FLORIDA DEPARTMENT OF AGRICULTURE AND CONSUMER SERVICES

DIVISION OF FOOD SAFETY

FREQENTLY ASKED QUESTIONS - October 2025

Requirement to label the concentration of 7-hydroxymitragynine (7-OH) on Kratom Products pursuant to 5KER25-4.

The following information is provided to assist food establishments with ensuring kratom products are compliant with Florida law. This information is not intended to replace or supersede legal requirements. If you are unsure whether your product is compliant, then you should consult with your attorney.

Where can I find 2ER25-2 and 5KER25-4?

2ER25-2

5KER25-4

Will FDACS issue stop sale orders for products that contain 7-Hydroxymitragynine (7-OH) at a level above 400 parts per million (ppm) on a dry weight basis?

Pursuant to the Florida Attorney General's emergency rule 2ER25-2, products containing 7-OH at levels above 400 ppm on a dry weight basis are Schedule I controlled substances. FDACS will immediately place these violative products under stop sale order. Retailers should ensure they have reviewed kratom products being offered for sale in their stores to ensure compliance.

Will FDACS issue stop sale orders for kratom products that contain less than the 400 ppm 7-OH limit set by emergency rule 2ER25-2, but that do not have the concentration of 7-OH in ppm on a dry weight basis listed on the label as required by the FDACS's emergency rule 5KER25-4?

FDACS will not typically place products under a stop sale order solely for failing to list the 7-OH concentration in ppm on the label when it is the first time the food establishment has been cited for the violation, and the product is otherwise compliant with Florida law. However, the product must contain sufficient information to determine the concentration of 7-OH in the package. Products that do not contain sufficient labeling to determine if the concentration of 7-OH is in compliance with emergency rule 2ER25-2 may be subject to stop sale order until the concentration of 7-OH can be adequately evaluated.

What happens if a product does not comply with FDACS emergency rule 5KER25-4: Requirement to Label the Concentration of 7-Hydroxymitragynine on Kratom Products?

For a first violation (and otherwise complaint with Florida law), FDACS will typically cite a violation and check back with the food establishment to ensure future compliance; however, the presence of other violations or aggravating factors as set forth in rule 5K-4.035, Florida Administrative Code, may warrant the issuance of a stop sale order. Manufacturers should begin proactively updating labels to include the 7-OH concentration in ppm on a dry weight basis to come into compliance as quickly as possible.

What should food establishments do to help ensure compliance?

- Retailers should review certificates of analysis for all kratom products to confirm that all products are below the 7-OH limit of 400 ppm on a dry weight basis and review all kratom products to ensure they are properly labeled.
- It is recommended that retailers maintain copies of certificates of analysis for all kratom products to demonstrate the products are compliant.
- Retailers, manufacturers, and distributors should be aware that they may be cited
 or fined for selling, offering for sale, or distributing kratom products that are not
 compliant, including for labeling violations, if the 7-OH concentration is not listed
 on the package in "ppm on a dry weight basis."

What should manufacturers do right now to stay compliant?

- Proactively update labels to include the concentration of 7-OH in ppm on a dry weight basis.
- Ensure all products shipped into Florida are compliant with the 400 ppm 7-OH limit set by emergency rule 2ER25-2.