Proposal P1057 - Review of the kava standard

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Executive Summary

Thank you for the opportunity to make a submission on your proposed revised kava standard 2.6.3.

In March 2022, the FSANZ Board agreed amendments to the Code to:

- make explicit the current prohibition on the use of processing aids and food additives in the manufacture or processing of dried or raw kava root and kava beverages, and
- require that kava is sourced from Noble varieties of the kava plant, which have a history of safe use.

We are broadly supportive of the latter proposal. We believe that the first proposal is overly broad in scope, and open to misinterpretation as a blanket ban on kava processing, rather than a restriction on how kava beverages are prepared.

We note that Government is seeking a balance between supporting Pasifika peoples and economies to develop markets for traditional products and foodstuffs, with mitigating harms.

The proposal acknowledges both the ready availability and inconsistent treatment of kava health supplements in Australia and New Zealand. It then places the therapeutic use of kava out of scope of the proposed Code. The health and medicinal market is clearly the fastest growing market and is the market with the greatest upside for Kava growers and Pacific Island exporters.

We consider that defining health and therapeutic purposes out of scope of the Proposed Code perpetuates the current situation where kava exists in a regulatory "grey area". We do not think that regulatory uncertainty is either helpful, or consistent with Government's policy intent expressed in the Pacific Step-up Kava Pilot.

We would like to see Australian and New Zealand regulators behaving towards kava extract in a manner consistent with the treatment of other non-traditional medicines, for example medical marijuana or the active ingredients in honey. We note that Callaghan Innovation in New Zealand has taken this approach and suggest that closer whole of government alignment would be beneficial.

There is growing peer-reviewed evidence of the health benefits of Kava (particularly for anxiety and sleep disorders). These studies were deliberately excluded from the Risk Assessment.

We think that the proposed code is over-weighted towards mitigating harms and fails to adequately note the benefits of moderate kava consumption. We also note that the risk assessment is a very limited and highly qualitative study, from which overly confident conclusions seem to have been drawn. On balance, we consider that the statement of risks verges on the alarmist, and the recognition of benefits is confined to a factual acknowledgement that traditional usage is both common and widespread. We would like to see a more balanced, and scientific approach to quantifying and evaluating benefits and harms.

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Submission from Viktual+

We have outlined some brief notes that reflect our concerns about the Proposed Code revision

The Code makes modest revisions limited to the preparation and sale of kava beverages

We are broadly supportive of the modest changes proposed in the draft Code. We think that confining kava to Noble varietals makes sense. For kava beverages, it is appropriate to maintain a traditional approach to preparation and extraction of kava root.

We think the move to allowing preparation of beverage for consumption offsite is also sensible, and note as the proposal did, that the shelf-life of prepared beverage is short, and therefore risks are likely to be low.

The proposal determined that the health and medicinal benefits of kava were out of scope

Kava is a well-known traditional medicine, and the health benefits are well understood in Pacific societies, and increasingly more broadly. The medicinal and health usage of Kava is a growing market in Australia and internationally.

The Proposal discusses only the traditional use of kava beverage. It explicitly takes health benefits out of scope.

This is a surprise to us, since there is a growing literature on the benefits of Kava in providing a natural product that can reduce anxiety, and can address insomnia in patients, for example MH Pittler, E Ernst, Kava extract for treating anxiety, Cochrane Database Syst Rev. 2002;(2):CD003383. doi: 10.1002/14651858.CD003383, or S Witte, D Loew, W Gaus, Meta-analysis of the efficacy of the acetonic kava-kava extract WS1490 in patients with non-psychotic anxiety disorders, Phytotherapy Research, Vol 19, Issue 3, March 2005 pp183-188.

It is highly likely that the growth of kava products will be in the international food and nutraceutical industries, and we consider that the benefits (and harms) of kava will need to be addressed using the same frameworks as used for medical marijuana and the active ingredients of honey preparations.

Consequently, therapeutic or nutraceutical use is left in a regulatory "grey area"

We note that the use of kava extracts or non-beverage use of kava is "out of scope" for the proposed Code. The discussion document notes that kava based medicinal compounds are freely available in Australia and New Zealand, but in New Zealand may not be permitted to be used as a therapeutic supplement.

Kava is increasingly used as a nutraceutical supplement, and as noted above, there is a growing literature on the health benefits of kava, particularly in reducing anxiety and promoting sleep. There are a growing number of Pasifika owned companies that seek to blend traditional medicines with modern science and to help provide natural therapeutic compounds to our customers. Just as the medical marijuana industry is looking to take advantage of better understanding of the benefits of their product, we think it is timely that the medicinal properties of kava which have been known to Pasifika peoples for generations, are respected and treated as the Meealofa that it is.

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Our products are not sold as food, they are nutraceutical supplements. The standard doses are very low compared to the dosages that the harm mitigation analysis supporting the proposed code is seeking to address.

We think this is a matter that needs to be referred to MedSafe, and that kava based medicines be the subject of further research.

The risk assessment is very limited in scope, and is highly qualitative

The focus of the assessment is exclusively on harms, we regard this as potentially leading to an unbalanced assessment. We would have expected that there would also be an acknowledgement of benefits. The literature review has specifically excluded studies that addressed health benefits, or anything other than traditional aqueous preparation of kava as a beverage.

Within its limited scope, the risk assessment is dependent on very small sample sizes and surveys reliant on a subset of the Tongan community, anecdotes, and personal testimony. Where data is identified, the studies have very broad standard deviations. We suggest therefore that the weight that can be confidently placed on the risk assessment is highly limited.

The Proposed Code may inadvertently be supporting anti-competitive behaviours, and suppressing smaller players in the kava market

We have had concerns expressed to us by a number of smaller players in the market, that the proposed Code is being used as a threat by some players to discourage them investing in sourcing kava. We do not have anyone prepared to go "on record", but we are aware that there is consolidation in the kava market, and that there are some large players who are telling potential competitors and entrants that only they are likely to be certified as approved suppliers and exporters.

We think it will be very important that the preparation and presentation of the Code, and the facilitation of its roll-out, emphasise that the Code is intended to be competitively neutral, and that all suppliers will be given simple, clear guidance and support to facilitate certification and compliance.

It will be important to tie roll-out of the revised Code to trade facilitation and capability strategy within the Pacific

Given that part of the impetus for the Code review is the Pacific Step-up Kava Pilot, we consider that it be important to draw to FSANZ attention, and to the attention of Governments on both sides of the Tasman, that changes to the Code, and requirements to demonstrate compliance will inevitably add compliance costs to producers.

We suggest that simple rules and active facilitation will be an important part of the roll-out to encourage high levels of confidence and compliance.

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