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In reply, please refer to:
File:

Generally Recognized as Safe (GRAS) Determination for 'Awa January 23, 2024

The University of Hawai'i (UH) College of Tropical Agriculture and Human Resources (CTAHR) Department of Tropical Plant and Soil Sciences, through representative experts in the field of indigenous agricultural, medical, and Polynesian cultural practices, observed in a letter to Hawai'i's congressional representatives dated October 5, 2023 and subsequently forwarded to the Director of the Hawai'i State Department of Health (DOH) via email, that the United States Food and Drug Administration (U.S. FDA) erroneously classified the traditionally prepared 'awa beverage (also known as "kava") as unsafe for human consumption (See Attachment A). By way of this memorandum, DOH seeks to clarify its position with respect to the sale and distribution of 'awa in the State of Hawai'i and, under the conditions detailed herein, hereby recognizes as GRAS 'awa for its intended use in the preparation of the traditional and customary beverage pursuant to the applicable federal exception.

'Awa (*Piper methysticum*) is a shrub that grows from about four to eight feet high with heart-shaped, pointed, green leaves and a root that becomes three to five inches thick at maturity. Globally, there are more than two hundred varieties of 'awa, with the 'awa beverage being made using the roots of the noble variety.

The 'awa beverage was traditionally prepared by cutting the root into bite-sized pieces, chewing the pieces to mince the root, and steeping the minced root product in water. However, for at least the past one hundred years, the beverage has been more commonly prepared by grinding or pounding the noble root prior to mixing with water, in lieu of chewing.

The 'awa plant contains six major kavalactones, which are the active pharmacological components of 'awa. Extraction of the kavalactones ordinarily occurs when 'awa is steeped in a liquid. **However, organic extraction (i.e., using acetone, ethanol, or similar solvents for extraction) results in two to ten times the total amount of kavalactones than is extracted via aqueous extraction (i.e., using water). Per the U.S. FDA, the highly concentrated amount of kavalactones extracted via non-traditional methods may pose a significant health hazard due to liver toxicity.**

Regulatory Authority

Title 21 of the Code of Federal Regulations (CFR) regulates food and drugs, with subchapter B, part 170, subpart B specific to food additive safety in food for human consumption. 21 CFR §170.30 details the eligibility for classifying a food additive as GRAS.

Unfortunately, DOH lacks the necessary resources to conduct the quantity and/or quality of scientific procedures necessary to evaluate the safety of the 'awa beverage as prescribed by federal law under 21 CFR §170.30(a) or (b). 21 CFR §170.30(c)(2) is also inapplicable as Hawai'i has been a territory of the United States since 1898.

However, 21 CFR §170.30(c)(1) outlines the following exception:

“General recognition of safety through experience based on common use in food prior to January 1, 1958, may be achieved without the quantity or quality of scientific procedures required for approval of a food additive. General recognition of safety through experience based on common use in food prior to January 1, 1958, shall be based solely on food use of the substance prior to January 1, 1958, and shall ordinarily be based upon generally available data and information. An ingredient not in common use in food prior to January 1, 1958, may achieve general recognition of safety only through scientific procedures.”

“Common use in food” is defined in 21 CFR §170.3(f) as “a substantial history of consumption of a substance for food use by a significant number of consumers.”

Per §328-1, Hawaii Revised Statutes (HRS), Definitions:

“‘Food Additive’ means any substance, the intended use of which results or may be reasonably expected to result, directly or indirectly, in its becoming a component or otherwise affecting the characteristics of any food (including any substance intended for use in producing, manufacturing, packing, processing, preparing, treating, packaging, transporting, or holding food; and including any source of radiation intended for any such use), if the substance is not generally recognized, among experts qualified by scientific training and experience to evaluate its safety, as having been adequately shown through scientific procedures (or, in the case of a substance used in a food prior to January 1, 1958, through either scientific procedures or experience based on common use in food) to be safe under the conditions of its intended use, except that the term does not include:

- (1) A pesticide chemical in or on a raw agricultural commodity;
- (2) A pesticide chemical to the extent that it is intended for use or is used in the production, storage, or transportation of any raw agricultural commodity;
- (3) A color additive; or
- (4) Any substance used in accordance with a sanction or approval granted prior to the enactment of the Food Additives Amendment of 1958, pursuant to the Federal Act, the Poultry Products Inspection Act (21 U.S.C. §§451-470), or the

Meat Inspection Act of March 4, 1907 (34 Stat. 1260), as amended and extended (21 U.S.C. §§601-695).”

DOH adopted 21 CFR §170, including the common use exception found in 21 CFR §170(c)(1), via §11-29-8(a), Hawaii Administrative Rules (HAR):

“The following food regulations of the United States Food and Drug Administration shall be adopted insofar as they do not conflict with the provisions of this chapter or any other rule enforced by the department of health:... 21 CFR Part 170 Food Additives...”

Based upon this regulatory authority, DOH has the discretion to recognize 'awa in the context of its intended use as GRAS, provided that its history of safe consumption conforms with the exception detailed in 21 CFR §170.30(c)(1).

Common Use of the 'Awa Beverage in Hawai'i

In 2016, the United Nations Food and Agriculture Organization (UNFAO) and the World Health Organization (WHO) jointly published “Kava: a review of the safety of traditional and recreational beverage consumption,” a technical report that reviewed existing scientific information on the safety of 'awa when consumed as a beverage (See Attachment C). The WHO report notes that the 'awa beverage has a long history of consumption in the South Pacific, as it has been consumed for more than two thousand years and plays an important role in traditional community ceremonies, with little documented evidence of adverse health effects. The WHO report also notes that commercialization and increased recreational use of 'awa has resulted in preparation methods that did not exist traditionally (like organic extraction described above), use 'awa varieties other than the noble variety, and lack sufficient history and documentation of the effects on human health.

DOH finds the WHO report's conclusion that consumption of the traditional 'awa beverage has a low-level health risk, and that there is a long and documented history of 'awa consumption throughout the South Pacific, to be persuasive. However, because the WHO report is centered on the South Pacific, DOH has collected additional literature from UH CTAHR to ascertain common use and traditional preparation of the 'awa beverage, specific to Hawai'i, prior to January 1, 1958.

The source of 'awa in Hawai'i is unclear, however 'awa was cultivated throughout Polynesia wherever it could be grown and it is likely that it was introduced to Hawai'i by Polynesian voyagers. In *The Hawaiian Planter Volume 1: His Plants, Methods and Areas of Cultivation* by E.S. Craighill Handy (1940), “Native tradition reports that awa was first planted in the Hawaiian Islands on Kauai by Oilikukaheana (Fornander, 25, vol. 5, pp. 606-608), who brought it from Tahiti (Kahiki).”

Per Handy, “Awa grows well only where there is constant moisture and not too much sun. Formerly, when it was cultivated, the Hawaiians planted it in or just below the borders of the lower forest zone, in clearings within the lower ranges of the forest, along streams, and in pockets along the base of and upon wet escarpments... There are certain localities on each of

the islands which used to be famous for their awa. Kamakau (40) names some of these: Koukou on Kauai, Hena on Oahu, Lanakila on Maui, and Puna on Hawaii.”

Finally, Handy writes: “In historic times [‘awa] has been so used by all classes of people, especially fishermen, farmers, hunters, and the like whose strenuous work left them stiff and taut with fatigue... The distinction between the awa drinking of the alii and commoners was one of manner and purpose of using the drink. The alii class drank for pleasure largely, the kahuna class ceremonially, and the working people for relaxation after labor. There was an abundance of awa for everyone.”

Margaret Titcomb’s article “Kava in Hawaii” published in *The Journal of the Polynesian Society*, Vol. 57, No. 2 (June 1948) states that “The ‘awa custom is of interest in Hawaii because it was a sacred drink of importance in many phases of Hawaiian life. Outside of water and drinking coconut, no other drink was known. Its effect is to relax mind and body and it was used by farmer and fisherman for this purpose. Medical kahunas had many uses for it. It was customary for chiefs to drink it before meals, for commoners also if obtainable.”

In February 1918, the *Hawaii Herald* newspaper published an article that included a recipe for making the ‘awa beverage and reported that Hawaiian ‘awa roots were shipped and sold in San Francisco for \$60 to \$70 a ton (roughly \$1,300 to \$1,500 a ton today) for medicinal purposes. Dried ‘awa powder was also available for purchase nationally in the early 1900s from Sears, Roebuck, and Co. shopping catalogs, to be mixed with water and consumed as a non-alcoholic temperance wine.

Other examples documenting the common use of ‘awa in Hawai‘i include:

- *Roughing It* (1866) by Mark Twain describes ‘awa being sold in Hawaiian markets.
- *The Cultivation of Kava* (1869), quoting historian Samuel M. Kamakau, “Kava was one of the choice foods of the planter” in Hawai‘i.
- *Overland Monthly Out West* magazine (1889) published F.L. Clarke’s account of visiting Hawaiian family homes as a dinner guest and describes in detail the making of the ‘awa beverage. All family members consume the beverage before eating dinner.

Traditional Preparation of the ‘Awa Beverage in Hawai‘i

The traditional preparation of the ‘awa beverage is described in Titcomb’s “Kava in Hawaii” journal article. Using fresh ‘awa root that had just been dried was preferable, but fresh roots were not always obtainable. As such, “a supply of roots was often kept in reserve, thoroughly dried by hanging in the sun. Strength was not lost in drying, and soaking brought back something of the crispness... The root was scraped and washed, then reduced to small pieces. This was done by breaking with a sharp-edged stone if the root was large; by cutting into small pieces with a bamboo knife if small, young and fresh. It was then ready to chew and mix with water to make a cold water infusion.”

“In later days, chewing was replaced by grinding or pounding.” Titcomb further elaborates: “In Hawai’i, the pounding process finally superseded the chewing process, special tools being developed for the new method.” She quotes O.P. Emerson, who wrote in 1903 that: “It is prepared by pulverizing the root in a mortar; if it is the dry article of commerce it is kept sufficiently moist to prevent its scattering and forming dust.” The resulting mash was mixed with water and “thoroughly kneaded with the hands, and stirred, then strained.” Titcomb also mentions that while water was most commonly used to prepare the ‘awa beverage, “For chiefs, and on rare occasions, water from coconuts was used.”

GRAS Determination

The articles and examples cited above are a small sample of the many references that document and describe a substantial history of consumption, by a significant number of consumers, of the ‘awa beverage in Hawai’i. Notably, the articles referenced in this memorandum specific to Hawai’i, documenting and describing the common use of ‘awa, were all published prior to January 1, 1958.

DOH concludes that the use of the noble variety of ‘awa root, mixed with water or coconut water to make a beverage through aqueous extraction, as comporting with the substance and intent of the exception detailed in 21 CFR §170.30(c)(1) and determines ‘awa to be GRAS under those specific set of circumstances consistent with §11-29-8(a), HAR. Consequently, ‘awa root of the noble variety as a food additive for use in a beverage prepared in this specific, traditional, and customary manner shall not be deemed a violation of chapter 328, HRS, provided that all other relevant federal and state food safety laws are satisfied.

'Awa as a Dietary Supplement

Any ‘awa, including the noble variety, in the form of a dietary ingredient in a dietary supplement, falls under the requirements of the federal Dietary Supplement Health Education Act and may only be offered in its packaged form identifying it as a dietary supplement. All dietary supplements can only be manufactured, processed, or packaged (and must be labeled as a dietary supplement) in a facility registered under the U.S. FDA. ‘Awa as a dietary supplement is not permitted to be used as an ingredient or component of a conventional food item, including but not limited to teas, smoothies, or other beverages. A facility that mixes ‘awa as a supplement with a food or beverage may be cited by DOH under chapter 328, HRS.

Any other preparation of ‘awa, or the use of any other variety of ‘awa, will be considered an adulterated food and/or an unapproved food additive by DOH pursuant to §328-9, HRS, and a violation of chapter 11-29, HAR, and/or chapter 11-50, HAR, unless the elements of 21 CFR §170.30 can be satisfied.

Consumer Advisory

Despite finding ‘awa, as a food additive introduced into water or coconut water and prepared in the traditional and customary manner, to be GRAS pursuant to the applicable regulations, U.S. FDA research suggests a possible toxicological risk associated with its consumption or with its consumption combined with other contributing factors (e.g., alcohol) and there is concern about interference with other medications. There appears to be no scientific consensus at this time, but ‘awa has been linked to liver failure, as summarized in the U.S. FDA memorandum,

“Review of the published literature pertaining to the safety of Kava for use in conventional foods” (See Attachment B).

With the understanding that the concentration of kavalactones can vary depending on preparation methodology, and also recognizing that individuals can react differently to similar concentrations of the same compounds, DOH recommends posting or providing the following consumer advisory statement:

“Please be advised that ‘awa/kava should not be used by persons under 18 years of age, or by pregnant or breastfeeding women. ‘Awa/kava should not be used with alcoholic beverages. If taking medication, consultation with your doctor prior to ‘awa consumption is strongly advised. Excessive use, or use with products that cause drowsiness, may impair your ability to operate a vehicle or heavy equipment. A potential risk of rare, but severe, liver injury may be associated with ‘awa/kava-containing dietary supplements.”

Disclaimer

DOH’s findings and determination regarding ‘awa herein are not intended to, nor do they in fact, create any right or cause of action for or against any individual or entities nor does this document constitute a warranty or guarantee of quality, or of fitness for consumption, with respect to ‘awa/kawa by DOH or any of its employees.

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