



AMERICAN KRATOM ASSOCIATION

June 10, 2024

Assemblymember Matt Haney
District 17
California Assembly
1021 O Street, Suite 5740
P.O. Box 942849
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Assemblymember Haney:

The American Kratom Association (“AKA”), the oldest kratom consumer advocacy organization representing the 15 million+ kratom consumers in America since 2014, writes to express its opposition to AB 2365 as it is currently drafted. While there have been improvements in the bill from its originally filed version, in its current form we believe this legislation will impose debilitating regulatory burdens on small retail and manufacturing businesses in California that will stifle innovation and interfere with the freedoms of consumers to make informed choices on the kratom products they choose for their health and well-being.

Most important, in its current form, AB 2365 will limit consumer choices on otherwise safe kratom products.

The AKA has advocated for passage of model legislation across the country, known as the Kratom Consumer Protection Act (“KCPA”), since 2019. With the recent enactment of KCPA legislation in Kentucky and Maryland, there are now 13 states that have KCPA legislation in effect. None of these enacted KCPA bills have the level of regulatory burdens imposed by AB 2365. It is expected that North Carolina and Rhode Island will add two more states to that list in the next few weeks.

The AKA supports the framework of your bill, but we strongly believe the amendments we have recommended will provide needed provisions to ensure a balanced regulatory framework that fills the gap created by the FDA’s unwillingness to properly regulate kratom that protects consumers. We do not believe kratom should be regulated as a drug because the science does not support that concept, but portions of the current bill

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actually does that. As a botanical supplement, kratom should be regulated appropriately under the existing paradigm for dietary and botanical supplements.

The AKA asks your consideration of the attached list of amendments that we believe would, if accepted, provide appropriate protections for kratom consumers.

Respectfully submitted,

A handwritten signature in blue ink that reads "Mac Haddow". The signature is fluid and cursive, with the first name "Mac" and last name "Haddow" clearly distinguishable.

Mac Haddow
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AKA Proposed Amendments to AB 2365

AMENDMENT #1:

Page 2, lines 9-16:

~~(a) “Kratom leaf” means the leaf of the kratom plant, also known as mitragyna speciosa, in fresh or dehydrated form, and subjected to no postharvest processing except for drying or size reduction, by cutting, milling, or similar procedure, and to cleaning or sterilization through application of heat, steam, pressurization, irradiation, or other standard treatments applied to food ingredients. The total alkaloid content of kratom leaf material used in a kratom product shall not exceed 4% percent on a dried weight basis.~~

Recommended language:

“Kratom product” means a botanical supplement product or dietary ingredient containing any part of the leaf of the plant *Mitragyna speciosa* or an extract of it, and is manufactured as a powder, capsule, pill, beverage, or other edible form. All kratom products are foods, botanical supplements or dietary ingredients based on their conditions of use.

Rationale for the proposed change:

Supplement manufacturers ALWAYS seek improved concentrations of active ingredients - this gives more freedom to develop products as they typically include multiple supplements, vitamins, and minerals. The appropriate control mechanism is in the labeling, and specific requirements that alkaloids are labeled to show that the specific contents “do not exceed” levels – to address variability in batch-to-batch raw materials. These conditions of use are consistent with federal FDA statutes and regulations.

The 4% limit is unnecessary and appears, at best, to be arbitrary and will limit farms that either naturally, or through improved methods like selective breeding or innovative fertilizing, improve the yield of the plant. Innovative growers have selectively cultivated crops for improved yield for thousands of years.

The language in this provision that specifically describes the postharvest processing requirements would require some regulatory action that would place an onerous and expensive burden on the Department of Health to have oversight facilities in the country of origin of the kratom plant material. This issue is resolved with the requirement for independent testing of the kratom product to assure they are not adulterated or have contaminants as a part of the product registration procedures.

AMENDMENT #2:

Page 3, lines 1-2:

~~(2) That contains mitragynine as the most abundant alkaloid on a weight-by-weight basis and at a level that is more than twofold that of any other alkaloid present.~~

Rationale for the proposed change:

This creates a complex math equation that undermines the objective of the language.

As written, the language appears to include leaf powders that (1) have mitragynine at levels equal to (1x) the most abundant other alkaloid, or (2) have mitragynine at levels >2x the most abundant other alkaloids; but EXCLUDES leaf powders that have mitragynine at levels >1x but <2x the most abundant alkaloid.

This provision excludes low-mitragynine kratom leaf powder, which is known to exist. This provision would potentially ban a lower level of kratom leaf powder simply to protect kratom products with a higher mitragynine content. Some consumers may prefer a lower mitragynine content product and, based on the conditions of use, find that product to be a lower risk of adverse events.

AMENDMENT #3:

Page 3, lines 4-5:

The ratio of mitragynine to other alkaloids ~~is the same~~ or greater than that of the starting material.

Recommended language:

The ratio of mitragynine to other alkaloids **is substantially similar to** or greater than that of the starting material.

Rationale for the proposed change:

Replacing the phrase “is the same” with “is substantially similar” will avoid natural variations in the kratom plant material that is impacted by the time of harvest, the conditions under which drying and processing occurs, and other factors that create variances in the alkaloid levels that would be potentially banned under the strict “is the same” requirement.

AMENDMENT #4:

Page 3, lines 12-16:

~~(C) The level of 7-hydroxymitragynine on a percent weight basis is not greater than 1 percent of the amount of total kratom alkaloids confirmed with a high-pressure high-performance liquid chromatography or an ultra-performance liquid chromatography testing method.~~

Rationale for the proposed change:

This provision is unnecessary given that Section B on page 3, lines 9-11 already limit any synthesized kratom alkaloids; and the provision in (C)(2) (page 3, lines 17-20) also provides a specific limit on what a “synthesized” kratom alkaloid is.

AMENDMENT #5:

Page 3, lines 12-16:

~~“Total kratom alkaloids” means the sum of mitragynine, speciociliatine, speciogynine, paynantheine, and 7-hydroxymitragynine in a kratom product.~~

Rationale for the proposed change:

The kratom plant contains more than 50 alkaloids. This provision arbitrarily names 4 alkaloids and 1 metabolite of the kratom plant. As science advances, and it is doing so rapidly, we will understand better the “symphony” of how kratom’s alkaloids produce its beneficial effects for consumers. Limiting the calculation to just these identified alkaloids ignores the reality and the science of the total alkaloid content of the kratom plant.

This provision appears to be a limitation to benefit specific kratom product manufacturers and would stifle innovation, create an onerous regulatory burden, and limit otherwise safe kratom products to consumers.

AMENDMENT #6:

Page 4. Lines 36-38, and Page 5, lines 1-2:

- ~~(b) A kratom product offered for retail sale that is in liquid form and contains more than three servings shall include a calibrated measuring device.~~
- ~~(c) If the kratom product is in powdered form, the package shall include a calibrated measuring device.~~

Recommended language:

A kratom product offered for retail sale shall provide clear directions of use by serving size, and when appropriate, a clear demarcation on the package or container to assist the consumer in identifying the quantity of the package or container that constitutes a single serving.

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Rationale for the proposed change:

A requirement for a calibrated measuring device for any kratom product is unprecedented in any statute for a dietary or botanical supplement. This requirement imposes a costly regulation on small businesses and provides a clear marketing advantage to larger kratom manufacturers. Any kratom manufacturer who seeks to differentiate its product in the market by adding a calibrated measuring device to attract consumers is free to do so.