



July 5, 2024

The Honorable Ed Case
U.S. House of Representatives
Washington, D.C. 20515

Dear Representative Case:

Thank you for your letter regarding kava. The Food and Drug Administration (FDA or the Agency) recognizes that consumption of kava has a longstanding and culturally rich history among Native Hawaiian and Pacific Islander populations. This traditional use of kava prepared in the customary manner is considered a conventional food, and as such the Generally Recognized as Safe (GRAS) provision of the Federal Food, Drug, and Cosmetic Act (FD&C Act) does not apply (section 201(s) of the FD&C Act; see also 21 CFR 170.30). The GRAS provision only concerns certain substances added to food that would otherwise require pre-market approval as a food additive. Nevertheless, FDA remains concerned about the safety of kava due to the scientific data on the relationship between kava and hepatotoxicity and carcinogenicity.

As you requested, FDA experts reviewed the memo from Dr. Vincent Lebot, Dr. Noa Lincoln, Mr. Michael Louse, Dr. Harry C. Bittenbender, Mr. Edward Johnson, and Dr. Jonathan Baker (hereinafter referred to as “the memo”), and we provide our comments on their analysis and conclusions below.

Safety of kava

The memo raises concerns about FDA’s review of the published literature pertaining to the safety of kava for use in conventional foods,¹ dated August 11, 2020. FDA subject matter experts reviewed the memo and did not find any new information that would change our evaluation of the safety of the use of kava in conventional food.

FDA has serious safety concerns with the use of kava in conventional food products, including beverages. Data from humans have repeatedly shown an association between kava and/or kava extracts and clinical biomarkers of abnormal liver function or cases of hepatic injury. In 2018, the National Institute of Diabetes and Digestive and Kidney Diseases reported as many as 100 published cases of liver injury associated with kava and/or kava extracts. Case reports of kava-associated hepatotoxicity include hepatitis, cirrhosis and liver failure, and death. After reviewing nearly 100 case reports, including 14 liver transplantations and 7 deaths, the World Health Organization (WHO) concluded that there is “... a significant concern of a cause-and-effect relationship between kava products and hepatotoxicity.” Rodent toxicity and carcinogenicity studies of kava extract report adverse effects on various organs, including the liver, and clear evidence of carcinogenic activity corresponding to increased incidences of hepatic tumors in

¹ By conventional food, we are referring to food that is not regulated as a dietary supplement.
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mice. Additionally, the intoxicating and psychoactive effects of kava consumption may be associated with impairment and increased risk of vehicular accident.

Moreover, the exact causes of kava-associated hepatotoxicity are not fully known, and current guidelines of use prescribed by WHO are based on principles of harm minimization; no safe level of daily dietary exposure to kava or its components has been established. Safety data and information on kava extracts are relevant to the safety of traditional kava beverages, which are aqueous extracts of kava. Each component of a kava extract came from kava, and many components of kava extracts, including many kavalactones, are also present in traditional kava beverages.

Types of Kava Commodities

The memo states that FDA has classified kava as a dietary supplement. FDA has not determined kava or its derivatives are dietary supplements or conventional food *per se* without regard for their composition, labeling, or intended use, nor would the FD&C Act permit FDA to do so. The definitions contained within the FD&C Act for what is a food, food additive, or dietary supplement are spelled out in sections 201(f), 201(s), and 201(ff), respectively. Whether a product is regulated as a conventional food, a food additive, or a dietary supplement depends on a product's composition, labeling, and intended use. A substance may be a conventional food when used as a beverage in one context, but it could be used as a dietary supplement in another.

We further note that kava, used to brew tea, as described in the recently adopted Codex Alimentarius Regional Standard for Kava Products for Use as a Beverage When Mixed with Water, would generally not be regulated as a food additive if it is only steeped in water and consumed as a food. However, such use could still present safety concerns and the kava tea would be deemed an adulterated food under the FD&C Act if it were found to be ordinarily injurious to health.

GRAS Considerations

The memo urges FDA to consider traditional kava beverages as Generally Recognized as Safe (GRAS) due to the use before 1958. The GRAS provision under the FD&C Act is not relevant to traditional kava beverages. As discussed above, kava steeped in water used to brew tea as a single ingredient beverage would be regulated as a conventional food. Unlike food additives, conventional foods do not require pre-market approval.

The GRAS provision only concerns certain substances added to food that would otherwise require pre-market approval as a food additive. For example, when kava is intentionally added as an ingredient to conventional food, such use must be approved as a food additive unless it is GRAS. As explained in FDA's 2020 review, FDA does not consider adding kava to a conventional food to be GRAS. We note that the mere fact that something was used in food at all prior to 1958 does not in itself afford GRAS status. A conclusion of GRAS status through experience based on common use in food requires that the substance be "safe," as defined in 21 CFR 170.3(i), under the conditions of its intended use. Examples of substances meeting this basis for a GRAS conclusion are many commonly consumed herbs and spices, such as black pepper and basil, when used to flavor food. We acknowledge that the traditional use of kava in beverages extends before 1958. As we say in our 2020 review, "Kava beverages have been used ceremonially and socially in the South Pacific for many centuries." However, we are not aware

of a history prior to 1958 of kava in common use as an ingredient in food that provides sufficient experience to the community of qualified experts to overcome the documented safety concerns with consumption of kava and its derivatives.

For a substance to be eligible for GRAS status, there must be affirmative evidence that the intended use is safe and there must be a consensus among the community of qualified experts that its intended use in food is safe (section 201(s) of the FD&C Act; 21 CFR 170.30). The authors of the memo and other organizations have cited a report from WHO on kava (Attachment 1 of the memo) to argue for GRAS status, but the WHO memo concludes much more information is needed to ensure kava's use in food would be safe and argues against GRAS status, not for it.

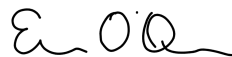
Kava in Food Establishments

FDA considers the statements asserting kava to be GRAS in the included memo from Michigan's Department of Agriculture and Rural Development (MDARD) to All Local Health Departments to be incorrect. As stated above, kava used to brew tea would generally not be regulated as a food additive if it is only steeped in water and consumed as a single-component food, and therefore the GRAS provision, as well as Section 3-202.12 Additives of the 2022 Food Code, would not apply. Additionally, at the retail level, kava is considered an unsafe food additive if added as an ingredient to conventional foods, such as beverages served within a food establishment, under Section 3-101.11 Safe, Unadulterated, and Honestly Presented of the 2022 Food Code because of the safety concerns associated with the consumption of kava.

The production and sale of kava products directly to consumers at restaurants and retail food establishments is regulated at the state, local, tribal, and territorial (SLTT) levels. Each SLTT regulatory authority has jurisdiction over foods sold directly to consumers and may have specific prohibitions or requirements regarding preparing and serving kava in a retail establishment. The Food Code is a model for safeguarding public health and ensuring food is unadulterated and honestly presented when offered to the consumer. This model is offered for adoption by local, state, and federal governmental jurisdictions. The model Food Code does not supersede an SLTT regulatory authority's applicable governing food safety regulations.

We appreciate the opportunity to respond to your letter. Please let us know if we may be of any further assistance.

Sincerely,



Erin O'Quinn
Acting Associate Commissioner for
Legislative Affairs