

R70. Agriculture and Food, Regulatory Services.

R70-580. Kratom Product Registration and Labeling.

R70-580-1. Authority and Purpose.

Pursuant to Section 4-45-107, this rule establishes the requirements for labeling and registration of products made from and containing kratom.

R70-580-2. Definitions.

- (1) "Certificate of Analysis (COA)" means a certificate from a laboratory describing the results of the laboratory's analytical testing of a sample.
- (2) "End Consumer" means an individual who does not resell the purchased kratom product.
- (3) "Food" means a raw, cooked, or processed edible substance, ice, or ingredient used or intended for use or for sale in whole or in part for human consumption, or chewing gum.
- (4) "Label" means the display of any written, printed, or graphic matter upon the immediate container of a kratom product or a statement by or under the control of the kratom processor or distributor, which is directly related to the kratom product bearing the label.
- (5) "Third-party Laboratory" means a laboratory that has no direct interest in a processor or distributor of kratom products that can perform mandated testing utilizing validated methods.
- (6) "Approved Kratom Delivery Form" means a kratom product in raw leaf, capsule, tablet, powder, liquid, tea bag, concentrated, extract, or gummy forms. The following are not approved kratom delivery forms:
 - (a) any form that is combustible or intended to be used for vaporization;
 - (b) any form that is intended to be added to food; or
 - (c) any form that mimics a candy product or is manufactured, packaged, or advertised in a way that appeals to children.
- (7) "Kratom Type" means the specified strain of the botanical *Mitragyna speciosa*.
- (8) "Kratom Processor" means any kratom product manufacturer, distributor, or retailer who offers a kratom product for sale or resale to consumers.
- (9) "Kratom Product" means a product manufactured or processed from kratom acquired by a kratom processor that is certified to be compliant with Title 4, Chapter 45, Kratom Consumer Protection Act.
- (10) "Kratom Retailer" means a kratom processor who sells a kratom product to an end consumer.

R70-580-3. Product Registration.

- (1) A kratom product distributed or available for distribution that is intended to be offered for sale to an end consumer in Utah, including on the internet or social media platforms, shall be:
 - (a) in an approved kratom delivery form; and
 - (b) registered with the department annually by the kratom processor.
- (2) A product that contains the same kratom ingredients in the same kratom delivery form but a different container, package, or volume shall be included in a single registration.
- (3) Application for registration shall be made on a form provided by the department that includes the following information:
 - (a) the name and address of the kratom processor and the name and address of the kratom processor whose name will appear on the label, if other than the kratom processor making the registration;
 - (b) the name of the kratom product included in the registration;
 - (c) the kratom type and recommended usage, including directions for use or serving size for the kratom product;
 - (d) the approved kratom delivery form;
 - (e) the weights or volumes, as appropriate, of the package of kratom product, offered for sale for the recommended usage and the entire package;
 - (f) a complete copy of the label that will appear on the kratom product or the document that can be reached via a scannable bar code, QR code, or web address, pursuant to Subsection R70-580-6(7);
 - (g) a certificate of analysis for the kratom product from a third-party laboratory that shall obtain and keep the International Organization for Standardization (ISO) 17025:2017 accreditation from an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
 - (i) a third-party laboratory may test kratom product before obtaining ISO/IEC 17025:2017 accreditation provided by the third-party laboratory:
 - (A) adopts and follows minimum good laboratory practices which satisfy the OECD Principles of Good Laboratory Practice and Compliance Monitoring published by the Organization for Economic Co-operation and Development; and
 - (B) becomes ISO/IEC 17025:2017 accredited within 18 months, by an accreditation body that is a signatory to the International Laboratory Accreditation Cooperation (ILAC) Mutual Recognition Arrangement;
 - (ii) if a kratom processor uses an out-of-state third-party laboratory they shall include a copy of the laboratory accreditation with the registration;
 - (h) certification that:
 - (i) the kratom processor has not added any substance to the kratom product that is listed in Title 58, Chapter 37, Utah Controlled Substances Act;

- (ii) the kratom processor has not mixed or packed any nonkratom substance that affects the quality or strength of the kratom product to such a degree as to make the kratom product injurious to a consumer;
 - (iii) the kratom product manufacturer has not added any synthetic mitragynine, synthetic 7-hydroxymitragynine, or any other synthetically derived compound of the kratom plant;
 - (iv) the registrant assumes responsibility and liability for the product based on their role in the processing of the kratom product and whether they are a kratom manufacturer, distributor, or retailer; and
 - (v) that the registered kratom product is compliant with applicable current state and federal guidelines for food safety.
- (4) A non-refundable registration fee, as outlined in the fee schedule approved by the legislature, shall be paid to the department with the submission of a registration application.
- (5) A separate registration fee shall be required for each kratom product manufactured or processed from raw materials with the same specifications, same name, and same kratom delivery form.
- (6) The department may deny registration for an incomplete application.
- (7) The department shall deny or withdraw registration for a kratom product that:
- (a) violates Title 4, Chapter 45, Kratom Consumer Protection Act;
 - (b) is adulterated or contaminated with foreign materials that would be injurious to a consumer; or
 - (c) if there is any reasonable basis to suspect that the kratom product is unsafe or that ingredients violate state law.
- (8) A new registration application is required for the following:
- (a) a change in the kratom product ingredients or processes that materially alters the product;
 - (b) a change to the recommended usage; and
 - (c) a change of name for the product.
- (9) Other changes shall not require a new registration application but the registrant shall submit copies of all label changes to the department as soon as they are effective.
- (10) The kratom processor registering the kratom product is responsible for the accuracy and completeness of the information submitted.
- (11) A registration is renewable for up to one-year with an annual renewal fee per kratom product that shall be paid on or before June 30th of each year.
- (12) A kratom product that has been discontinued shall continue to be registered until the kratom product is no longer available for distribution.
- (13) A late fee shall be assessed for a renewal of a kratom product registration submitted after June 30th and shall be paid before the registration renewal is issued.

R70-580-4. Establishment Registration.

- (1) Pursuant to Subsection 4-45-104(5), a kratom processor shall register as a food establishment under Section 4-5-301.
- (2) A kratom processor may be registered in another state that meets or exceeds the requirements in Section 4-5-301 if they provide the department with a copy of the registration from the federal or state regulatory agency.
- (3) A kratom processor shall be subject to any statutes, rules, regulations, policies, and procedures for food establishments specific to the form of the kratom product offered for sale.
- (4) In their application for registration, each kratom processor shall identify any DBAs they operate that involve the production of kratom products and the person that is legally responsible to produce the kratom product. If the legally responsible person changes, the department shall be notified of the change within 30 days.
- (5) The application for registration shall include a certification that the products manufacturer maintains a manufacturing batch record (MBR) that documents:
- (a) batch-to-batch uniformity;
 - (b) that each batch conforms to kratom raw material specifications;
 - (c) that each batch record shows that each step of the MBR was performed;
 - (d) that the production processes, controls, and tests ensure reliable, reproducible results; and
 - (e) that the finished kratom product meets each specification before the product is released for distribution.
- (5) MBR testing shall be performed on finished kratom products as identified by lot or batch number.
- (6) Each MBR shall also include the following information:
- (a) the lot or batch identification number of the tested product;
 - (b) the date received;
 - (c) the date of testing completion;
 - (d) the method of analysis for each test conducted;
 - (e) a photo of the kratom product that was tested;
 - (f) the name and address of the kratom processor that manufactured the product; and
 - (g) the name and address where the MBR records are maintained and available for inspection by the department.

R70-580-5. Certificate of Analysis.

- (1) At a minimum, the certificate of analysis for each batch of kratom product shall include the following test results:
- (a) the contents of mitragynine and 7-hydroxymitragynine in the kratom product certifying compliance with this rule and Subsection 4-45-104(1);

(b) the level of pathogens in the kratom product does not exceed the amounts listed in Table 1 when one gram or greater sample is tested; and

TABLE 1	
Microbial Analytes and Action Levels	Microbial Limit Requirement
Total Aerobic Microbial Count	NMT $\leq 10,000,000$ cfu/g
Total Combined Yeast and Mold	NMT $\leq 100,000$ cfu/g
Total Bile-tolerant Gram-negative Bacteria	NMT $< 10,000$ cfu/g
Salmonella spp. & E. coli	Absence in 100g

(c) that the levels of heavy metals in the kratom product do not exceed the amounts listed in Table 2.

TABLE 2 Heavy Metals	
Metals	Natural Health Products Acceptable limits in parts per million
Arsenic	< 2
Cadmium	< 0.82
Lead	< 1.2
Mercury	< 0.4

- 2) Testing shall be performed on finished kratom products as identified by lot or batch number.
- 3) The certificate of analysis shall also include the following information:
 - a) the lot or batch identification number of the tested product;
 - b) the date received;
 - c) the date of testing completion;
 - d) the method of analysis for each test conducted;
 - e) a photo of the kratom product that was tested;
 - f) the name and address of the kratom processor that manufactured the product; and
 - g) the name and address of the laboratory that completed the testing.
- 4) The lot or batch number on the certificate of analysis shall match the lot or batch number on the kratom product and shall be conspicuously placed on the container or label of the kratom product.
- 5) Upon receipt of an adverse or non-compliant test result, the kratom processor shall be required to produce a new certificate of analysis from an independent third-party laboratory on the reported product to affirm compliance.
- 6) Failure to submit a new certificate of analysis shall be cause for withdrawal or denial of product registration.
- 7) Mycotoxin testing of a kratom product may be required if the department has reason to believe that mycotoxins may be present.

R70-580-6. Label Requirements.

- (1) A kratom product that is marketed as conventional food as defined in Sections 4-5-102 and 4-45-102 shall be labeled pursuant to the labeling requirements of Section 4-5-201.
- (2) A kratom product marketed as a dietary supplement as defined in Section 4-1-109 shall be labeled pursuant to the requirements of 21 CFR 101.36.
- (3) The label shall contain the factual basis upon which the kratom processor represents the product as a kratom product by identifying kratom within the list of ingredients.
- (4) The label shall identify each kratom product by a unique batch or lot number specifically linking each kratom product to a specific batch or a lot manufactured by the kratom processor.
- (5) A kratom product shall not contain claims that the product is intended to diagnose, treat, cure, or prevent any medical condition or disease on the label or labeling.
- (6) The label of each kratom product label shall include the following text pursuant to 21 CFR 101.93 (c), prominently displayed:

"This product has not been evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure, or prevent any disease."

(7) A kratom product shall meet the standards in 21 U.S.C. 9, the Food Drug and Cosmetic Act, other applicable federal laws and regulations, and any applicable state laws and regulations relating to the labeling of food and cosmetics.

(8) If there is not sufficient room on the kratom product label, the kratom product shall display on the label a scannable bar code, QR code, or web address linked to a document containing the information required in Subsections R70-580-6(1) through R70-580-6(7).

(9) No information, illustration, or depiction that the processor knows or should know appeals to children shall appear on the label.

R70-580-7. Product Appearance and Flavor.

(1) A kratom processor may not produce a kratom product that is designed to mimic a candy product.

(2) A kratom processor may not produce a product that includes a candy-like flavor or another flavor the kratom processor knows or should know appeals to children.

(3) A kratom processor may not shape a kratom product in any way that appeals to children, including products that are shaped like fruit, stars, cartoon renderings, humans, or animals.

(4) A kratom product shall be packaged in child-resistant packaging, pursuant to 16 CFR 1700.

R70-580-8. Inspection and Testing.

(1) The department shall conduct a randomized inspection of the kratom product distributed or available for distribution for compliance with this rule.

(2) The department shall periodically sample, analyze, and test a kratom product distributed for compliance with registration and labeling requirements and the certificate of analysis.

(a) Each department sample shall include at least ten grams of kratom product.

(b) The department may test kratom product for any substance listed in Subsection R70-580-5(1) as well as for any of the following prohibited substances, at the discretion of the department:

(i) any pesticide;

(ii) any fentanyl derivative;

(iii) any of the following cannabinoids with an action level of 0.01% (w/w):

(A) delta-9-THC;

(B) delta-8-THC;

(C) THCA;

(D) CBD;

(E) CBDA;

(F) CBG;

(G) CBGA; or

(H) any other cannabinoid tested for by the laboratory with an action level of 0.01% (w/w);

(iv) cocaine; or

(v) any of the following Benzodiazepines:

(A) diazepam;

(B) alprazolam;

(C) triazolam;

(D) lorazepam; or

(E) clonazepam.

(c) Kratom product that is found to contain a prohibited substance shall be considered adulterated in violation of this rule.

(3) The department may conduct an inspection of any kratom product distributed or available for distribution if there is any reasonable basis to suspect that the kratom product is unsafe or that ingredients violate state law or rules.

(4) The test results from the department inspection samples shall be the official sample results.

(5) Upon request, a kratom processor shall provide documentation certifying that any batch of kratom raw materials acquired pursuant to a compliant specification purchase that is used to process or manufacture a kratom product is compliant with Section R70-580-5.

R70-580-9. Retailer Responsibilities.

(1) A retailer shall:

(a) ensure that kratom product is labeled correctly; and

(b) ensure that the kratom product offered for sale is properly registered with the department.

(2) A retailer shall provide the identity of the processor or manufacturer of a kratom product sold by the retailer upon request of the department.

(3) A retailer shall register a kratom product instead of the kratom processor if the product is not registered.

R70-580-10. Violation.

- (1) Each improperly labeled kratom product shall be a separate violation of this rule.
- (2) A kratom product shall be considered misbranded if it does not meet the labeling requirements of this rule.
- (3) A kratom product shall be considered adulterated based on the definition in Subsection 4-5-103(1).
- (4) It is a violation to distribute or market a kratom product that is not registered with the department.
- (5) Each unit manufactured or processed from a batch of raw material or on a single retail invoice shall be considered a separate violation of this rule for an unregistered product marketed for sale.
- (6) It is a violation:
 - (a) to prepare, distribute, sell, or offer for sale a kratom product that violates Subsection 4-45-104 (1);
 - (b) to prepare, distribute, sell, or offer for sale a kratom product that is not in an approved kratom delivery form, including adding or processing kratom into any food consumed for taste, aroma, and nutritive value;
 - (c) to prepare, distribute, sell, or offer for sale a kratom product that would be potentially harmful to consumers;
 - (d) for a kratom processor to fail to register as a food establishment pursuant to Section 4-5-301 or Subsection R70-580-4(2);
 - (e) for a kratom processor to distribute, sell, or offer for sale a kratom product to an individual under 18 years of age; and
 - (f) for a kratom processor to improperly sample, test, falsify a certificate of analysis, or knowingly submits a falsified certificate of analysis for a kratom product.

R70-580-11. Penalties.

Any violation of or failure to comply with this rule or any specific requirements may be grounds for issuance of citations, fines, recall of kratom product, revocation of registration, or denial of future registration pursuant to Sections 4-2-303 and 4-2-304.

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