

Proposal 1057

Review of the kava standard – NSW Submission

1st call for submission

Summary

NSW appreciates the opportunity to comment on Proposal 1057 Review of the kava standard – Call for Submissions for 12-month review.

NSW supports reaffirming the change to Standard 2.6.3 in the Australia New Zealand Food Standards Code (the Code) through Urgent Proposal 1057, namely:

- Explicitly prohibiting the use of processing aids and food additives in kava (section 2.6.3–5)
- Only permitting Noble varieties of kava to be used as food (subsection 1.1.2–3(2))

This is consistent with the policy intent to limit consumption of kava to the traditionally prepared beverage consumed by sub-populations familiar with its occasional and ceremonial use. NSW suggests these requirements should be retained in the Code regardless of the status of the kava pilot.

However, NSW is not supportive of FSANZ's proposal to defer consideration of additional warning statements until the conclusion of the kava pilot. FSANZ statements in SD1 (pg 1) suggesting that kava may pose a risk to pregnant or lactating women or children or adolescents or person with reduced liver function should necessitate the raising of a proposal now. FSANZ further recommend that kava should not be consumed by these populations (SD1 pg 7). NSW concurs with FSANZ that the lipophilic nature and low molecular weight of kavalactones presents favourable conditions for passive transfer of kavalactones across the placenta to developing fetuses or to accumulate in human milk (SD 1 pg 8).

NSW further suggests that advisory statements to avoid consuming in conjunction with alcohol should also be added to labels for kava sold as food as FSANZ informs that consuming these two psychoactive materials together increases the impacts of alcohol on cognition (SD 1 pg 1). Kava beverage is consumed for its psychoactive effects, therefore appropriate advisory/warning statements are required with this purpose in mind.

NSW Food Authority has prepared this submission in consultation with other NSW government entities, including NSW Police and NSW Health.

Retention of additional drafting to the Code provided through Proposal 1057

NSW supports retention of additional content to the Code concerning Kava provided through Urgent Proposal 1057. It is important to remove doubt on the possible addition of Schedule

16 food additives to kava beverage, or consideration of kava beverage as a food with category 20 Schedule 15 additive permissions as a 'foods not included in items 0 to 14'.

Urgent proposal 1057 further clarifies that processing aids may not be used in kava beverages. NSW supports retention of this explicit prohibition as this removes doubt on the addition of Schedule 16 or Schedule 18-2 substances to kava beverages.

NSW further supports retention of the specific reference to Noble kava varieties only in the Code as safety concerns have been raised on the use of *Tu-dei* kava varieties in kava beverages.

Additional warning statements

NSW recommends additional warning/advisory statements to address risks to the sensitive sub-populations

NSW agrees with FSANZ's concern that kava consumption may pose a health risk to pregnant and lactating women, children, adolescents and individuals with reduced liver function. NSW further concurs with FSANZ's recommendation that kava should not be consumed by these sensitive sub-populations (SD1 pg 8).

NSW raises concerns that the existing warning statements (*Use in moderation; May cause drowsiness*) are not satisfactory to fully inform consumers of the above-mentioned risks posed by kava. FSANZ states that the rationale for the specific wording of the existing warning statements when they were developed is unknown (SD3 pg 5). FSANZ has provided some justification of the existing statements (SD3 pg 5-6), however NSW considers that the justification provided invites consideration of additional warnings, especially the implied relationship between 'use in moderation' and alcohol consumption. NSW considers existing statements in isolation are inadequate as the only labelling advice provided to consumers. Additional statements are required.

NSW suggests that the identified health risk and insufficient evidence to support safety in the sensitive sub-populations should provide sufficient rationale to warrant additional statements. This is supported by the statement¹ of the Government of the Republic of Vanuatu, one of the major global suppliers of kava with significant cultural and historical ties to kava consumption, which expressed support against the sale of kava to children and support for warning statements that '*pregnant women should either avoid kava altogether, or that they should drink limited quantities with caution*'.

FSANZ makes conflicting statements about kava and the need for warning labels. For example, '*there is insufficient evidence of health risks from the consumption of kava beverage to justify additional warning or advisory statements on kava foods*' (CFS pg 3) and '*warning statements are generally only required when the risk to the public of consuming a food may result in death*' (SD3 pg 9) compared with '*[kava] may pose a risk*' and '*consumption of kava beverage by pregnant or lactating women, children, adolescents, or individuals with reduced liver function, is not recommended*'.

NSW considers that proactive action is required.

The National Coronial Information System (NCIS) was searched for closed cases during 1 January 2001 – 31 October 2022 for deaths in Australia associated with kava.² The cause of

¹ <https://www.odc.gov.au/sites/default/files/consultation-kava-pilot-phase-2-allowing-commercial-importation-kava-grv.pdf>

² The NSW Poisons Information Centre as part of NSW Health have provided this data. They acknowledge the Victorian Department of Justice and Community Safety as the organisation source of data, and the NCIS as the database source of data.

death (any level) or the 'pharmaceutical substance producing injury' was searched for 'kava'. There were 11 cases found, with 5 of these cases specifically naming kava in the medical cause of death. A variety of circumstances of death were reported: kava intoxication, mixed drug toxicity, hanging, motor vehicle accidents, coronary heart disease, liver failure and undetermined.

Noting that kava use has been associated with human fatalities in Australia, NSW advocates that proactive action is required and proposes that FSANZ raise an additional proposal to amend the Code now, so that additional warning/advisory statements about the consumption of kava may be considered.

NSW recommends FSANZ address the current clear disparity in warning statements between kava as foods and therapeutic goods

NSW raises FSANZ's attention to P256 Final Assessment Report which assessed kava consumption in the social and ceremonial use in the Pacific communities in 2004 as below:

- *'The drink is consumed for the sense of relaxation and tranquillity and to manifest a sociable attitude.'* (pg 13)
- *'Kava is generally consumed for its intoxicating affects. As such, a discussion of the regulation of alcohol, another intoxicating substance, is relevant for the purposes of comparison.'* (pg 22)
- *'Kava is consumed for its intoxicating properties rather than for satisfying thirst or hunger and would not contribute significant nutrients to the diet. Information about its nutritional value would not be considered relevant or used by consumers.'* (pg 26)

As reported in SD2, today's kava consumption in Australia and New Zealand still predominantly relates to social contexts according to the Pacific cultural customs. This suggests that the assessment in P256 that kava is consumed for its psychoactive property rather than nutritional value (as quoted above) is still relevant to today's consumption of kava. NSW agrees with FSANZ that kava consumption in conjunction with alcohol increase the impact of alcohol on cognition (SD 1 pg 1 and 9).

Therefore NSW does not understand the following explanation by FSANZ to allow the disparity in warning statements between kava as foods and therapeutic goods.

- *'FSANZ considers supplements or medicines containing kava that are designed to have a physiological effect (e.g. help relieve stress or insomnia) serve a different purpose compared with a food.'* (SD3 pg 10)
- *'FSANZ has differentiated between kava beverage preparations with a history of safe use (cold water extraction from kava root) and kava extracts (organic solvent extraction and standardisation). This recognises that kava beverage has a different risk profile to kava extracts used as complementary medicines or therapeutic products. Therefore, risk management approaches including labelling of complementary medicines cannot be directly applied to kava beverage.'* (P1057 FCR pg 17)

NSW requests that FSANZ define the nutritional purpose of kava in the approval report for P1057 given the statement in the final assessment report for Proposal 256 that kava is not consumed to satisfy thirst or hunger.

NSW considers that intoxicating properties of kava as foods are not distinguishable from anxiolytic effects of kava as therapeutic goods as the active ingredient in both cases is kavalactones. Kavalactones, are psychotropic substances with known sedative effect (hence the existing warning statement 'may cause drowsiness'). FSANZ informs that levels of kavalactones consumed as a beverage may result in kavalactone intakes greater than the

recommended maximum daily dose (250 mg kavalactones) for therapeutic goods (listed medicine), and kava beverage has the potential to become a substance of abuse in certain contexts (SD 1 pg 7). This is evidenced by kavalactones being included in the Australian Standard Classification of Drugs of Concern³.

Table 1 below shows the difference in required warning/advisory statements between kava as foods and therapeutic goods. Considering the known health risk of kava/kavalactones and the consumption volume of kava as foods, NSW does not understand the rationale for allowing less warning statements on kava as foods compared to kava as therapeutic goods. In particular NSW suggests that the statements advising against consumption by the sensitive sub-populations (underlined in the table below) should be required in kava as foods.

Table 1: Required warning/advisory statements between kava (*Piper Methysticum*) as foods and as therapeutic goods

| Food (section 2.6.3–4) | Therapeutic goods (Therapeutic Goods (Medicines Advisory Statements) Specification 2021, Therapeutic Goods (Permissible Ingredients) Determination (No. 4) 2022), Poisons Standard October 2022) |
|---|--|
| <ul style="list-style-type: none"> • ‘Use in moderation’ • ‘May cause drowsiness’ | <p>For kava as a Listed medicine</p> <ul style="list-style-type: none"> • ‘Not for prolonged use’ • ‘If symptoms persist - seek advice from a healthcare practitioner’ • <u>‘Not recommended for use by pregnant or lactating women.’</u> • <u>‘May harm the liver’</u> <p>For kava as the Poisons Standard Schedule 4 medicine</p> <p>‘KEEP OUT OF REACH OF CHILDREN’</p> |

Considering evidence that co-consumption of kava beverage and alcohol intensifies the effects of alcohol on cognition, there is further merit in exploring a warning/advisory statement to the effect of advising against the consumption of alcohol in conjunction with kava.

NSW request further explanation from FSANZ in the approval report as to why ‘not recommended for use by pregnant or lactating women’ is not proposed by FSANZ as an additional labelling statement when this is the conclusion of the risk assessment in this CFS (SD 1 pg 2).

NSW further requests explanation from FSANZ as to why additional warning/advisory statements are not proposed as FSANZ has reported increasing kava consumption in informal contexts in Australia and New Zealand without strict cultural protocols (SD2 pg 14-15). SD2 also suggests that kava is believed by consumers to be safer than other drugs and as a result parents may encourage their children to consume kava rather than alcohol (SD2 pg 2 and 23). NSW is concerned about the lack of evidence to ensure that safety in kava consumption is/will be culturally managed properly and requests that FSANZ re-assess its

³ <https://www.abs.gov.au/statistics/classifications/australian-standard-classification-drugs-concern/2011>

current position to defer further work on additional warning/advisory statements for kava until the conclusion of the kava pilot evaluation.

For the reasons stated above, NSW recommends additional warning/advisory statements against kava consumption by:

- pregnant and breastfeeding women,
- children,
- individuals with reduced liver function
- consumption of kava in conjunction with alcohol.

ENDS

The views expressed in this submission may or may not accord with those of other NSW Government agencies. The NSW Food Authority has a policy which encourages the full range of NSW agency views to be submitted during the standards development stages before final assessment. Other relevant NSW Government agencies are aware of and agree with this policy.

Dated as 15 November 2022