Date of Hearing: April 29, 2025

ASSEMBLY COMMITTEE ON ENVIRONMENTAL SAFETY AND TOXIC MATERIALS
Damon Connolly, Chair
AB 1088 (Bains) – As Amended April 21, 2025

SUBJECT: Public health: kratom

SUMMARY: Adds kratom products and products containing 7-hydroxymitragynine (7-OH), as defined, to the Sherman Food, Drug, and Cosmetic Law (Sherman Law); prohibits the sale of kratom products and 7-OH products to persons under 21 years of age; requires the packaging of kratom products and 7-OH products to be child resistant; prohibits the sale of a kratom product or 7-OH product that is attractive to children, or that contains a level of 7-OH that exceeds 2% of the total kratom alkaloids in the product. Specifically, **this bill**:

1) Defines, for purposes of this bill, the following terms:

    a) "7-OH product" to mean a product containing 7-hydroxymitragynine;

    b) "Attractive to children" to mean any of the following:

        i) Use of images that are attractive to children, including but not limited to images of any of the following, except as part of required health warnings:

            (1) Cartoons, toys, or robots;

            (2) Any real or fictional humans;

            (3) Fictional animals or creatures; and,

            (4) Fruits or vegetables, except when used to accurately describe ingredients or flavors contained in a product.

        ii) Likeness to images, characters, or phrases that are popularly used to advertise to children;

        iii) Imitation of candy packaging or labeling, or other packaging and labeling of cereals, sweets, chips, or other food products typically marketed to children;

        iv) The terms "candy" or "candies" or variants in spelling such as "kandy" or "kandee";

        v) Brand names or close imitations of brand names of candies, cereals, sweets, chips, or other food products typically marketed to children;

        vi) Any other image or packaging that is easily confused with commercially available foods that do not contain kratom and are typically marketed to children;

        vii) Anything else that the California Department of Public Health (CDPH) determines in regulation to be attractive to children; and,

viii) Anything else that is attractive to children in light of all relevant facts and circumstances;

c) "Kratom leaf" to mean the leaf of the kratom plant, also known as *Mitragyna speciosa*, in any form;

d) "Kratom leaf extract" to mean the material obtained by extraction of kratom leaves by any means;

e) "Kratom product" to mean a product consisting of kratom leaf, kratom leaf extract, or both; and,

f) "Total kratom alkaloids" to mean the sum of mitragynine, speciociliatine, speciogynine, paynantheine, and 7-OH in a kratom product.

2) Requires packaging of a kratom product or a 7-OH product offered for retail sale to be child resistant for the life of the product; specifies that both of the following packages are considered child resistant for the purposes of this bill:

a) A package that has been certified as child resistant under the requirements of the federal Poison Prevention Packaging Act of 1970 (Act) and any regulations promulgated pursuant to the Act; and,

b) Plastic packaging that is at least four mils thick (one mil is a thousandth of an inch) and heat sealed without an easy-open tab, dimple, corner, or flap, provided that the package maintains its child resistance throughout the life of the product.

3) Prohibits an individual, business, or other entity from selling, offering for sale, providing, or distributing a kratom product or 7-OH product to a person under 21 years of age; requires an online retailer or marketplace of a kratom product or 7-OH product to implement an age-verification system to ensure compliance with this prohibition.

4) Prohibits an individual, business, or other entity from selling, offering for sale, providing, or distributing a kratom product or 7-OH product that is attractive to children.

5) Prohibits an individual, business, or other entity from selling, offering for sale, providing, or distributing a kratom product or 7-OH product with a level of 7-OH that is greater than 2% of the total kratom alkaloids in the product.

EXISTING LAW:

1) Establishes the state's Sherman Law, administered by CDPH, which regulates the manufacture, packaging, labeling, and advertising of food, drugs, and cosmetics. (Health and Safety Code (HSC) § 109875-111929.4)

2) Establishes penalties for violations of the Sherman Law, including a fine of up to $1,000, or up to $10,000 for repeated violations. (HSC § 111825)

3) Prohibits any manufacturer, wholesaler, retailer, or other person from selling, transferring, or otherwise furnishing a dietary supplement containing either of the following to a person under 18 years of age:

   a) A dietary supplement containing an ephedrine group alkaloid; or

   b) A dietary supplement containing any of the following: androstanediol, androstanedione, androstenedione, norandrostenediol, norandrostenedione, or dehydroepiandrosterone. (HSC § 110423.2)

4) Establishes a regulatory structure in CDPH, under the Sherman Law, for food, beverage, and cosmetic products containing industrial hemp, and limits these products to containing no more than 0.3% concentration of tetrahydrocannabinol (THC); prohibits industrial hemp from including cannabinoids produced through chemical synthesis. (HSC § 111920, et seq.; HSC § 111920(f))

5) Enacts the Medicinal and Adult-Use Cannabis Regulation and Safety Act to establish a comprehensive system to control and regulate the cultivation, distribution, transport, storage, manufacturing, processing, and sale of both medicinal cannabis and cannabis products, and adult-use cannabis and cannabis products for adults 21 years of age and over, regulated by the Department of Cannabis Control. (Business and Professions Code § 26000, et seq.)

FISCAL EFFECT: Unknown.

COMMENTS:

Need for the bill: According to the author:

> "As a physician specializing in addiction treatment, I have grown increasingly concerned about the use of kratom and especially its derivative 7-OH. We have reached the point that state and federal regulators can no longer ignore these products. Until the federal government does its job, California must act to protect our residents and especially our children. AB 1088 is a reasonable first step to age gate these products as we consider additional regulatory protections to put in place."

What is kratom? Kratom (*Mitragyna speciosa*) is a tree in the coffee family, found in Thailand and neighboring countries, where kratom leaves are crushed and then smoked, brewed with tea, or placed into gel capsules. Kratom has a long history of traditional use in Southeast Asia, where it has been used during religious ceremonies, to treat symptoms such as pain and diarrhea, and as a substitute for opium.

What are kratom alkaloids? Kratom leaves contain a number of chemicals called alkaloids. According to the National Cancer Institute (housed in the National Institutes of Health), alkaloids are a large group of substances that contain nitrogen and are found in plants and in some fungi. Alkaloids can often be made in a laboratory, and include well-known chemicals with neuropsychological effects, including nicotine, caffeine, and codeine. Some alkaloids are also used as medications to treat diseases such as cancer. According to the 2019 study, "7-Hydroxymitragynine is an Active Metabolite of Mitragynine and a Key Mediator of its Analgesic Effects," published in the American Chemical Society's *ACS Central Science* journal (2019 ACS Study), the major active alkaloid found in kratom is mitragynine. Studies suggest

that mitragynine is converted into the metabolite 7-OH, another alkaloid, in the liver. Authors of the 2019 ACS Study cite research showing that mitragynine typically constitutes 1-2% of the dry leaf mass and up to approximately two-thirds of the total alkaloid content. 7-OH occurs in much lower concentrations in the kratom leaf, typically less than 0.05% of the dried leaf mass. The other predominant alkaloids in kratom leaf are speciociliatine, speciogynine, and paynantheine.

Kratom use and alkaloid effects: In a description of kratom use, the 2019 ACS Study states:

> "Over the past decade, kratom use has become increasingly popular in the United States (US). Many thousands of US users have reported that consumption of kratom preparations (most often in the form of dried, powdered leaf material) is an efficacious treatment not only for physical pain, but also for mood and anxiety disorders, particularly in cases where other available treatments have either failed or elicited intolerable side effects. A significant portion of users have also reported use of kratom as a tool to stop or reduce consumption of prescription or illicit opioids, a potential application that is presently of high interest given the ongoing opioid abuse epidemic in the US. Unfortunately, there have been no controlled clinical studies either examining these alleged therapeutic effects or quantifying any potential risks of kratom use. At the same time, kratom is primarily distributed through unregulated Internet sales and used outside medical supervision."

The study's authors also report that 7-OH is a much more potent opioid receptor agonist (meaning that it is a much stronger activator of systems in the brain that are sensitive to opioids), and that the brain concentrations of 7-OH are "sufficient to explain most or all" of the pain relieving effects of mitragynine, which they posit does not directly activate opioid receptors. In other words, 7-OH seems to be the alkaloid most responsible for kratom's opioid-like effects.

The Mayo Clinic, on its webpage, "Kratom: Unsafe and ineffective," (last updated on June 18, 2024), summarizes some of the reasons that people use kratom; potential challenges with products currently on the market; and possible effects, including adverse effects, from kratom usage:

> "People who use kratom report that at low doses, kratom acts as an upper, called a stimulant. That means it makes them more alert and gives them more energy. At higher doses, people who use it report that it reduces pain and makes them feel calm and less anxious, also called a sedative.
>
> Some people take kratom to ease the symptoms of quitting opioids, called withdrawal. Kratom may be easier to get than prescription medicines. But it carries its own risk of addiction.
>
> People who use kratom to relax or to be more social most likely think that kratom is natural and safe because it comes from a plant. But the amount of the active part in kratom leaves can vary greatly. So it's hard to know the effects of a given dose.
>
> Some studies have found that some kratom sellers add more of the active ingredient than kratom naturally has. And because kratom products lack clear labels, it's not possible to know how much kratom people who use it take.
>
> Kratom starts to work in minutes. The effects last a few hours. The more kratom you take, the stronger the effects are.

> Depending on the amount of active ingredient in the product and the health of the user, taking kratom can be harmful. There are too few studies to be able to rate the claims about the benefits of kratom."

The Mayo Clinic webpage goes on to state that "kratom hasn't been shown to be safe or to treat any medical conditions" and lists known side effects as including: weight loss, dry mouth, nausea and vomiting, constipation, liver damage, muscle pain, dizziness, drowsiness, hallucinations, delusions, depression, and trouble breathing. In addition, kratom has also been reported to react with other medications, and kratom products have occasionally been found to be contaminated with heavy metals and bacteria. The Mayo Clinic also states that "experts don't know what level of kratom" causes adverse effects.

National poison center data and use of kratom with other drugs: According to the 2019 literature review, "Current perspectives on the impact of Kratom use," published in *Substance Abuse and Rehabilitation*, the national poison center reporting database documented 1,807 calls related to kratom exposure from 2011 to 2017. The Centers for Disease Control and Prevention analyzed data on unintentional and undetermined opioid overdose deaths from the State Unintentional Drug Overdose Reporting System. Kratom was detected on postmortem toxicology testing in 152 cases of 27,338 overdose deaths from data collected from 11 states from July 2016 to June 2017, and 27 states from July 2017 to December 2017. Kratom was identified as the cause of death by a medical examiner in 91 of the 152 kratom-positive deaths. In seven of these cases, kratom was the only identified substance, although the presence of additional substances in these kratom-only cases could not be ruled out. For cases where kratom was identified as the cause of death, co-occurring substances included fentanyl, heroin, benzodiazepines, prescription opioids, cocaine, and alcohol. According to the authors, the combination of kratom with other substances was associated with an increased probability of admittance to a health care facility and occurrence of a serious medical outcome, when compared to kratom-only exposure. Based on their review, the study's authors conclude that kratom use is "associated with a complex population of poly-drug users and especially with opioid use disorder," and that additional research on kratom's toxicity is needed.

Kratom use among teens: According to the Child Mind Institute, kratom addiction is becoming more common among teens. On its webpage, "Kratom: A legal drug that's dangerously addictive" (last updated on October 30, 2024), the Child Mind Institute states, "It's easy for teens to get kratom in smoke shops and on the internet. One of the reasons they like it is because it doesn't show up on standard drug tests. Only some labs test for kratom, and doing so is expensive." Dr. Mike Milham—a child and adolescent psychiatrist at the Child Mind Institute, and the founding director of the Child Mind Institute's Center for the Developing Brain—states, "High school and college students are surrounded by kratom these days—in smoke shops and on the internet…For students especially, you can imagine the allure of the stimulant effects, but once you start experiencing the euphoria of the opioid aspect, you're at risk for addiction." On the issue of kratom regulation and safety, Dr. Milham also states: "Making [kratom] completely illegal isn't necessarily a good idea, because at this point you do have portions of the community that actually are using it to help with opioid withdrawal, and to just make it illegal and take it completely off schedule doesn't really make sense." Instead, Dr. Milham suggests that the best solution would be to make kratom a Schedule II drug, a classification by the DEA that is applied to medications "with a high potential for abuse, with use potentially leading to severe psychological or physical dependence." Under that classification, kratom could be used in a controlled fashion, with reliable quantities of active ingredients. As noted below, the DEA has not exercised its authority to schedule kratom.

Legal status and regulation of kratom: Below is an overview of the legal status and regulation of kratom, at the national and state levels:

- *National level:* Kratom is currently legal and accessible online and in stores in many areas of the United States (U.S.). In 2016, the DEA published notice of its intent to place mitragynine and 7-OH in Schedule I on an emergency basis, which would have criminalized possession of kratom and made distribution a felony. However, after receiving numerous comments from some Members of Congress, advocacy groups, and others, the DEA withdrew its notice. The DEA has listed kratom as a Drug and Chemical of Concern, but to date has not exercised its authority to schedule kratom or its active compounds under the federal Controlled Substances Act.

  Kratom cannot be lawfully marketed in the U.S. as a drug product, dietary supplement, or a food additive in conventional food. According to the FDA's webpage, "FDA and Kratom," the FDA has not approved any prescription or over-the-counter drug products containing kratom, or its two main chemical components, mitragynine and 7-OH. Consistent with FDA's practice regarding unapproved substances, until its agency scientists can evaluate the safety and effectiveness of kratom (or its components) in the treatment of any medical conditions, FDA will continue to warn the public against the use of kratom for medical treatment. The FDA has also concluded from available information, including scientific data, that kratom is a new dietary ingredient for which there is inadequate information to provide reasonable assurance that it does not present a significant or unreasonable risk of illness or injury and, therefore, dietary supplements that are or contain kratom are adulterated under the federal Food, Drug, and Cosmetic Act. In addition, the FDA has determined that kratom, when added to food, is an unsafe food additive, which means that food containing kratom is considered adulterated under federal law.

  The FDA has issued a series of import alerts, most recently in July 2023, authorizing its personnel to seize imported kratom products from specified firms without physical inspection. The FDA has also seized kratom products manufactured in the U.S., including an April 2023 seizure of kratom products worth approximately $3 million from an Oklahoma company.

- *Other States:* Other states have taken a variety of approaches for regulating kratom, including the implementation of bans, age restrictions, dosage caps, and child protections. Below is a summary of different approaches used across states:

  - *Kratom bans:* Alabama, Arkansas, Indiana, Rhode Island, Vermont, and Wisconsin currently ban mitragynine and hydroxymitragynine or 7-OH. Legislators in Indiana, Rhode Island, Wisconsin, and Vermont have introduced bills to replace existing bans with regulations that would permit the sale of kratom products;

  - *Age restriction:* Arizona, Georgia, Illinois, Minnesota, Nevada, Oklahoma, Texas, and Utah ban sales to persons under 18 years of age;

  - *Strength:* Arizona, Oklahoma, Texas, and Utah prohibit sale of products in which 7-OH is greater than 2% of the total alkaloid content; and,

- *Marketing to children:* Utah prohibits flavoring or packaging that appeals to children and requires child-safe packaging. West Virginia's recently adopted law requires the commissioner of agriculture to develop similar standards.

- *California:* In the absence of statewide laws, some municipalities in California have taken steps to regulate kratom. In March 2024, the city of Newport Beach approved an ordinance to prohibit the sale and distribution of kratom. The cities of San Diego and Oceanside banned the use and sale of kratom in 2016.

Concerns regarding attractiveness of kratom products to children: In October 2024, the Kratom Consumer Advisory Council (KCAC)—which is affiliated with the Global Kratom Coalition (self-described as an alliance of kratom consumers, experts, and industry leaders)—released a position statement highlighting concerns regarding the marketing of kratom products in ways that may appeal to children, either intentionally or unintentionally. KCAC notes that some products are sold in forms resembling popular candies, such as gummies, lollipops, chocolate bars, and cookies. These products often feature bright colors, mascots, and flavors that could attract young children or be mistaken for regular candy. KCAC notes that the ease of access to these products and their resemblance to well-known candy items raise concerns about accidental ingestion by younger children.

This bill: Kratom and 7-OH products remain unregulated by the state of California, despite potential risks associated with their use. AB 1088 proposes several guardrails to help protect consumers, by prohibiting the sale of these products to persons under 21 years of age; requiring that packaging for these products be child resistant; prohibiting the sale of products that are attractive to children; and prohibiting the sale of products that contain levels of 7-OH that exceed 2% of the total kratom alkaloids. As noted in the Assembly Health Committee's analysis for AB 1088, the author may wish to consider continued discussions with stakeholders regarding the proposed cap on 7-OH levels, including whether milligrams would be an effective form of measurement.

Arguments in support: According to a coalition of law enforcement organizations:

> "Synthesized [7-OH] products, referred to as 'legal morphine,' are developed from kratom and have become 30 times more potent than morphine…Natural kratom products generally contain no more than 66% of mitragynine as the main alkaloid and 2% of [7-OH] in the alkaloid fraction of the extract. A number of states including Arizona, Oklahoma, Texas, and Utah have enacted bans on synthetic 7-OH exceeding 2% of total alkaloid content in products.
>
> In California, natural kratom products remain unregulated and unrestricted. Any one of any age can purchase kratom and synthesized [7-OH] products.
>
> AB 1088 addresses safety concerns about natural kratom and 7-OH products by implementing some common-sense measures to protect the public and our youth by establishing a:
>
> - Minimum age of 21 to purchase
>
> - Requirement for child-resistant packaging

- Ban on marketing that appeals to children

- Limit on 7-OH content not to exceed 2% of the product's total alkaloid content."

Arguments in opposition: According to the Holistic Alternative Recovery Trust:

> "Of greatest concern is a proposed percentage cap on 7-OH in section 111224.8(d)(C) that would create a de facto ban on 7-OH.
>
> The U.S. opioid crisis is the leading public health challenge of the new millennium. There are more than 200 opioid overdoses and poisonings every day—and drug overdose is now the number one cause of death for 18-45 year olds. To address this unprecedented crisis, policymakers and public health officials need to identify new tools for the toolbox…
>
> We agree that a cap on 7-OH in any product may make sense from a consumer protection standpoint, and we are more than willing to have that discussion. However, as the recent debate over hemp products has amply demonstrated, a percentage cap is a fatally flawed measurement. Bad actor product manufacturers who wish to create a high [milligram] 7-OH product can easily adhere to the percentage cap and add the corresponding amount of mitragynine, thereby releasing a potentially dangerous, but compliant, product out into the marketplace."

Related legislation:

1) AB 2365 (Haney, 2024). Would have established the Kratom Consumer Protection Program, to provide a regulatory structure for kratom products, as provided. This bill was held on the suspense file in the Senate Appropriations Committee.

2) AB 45 (Aguiar-Curry, Chapter 576, Statutes of 2021). Establishes a regulatory structure in CDPH for food, beverage, and cosmetic products containing industrial hemp, and limits these products to containing no more than 0.3% concentration of THC.

3) SB 94 (Committee on Budget and Fiscal Review, Chapter 27, Statutes of 2017). Establishes a single system of administration for cannabis laws in California, combining the Medicinal Cannabis Regulation and Safety Act with the Adult Use of Marijuana Act, to create the Medicinal and Adult-Use Cannabis Regulation and Safety Act.

REGISTERED SUPPORT / OPPOSITION:

Support

Arcadia Police Officers' Association
Brea Police Association
Burbank Police Officers' Association
California Association of School Police Chiefs
California Coalition of School Safety Professionals
California District Attorneys Association
California Narcotic Officers' Association
California Reserve Peace Officers' Association
Claremont Police Officers Association

Cleanearth4kids.org
Corona Police Officers' Association
Culver City Police Officers' Association
Fullerton Police Officers' Association
Los Angeles School Police Management Association
Los Angeles School Police Officers' Association
Murrieta Police Officers' Association
Newport Beach Police Association
Palos Verdes Police Officers' Association
Placer County Deputy Sheriffs' Association
Pomona Police Officers' Association
Riverside Police Officers Association
Riverside Sheriffs' Association
Santa Ana Police Officers Association

Opposition

Holistic Alternative Recovery Trust

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