

What is Kratom?

August 23, 2022



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Overview of SB22-120 and Current Local Regulations

Jaclyn Terwey, CML Legislative & Policy Advocate
Eric Bergman, CCI Policy Director



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SB22-120

- Department of Revenue conduct feasibility report by 1/4/2023
 - Regulating kratom products, kratom processors and kratom retailers
 - Recommend appropriate state agency
 - Define terms such as “processing”, “selling”, “advertising”, “Kratom” and “Kratom products”
 - Age restrictions, Underage compliance checks
 - Kratom testing
 - Kratom food products
 - Labeling requirements
 - Adverse health reporting
 - Fiscal consideration, reporting requirements



SB22-120 cont.

Effective July 1, 2024

- No adulterated products
- Labeling requirements: identity and address of manufacturer, full list of ingredients
- 21+ age restricted

Effective August 10, 2022

- 21+ age restricted
- Civil penalties with \$200 fine for underage sale
- Statutory or Home Rule municipality, county, or city and county may enact stricter ordinance



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Current Local Regulations

Sale of Kratom Banned

- Parker
- Monument

Strict Labeling Requirements

- Denver

Age Restricted*

- Castle Rock



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Overview of SB22-120
Colorado Municipal League
August 23, 2022



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What is kratom?



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Kratom
shots. Are
they safe?



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Should kratom be banned?



Is any decision on whether to ban kratom based on opinions, biased views, or on science?



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OCTOBER 13, 2016



DEA is withdrawing the August 31, 2016 notice of intent; and soliciting comments from the public regarding the scheduling of mitragynine and 7-hydroxymitragynine under the Controlled Substances Act.



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Dr. Brett Girior
Assistant Secretary of Health

AUGUST 16, 2018 WITHDRAWAL OF KRATOM
SCHEDULING RECOMMENDATION

FDA's recommendation [to ban kratom] was rejected because of embarrassingly poor evidence and data, and a failure to consider overall public health.



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March 16, 2022 response to Congressional inquiry:



Xavier Becerra
Secretary of HHS

To that end, HHS and its component agencies are working to address knowledge gaps through research. Both the National Institutes of Health and the Food and Drug Administration (FDA) are supporting studies on the pharmacology of kratom's constituents, their toxicity and addictive liability, as well as their potential therapeutic benefits for pain and substance use disorder.

To your final point regarding kratom safety and consumer protections, I agree with your concerns. Indeed, FDA continues to receive concerning reports describing safety concerns associated with kratom, including death. **Many kratom-involved overdose deaths have occurred after use of adulterated kratom products or taking kratom with other substances.**



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Dr. Nora Volkow
NIDA Director

CONGRESSIONAL TESTIMONY ON MAY 17, 2022, ON
WHETHER KRATOM SHOULD BE BANNED.

“ . . . There's also interest in the community to test other products that may serve as harm reduction. For example, the use of kratom which is sold as tea and that contains a drug/molecule that has effects that are similar to a dose of buprenorphine [a safe and effective treatment for opiate use disorder] but could be utilized also for decreasing withdrawal or depression. . . .”



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Summary of
assessments, findings
and recommendations of
the 44th World Health
Organization's (WHO)
Expert Committee on
Drug Dependence (ECDD)

December 1, 2021

**The Committee concluded
that there is insufficient
evidence to recommend a
critical review of kratom.**



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FISCAL YEAR 2023 APPROPRIATIONS

“Kratom.—The Committee recognizes that NIH- and NIDA-funded research has contributed to the continued understanding of the health impacts of kratom, including its constituent compounds, mitragynine and 7-

hydroxymitragynine. The Committee is aware of the **potential promising results of kratom for acute and chronic pain patients who seek safer alternatives to sometimes dangerously addictive and potentially deadly prescription opioids** and of research investigating the use of

kratom’s constituent compounds for opioid use disorder.

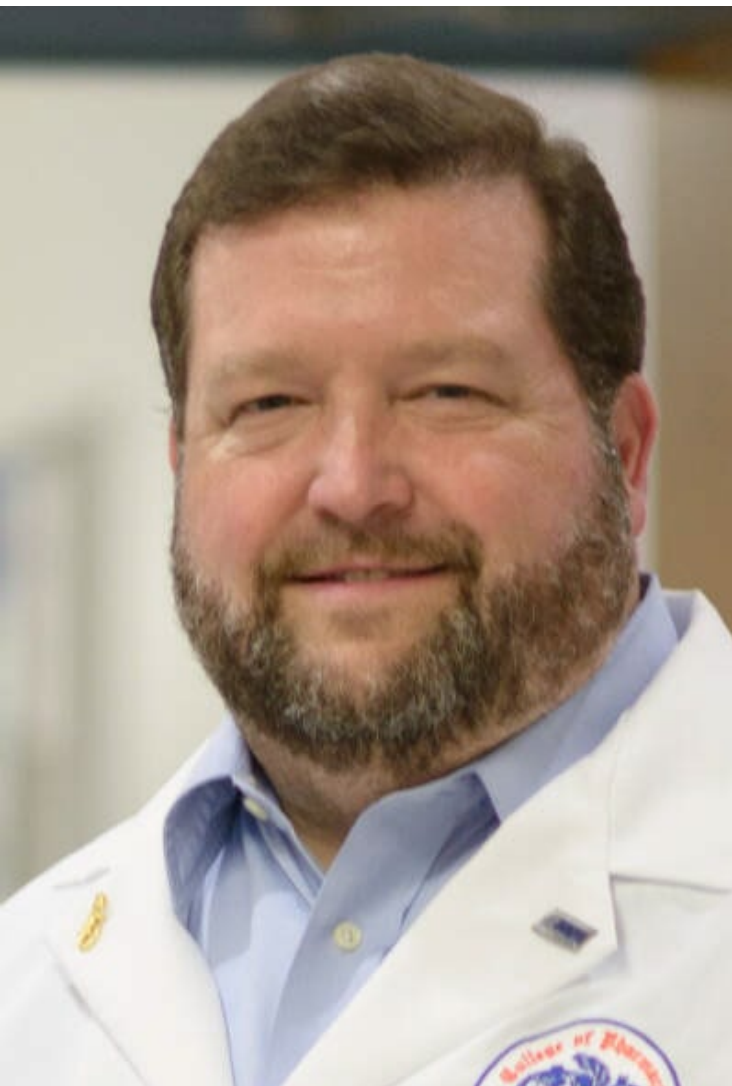
[...] “



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Christopher McCurdy, PhD

Leading scientist on kratom safety and addiction --
NIDA

University of Florida

University of Mississippi

“What we learned was that across a wide dosing range — all the way up to the average human equivalence dose that people use — kratom was very safe and did not affect respiration or coordination. It looks to be a very safe and efficacious product in the model we used and in the more traditional-inspired form of medication that we used.”



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Albert Garcia-Romeu, PhD

Johns Hopkins University

“Kratom is used among White, middle-aged Americans for symptoms of pain, anxiety, depression, and opioid withdrawal. Although regular use was typical, kratom-related SUD and serious adverse effects were uncommon.”

Among those treating opioid dependence:

- 87% reported relief from withdrawal symptoms
- 35% were free from opioids >1 year



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Is Kratom Dangerously Addictive?

**Abuse liability and therapeutic potential of the
Mitragyna speciosa (kratom) alkaloids mitragynine
and 7-hydroxymitragynine**

Scott E Hemby ¹, Scot McIntosh ¹, Francisco Leon ², Stephen J Cutler ³,
Christopher R McCurdy ²

The present findings indicate that MG does not have abuse potential and reduces morphine intake, desired characteristics of candidate pharmacotherapies for opiate addiction and withdrawal . . .



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Is Kratom Dangerously Addictive?



Abuse liability of mitragynine assessed with a self-administration procedure in rats

Kai Yue ¹, Theresa A Kopajtic ², Jonathan L Katz ³

These results suggest a limited abuse liability of mitragynine and potential for mitragynine treatment to specifically reduce opioid abuse . . .



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Common
food
products
that are
adulterated

HONEY



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[Foods](#). 2020 Nov; 9(11): 1538.

PMCID: PMC7692231

Published online 2020 Oct 26. doi: [10.3390/foods9111538](https://doi.org/10.3390/foods9111538)

PMID: [33114468](https://pubmed.ncbi.nlm.nih.gov/33114468/)

The Toxic Impact of Honey Adulteration: A Review

[Rafieh Fakhlaei](#),¹ [Jinap Selamat](#),^{1,2,*} [Alfi Khatib](#),^{3,4} [Ahmad Faizal Abdull Razis](#),^{2,5} [Rashidah Sukor](#),²
[Syahida Ahmad](#),⁶ and [Arman Amani Babadi](#)⁷

Adulteration increases the consumer's blood sugar, which can cause diabetes, abdominal weight gain, and obesity, raise the level of blood lipids and can cause high blood pressure. The most common organ affected by honey adulterants is the liver followed by the kidney, heart, and brain, as shown in several in vivo research designs.



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Common
food
products
that are
adulterated

RED CHILI
POWDER



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Chilli powder



- Adulterants: Sudan red, red brick powder, grit, sand, dirt, non-permitted colors, saw dust

Health effect:

brick powder, saw dust: Stomach disorder,
Sudan dye is carcinogenic

Sprinkle the Chilli powder in the container of water



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Common
food
products
that are
adulterated

MILK



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Adulterant	Added for	damage
water	Increase the milk volume	Decreases the nutritive value and poses health hazard to infants
Benzoic acid & Salicylic acid	Increases shelf life for long distance transport	Linked to asthma & increases level of hyperactivity in children
Detergents	Increases foaming in milk & increases whiteness and thickness	Causes gastro intestinal & renal problems
Urea	Provides whiteness and increases the consistency of milk, improves solid not fat percentage(SNF)	Overburdens the kidney and may cause renal failure



Krypton

Adulterated
kratom product



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> [J Anal Toxicol](#). 2011 May;35(4):242-7. doi: 10.1093/anatox/35.4.242.

Unintentional fatal intoxications with mitragynine and O-desmethylnaloxone from the herbal blend Krypton

Robert Kronstrand ¹, Markus Roman, Gunilla Thelander, Anders Eriksson

We believe that the addition of the potent mu-receptor agonist O-desmethylnaloxone to powdered leaves from kratom contributed to the unintentional death of the nine cases presented . . .



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➤ [J Med Toxicol](#). 2016 Dec;12(4):341-349. doi: 10.1007/s13181-016-0588-y. Epub 2016 Oct 17.

Suspected Adulteration of Commercial Kratom Products with 7-Hydroxymitragynine

Alicia G Lydecker¹, Abhisheak Sharma², Christopher R McCurdy³, Bonnie A Avery^{2 3},
Kavita M Babu⁴, Edward W Boyer⁴

We purchased several commercially available Kratom analogs for analysis and through our results, present evidence of probable adulteration with the highly potent and addictive plant alkaloid, 7-hydroxymitragynine.



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> Journal of Emergency Medicine, March 4, 2022

Acute Renal Insufficiency Associated With Consumption of Hydrocodone- and Morphine-Adulterated Kratom (*Mitragyna Speciosa*)

Kathy T. LeSaint,^{*} Shan Yin,^{†,‡} Abhisheak Sharma,^{||} Bonnie A. Avery,^{||} Christopher R. McCurdy,^{||,¶} and Javier C. Waksman[#]

It is important for the public to be aware of **this kind of adulteration as unintended consumption of a synthetic opioid can have widespread health and social consequences.** In the future, federal requirements for standardization of kratom products intended for human consumption will help to mitigate this issue.



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The Solution: Kratom Consumer Protection Act (KCPA) – SB22-120

- Recommendations for Rules on the sale of kratom products:
 - No adulterated kratom products can be sold in Colorado
 - No synthetic kratom alkaloids
 - No kratom extract with residual solvents higher than allowed by USP 467 for food products
 - No kratom containing a 7-Hydroxymitragynine in the alkaloid fraction greater than 2% of the overall alkaloid composition of the product
 - No kratom product that is not labeled with ingredients and directions for use – and no illegal therapeutic claims
 - No sales to minors under that age of 21



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Kratom Regulation

Colorado Association of Local Public Health Officials – August 2022

Views of CALPHO Policy Committee

- There are no FDA-approved uses for kratom.
- Local public health officials have concerns that any regulation of kratom could legitimize and increase its sales under a false pretense of government approval and a presumption of safety and effectiveness.

Views of CALPHO Policy Committee, cont.

- According to the FDA, serious concerns exist regarding the toxicity of kratom in multiple organ systems.
- Kratom has been indicated to have both narcotic and stimulant-like effects, and cause withdrawal symptoms.
- The FDA encourages more research to better understand kratom's safety profile, including the use of kratom combined with other drugs.

Views of CALPHO Policy Committee, cont.

- Currently there are few controls on the sale of kratom across the state and products are easily accessible to the general population at gas stations, head shops, and other locations.
- Kratom regulation has been proposed as a solution to adulterated products that present risk to consumers (1-2% of Colorado population).
- Regulation could provide some basic consumer protections and oversight, although without corresponding Federal requirements and state and local inspections and enforcement, it is a measure with limited efficacy.

Views of CALPHO Policy Committee, cont.

- Harm reductionists argue that kratom products can provide critical support for people recovering from opioid addiction.
- While the utmost caution must be taken in evaluating these claims and extensive research is needed to understand the potential for any therapeutic use, the anecdotal feedback from many people suggests that an inability to access kratom could be linked to opioid use increase or relapse.

Kratom Regulation – CALPHO Policy Committee Positions

- Restrict sales to age 21+
- Ensure there is no local pre-emption, i.e., local governments can regulate Kratom in ways that exceed any state regulation
- Require clear packaging, labeling, and purity testing – no allowable health claims by retailers
- Specific language prohibiting the addition of kratom to food (as defined in the Food Protection Act) in the retail setting
- Monitor unintended consequences (i.e., increased sales/use, use amongst youth)