



DEPARTMENT OF HEALTH

JOSH GREEN, M.D.

GOVERNOR

KE KIA'ĀINA

KENNETH S. FINK, MD, MGA, MPH

DIRECTOR

KA LUNA HO'OKELE

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Department of Health announces a Generally Recognized as Safe (GRAS) determination for 'awa

HONOLULU – The Hawai'i State Department of Health (DOH), in collaboration with the University of Hawai'i (UH) College of Tropical Agriculture and Human Resources (CTAHR) has issued a memorandum this week detailing a Generally Recognized as Safe (GRAS) determination for 'awa (also known as "kava"). The DOH memorandum was developed to recognize the substantial history of consumption of the traditional 'awa beverage by Native Hawaiians.

This week's determination by DOH was in response to a 2020 memorandum published by the United States Food and Drug Administration (FDA) titled "Review of the published literature pertaining to the safety of kava for use in conventional foods." The FDA concluded that 'awa is not safe for human consumption but did not clarify that the studies referenced describe the use of organic 'awa extraction and did not review the health effects from consumption of the traditional 'awa beverage.

Extraction of kavalactones, the active ingredient in 'awa, ordinarily involves steeping the root in a liquid. Organic extraction (i.e., using acetone, ethanol, or similar solvents) results in two to 10 times the total amount of kavalactones than is extracted via aqueous extraction (i.e., using water). Per the FDA, the highly concentrated amount of kavalactones extracted via non-traditional methods may pose a significant health hazard due to liver toxicity.

Based on numerous scientific journals and publications provided to DOH by UH CTAHR, 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, comports with the substance and intent of the federal Title 21 of the Code of Federal Regulations (CFR) §170.30(c)(1) GRAS exception, based on common use in food prior to January 1, 1958. 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, Hawaii Revised Statutes, provided that all other

relevant federal and state food safety laws are satisfied.

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, Hawaii Administrative Rules (HAR), and/or chapter 11-50, HAR, unless the elements of 21 CFR §170.30 can be satisfied.

Please visit the DOH Food and Drug Branch website to review the entire DOH memorandum, including the 2020 FDA memorandum and additional dietary supplement, safety, and advisory information at the following link: <https://health.hawaii.gov/food-drug/recalls-guidance/>

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