codex codes of practice, including codes of hygienic practice, define the production, processing, manufacturing, transport and storage practices for individual foods or groups of foods that are considered

[90] Panel Report on EC — Hormones (Canada), para. 8.72; Panel Report on EC — Hormones (US), para. 8.69.

[91] Codex Alimentarius Commission, STRATEGIC PLAN 2014–2019, p. 3; available at: http://www.codexalimentarius.org/procedures-strategies/strategic-planning/en/.

essential to ensure the safety and suitability of food for consumption. For food hygiene, the basic text is the Codex General Principles of Food Hygiene, which introduces the use of the *HACCP* food safety management system. The publication of the Codex Alimentarius is intended to guide and promote the elaboration and establishment of definitions and requirements for foods to assist in their harmonization and in doing so to facilitate international trade.

The Codex Alimentarius includes standards for all the principle foods, whether processed, semi-processed or raw, for distribution to the consumer. Materials for further processing into foods should be included to the extent necessary to achieve the purposes of the Codex Alimentarius as defined.

Codex standards and related texts are not a substitute for, or alternative to, national legislation. Every country's laws and administrative procedures contain provisions with which it is essential to comply. Codex standards and related texts contain requirements for food aimed at ensuring for the consumer a safe, wholesome food product free from adulteration, correctly labelled and presented. A Codex standard for any food or foods should be drawn up in accordance with the Format for Codex Commodity Standards and contain, as appropriate, the sections listed therein.[92]

4.2.3 Procedures for the Elaboration of Codex Standards and Related Texts

The Procedural Manual of the Codex Alimentarius Commission[93] describes the legal foundations and practical functioning of the Commission and its subsidiary bodies. The detailed procedures for the elaboration of Codex Standards and related texts (*e.g.*, codes of hygienic practice) are compiled in Section II of the Codex Procedural Manual, which is based on the following texts:

- Procedures for the Elaboration of Codex Standards and Related Texts. (Adopted in 1965. Revised in 1993 and 2004. Amended in 1966, 1969, 1976, 1981, 2005, 2006 and 2008);
- Format for Codex Commodity Standards. (Adopted in 1969. Amended in 2007, 2008 and 2010); and
- Guidelines on the Elaboration and/or Revision of Codes of Hygienic Practice for Specific Commodities. (Adopted in 1997).

The full procedure for the elaboration and adoption of Codex Alimentarius standards is described in detail in the Manual.[94]

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[92] See General Principles of the Codex Alimentarius, Joint FAO/WHO Food Standards Programme, PROCEDURAL MANUAL CODEX ALIMENTARIUS COMMISSION, 23rd edition, Rome, 2015. Available at: ftp://ftp.fao.org/codex/Publications/ProcManuals/Manual_23e.pdf, p. 20.

[93] Supra. The Procedural Manual (hereinafter, the Manual) contains the Uniform Procedure for the Elaboration of Codex Standards and Related Texts; the criteria for the establishment of work priorities and subsidiary bodies; guidance on relations between Commodity Committees and General Committees; a format for Codex Commodity standards; procedures for consideration of food additive provisions; and guidelines on the elaboration or revision of codes of hygienic practice and principles for selection of methods of analysis and sampling procedures. See also: PROCEDURES FOR THE ELABORATION OF CODEX STANDARDS AND RELATED TEXTS http://www.fao.org/docrep/W5975E/w5975e04.htm .

[94] See pp. 26-87 of the Manual.

4.2.4 Development of a Codex Standard

As to the procedure to follow, the first question is who is entitled to propose new work to the Codex Alimentarius Commission and to develop a standard for kava.

Rule XI of the Rules of Procedure of the Codex Alimentarius Commission[95] concerns the work of Subsidiary Bodies. According to point 1(b) of Rule XI, the Commission establishes subsidiary bodies in the form of (i) Codex Committees for the preparation of draft standards for submission to the Commission, whether intended for worldwide use, for a given region or for a group of Countries specifically enumerated by the Commission and (ii) Coordinating Committees for regions or groups of countries, which shall exercise general coordination in the preparation of standards relating to such regions or groups of Countries and such other functions as may be entrusted to them.

Therefore, there are Coordinating Committees for regions or groups of Countries who exercise general coordination in the preparation of standards relating to such regions or groups of Countries. For the Pacific Region, FAO/WHO have established the *Coordinating Committee for North America and the South West Pacific* (*CCNASWP*). Therefore, as to the procedure to follow, it is the *CCNASWP* who should decide to recommend to the Codex Alimentarius Commission to consider and approve new work in form of a Standard for Kava. The *CCNASWP* Codex Standard for Kava will then be drafted in accordance with the Codex uniform layout for food products.

4.2.5 Proposals to Undertake New Work of to Revise a Standard

Prior to the approval for development, each proposal for new work or revision of a standard must be accompanied by a project document, prepared by the Committee or Member proposing new work or revision of a standard[96], detailing:

- The purposes and the scope of the standard;
- Its relevance and timeliness;
- The main aspects to be covered;
- An assessment against the Criteria for the establishment of work priorities;
- Relevance to the Codex strategic objectives;
- Information on the relation between the proposal and other existing Codex documents;
- Identification of any requirement for and availability of expert scientific advice;
- Identification of any need for technical input to the standard from external bodies so that this can be planned for; and
- The proposed time-line for completion of the new work, including the start date, the proposed date for adoption at Step 5, and the proposed date for adoption by the Commission; the time frame for developing a standard should not normally exceed five years.

[95] See p. 15-17 of the Manual.

[96] See http://www.codexalimentarius.org/procedures-strategies/standard-management/critical-review/en/

The decision to undertake new work or to revise standards shall be taken by the Commission taking into account a critical review conducted by the Executive Committee. The critical review includes:

- Examination of proposals for development/revision of standards, taking into account the "*Criteria for the Establishment of Work Priorities*", the strategic plan of the Commission and the required supporting work of independent risk assessment;
- Identifying the standard setting needs of developing Countries;
- Advice on establishment and dissolution of committees and task forces, including *ad hoc* cross-committee task forces (in areas where work falls within several committee mandates); and
- Preliminary assessment of the need for expert scientific advice and the availability of such advice from FAO, WHO or other relevant expert bodies, and the prioritisation of that advice.

The standard drafting process is as follows: Taking into account the outcome of the on-going critical review conducted by the Executive Committee, the Commission decides that a standard should be elaborated and also which subsidiary body or other body should undertake the work. Decisions to elaborate standards may also be taken by subsidiary bodies of the Commission in accordance with the abovementioned outcome subject to subsequent approval by the Commission at the earliest possible opportunity. The Secretariat arranges for the preparation of a "*proposed draft standard*", which is circulated to governments for comments and is then considered in the light of these by the subsidiary body concerned which may present the text to the Commission as a "*draft standard*". If the Commission adopts the "*draft standard*", it is sent to governments for further comments and in the light of these, and after further consideration by the subsidiary body concerned, the Commission reconsiders the draft and may adopt it as a "*Codex standard*".

Codex standards and related texts are published and are sent to governments as well as to international organizations to which competence in the matter has been transferred by their Member States.

Significant work has already been undertaken in proposing new work in the Coordinating Committee for North America and the South West Pacific (*CCNASWP*) with the Discussion paper on kava[97] and in various meetings of the *CCNASWP*. In particular, an Electronic Working Group (*EWG*), led by Vanuatu, has been established. However, this work needs to be complimented and put into context with the scientific work in relation to the quality of kava, which is carried out under this project.

[97] DISCUSSION PAPER ON THE DEVELOPMENT OF A STANDARD FOR KAVA, Document CX/NWSWP 10/11/8 of September 2010; available at: ftp://ftp.fao.org/codex/ccnaswp11/na11_08e.pdf .

4.2.6 Format of Codex Commodity Standards

The Codex Alimentarius Commission has developed a standard format intended for use as a guide by the subsidiary bodies (for example, the coordination committees) in presenting their standards, with the object of achieving, as far as possible, a uniform presentation of commodity standards. The standard format also indicates the statements, which should be included in standards as appropriate under the relevant headings of the standard. The sections of the standard format require to be completed in a standard only insofar as such provisions are appropriate to an international standard for the food in question.[98]

The standard format includes the following sections:

Name of the Standard

The name of the standard should be clear and as concise as possible. It should usually be the common name by which the food covered by the standard is known or, if more than one food is dealt with in the standard, by a generic name covering them all. If a fully informative title should be inordinately long, a subtitle could be added.

Scope

This section should contain a clear, concise statement as to the food or foods to which the standard is applicable unless this is self-explanatory in the name of the standard. In the case of a general standard covering more than one specific product, it should be made clear as to which specific products the standard applies.

Description

This section should contain a definition of the product or products with an indication, where appropriate, of the raw materials from which it is derived and any necessary references to processes of manufacture. It may also include references to types and styles of product and to type of pack. There may also be additional definitions when these are required to clarify the meaning of the standard.

Essential Composition and Quality Factors

This section should contain all quantitative and other requirements as to composition including, where necessary, identity characteristics, provisions on packing media and requirements as to compulsory and optional ingredients. It should also include quality factors which are essential for the designation, definition or composition of the product concerned. Such factors could include the quality of the raw material, with the object of protecting the health of the consumer, provisions on taste, odour, colour and texture which may be apprehended by the senses, and basic quality criteria for the finished products, with the object of preventing fraud. This section may refer to tolerances for defects, such as blemishes or imperfect material, but this information should be contained in an appendix to the standard or in another advisory text.

[98] The standard format of codex commodity standards is available on p. 49 of the Manual.

Other sections

Furthermore, there are sections on food additives, contaminants, hygiene, weights and measures, labelling and methods of analysis and sampling, which require to be completed in a standard only insofar as such provisions are appropriate to an international standard for the food in question. According to the standard format, provisions of Codex General Standards, Codes or Guidelines must only be incorporated into Codex Commodity Standards by reference unless there is a need for doing otherwise.

These sections need to be properly addressed when proposing a draft standard for kava. Some work has been done in the Discussion Paper on the development of a Standard for Kava[99]. However, the need for more scientific evidence on the quality of kava products and more clarity on the nature of the products to be standardised, were identified.

Another issue to consider in addition to a standard or instead of a standard are codes of good practice. For example, the Working principles for risk analysis for application in the framework of the Codex Alimentarius[100] provide under point 10 that "*When there is evidence that a risk to human health exists but scientific data are insufficient or incomplete, the Codex Alimentarius Commission should not proceed to elaborate a standard but should consider elaborating a related text, such as a code of practice, provided that such a text would be supported by the available scientific evidence*."

The scientific work carried out in the context of this study is aimed at providing important input as to the description of standardised kava and the essential composition and quality factors of it.

4.2.7 The Role of Science in the Codex Decision-making Process

The role of science in the development of Codex Standards is addressed in the Statements of Principle concerning the role of science in the codex decision-making process and the extent to which other factors are taken into account.[101]

It provides that (1) the food standards, guidelines and other recommendations of Codex Alimentarius shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply; (2) When elaborating and deciding upon food standards Codex Alimentarius will have regard, where appropriate, to other legitimate factors relevant for the health protection of consumers and for the promotion of fair practices in food trade; (3) In this regard it is noted that food labelling plays an important role in furthering both of these objectives; and (4) When the situation arises that members of Codex agree on the necessary level of protection of public health but hold differing views about other considerations, members may abstain from acceptance of the relevant standard without necessarily preventing the decision by Codex.

The Statements of Principle concerning the role of science in the codex decision-making process provide for the following c*riteria for the Consideration of the Other Factors Referred to in the Second Statement of*

[99] See at www.codexalimentarius.net/download/report/745/REP11_NAe.pdf .

[100] See at p. 110 of the Manual.

[101] Decision of the 21st Session of the Commission, 1995. Manual p. 216.

Principle:[102]

- When health and safety matters are concerned, the Statements of Principle Concerning the Role of Science and the Statements of Principle Relating to the Role of Food Safety Risk Assessment should be followed;
- Other legitimate factors relevant for health protection and fair trade practices may be identified in the risk management process, and risk managers should indicate how these factors affect the selection of risk management options and the development of standards, guidelines and related texts;
- Consideration of other factors should not affect the scientific basis of risk analysis; in this process, the separation between risk assessment and risk management should be respected, in order to ensure the scientific integrity of the risk assessment;
- Recognized that some legitimate concerns of governments when establishing their national legislation are not generally applicable or relevant worldwide;[103]
- Only those other factors, which can be accepted on a worldwide basis, or on a regional basis in the case of regional standards and related texts, should be taken into account in the framework of Codex;
- The consideration of specific other factors in the development of risk management recommendations of the Codex Alimentarius Commission and its subsidiary bodies should be clearly documented, including the rationale for their integration, on a case-by-case basis;
- The feasibility of risk management options due to the nature and particular constraints of the production or processing methods, transport and storage, especially in developing countries, may be considered;
- Concerns related to economic interests and trade issues in general should be substantiated by quantifiable data; and
- The integration of other legitimate factors in risk management should not create unjustified barriers to trade[104]; particular attention should be given to the impact on developing countries of the inclusion of such other factors.

Therefore, a key element of this study is that the Codex standard for kava to be developed shall be based on the principle of sound scientific analysis and evidence, involving a thorough review of all relevant information, in order that the standards assure the quality and safety of the food supply.

[102] Decision of the 24th Session of the Commission, 2001.

[103] A footnote to the text states that "*Confusion should be avoided between justification of national measures under the SPS and TBT Agreements and their validity at the international level*."

[104] According to the WTO principles, and taking into account the particular provisions of the SPS and TBT Agreements.

4.3. History of a Kava Standard in Codex: Work Undertaken in the *CCNASWP*

This part of the report summarises the steps, which have already been taken in the past in relation to the development of a Codex Alimentarius Standard for kava. There has been work undertaken in the FAO/WHO Coordinating Committee for North America and South West Pacific (*CCNASWP*), which concluded so far in a Discussion Paper on the development of a Standard for Kava[105]. In view of the Discussion Paper, the *CCNASWP* identified, in particular, the need for more scientific evidence on the safety and quality of kava products and more clarity on the nature of the products to be standardised and the need to decide whether the proposal was for a regional or a worldwide standard.

Discussions on a Codex Standard for Kava have been carried out since (at least) 2004 in the FAO/WHO Coordinating Committee for North America and South West Pacific (*CCNASWP*). Codex members in the *CCNASWP* include: from North America (Canada and the United States of America); and from the South West Pacific (Australia, Cook Islands, Federated States of Micronesia, Fiji, Kiribati, New Zealand, Papua New Guinea, Samoa, Solomon Islands, Tonga, and Vanuatu).

According to its Terms of Reference[106], the FAO/WHO Coordinating Committee for North America and South West Pacific (*CCNASWP*):

(a) defines the problems and needs of the region concerning food standards and food control;
(b) promotes within the Committee contacts for the mutual exchange of information on proposed regulatory initiatives and problems arising from food control and stimulates the strengthening of food control infrastructures;
(c) recommends to the Commission the development of worldwide standards for products of interest to the region, including products considered by the Committee to have an international market potential in the future;
(d) develops regional standards for food products moving exclusively or almost exclusively in intra-regional trade;
(e) draws the attention of the Commission to any aspects of the Commission's work of particular significance to the region;
(f) promotes coordination of all regional food standards work undertaken by international governmental and non-governmental organizations within the region;
(g) exercises a general coordinating role for the region and such other functions as may be entrusted to it by the Commission; and
(h) promotes the acceptance of Codex standards and maximum limits for residues by member countries.

The *CCNASWP* is, therefore, responsible for defining problems and needs concerning food standards and food control of all Codex member Countries of the region. The host government rotates among the committee members.

[105] See at www.codexalimentarius.net/download/report/745/REP11_NAe.pdf .
[106] http://www.codexalimentarius.net/web/comm_info.jsp?id_lst=32.

The following is a summary of the work undertaken since 2004 in the *CCASWP* in relation to a standard for kava:

8th session of the CCNASWP in 2004

At the 8th session of the *CCNASWP*, held in Apia, Samoa, from 19 – 22 October 2004[107], the Delegation of Fiji presented a proposal for the development of a Codex Standard for Kava, which, according to the report of the session, was supported by some Countries of the region. In noting that kava was an important commodity for the Pacific Island Countries, the Committee recommended that the proposal be submitted to the appropriate Committee, according to the new Codex procedures for the submission of new work. It was noted that the determination of whether kava was considered a "*food*" or "*dietary supplement*" would guide the selection of the appropriate Committee.

9th session of the *CCNASWP* in 2006

At the 9th session of the *CCNASWP*, held in Apia, Samoa, from 10-13 October 2006[108], the Coordinating Committee noted the proposals presented by the delegations of Vanuatu (proposal for a Kava Standard) and Fiji (Proposal for Dried Kava Products, submitted by Fiji, Papua New Guinea, Samoa and Tonga) regarding the development of an international standard for kava beverages and of a regional standard for dried kava products respectively. The Coordinating Committee noted that the two proposals presented many areas of commonalities and some differences and that some additional work was still needed in order to allow the Coordinating Committee to take a decision with regard to new work in this area. In particular it was indicated that: all data and information needed to be referenced; different varieties of kava needed to be identified; and more scientific evidence needed to be presented in order to substantiate statements on the safety of kava products. With regard to this latter point, it was noted that WHO would soon release a report on kava products.

10th session of the *CCNASWP* in 2008

During the 10th session of the *CCNASWP* in 2008, held in *Nuku'alofa*, Tonga, from 28-31 October 2008[109], a Discussion Paper on the Development of a Standard for Kava was discussed as summarised in points 38-44 of the report of the session:

> *"38. The Coordinating Committee recalled that at its 9th Session, it had agreed that a*

[107] Report of the eighth session of the FAO/WHO Coordinating Committee For North America And The South West Pacific, Apia, Samoa 19 – 22 October 2004, www.codexalimentarius.net/download/report/709/al32_32e.pdf .

[108] Report of the ninth session of the FAO/WHO Coordinating Committee for North America and the South West Pacific, Apia, Samoa 10-13 October 2006, www.codexalimentarius.net/download/report/667/al30_32e.pdf .

[109] Report of the tenth session of the FAO/WHO Coordinating Committee for North America and the South West Pacific, Nuku'alofa, Tonga 28-31 October 2008, www.codexalimentarius.net/download/report/709/al32_32e.pdf .

comprehensive discussion paper was to be prepared by an electronic working group (Cook Islands, Federated States of Micronesia, Fiji, Papua New Guinea, Kiribati, Samoa, Solomon Islands, Tonga and Vanuatu participated in the electronic working group), led by the Coordinator (Tonga), to justify the need to develop a standard for kava for consideration at the current session;

39. The Coordinator briefly introduced the discussion paper, as presented in CX/NASWP 08/10/7, which also included a project document, and highlighted that kava was an important agricultural commodity, which could offer significant potential trade opportunities to Pacific Island Countries. He explained that the working group, in preparing the discussion paper, had considered the WHO Report on "Assessment of the risk of hepatotoxicity with kava products (WHO, 2007)". In addition, the Coordinator stressed the importance of the long-term traditional use of kava in Pacific Island Countries with defined varieties and plant parts and the traditional use of cold water for extraction;

40. The Representative of WHO, referring to WHO written comments in CRD 1, stated that the WHO had conducted an assessment of the risk of hepatotoxicity associated with several substances in kava products. The report recommended that further research was necessary, e.g. on the differences of toxicology between roots and other parts of kava. The Representative noted the diversity of kava products and uncertainty on their safety and stated that appropriate measures needed to be applied for the prevention of health risk arising from kava consumption. He further stressed that it was premature to treat kava as a food due to the effects attributed to its pharmacological properties;

41. Some delegations pointed out that kava and kava products had been variously regulated by countries and that there were still information / knowledge gaps on the scope of kava products used as food and on how they should be differentiated from pharmaceutical products. It was further pointed out that information on situation of kava trade included in the document CX/NASWP 08/10/7 needed to be updated;

42. The Coordinating Committee generally agreed on the need for further scientific research to clarify a number of safety issues, prior to considering the standardization of kava for food;

43. After some discussion, the Coordinating Committee agreed to recommend FAO and WHO to assist countries to carry out research and studies, in particular on those aspects indicated in Points 7 and 8 of the project document attached to CX/NASWP 08/10/7. The Representatives of WHO and FAO concurred with his recommendation and noted that clear identification of the need for technical inputs were required to facilitate necessary assistance, including data generation for safety assessment of kava as food; and

44. In order to address the uncertainties regarding the scope of kava products, the Coordinating Committee agreed that the Coordinator (Tonga), in consultation with the Pacific Island Countries, would prepare a paper, which should compile information on: i) scope of kava products and evidence of the use of kava as food; ii) processing methods, iii) regulatory measures for safety control of these products by countries, and iv) markets of export; and other relevant issues, for consideration at its next Session."

11th session of the *CCNASWP* in 2010

At the 11th session of the *CCNASWP*[110], a new Discussion Paper on the Development of a Standard for Kava (prepared by Tonga with the Assistance of Cook Islands, Federated States of Micronesia, Fiji, Papua New Guinea, Kiribati, Samoa, Solomon Islands, Vanuatu) was presented.[111]

The Discussion Paper provides the following Rationale for the development of a standard for kava:

1. Kava (*Piper methysticum*) 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 3,000 years[112], and is being traded within and outside of the region in important quantities and value;

2. The kava drink, which has been consumed in Pacific Island Countries for centuries without any reported ill effects on the liver[113], 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 hepatotoxicity as a problem*"[114] suggesting that "*water extracts are devoid of toxic effects*"[115] and recommending that "*products should be developed from water-based suspensions of kava*"[116]. The safety of water based kava drinks is supported by long-term ethno-pharmacological observations;

3. 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*";[117] and

4. Pacific producing countries are currently at various stages of establishing national level legislation[118] 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.

The discussion paper includes an annex with the Project Documentation in relation to the proposal to develop a Codex Standard for Kava. The purpose is to develop a Codex standard for kava products, intended for human consumption. This proposal is intended to cover kava products whether processed,

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[110] Report of the eleventh Session of the FAO/WHO Coordinating Committee for North America and the South West Pacific, Nuku'alofa, Tonga 28 September - 1 October 2010, available at www.codexalimentarius.net/download/report/745/REP11_NAe.pdf .

[111] Discussion paper on the development of a standard for kava, Document CX/NWSWP 10/11/8 of September 2010; available at: ftp://ftp.fao.org/codex/ccnaswp11/na11_08e.pdf .

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

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

[114] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 62.

[115] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 59.

[116] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p. 62.

[117] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, p.63.

[118] Kava Act 2002, Vanuatu.

semi-processed or raw intended as a food for human consumption in accordance with the Codex definition.[119] Under '*product definition*', the discussion paper states that "*Kava is the name used in the Pacific Island Countries to describe a local traditional drink which has been used for cultural / ceremonial / social purposes for centuries. Other names for kava include 'ava (Samoa), awa (Hawaii), sakau (Pohnpei, FSM) and yaqona (Fiji). The word kava is used to refer both to the plant and the beverage produced from it.[120] The plant from which it is derived is botanically known as Piper methysticum (G Forst f.), a Pacific plant species of the pepper family.[121] The kava drink is made from a water extract of only the root and/or rhizome (i.e., the elongated enlarged plant part located between the stem and the roots) of Piper methysticum*."

The varieties, to which this standard should refer, are listed as follows (local vernacular names)[81]:

- Vanuatu Kava Noble Varieties[122]: *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, Damu Gona vula, Dokobana vula, Qila balavu, Dokobana loa, Vula kasa balavu, Loa kasa leka, Kabra, Loa, Vula kasa leka;*
- Samoa Kava varieties: *Ava Lea, Ava La'au, Ava Loa, Ava Tonga;*
- Tonga Kava varieties: *Lekakula, Lekakula 'akau, Lekahina 'akau, kava Tea, kava Kula, kava Fulufulu;*
- Solomon Islands Kava varieties: *Melomelo*;
- FSM Kava varieties: *Rahmwahnger; and*
- PNG Kava varieties: *Kau kupwe (from Baluan Island).*

Kava products intended for food use in this standard are classified as follows:

- Raw/fresh (including frozen);
- Dried (in form of chips or roots) ;
- Powdered; and
- Water extract.

As to the safety of kava products, the discussion paper states that a recent WHO risk assessment of kava products has found that "*kava has had at least a 1500-year history of relatively safe use, with liver side effects never having arisen in the ethno pharmacological data*"[123] and concludes that "*clinical trials of kava have not revealed hepatotoxicity as a problem*"[124]. This has been confirmed by further studies evaluating

[119] Codex Alimentarius Commission (FAO/WHO): Procedural Manual, 17th Edition, Rome 2007, p.41.
[120] Piscopo G. in: Pacific Health Research Council: Kava and Pacific Health, Suva, Fiji, 2002, p.1.
[121] Secretariat of the Pacific Community. Pacific kava: a producer's guide. Suva, Fiji Islands, 2001, p. 5.
[122] Kava Act 2002, Vanuatu.
[123] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, Geneva 2007, p. 11
[124] WHO (2007): Assessment of the risk of hepatotoxicity with kava products, Geneva 2007, p. 62

the toxicology of kava drink.[125] Based on available scientific information, it can be inferred that kava as a traditional beverage is safe for human consumption.

Under point 2, the discussion paper informs about the relevance and timeliness and provides data in relation to kava production and kava trade (exports). Section 3 (The Main Aspects to be covered) states that, 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, labelling in order to provide certainty and assurance to consumers.

However, after discussing the matter, the *CCNASWP* considered that the Discussion Paper did not address properly the safety issues with kava. The summary report of the 11th session of the *CCNASWP* in 2010, held in *Nuku'alofa*, Tonga, from 28 September to 1 October 2010[126]*, concludes the following in relation to the D*iscussion paper on the development of a standard for kava[127]:

> *"90. The Coordinating Committee recalled that at its 10th Session it had generally agreed on the need for further scientific research to clarify a number of safety issues, prior to considering the standardization of kava for food; and to recommend FAO and WHO to assist countries to carry out research and studies; and that the Coordinator (Tonga), in consultation with the Pacific Island Countries, would prepare a paper, which should compile information on: (i) scope of kava products and evidence of the use of kava as food; (ii) processing methods; (iii) regulatory measures for safety control of these products by countries; and (iv) markets of export; and other relevant issues, for consideration at the present session.*
>
> *91. The Delegation of Tonga briefly introduced the discussion paper, which also included a project document, as presented in CX/NASWP 10/11/8. The paper highlighted that kava was an important agricultural commodity, which could offer significant potential trade opportunities to Pacific Island Countries and recommended to request the Commission to initiate work on the development of a Codex standard for kava.*
>
> *92. The Representative of WHO, referring to CRD 2 "WHO Response to Agenda Item 5", advised the Coordinating Committee that the WHO position presented at the last session, as CX/NASWP 08/10/7, remained relevant. Given the diversity of kava and kava products across the Pacific and the uncertainty on safety, WHO remained not in a position to present its definitive view as to whether kava should be considered as a food within the meaning of the Codex definition. Furthermore, WHO, recognized the need for further research in the areas, which had been identified at the last session of CCNASWP, and noted that preliminary work*

[125] National Botanical Research Institute. Toxicological Evaluations of Kava Drink., 2008, p.4

[126] Report of the eleventh session of the FAO/WHO Coordinating Committee for North America and the South West Pacific, Nuku'alofa, Tonga 28 September - 1 October 2010, www.codexalimentarius.net/download/report/745/REP11_NAe.pdf .

[127] ftp://ftp.fao.org/codex/ccnaswp11/na11_08e.pdf .

to compile information on the scope of kava products, processing methods, current regulatory measures and export market barriers still needed to be done by members prior to FAO or WHO being able to assist, if Member States were to request assistance related to scientific advice.

93. Delegations, which intervened, pointed out that there were still difficulties in identifying the nature of the products to be standardized and that the different frameworks regulating kava in various countries within and outside the region, i.e. either as food, food supplement, medicinal products, etc., added further complexity to the proposal. It was further noted that coordinating committees could only develop regional standards or recommend to the Commission the development of worldwide standards for products of interest to the region; and that procedures had been established for conversion of a regional standard into a worldwide standard.

94. Other delegations pointed out that an effort had been made by Pacific Island Countries to prepare the discussion paper, as agreed by the 10th CCNASWP, and that assistance from FAO and WHO was needed on how to request and use scientific advice around the safety of kava. It was noted that the proposal for this work was consistent with Goal 6 "Promote the development of standards for food products in the Pacific Island countries" and Activity 6.3 "Submit all proposals for new standards for products of interest to the PICs to CCNASWP for consideration prior to submission to the Commission or other Committees and Task Force"; that it was still necessary to discuss whether to develop a regional or a worldwide standard; and that assistance was necessary to prepare a proposal in line with Codex procedures.

95. In view of the need for 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 decide whether the proposal was for a regional or a worldwide standard, the Coordinating Committee agreed to establish an electronic Working Group, led by Tonga, open to all members of the Region and Observers and working in English only, to revise the discussion paper, including the project document, on the basis of the above discussion for consideration at its next session."

12th session of the *CCNASWP* in 2012

The 12th session of the *CCNASWP* was held from 19 to 22 September 2012 in Madang, Papua New Guinea. The Session largely focused on issues referred from the 35th Session of the Codex Alimentarius Commission (*CAC*) held in July 2012. Regarding the discussion paper on Kava, the FAO and WHO announced that the will provide technical assistance to answer some of the outstanding scientific issues.

According to the USDA Delegate's Report of the session[128], "*the discussion paper on Kava came up once again for consideration, but unfortunately, many of the core questions previously raised at the last Session by the US and other delegations, as well as the WHO, were still not addressed. Nevertheless, a number of PICs supported the development of a regional standard for Kava since in certain PICs it was a major crop,*

128 http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/recent-delegation-reports/delegate-report-12th-session-ccnaswp

while in others, it was imported and consumed by a significant part of the population. They noted that the lack of such a standard might result in a risk to consumers, due to the potential risk of using unsafe varieties of Kava. The US, along with other delegations, reiterated their concerns expressed at previous CCNASWP sessions and in written comments submitted to the electronic Working Group (eWG), on the safety of Kava and on whether it could be classified as a food. The US Delegate also suggested that if this were ever to be developed, perhaps an international standard would be better suited if the intent was to eventually trade Kava beyond the region, to other areas including the EU, China, India, and Africa. The Committee agreed to establish an eWG, chaired by Vanuatu, to revise the proposal for the development of a regional standard for Kava focusing on the dried product that can be used as a beverage when mixed with water. It also accepted the FAO and WHO's offer to assist in the review of existing scientific information and identification of data gaps that may be impacting a proper safety assessment."

The *CCNASWP* meeting's report states the following in relation to the Discussion paper on kava (Agenda Item 6)[129]:

> *"109. The Delegation of Tonga, as the Chair of the electronic Working Group, introduced the discussion paper and emphasized the importance of kava for PICs, as consumers and exporters. The Delegation recalled that the mandate of the Working Group was to revise the discussion paper and the project document, presented at the 11th CCNASWP, to: (i) provide more scientific evidence on the safety of kava products; (ii) clarify the nature of the products to be standardized; and (iii) clarify whether the proposal was for a regional or a worldwide standard.*[130]
>
> *110. The Delegation explained that data showing that kava was traded internationally mainly referred to the form of kava used by the pharmaceutical industry and that the trade of kava, as food, was mainly within the Region. The Delegation also highlighted that the section "Product definition" defined the species, varieties, plant parts and extraction methods of kava consumed in the Pacific. He also stated that scientific analytical methods could detect the use of (i) unsafe kava varieties; (ii) skin peels of stems; and (iii) leaves. He further highlighted that safety of the products was based on the long-term history of use of the traditional beverage in the Pacific and that most of the safety problems surrounding kava had arisen when the pharmaceutical industry started extraction from kava leaves and stems.*
>
> *111. He further explained that the proposal was for the development of a regional standard, which would contribute to increase confidence in and knowledge of kava, as food.*
>
> *112. The Delegation of Vanuatu, in supporting the development of a standard for kava, explained that according to recent studies, higher quality kava, called "noble kava", contained less flavokavin, especially flavokavin B, which might be a major contributor to the observed liver toxicity. The Delegation said that PICs were trading kava-derived products with various countries and noted the lack of international benchmarks to establish SPS measures against. The Delegation was of the view that a regional standard for kava with a limited scope on "noble kava", as described in the discussion*

[129] CX/NASWP 12/12/8.
[130] REP11/NASWP, para.95

paper, should be developed to ensure the safe use of these products. He further added that Vanuatu was developing guides on kava products that would define the quality parameters for these types of products.

113. A number of delegations intervened supporting the views expressed and the development of a regional standard for kava. They said that kava in certain PICs was a major crop, while in others was imported and consumed by part of the population; they noted that the development of a regional standard was an opportunity for the PICs and that the lack of such a standard might result in a risk to consumers, due to the potential risk of using unsafe varieties of kava.

114. Other delegations reiterated their concerns, expressed at previous CCNASWP sessions and in written comments submitted to the electronic Working Group, for the safety of kava and on whether kava could be classified as a food. They noted that the nature of the products to be standardized remained unclear; that there seemed to be some gaps in scientific information on the safety of kava; that more data for each species described and on toxicology of kava were required; and that the project document had some limitations and needed to be revised to meet the requirements of the Codex Critical Review; that an international standard would perhaps be better suited if the intent was to trade kava beyond the Region, to the European Union, China, India, Africa, etc. It was suggested to look more closely at the types of products to be standardized, noting that some countries legislation, while allowing the use of kava as a food (i.e. consumed as a beverage) do not allow its use as a food ingredient. It was also suggested to consider whether organizations, such as the International Kava Executive Council, could be a better venue for the development of this standard.

115. One delegation suggested that CCNASWP could commit to gathering the scientific data required, including consumption data, and solicit guidance from FAO and WHO on the adequacy of such information. Several delegations noted that they had additional data to contribute to this process.

116. The Representative of WHO in response to country requests for clarification on the applicability of the WHO report from 2007 on 'Assessment of the Risk of Hepatotoxicity of Kava Products' to kava as a food, noted that this report did not evaluate safety of kava for food use, but examined pharmacological properties of several substances in kava.

117. The Representative of WHO, on behalf on FAO and WHO, went on to note the significant importance of this product to the region and acknowledged the challenges discussed by the Coordinating Committee, including aspects of safety assessment. In light of these factors FAO and WHO, working with PICs and other interested countries, would be willing to assist in reviewing current food safety data and information on kava, including the identification of any data gaps. The Delegation of Canada expressed willingness to support this review.

118. The Representative pointed out that before this review could be undertaken, it was necessary to clarify the scope of the product and its use as a food. It was also noted that FAO and WHO were not able to commit to address any data gaps identified at this time and that there were mechanisms

in place, which could be utilised to do this.

119. The Coordinating Committee noted that there was clearly an interest in the development of a regional standard and to address the gaps on the safety of kava and to prepare a robust project document for new work that could pass the scrutiny of the Codex Critical Review.

120. In response to a request from the Coordinating Committee to clarify potential support on a review of safety data and timelines, the Representative of FAO re-stressed the need to take a stepwise approach to this issue. The first important step was to review existing data on the safety of kava as a food, once the scope of the product was clarified. This would facilitate a better understanding of the safety of kava and identify any data gaps that might exist, but would not include a full toxicological assessment. A possible lead in time for this step could be 6-9 months, and information on findings could be available at the next CCNASWP. The results of this first step would inform on any required further steps.

The following was concluded:

"121. The Coordinating Committee agreed to focus the proposal for the development of a regional standard for kava as the dried product that can be used as a beverage when mixed with water.

122. Regarding the safety of kava, the Coordinating Committee accepted FAO and WHO's offer to assist by:

- *Reviewing existing scientific information on kava as the dried product that can be used as a beverage when mixed with water in the context of a safety assessment; and*
- *Identify data gaps (if they exist) and their impact on conducting a safety assessment.*

123. The Coordinating Committee agreed to establish an electronic Working Group, chaired by Vanuatu and open to all Members of the Region and Observers, to revise the project document proposing a regional standard with emphasis on:

- *Amending the scope and use to limit it to kava as the dried product that can be used as a beverage when mixed with water;*
- *Update trade and production data where available; and*
- *Reflect on the outcome of the FAO/WHO review of data in the relevant section of the project document.*

124. The Coordinating Committee also noted that active participation in the electronic Working Group of all Members, as well as FAO and WHO, was necessary."

13th session of the CCNASWP in 2014

According to the *USDA* Delegate's Report of the session[131], "*the proposal for a draft regional standard for kava came up once again for consideration at this Session of CCNASWP. Vanuatu, as Chair of the electronic Working Group (eWG), indicated that since there had not been sufficient time to fully consider the recent FAO/WHO report on kava, as well as other information, that it was not necessary to have a full discussion on kava at this Session. As such, the Coordinating Committee agreed to reconvene the EWG, led by Vanuatu, to further develop the discussion paper (on kava as a dried product that can be used as a beverage when mixed with water), taking into account the recent FAO/WHO report and all new available information, and to consider the possibility of other risk management options, such as a code of practice.*"

According to its minutes, in the 13th session of the FAO/WHO *CCNASWP*, held in *Kokopo*, Papua New Guinea on 23 - 26 September 2014, the Delegation of Vanuatu introduced a discussion paper on kava and noted that the issue of kava was a very complex one, and that the import ban on kava products in general by certain Codex member Countries contributes to the misunderstanding of the safety of the product. Ahead of the 13th session of the FAO/WHO *CCNASWP*, the eWG (Electronic Working Group on kava, led by Vanuatu) had not had sufficient time to consider in detail the FAO/WHO Technical Report on Kava: a review of the safety of traditional and recreational beverage consumption and also the results of the EU-funded 2012 ACP-MTS Project. The *CCNASWP* agreed to reconvene the EWG, led by Vanuatu, in order to: (i) further develop the discussion paper taking into account the FAO/WHO report and other available information; and (ii) consider the possibility of other risk management options, such as a code of practice.

Current work undertaken in the *CCNASWP*

The discussions on a Codex Standard for Kava, carried out since (at least) 2004 in the FAO/WHO Coordinating Committee for North America and South West Pacific (CCNASWP), have not been fruitful so far. The Electronic Working Group (eWG) has, in the meantime, done work on the discrimination of varieties into '*noble*' and '*non-noble*' by introducing new analytical techniques that may serve as quick tests at the point of export/import, notably an easily applicable colour test.[132]

During the meetings of KE1 with the eWG in the course of the field mission, it was discussed that the results presented herein should rather be handed to the eWG to strengthen their position instead of attempting a parallel and independent approach. The combined scientific findings should be ideally presented at the 14th session of the *CCNASWP* in 2016.

131 http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/us-codex-alimentarius/recent-delegation-reports/delegate-report-13-ccnaswp

132 V. Lebot: What went wrong in the South Pacific? A few practical solutions. KavaCon 2015 – International Conference on Kava. Honolulu, Hawaii, 25. July 2015

4.4 Kava: Food or drug?

The question raised in the *CCNASWP* whether to consider kava as a food, food supplement or a drug (see above in this report) is clearly answered by the wealth of publications on the recreational use of kava in the South Pacific[133,134,135]. Kava is consumed as a drink in the South Pacific, not as a supplement, its relaxing properties notwithstanding. The fact that kavalactones have pharmacological effects is no contradiction to kava drinking: caffeine in tea of coffee also has pharmacological effects, so have the polyphenols in rooibos tea or the constituents of chamomile or peppermint tea.

Within the European medicinal system, a given plant preparation would receive drug status based on the claims made for this plant: kava preparations were officially authorised in Germany for the use against anxiety disorders, hence for the treatment of a medical condition. As such, kava extract preparations were considered drugs in Germany, whereas kava without medicinal claims were used as food supplements in other EU Member States, or even used in the traditional way by kava drinking.

When it comes to quality, EU legislation does not make a difference between food and food supplements, in both cases the standards of food safety would apply.[136] A Codex standard for kava as a beverage would, therefore, not specifically have to take the legal status of food supplements into account. Kava-containing drug preparations cannot be regulated by a Codex standard, this would be the task of a pharmacopoeial monograph. In conclusion, the ethnobotanic observations of traditional kava drinking support the classification of kava as a beverage.

4.5 Applicable General Codex Standards and Examples of other Standards

This part of the report mentions the general Codex standards applicable and gives examples of other Codex Alimentarius Standards for other "*herbal substances*" like ginseng, gari, ginger and tannia to show (from a comparative perspective) language used in these standards, which could be of relevance for the development and drafting of a Codex standard for kava.

While there is no specific standard for kava yet[137], the general Codex standards apply. Kava products should be prepared and handled in accordance with the appropriate sections of the Recommended International Code of Practice - General Principles of Food Hygiene (CAC/RCP 1-1969).[138] The Codex General Principles of Food Hygiene lay a foundation for ensuring food hygiene. They provide guidance to

[133] Siméoni P, Lebot V. Buveurs de, Kava. Géoconsulte, Port Vila (Vanuatu); 2014.

[134] Lebot V, Merlin M, Lindstrom L., Kava, the Pacific elixir. Yale University Press, New Haven; 1992.

[135] Singh Y (Ed.).Kava: From ethnology to pharmacology. Medicinal and Aromatic Plants – Industrial Profiles. CRC Press, Bocaraton; 2004.

[136] Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1.

[137] A full list of existing Codex Standards and the respective texts are available here: http://www.codexalimentarius.org/standards/en/.

[138] Adopted in 1969, amended in 1999 and revised 1997 and 2003. Available here: http://www.codexalimentarius.org/standards/en/.

the food chain from primary production to the final consumer, highlighting the key hygiene controls at each stage, and recommending an *HACCP* (Hazard Analysis and Critical Control Point)-based approach to enhance food safety as described in the *HACCP* system and guidelines for its application.[139] These controls are internationally recognised as essential to ensure the safety and suitability of food consumption. The general principles are recommended to governments, industry and consumers alike. The requirements of the General Principles of Food Hygiene are considered to be the foundation for the development of an *HACCP*-based system for ensuring food safety. The application of the General Principles of Food Hygiene and of GMPs allows the producer to operate within environmental conditions favourable to the production of safe food. In implementing an *HACCP* system in an establishment, the first step is to review existing programmes for compliance with the General Principles of Food Hygiene and GMPs and to verify whether all the necessary controls and documentation (*e.g.*, programme description, individual responsible and monitoring records) are in place.

In practice, it appears that, for instance, at the point of the production process where kava is dried, there seem to be problems with moulds due to the humid climate. This is where *HACCP* systems seem to be needed to ensure food safety as moulds could result in contamination with aflatoxins – fungal toxins, which are restricted in food and drugs. Aflatoxins are considered carcinogens and hepatotoxins. They are restricted to specified levels in some EU member states in food and drug products.

Kava production should also comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria Related to Foods.[140]

In view of the future development of a standard for kava, indications on the content (and language to be used) of such standard can be drawn from a comparative perspective from already existing standards for other '*botanical*' substances, such as is the case for ginger, gari, ginseng and tannia:

- Codex Regional Standard for Ginseng Products (Codex STAN 295-2009) (now superseded by a global Codex Standard on *Ginseng* (Codex STAN 321-2015);
- Codex Standard for *Gari* (Codex STAN 151-1989) Adopted 1989. Revision 1995. Amendment 2013;
- Codex Standard for *Ginger* (Codex STAN 218-1999) amended in 2005; and
- Codex Standard for *Tannia* (Codex STAN 224-2001).

For orientation, the relevant passages of the existing ginseng standard are given below, next to a discussion of the transferability of similar formulations to the case of kava.

The Codex Standard Regional Standard for Ginseng Products (Codex STAN 295-2009) gives the following product definition: "*The compulsory ingredient of ginseng product is fresh ginseng roots suitable to eating, derived from Panax ginseng C.A. MEYER and P. quinquefolius L., cultivated for commercial purposes and*

[139] Annex to the Recommended International Code of Practice - General Principles of Food Hygiene, CAC/RCP 1-1969 (Adopted 1969. Amendment 1999. Revisions 1997 and 2003).
[140] CAC/GL 21-1997 (Revised and renamed 2013).

used for foods. Ginseng products should be packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products." Then it describes different types of GINSENG PRODUCTS (*i.e.*, Dried Ginseng, Dried Raw Ginseng, Dried Steamed Ginseng, Ginseng Extract, Raw Ginseng Extract, Steamed Ginseng Extract).

→ By principle, adapted definitions would be directly transferable to a kava standard.

Under '*quality factors*' the Standard states that "*Ginseng products shall have normal flavour, colour, taste and a ginsenoside pattern (the unique constituents of ginseng are found to be a complex mixture of saponins often referred to as ginsenosides, and more than 30 ginsenosides are known. Ginsenoside Rb1 or ginsenoside Rf is one of the major ginsenosides. Ginsenoside Rb1 is identified in all ginseng species in quantities, while ginsenoside Rf is identified mainly in Panax ginseng C.A. MEYER.) unique to ginseng as well as be free from foreign matters*."

→ Adapted definitions would be directly transferable to a kava standard, mentioning the kavalactones in this place.

Ginseng as a typical example for the formulation of a standard

Codex Standard on Ginseng (Codex STAN 321-2015)

> *1. SCOPE*
> *This Standard applies to the ginseng products as defined in Section 2 below and offered for direct consumption, including for catering purposes or for repacking, if required. This Standard applies to ginseng products used as a food or food ingredient and does not apply to products used for medicinal purposes.*

→ The restriction to food use would also have to be introduced into the draft kava standard. Medicinal use must be regulated by a pharmacopoeial monograph. The approach to a medicinal standard through a food standard is not unusual, and in the absence of a pharmacopoeial standard an existing Codex standard would be considered as applicable for quality definition by the drug regulatory authorities.

> *2. DESCRIPTION*
> *2.1 Product definition*
> *Ginseng product is the product:*
>
> *(a) prepared from all part of fresh and sound ginseng roots, derived from Panax ginseng C.A.Meyer or P. quinquefolius L., cultivated for commercial purposes and used for foods;*
> *(b) packaged in such a manner as to safeguard the safety and nutritional and quality characteristics of the products;*
> *(c) processed in an appropriate manner, undergoing operations such as drying, steaming, cutting, powdering, extraction and concentration in conformity with Section 2.2.*

→ Fully transferable to kava with additional adaptation to frozen-fresh and dried roots and peeled rhizomes.

2.2 Types of Ginseng Products
Ginseng products covered by this Standard may be as follows:

2.2.1 Dried Ginseng
Dried Ginseng is manufactured when ginseng roots defined in Section 2.1 (a) are dried in an appropriate manner such as sun drying, hot air drying or other recognized drying methods. The product may be classified into one of such product types that have the main root and/or lateral roots or that are powdered or sliced.

→ Transferable to kava with the appropriate adaptations.

2.2.2 Dried Steamed Ginseng
Dried Steamed Ginseng is manufactured when ginseng roots defined in Section 2.1 (a) are prepared using the steaming method and the drying method stated in Section 2.2.1. The product may be classified into one of such product types that have the main root and/or lateral roots or that are powdered or sliced.

→ This part would be replaced by the description of frozen/fresh kava.

2.2.3 Ginseng Extract
Ginseng Extract is manufactured when soluble components of ginseng roots defined in Section 2.1 (a) or Dried Ginseng defined in Section 2.2.1. are extracted by using water, ethanol or their mixture, filtered and concentrated. This product has a dark brown colour and a high viscosity. The product may be also presented as a powdered type through spray- or freeze-drying.

→ This part would be adapted to the situation with kava. Only water as extraction solvent should be mentioned. Ethanol extracts or extracts prepared with any other extraction solvent such as acetone of supercritical carbon dioxide are not covered by the traditional use.

2.2.4 Steamed Ginseng Extract
Steamed Ginseng Extract is manufactured when soluble components of Dried Steamed Ginseng defined in Section 2.2.2 are extracted by using water, ethanol or their mixture, filtered and concentrated. This product has a dark brown colour and a high viscosity. The product may be also presented as a powdered type through spray- or freeze-drying.

→ Not transferable.

2.3 Styles
Styles should be permitted provided that the product meets all relevant requirements of the Standard and is adequately described on the label to avoid confusing or misleading the consumer.

→ Not transferable.

3.2 Quality Criteria

3.2.1 Flavour, Colour, and Ginsenoside Pattern

Ginseng products shall have normal flavour, colour, taste and a ginsenoside pattern unique to specific species of ginseng as well as be free from foreign matter.

→ Transferable with change to kavalactones, see above.

3.2.2 Chemical and Physical Characteristics

3.2.2.1 Dried Ginseng and Dried Steamed Ginseng

(a) Moisture: no more than 14.0% (Powdered type: no more than 9.0%).

→ Transferable with conditions adapted to kava. 14 % moisture would have to be considered the absolute maximum in view of mould formation, less would be preferable.

(b) Ash: no more than 6.0%.

→ Transferable with conditions adapted to kava. 6% for ash appears relatively low by comparison with typical values found in the European Pharmacopoeia. Root preparations usually claim specifications of 10%.

(c) Water-saturated n-butanol extracts: no less than 20 mg/g3.

→ Not transferable.

(d) Ginsenoside Rb1: qualitatively detected.

In addition, in the case of product is manufactured from P. ginseng C.A. Meyer, ginsenoside Rf should be also be qualitatively detected.

→ Transferable with methods adapted to kavalactones.

3.2.2.2 Ginseng Extract and Steamed Ginseng Extract

3.2.2.2.1 Ginseng Extract (liquid form)

(a) Solids: no less than 60.0%.

(b) Water-insoluble solids: no more than 3.0%.

(c) Water-saturated n -butanol extracts: no less than 40 mg/g3.

(d) Ginsenoside Rb1: qualitatively detected.

In addition, in case of the product manufactured from P. ginseng C.A. Meyer, ginsenoside Rf should be also be qualitatively detected.

3.2.2.2.2 Ginseng Extract (powdered form)

(a) Moisture: no more than 8.0%.

(b) Water-insoluble solids: no more than 3.0%.

(c) Water-saturated n -butanol extracts: no less than 60 mg/g3.

(d) Ginsenoside Rb1: qualitatively detected.

In addition, in case of the product manufactured from P. ginseng C.A. Meyer, ginsenoside Rf should be also be qualitatively detected.

→ Transferable with methods and specifications adapted to kava water-based extract preparations.

4. FOOD ADDITIVES
No additives are permitted in the products covered by this standard.

→ Fully transferable.

5. CONTAMINANTS
5.1 The products covered by this Standard shall comply with the maximum levels of the General Standard for Contaminants and Toxins in Food and Feed (CODEX/STAN 193-1995).
5.2 The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

→ Fully transferable.

6. HYGIENE
6.1 It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the General Principles of Food Hygiene (CAC/RCP 1-1969), and other relevant Codex texts, such as codes of hygienic practice and codes of practice.
6.2 The products should comply with any microbiological criteria established in accordance with the Principles and Guidelines for the Establishment and Application of Microbiological Criteria related to Foods (CAC/GL 21-1997).

→ Fully transferable.

7. LABELLING
The products covered by this Standard shall be labelled in accordance with the General Standard for the Labelling of Pre-packaged Foods (CODEX STAN 1-1985). Any health claims should comply with the Guidelines for Use of Nutrition and Health Claims (CAC/GL 23-1997), if necessary.

In addition, the following specific provisions apply:

7.1 Name of the product
7.1.1 The name of the products defined in Sections 2.2.1, 2.2.2, 2.2.3 and 2.2.4 shall be Dried Ginseng, Dried Steamed Ginseng, Ginseng Extract and Steamed Ginseng Extract, respectively. In this case, the products manufactured with P. ginseng C.A. Meyer can be named White Ginseng, Red Ginseng, White Ginseng Extract and Red Ginseng Extract.

→ Transferable with adaptation to kava.

7.2.2 The style shall appear on the label in conjunction with, or in close proximity to the name of the product, to avoid misleading or confusing the consumer.

→ Not required for kava.

7.2 Name of the Ginseng species
All ginseng products shall be labelled with the scientific or common name of the ginseng that is used as raw material. The common names of the ginseng species shall be declared in accordance with the law and custom of the country where the products is consumed, in a manner not to mislead the consumer.

→ Transferable with adaptation to kava.

7.3 Country of origin
The country of origin of the product and/or raw material shall be declared if its omission is likely to mislead or deceive the consumer.

→ Fully transferable to kava.

7.4 Labelling of Non-retail Containers
Information about non-retail containers shall be given on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer, packer or distributor, as well as storage instructions, shall appear on the container. However, lot identification, and the name and address of the manufacturer, packer or distributor may be replaced by an identification mark, provided that such a mark is clearly shown in the accompanying documents.

→ Fully transferable to kava.

7.5 Optional labelling
The products may have a clear marking to indicate that they are not intended for medicinal purposes, including other labelling requirements stipulated by the country where ginseng products are distributed.

→ Transferable with adaptation to kava.

8. METHODS OF ANAYSIS AND SAMPLING
8.1 Methods of Analysis
Identification of ginsenosides Rb1, and Rf: As described in Annex III TLC or HPLC. IV

→ Transferable with methods and specifications adapted to kava.

4.6 Further Regulations to be Considered

In developing Codes of Good Practice for the production of kava, the content of (*inter alia*) the following texts could be considered, in particular since there seems to be a problem with kava and aflatoxins due to the humid climate and the current drying process of kava:

- Recommended international code of hygienic practice for groundnuts (peanuts) CAC/RCP 22-1979;
- Code of practice for the prevention and reduction of mycotoxin contamination in cereals, including annexes on ochratoxin a, zearalenone, fumonisins and tricothecenes CAC/RCP 51-2003;
- Code of practice for the prevention and reduction of aflatoxin contamination in tree nuts (CAC/RCP 59 -2005); and
- Code of practice for the prevention and reduction of ochratoxin a contamination in coffee (CAC/RCP 69-2009).

4.7 Next Steps in Relation to the Development of a Codex Standard for Kava

This part describes the next steps to be taken in relation to the development of a Codex standard for kava, in particular in relation to the assessment of quality of kava under this project. This work should ideally lead to a "*product description*" and "*essential composition and quality factors*" of kava, which should be the standardised product under the Codex Alimentarius. This part of the report looks also at the question of whether kava should be standardised by a regional or global Codex standard.

The scientific outcome of the study should be provided to the *CCNASWP*, which generally agreed that further scientific research was needed to clarify a number of safety issues, prior to considering the standardization of kava for food. The scientific findings should be ideally presented at the 14th session of the *CCNASWP* in 2016.

The *CCNASWP* should then decide to recommend to the Codex Alimentarius Commission to consider and approve this proposal for new work. A worldwide Codex Standard for Kava should then be drafted in accordance with the Codex uniform layout for food products for '*safe*' kava as defined by this study.

4.7.1 Description of Kava

According to the discussion paper, kava is highly amenable to standardisation, because the part of the plant used for food purposes is uniform throughout all Countries. The varieties proposed in the discussion paper on kava are those that have been traditionally consumed in the Pacific for centuries and can be identified by standard taxonomical means. The proposed standard will ensure consumer health protection by identifying suitable varieties of kava, parts of the plant and the process of preparation.[141]

In line with the scientific outcome of this study, only '*noble*' kava should be standardised due to potential

[141] Discussion paper on the development of a standard for kava, Document CX/NWSWP 10/11/8 of September 2010, p. 6 (see Annex 2).

safety and tolerability issues with '*non-noble*' kava (*i.e.*, '*two-day*' kava or *Piper wichmanii*-varieties). The varieties listed in the discussion paper could, as far as tested, all be identified as '*noble*' varieties, as defined in the Vanuatu Kava Act (Annex 1). However, the variety sampling and the documental analysis showed that identification of '*noble*' kava by variety name is not advisable. Names tend to change and are prone to regional differences, as can be demonstrated with the '*noble*' varieties of Vanuatu and of Fiji.[70,71]

For instance, the very same Vanuatu variety can be labelled with the name "*Borogu*", "*Boroguru*", "*Gorogoro*" or "*Gorgor*" [87]. The URS report of Fijian kava types[71] gives several examples of deviating designations of kava varieties in different regions. One example is "*Qila balavu*", which is called "*Dokobane vula*" in the island of *Taveuni*. "*Dokobana vula*" is, however, also a name for a different Fijian variety, which, to make things worse, was in turn found to be called "*Vula kasaleka*", a name used for yet another Fijian variety. The discussion paper also contains the name of "*Melo melo*" for the single variety listed for the Solomon Islands. There are currently two varieties harvested and exported from the Solomon Islands, and neither corresponds to *Melo melo*. The variety names of Tonga seem to have changed or at least to be used in a slightly different way, so even in Tonga there would be no clear correlation between name and variety. Only Samoa does not seem to have this kind of problem.

As a consequence of the problems encountered with the use of vernacular variety names, the Standard should refrain from listing such names. The names are not necessary for the distinction between '*noble*' and '*non-noble*' varieties. The distinction can be made through analyses, and as long as the test indicates '*noble*', the use of such material should be acceptable. The origin of the material should be controlled through agricultural protocols, not through names prone to changes.

Safety of kava is based on many Centuries of experience with traditional kava drinking. Until the German kava drug safety protocol – which today is known to not having been based on a demonstrated risk, but rather on regulatory issues[9,10,11] –, there was no suspicion of kava being responsible for adverse reactions. As already discussed in the 2012 ACP-MTS report, there is evidence for a change of kava raw material quality right before the first case reports of liver toxicity were filed. '*Two-day*' kava had been freshly introduced, together with the use of stem peelings. Consequently, only '*noble*' varieties should be harvested for kava drinking and exports in order to justify safety through the vast traditional experience. This does not exclude the development of commodities prepared from other plant parts of Piper methysticum, including '*two-day*' varieties, but such products would have to deliver their proper risk analysis or toxicological data.

With respect to plant parts, only roots and peeled root stumps (chips) should be selected. Stems as a low-value commodity (due to their very low content of kavalactones) would have to be regulated separately, if necessary.

What is also needed in the future is the elaboration and acceptance of a Code of Practice for kava by Codex, which will provide uniform guidance for all Countries to consider in attempting to control and manage the safety/contamination that are arising in kava production. Such a Code of Practice must necessarily be oriented at *HACCP* protocols and the definitions of the WHO *GACP* guideline.[73] It should, for example, address the issues of harvesting, labelling, cleaning, processing, drying, storage and transport of kava.

4.7.2 Regional or Global Standard?

Further to the need for more scientific evidence on the safety of kava products and more clarity on the nature of the products to be standardized, the *CCNASWP* identified the need to decide whether the proposal was for a regional or a global standard for kava.[142]

The difference between regional and global standard seems to be basically whether there is "*significant intra-regional trade*" vis-à-vis "*significant trade, between or within other regions*". There appears to be no Codex Decision with established criteria or any guidance on the question of whether proposing a regional or a worldwide Codex standard.

When proposing a regional standard, well-documented and objective evidence shall be provided that there is significant intra-regional trade, and that there is no significant trade, between or within other regions. In case there is substantial production and trade of a regional commodity in countries outside the region, the Executive Committee should recommend to the concerned commodity committee to consider elaborating a global standard taking into account its work program.[143]

A significant amount of kava is being traded within the Countries of the region. Kava (sourced exclusively from the Pacific Island Countries) is also being exported to Countries outside the region, such as Japan, New Zealand, Canada, China, and the US. Impediments to trade are the ban of pharmaceuticals containing processed kava products in 2002, which discontinued the export of any kava-based plant material as raw materials to Germany and other EU Member States. In addition, Australia imposed a total restriction on the import of kava products for human consumption in 2006.[144]

In view of the different approaches to the definition of kava and especially its processing (*e.g.*, fresh versus dry), a regional standard seems advisable for the achievement of a commonly accepted definition in the kava-producing Countries. In any event, it is open to the Codex Alimentarius Commission to consider at any time the possible extension of the territorial application of a Codex Regional Standard or its conversion into a Worldwide Codex Standard [145] , as it has been done in the case of ginseng.

[142] Point 95 of the summary report of 11th CCNASWP session.

[143] Guidelines on the application of the criteria for the establishment of work priorities applicable to commodities, ALINORM 08/31/3, available at: http://www.codexalimentarius.org/procedures-strategies/standard-management/work-priorities-applicable-to-commodities/en/

[144] Discussion paper on the development of a standard for kava, Document CX/NWSWP 10/11/8 of September 2010; available at: ftp://ftp.fao.org/codex/ccnaswp11/na11_08e.pdf , p. 5 and 6.

[145] Joint FAO/WHO Food Standards Programme, Procedural Manual Codex Alimentarius Commission, ISSN 1020-8070, Twentieth edition prepared by the Secretariat following the Thirty-third Session of the Codex Alimentarius Commission, Rome, 2010.

4.7.3 Reaching Protection through a System of Geographical Indications (GIs)

This part of the report describes how kava products from the region could benefit from a system of controlled origin, and eventually reach protection through a system of Geographical Indications (GIs).

According to the observations during the field mission in the context of this project and to published descriptions[87], kava is not planted in large monocultures typical of Western commodities. Small growers usually have only a handful of plants, used as a financial reserve. In Vanuatu there is the saying that "*having kava plants is as good as saving one's money in a bank account*": kava is growing by itself, similar to interests in an investment. This relatively small size of individual kava cultivation could, in theory, make differentiation and traceability of cultivars rather difficult. However, the typical situation on Santo was a mix of the '*noble*' cultivars *Borogu* and *Melomelo* with the '*two-day*' cultivar *Palisi* on the same site, with the growers perfectly capable to differentiate and deliver what is asked from them.

Accordingly, a future traceability program should not be too difficult to implement, if it is done with and not against the growers. With clear labelling of geographic indications and a testing according to Codex Alimentarius standards as firewall, the market can be expected to quickly regulate itself. With a traceability system in place, allowing the detection of mislabelling or intermixing of '*two-day*' kava in export quality material, a grower would quickly comprehend that he is damaging his own business by not following the standards. The installation of a system of GIs would also allow for rewards to be provided for those producers that adhere to the standards, as good experience with a given origin is likely to attract new customers and thus create welfare in the region.

Discussions with kava growers during the field missions showed that, especially in Fiji, there is an increasing interest in Geographical Indications, as such an approach is seen as a possibility of changing the current system of payment by quantity into payment by quality, and of reducing uncontrollable activities of middle-men.

4.8 Draft Proposal for a Regional Standard for Kava and Kava Products

It is necessary that precise technical specifications be developed and implemented for kava raw materials, with stringent quality control measures to ensure that only suitable kava varieties are grown and harvested. It is also suggested that training programmes be developed to enhance quality and capacity at all levels of the kava production and value-addition chain, including methods for drying and reducing the risk of aflatoxins formation.

The German '*ban*' of kava-derived products, and subsequently the '*ban*' in all of Europe and the repercussions in the US and Australia, were most likely caused by a problem with kava quality. A major problem identified in the course of this assistance is the lack of suitable specifications for kava as an export commodity, including the importers requirements in the context of food and/or drug use, and the exporter's knowledge of ethnobotanic issues, especially the selection of varieties.

Plant Parts

Kava is subdivided into different qualities according to plant parts:

- The (secondary) fine roots are considered the best part of the kava plant: they have the highest content of kavalactones;
- The root stump peeled and cut to slices (chips) is an acceptable quality. The kavalactone content is inferior to the roots, but the material makes approximately 70% of the weight of a harvested kava plant;
- The stem material of the first internode, when peeled, is in some cases used as well, but is regarded as inferior to the chips because of the very low contents of kavalactones; and
- The peels of the stems and root stumps as well as any above-ground material (stems, branches, leaves) are considered inacceptable and are potentially linked to adverse effects upon consumption.

1. SCOPE

This standard applies to the kava products as defined in Section 2 below and offered for direct consumption, including for catering purposes or for repacking if required. It also applies to the product when indicated as being intended for further processing (*e.g.*, extraction). This standard applies to kava products used as a food or food ingredient and does not apply to products used for medicinal purposes.

This Standard applies only in those jurisdictions where products defined in 2.1 are regulated as foods.

2. DESCRIPTION

2.1. Product Description

The compulsory ingredient of kava product is fresh or dried kava roots or peeled root stumps suitable to preparing kava drinks, derived from '*noble*' varieties of *Piper methysticum* Forst. f., cultivated for commercial purposes and used for foods. Kava products should be packaged in such a manner as to safeguard the hygienic, nutritional, technological and organoleptic quality of the products.

Plant parts of kava according to this description are whole or cut roots, and the peeled root stump, whole or cut to slices.

The use of aerial parts (unpeeled stems, leaves) and the use of peels must be avoided.

2.2. Types of kava products

2.2.1 Fresh kava

Fresh kava consists of total or cut fresh kava roots and peeled fresh rootstumps. The product may be deep-frozen for later use or transport.

2.2.1 Dried kava

Dried kava is manufactured when fresh kava roots and peeled rootstumps are sun dried or hot air dried or dried using other recognized methods. The product may be classified into one of such product types

that have the root stump or pieces of the main root and/or lateral roots or that are powdered or sliced.

2.2.2 Kava Extract

Kava Extract is manufactured when soluble components of fresh or dried kava roots are extracted using water. The extract may be filtered and concentrated. This product has a dark brown colour and a high viscosity when much of the water is removed from it. The product may be also presented as a powdered type through spray- or freeze-drying.

3. ESSENTIAL COMPOSITION AND QUALITY FACTORS

3.1 Ingredients

Kava preparations as defined in Section 2.1 contain kavalactones as their quality-defining constituents.

Kava also contains flavokavins. The content of flavokavin B is used as a quality marker.

3.2 Quality Factors

Kava products shall have normal flavour, colour, taste and a kavalactone pattern[146] unique to kava, as well as be free from foreign matters. The content of flavokavins[147], especially flavokavin B and its ratio with the kavalactone kavain is indicative for the quality of kava.

Fresh kava must not have a fermented smell or taste.

Kava must be well-peeled and not contain plant parts exposed to sunlight during growth. Light exposure or poor peeling are detectable through the content of chlorophyll in the sample.

3.2.1 Dried Kava

(a) Moisture:	No more than 14.0% (Powdered type: no more than 12.0%);
(b) Ash:	No more than 10%;
(c) '*Non-noble*' kava and chlorophyll:	The UV analysis must correspond to the absorption characteristics of '*noble*' kava. The presence of chlorophyll (evidenced through absorption maxima at 400 and 600-800 nm) still requires the definition of a limit[148];
(d) Kavalactones (identification):	To be identified: Kavain, dihydrokavain, methysticin, dihydromethysticin, yangonin, desmethoxyyangonin;
(3) Kavalactones (quantification):	To be quantified: Kavain, dihydrokavain, methysticin,

[146] The unique constituents of kava are found to be a complex mixture of phytochemicals often referred to as kavalactones, six kavalactones have been described to the major representatives: Kavain, dihydrokavain, methysticin, dihydromethysticin, yangonin and desmethoxyyangonin.

[147] Flavokavins, i.e., flavokavin A and flavokavin B, are found elevated in non-noble kava cultivars unsuitable for use in food.

[148] KE1 was made aware of this method by Dr. Gary Stoner in the discussions of the findings of this project. Corresponding tests have been started. The findings can be added to the proposal of the standard before submission to the CCNASWP.

	dihydromethysticin, yangonin, desmethoxyyangonin. The ratio of Kavain [% of dry matter]: (Total Kavalactones [% of dry matter] – Kavain [% of dry matter]) should be ≥ 25;
(f) Flavokavins:	To be determined: Flavokavin A and Flavokavin B. The content of flavokavin B must not exceed 0.15% of the dry matter. The ratio of Flavokavin B [% of dry matter]: Kavain [% of dry matter] * 100 must not exceed 8.5;

3.2.2 Kava extracts

(a) Moisture:	No more than 12.0%;
(b) Ash:	No more than 8%;
(c) '*Non-noble*' kava and chlorophyll:	The UV analysis must correspond to the absorption characteristics of '*noble*' kava. The presence of chlorophyll (evidenced through absorption maxima at 400 and 600-800 nm) still requires the definition of a limit[149];
(d) Kavalactones (identification):	To be identified: Kavain, dihydrokavain, methysticin, dihydromethysticin, yangonin, desmethoxyyangonin;
(e) Kavalatonces (quantification):	To be quantified: Kavain, dihydrokavain, methysticin, dihydromethysticin, yangonin, desmethoxyyangonin. The ratio of Kavain [% of dry matter]: (Total Kavalactones [% of dry matter] – Kavain [% of dry matter]) should be ≥ 25;
(f) Flavokavins:	To be determined: Flavokavin A and Flavokavin B. The content of flavokavin B must not exceed 0.15% of the dry matter. The ratio of Flavokavin B [% of dry matter]: Kavain [% of dry matter] * 100 must not exceed 8.5.;

The kava roots for manufacturing kava extracts must correspond to the description given in Section 3.2.1.

3.3 Definition of Defects

The following defects shall be applied to the dried kava:

(a) ***Unpeeled kava:*** Kava where the chips of the root stumps have not been peeled;
(b) ***Mouldy kava:*** Kava that is visibly affected by mould; and
(c) ***Peelings:*** The bark of stems and root stumps.

[149] KE1 was made aware of this method by Dr. Gary Stoner in the discussions of the findings of this project. Corresponding tests have been started. He findings can be added to the proposal of the standard before submission to the CCNASWP.

3.4 Classification of Defectives

A container that fails to meet one or more of the applicable quality requirements, set out in Sections 3.2 and 3.3, shall be considered as "*defective*".

3.5 Lot Acceptance

A lot can be considered as meeting the applicable quality requirements referred to in Sections 3.2 and 3.3, when the number of "*defectives*", defined in Section 3.4, does not exceed the acceptance number (c) of the appropriate sampling plan.

4. FOOD ADDITIVES

No additives are permitted in the products covered by this standard.

5. CONTAMINANTS

The products covered by this Standard shall comply with the maximum levels of the *Codex General Standard for Contaminants and Toxins in Foods* (Codex/STAN 193-1995).

The products covered by this Standard shall comply with the maximum residue limits for pesticides established by the Codex Alimentarius Commission.

6. HYGIENE

6.1 It is recommended that the products covered by the provisions of this Standard be prepared and handled in accordance with the appropriate sections of the *Recommended International Code of Practice - General Principles of Food Hygiene* (CAC/RCP 1-1969), and other relevant Codex texts, such as Codes of Hygienic Practice and Codes of Practice.

6.2 The products should comply with any microbiological criteria established in accordance with the *Principles for the Establishment and Application of Microbiological Criteria for Foods* (CAC/GL 21-1997).

7. LABELLING

The products covered by this Standard shall be labelled in accordance with the *Codex General Standard for the Labelling of Pre-packaged Foods* (Codex STAN 1-1985). In addition, the following specific provisions apply:

7.1 Name of the product

The name of the products defined in subsections 2.2.1. and 2.2.2 shall be "*Dried Kava", "Fresh Kava"* and "*Kava extract*", respectively.

7.2 Name of the kava variety

All kava products shall be labelled with the scientific name of kava and with the name of the kava variety that is used as raw material.

7.3 Country of Origin

The country of origin of the product and/or raw material shall be declared if its omission is likely to mislead or deceive the consumer.

7.4 Labelling of Non-Retail Containers

Information about non-retail containers shall be given on the container or in accompanying documents, except that the name of the product, lot identification and the name and address of the manufacturer, packer or distributor, as well as storage instructions, shall appear on the container. However, lot identification, and the name and address of the manufacturer, packer or distributor may be replaced by an identification mark, provided that such a mark is clearly shown in the accompanying documents.

7.5 Other labelling requirements

Labelling must conform to the requirements according to Good Agricultural and Collection Practise (*GACP*), especially with respect to traceability of the plant material.

8. METHODS OF ANALYSIS AND SAMPLING

8.1 Methods of Analysis

Provision	Method	Principle
Loss on drying (moisture)	AOAC	Gravimetry
Ash	AOAC	Calculation
Identification of '*non-noble*' kava	As described in 8.2	UV-Spectrophotometry
Identification of kavalactones (kavain, dihydrokavain, methysticin, dihydro-methysticin, yangonin, desmethoxy-yangonin) and flavokavins A and B	As described in 8.3	HPTLC
Quantification of kavalactones (kavain, dihydrokavain, methysticin, dihydro-methysticin, yangonin, desmethoxy-yangonin) and flavokavins A and B	As described in 8.4	HPLC

8.2 Identification of '*non-noble*' kava

The methodology has been developed by Dr. Gary Stoner and brought to the attention of KE1 in the debate of scientific findings within the project. The study of the applicability of this method is still ongoing, a full set of results will be available before submission of the proposal of the draft kava standard to *CCNASWP*. The methodology is described in Annex 8.

8.3 Identification of kavalactones and flavokavins

The methodology has been published by Dr. Vincent Lebot[150] and allows a quick orientation with respect to '*noble*' and '*non-noble*' kava.

8.4 Quantification of kavalactones and flavokavins

The methodology has been published by Meissner and Häberlein[80] and allows a reliable attribution of unknown kava samples to '*noble*' and '*non-noble*' kava. The validation report of this method is attached to this report as Annex 7.

[150] Lebot V, Do TK, Legendre L. Detection of flavokavins (A, B, C) in cultivars of kava (Piper methysticum) using high performance thin layer chromatography (HPTLC). Food Chem 151: 554-560; 2014

5. Main Conclusions

5.1 Conclusions from the Documental Analysis

- The debate on kava safety is inasmuch out or proportion, as the arguments leading to the German (and thereafter European) kava '*ban*' were primarily based on an assumed lack of efficacy of medications against anxiety containing kava preparations, whereas the safety debate was merely the trigger to re-investigate efficacy;
- There is still no convincing evidence for a relevant toxicity of '*noble*' kava, despite much efforts invested into kava research;
- Pharmacological studies do not confirm toxicity of flavokavin A or B in relevant dose ranges *in vivo*. Flavokavin B is a quality marker (see below) useful for the distinction between '*noble*' and '*two-day*' kava, but not a safety marker;
- Recent results point to potential pharmacokinetic interactions between kava and certain chemically defined medications metabolised through the metabolic systems cytochrome P450 1A or 2E – both only minor pathways, for which changes induced by kava would have limited or no effects for most conventional drugs. Such interactions would not explain the very few case reports of liver toxicity, where a culpability of kava is likely. Another recent finding is that kava might increase the liver-toxic potential of acetaminophen, and that this effect seems to be induced by flavokavin B in rather high quantities pointing to a '*non-noble*' variety. This would be the first publication linking a probable '*two-day*' kava to liver toxicity in animals;
- No toxicity or adverse effect on the liver was found in clinical studies with kava preparations; and
- Measures for improved quality control or corresponding education are already existing or under development in Vanuatu, Fiji, Tonga and Samoa. There is awareness that harvesting and processing protocols must be developed and established.

5.2 Collection of Kava Varieties

- A total of 148 samples of 45 kava varieties relevant for export activities were collected in Vanuatu, Fiji, Samoa, Solomon Islands, Tonga and Hawaii;
- Sample collection covered 100% of the varieties planted and exported in Fiji, Samoa, Solomon Islands and Tonga;
- The sampling further covered 100% of '*non-noble*' varieties exported from Vanuatu, as well as 80% of the '*noble*' varieties currently recommended for planting, with the selection covering practically the full commercial spectrum (the varieties *Borogu*, *Palarasul*, *Melo melo* and *Kelai* form the bulk of kava exports from Vanuatu);

- The sampling covered 74% of the Hawaiian varieties relevant for commercial activities; and
- Overall, the sampling fulfilled the requirements of the TORs.

5.3 Stakeholders' Meetings

- In all stakeholder meetings, the necessity for a kava standard and agricultural protocols was discussed;
- The kava standard should be a regional standard for the beverage;
- Material designated as "*kava*" can only consist of roots and peeled stumps of '*noble*' kava varieties. The age of kava upon harvesting should be at least three years;
- The kava standard must not be created based on specific variety names: vernacular names tend to shift and change all the time, and they are not unambiguous. A standard must define generic specifications allowing the distinction between '*noble*' and '*non-noble*' varieties;
- The new colour test proposed by Dr. Vincent Lebot (Vanuatu) seems to be an easy and fairly robust way for quick-testing kava. The method was not yet included into the proposals for the standard, because KE1 did not have sufficient details on the methodology and results. Inclusion into the final standard proposal would have to be made by the eWG;
- It is important to stress that the measurement of flavokavin B is proposed as a parameter of kava quality, not of kava safety. Flavokavin B was shown to be a good indicator of kava *nobility*, but was not convincingly shown to be toxic;
- The current practise of high amounts of '*two-day*' kava being exported from Vanuatu is due to a regulation in the Vanuatu Kava Act, which allows such exports provided the exporter can show an explicit order of the importing counterpart for this specific material. This loophole must be addressed by the legislator;
- Traceability of kava should be addressed through harvesting and processing documentations such as *HACCP*-protocols;
- Regional branding may increase the awareness towards quality and improve the situation of the growers by giving them a financial incentive to grow quality instead of quantity;
- The expected increase of kava trading after the lifting of the German kava '*ban*' must be carefully followed, as an increased demand might lead to the planting of the faster growing 'two-day' varieties;
- With Hawaii being one of the centres of kava production – with at least one notoriously '*non-noble*' variety (*Isa*) being grown there – the US should be brought into the discussion and definition of the regional standard; and
- There must not be a parallel approach of a standard proposal by this project and by the eWG – this would most likely cause confusion at the level of the *CCNASWP*, and lessen the

chances for a successful negotiation and adoption of a regional FAO Codex standard. The submission must be coordinated with the eWG.

5.4 Results of the Analyses of the Samples

- The method used for the analysis was fully validated to prove its specificity, linearity, the limits of detection and quantification, the range, repeatability, precision and robustness. With this validation the results presented herein are reproducible;
- Flavokavins are found elevated in '*non-noble*' varieties. Distinct differences can be seen with flavokavin B. A maximum threshold of 0.15% is proposed when FKB is used as a parameter for the distinction between '*noble*' and '*non-noble*' kava. Using the content of FKB would allow to safety recognise '*non-noble*' kava, but might in rare cases lead to the identification of '*noble*' kava as '*non-noble*';
- Calculating the ratio of flavokavin B to kavain allows the identification of '*noble*' or '*non-noble*' kava with a high degree of safety. The definition of a maximum limit value of 8.5 is proposed for the parameter FKB/K*100;
- The ratio "*Kavain to Total Kavalactones minus Kavain*" has been proposed by Dr. Vincent Lebot as a means for the distinction of '*noble*' and '*non-noble*' kava. It seems to work quite reliably with the HPTLC method published by Dr. Lebot[150]. The suitability was tested with the proposed method. It was found that this parameter is not entirely fail-proof, as in some cases '*noble*' kava was recognised as '*non-noble*' and *vice versa*. A minimum limit of 25 is suggested for '*noble*' kava with the ratio "*K:(KL-K)*100*". This parameter should be used in combination with the other proposed parameters when determining the proposed limits using the method presented herein; and
- The ratio of kavain to dihydromethysticin has been proposed by Dr. Gary Stoner (US). It gives a quick impression on the quality of commercial kava. With the method proposed herein, the results may partly overlap for '*noble*' and '*non-noble*' kava, making the interpretation of this parameter difficult. Values of K:DHM ≥ 2.5 would clearly indicate '*noble*' kava, but values below do not necessarily prove the presence of '*non-noble*' kava in a given sample.

5.5 Draft Codex Standard

- First approaches to a Kava Codex standard were made in 2004. A first detailed draft was submitted for the 11th session of the *CCNASWP* in 2010, after which the eWG was created to work on the still open question of kava safety and quality;
- The last discussion took place during the 13th session of the *CCNASWP* in 2014, where the process was still delayed because of insufficient information about the quality of kava. It was, however, also noted that the issue of safety may have been treated out of proportion

by the *CCNASWP*;

- The issue of a "*Code of Practice*" raised by the WHO and the *CCNASWP* will have to be addressed by the kava-producing Countries. This issue cannot be part of a Codex standard;
- The *CCNASWP* had also raised the issue of whether kava has to be regarded as drug or as food. The answer is very clear: Kava may be used as a starting material for the manufacture of drugs, but kava as a traditional social beverage is food;
- A draft proposal for a Codex standard on kava is presented herein, based on the analysis of the existing Codex standard for ginseng;
- The new draft proposal does not make reference to variety names. It has been drafted to allow distinguishing between '*noble*' and '*non-noble*' kava in a generic way;
- The draft Codex standard defines kava as roots and peeled stems of '*noble*' kava. There is no need for a description of '*non-noble*' kava, as any material not falling under the specifications of this draft Codex standard would automatically not be considered suitable for trading;
- The specifications for the distinction between '*noble*' and '*non-noble*' kava are derived from the sample analyses;
- Furthermore, equally important specifications refer to the absence of contaminants such as aflatoxins or microbiological load. There is no need for specific research for these issues, as there are already methods and defined limits generically applicable to any herbal material used as food. The same approach is made for physical specifications such as residual humidity or ashes;
- A further test by spectrophotometry, suggested by Dr. Gary Stoner, might be included as it allows testing for chlorophyll as an indicator of sun-exposed plant parts, next to a distinction between '*noble*' and '*non-noble*' kava. The decision for the method ultimately presented to the *CCNASWP (e.g.,* HPTLC versus spectrophotometry) will have to be made by the eWG;
- As way forward, the results presented in this report should be handed to the eWG on Kava to strengthen its position. The combined scientific findings should be ideally presented at the 14th session of the CCNASWP in 2016; and
- There will be a need for active engagement by the governments of the Pacific Countries to define, adopt and apply legislative/regulatory measures and enforcement mechanisms in their respective jurisdictions that will allow for implementation and enforcement of the requirements of the kava standard, as adopted within FAO Codex.

Overall, the results show that the task of a distinction between '*noble*' and '*non-noble*' kava can be overcome by reliable test methods suitable for inclusion in a Codex standard on kava.

6. Annexes

1 Translated German Court Decisions on Kava
2 Travel Schedule and Activities
3 Pictures of Kava Varieties
4 Pictures of Stakeholder Meetings and Activities
5 Media Reports on the Project
6 Analytical Results
7 Analytical Validation Report
8 Spectrophotometric Method for the Differentiation Between 'Noble' and 'Non-noble' kava
9 Regional Standard for Ginseng Products: Codex STAN 295R-2009
10 Global Standard for Ginseng Products: Codex STAN 321-2015