

OFFICE OF THE SECRETARY OF STATE

SHEMIA FAGAN
SECRETARY OF STATE

CHERYL MYERS
DEPUTY SECRETARY OF STATE



ARCHIVES DIVISION

STEPHANIE CLARK
DIRECTOR

800 SUMMER STREET NE
SALEM, OR 97310
503-373-0701

NOTICE OF PROPOSED RULEMAKING
INCLUDING STATEMENT OF NEED & FISCAL IMPACT

CHAPTER 150
DEPARTMENT OF REVENUE

FILED

03/27/2023 4:26 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Kratom Processor Annual Registration; Testing; Penalty for Unregistered Distribution

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 04/20/2023 5:00 PM

The Agency requests public comment on whether other options should be considered for achieving the rule's substantive goals while reducing negative economic impact of the rule on business.

CONTACT: Katie McCann
503-509-9787
RulesCoordinator.dor@oregon.gov

955 Center St NE
Director's Office - Room 457
Salem, OR 97301

Filed By:
Katie McCann
Rules Coordinator

HEARING(S)

Auxiliary aids for persons with disabilities are available upon advance request. Notify the contact listed above.

DATE: 04/20/2023

TIME: 1:00 AM

OFFICER: Kelvin Adkins-Heljeson

REMOTE MEETING DETAILS

MEETING URL: [Click here to join the meeting](#)

PHONE NUMBER: 503-446-4951

SPECIAL INSTRUCTIONS:

Meeting URL: <https://www.microsoft.com/en-us/microsoft-teams/join-a-meeting>

Meeting ID: 287 112 433 457

Passcode: ZHyqbf

Or call in (audio only)

+1 503-446-4951 United States, Portland

Phone Conference ID: 277 794 997#

NEED FOR THE RULE(S)

These rules are required to provide guidance to kratom processors related to the requirement to register with the Department of Revenue and certify the kratom products will be tested and how the department will issue civil penalties to unregistered kratom processors.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

Oregon Laws 2022, chapter 41

STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

These rules will have no direct impact on racial equity in this state. The rules inform kratom processors about how the department will administer Oregon Laws 2022, chapter 41.

FISCAL AND ECONOMIC IMPACT:

These rules are required by Oregon Laws 2022, chapter 41. These rules adopt an annual registration fee for Kratom Processors intended to cover the Department of Revenue's costs of administering Oregon Laws 2022, chapter 41.

COST OF COMPLIANCE:

(1) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s). (2) Effect on Small Businesses: (a) Estimate the number and type of small businesses subject to the rule(s); (b) Describe the expected reporting, recordkeeping and administrative activities and cost required to comply with the rule(s); (c) Estimate the cost of professional services, equipment supplies, labor and increased administration required to comply with the rule(s).

(1) There is no impact on state agencies or units of local government. There is a fiscal impact to kratom processors who register with the department of revenue. This impact is the annual registration fee, and the costs associated with testing kratom products to ensure no dangerous non-kratom substances are included in the kratom items.

(2a) The department estimates there are approximately 10 kratom processors who will be subject to these rules.

(2b) Kratom processors will be required to register annually and maintain records related to third-party testing of kratom products.

(2c) Access to a computer with internet access will be required to apply for a registration. Submitting samples to a third-party laboratory and associated costs.

DESCRIBE HOW SMALL BUSINESSES WERE INVOLVED IN THE DEVELOPMENT OF THESE RULE(S):

Small businesses were included in outreach through direct email correspondence and involvement in the Rules Advisory Committee, as well as through a list serv with information on Rules Advisory Committee meetings and the public hearing soliciting participation, feedback, and/or comments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

150-475-6010, 150-475-6020, 150-475-6030

ADOPT: 150-475-6010

RULE SUMMARY: Adopts registration fee for Kratom Processors to register with the Oregon Department of Revenue and annual registration renewal.

CHANGES TO RULE:

150-475-6010

Kratom Processor Definitions; Annual Registration

(1) Definitions. The definitions in Oregon Laws 2022, chapter 41, section 2 apply to the terms used in OAR 150-475-6010, OAR 150-475-6020, and OAR 150-475-6030, in addition to the following definitions.¶

(a) "Dangerous non-kratom substance" means any substance present in a finished kratom product formulation or unfinished kratom product that exceeds the amount allowable in OAR 150-475-6020 (3).¶

(b) "Department" means the Oregon Department of Revenue.¶

(c) "Finished kratom product" means a food, food product, food ingredient, dietary ingredient, dietary supplement, or beverage that has been produced or processed by a kratom processor in its final state as intended for sale to a

consumer.

(d) "Finished kratom product formulation" means a combination of unfinished kratom products with another substance or unfinished kratom products altered from their original state into a final form to be sold to a consumer.

(e) "Kratom processor annual registration fee" or "annual fee" means the fee adopted by the department in this rule to be paid by kratom processors at the time the registrant submits a registration under this rule.

(f) "Registration" means the registration form and any additional documentation or information requested by the department from a kratom processor to verify compliance with this rule and includes both the initial registration and any renewal registrations submitted by a kratom processor.

(g) "Unfinished kratom product" means any part of the plant *Mitragyna speciosa* that has not been processed into a finished kratom product or kratom product formulation and that is intended to be sold, distributed, or exposed for sale to a consumer in its original state.

(2) Kratom Processor Initial Registration

(a) Each kratom processor engaging in the sale, distribution, or exposure for sale in the state of Oregon must submit a registration form to the department on an annual basis. Beginning on and after July 1, 2023, a kratom processor may not sell, distribute, or expose for sale kratom products on a wholesale or retail basis in the state of Oregon without first receiving a certificate of registration described in subsection (d) of this section.

(b) The department will not consider a registration submitted as complete until the kratom processor has paid the kratom processor annual registration fee in full for each registration form submitted to the department.

(A) If a kratom processor submits a registration without full payment of the kratom processor annual registration fee, the department will notify the kratom processor the registration is incomplete.

(B) If the kratom processor does not remit full payment of the registration fee within 14 days of the notice, the department will consider the registration withdrawn and refund any amount paid.

(c) The department will not consider a registration submitted for review unless the kratom processor certifies that all kratom products that will be distributed, sold, or exposed for sale by the kratom processor will be third-party tested for dangerous non-kratom substances in compliance with the requirements of OAR 150-475-6020 and Oregon Laws 2022, Chapter 41, Section 3.

(d) If the department determines the registration is complete, it will provide the kratom processor a certificate of registration.

(e) Completed registrations that are received prior to July 1, 2023, will be effective from July 1, 2023, through June 30, 2024. Completed registrations received after July 1, 2023, will be effective for a one-year period from the issuance date on the certificate of registration through the end of the calendar month of the issuance date. Example: Delaney submits a registration on June 20, 2023, and remits payment on June 20, 2023. The department issues a certificate of registration effective from July 1, 2023, through June 30, 2024. Evelyn submits a registration on July 15, 2023, and remits payment on July 15, 2023. The department determines the registration is complete and issues a certificate of registration effective from July 15, 2023, through July 31, 2024. Wesley submits a registration on July 31, 2023, but does not remit payment until August 1, 2023. The department determines the registration is complete and issues a certificate of registration effective from August 1, 2023, through August 31, 2024.

(3) Kratom Processor Annual Registration Fee. The kratom processor annual registration fee for registrations effective beginning on or after July 1, 2023, is \$460. The department shall review the registration fee amount annually.

(4) Kratom Processor Registration Renewal. A kratom processor may renew its registration beginning the first day of the calendar month of expiration. A kratom processor must remit the full kratom processor annual registration fee in effect at time the kratom processor submits its registration renewal.

(5) Kratom Processor Annual Registration Fee Nonrefundable. If the department verifies that a kratom processor's registration is complete, then any kratom processor annual registration fee submitted with the registration is nonrefundable.

Statutory/Other Authority: Oregon Laws 2022, chapter 41, section 7

Statutes/Other Implemented: Oregon Laws 2022, chapter 41, section 3, Oregon Laws 2022, chapter 41, section 7

RULE SUMMARY: Provides guidance to kratom processors on kratom product testing requirements.

CHANGES TO RULE:

150-475-6020

Kratom Processor Testing

(1) Finished Processed Kratom Product Batches.

(a) For the purposes of this rule, a "product formulation batch" of finished kratom products means all kratom products of a unique finished kratom product formulation produced on the same day in the same facility by a manufacturer of finished kratom products.

(b) A kratom processor that distributes, sells, or exposes for sale a finished kratom product on a wholesale or retail basis must ensure that each product formulation batch is tested as described in section (3) of this rule.

(2) Unfinished Kratom Product Testing.

(a) A kratom processor processing unfinished kratom must separate the unfinished kratom products into a lot or batch of no more than 1,000 pounds for testing.

(b) A kratom processor that distributes, sells, or exposes for sale unfinished kratom products on a wholesale or retail basis must ensure each batch of unfinished kratom products is tested as described in section (3) of this rule.

(3) Third-Party testing. As required in sections (1)(b) and (2)(b) of this rule, a kratom processor must ensure a minimum of 0.5 percent by volume of each batch of kratom products is tested by a third party to ensure the products do not contain dangerous non-kratom substances. A batch of kratom products must be tested for the following contaminants in a manner consistent with the standards in the referenced administrative rules:

(a) Microbiological contaminants under the standards in OAR 333-007-0390.

(b) Pesticides under the standards in OAR 333-007-0400.

(c) Solvents under the standards in OAR 333-007-0410.

(d) Heavy metals under the standards in OAR 333-007-0415.

(e) Mycotoxins under the standards in OAR 333-007-0425.

(4) Kratom processors must retain records of third-party test results for a period of 3 years from the date of the test results or while the kratom products are in their possession, whichever is longer, and provide the records to the Department upon request. Records may be kept in hard copy or machine-sensible format as those terms are defined in OAR 150-475-2050.

(5) Kratom processor's obligations when product has been tested by another registered Kratom processor.

(a) If a kratom processor acquires finished or unfinished kratom products from a registered Oregon kratom processor at wholesale, and those kratom products have been tested in accordance with section (3) of this rule, the kratom processor wholesaler may satisfy the testing requirements of section (3) of this rule by:

(A) retaining copies of the seller's test results for the previously tested batches purchased by the kratom processor, or;

(B) by retaining invoices for the kratom products that include the Oregon kratom processor's registration certificate number of the seller on the invoice and a statement that all kratom products on the invoice have been tested in accordance with OAR 150-475-6020.

(b) The following examples illustrate the requirements of subsection (a) of this section.

Example 1: Annie, a registered Oregon kratom processor, purchases finished kratom products at wholesale from Brandon, also a registered Oregon kratom processor. Brandon has tested all finished kratom products included in the invoice in accordance with section (3) of this rule and provides Annie with an invoice complete with his registration certificate number and a statement that all kratom products on the invoice have been tested in accordance with OAR 150-475-6020. Annie must retain copies of those invoices and does not need to retest the kratom products to satisfy the requirements of section (3) of this rule. Brandon must retain test results records in accordance with section (4) of this rule.

Example 2: Jake, a registered Oregon kratom processor, purchases finished kratom products at wholesale from Jamie, who is not a registered Oregon kratom processor. Jake must ensure each batch of finished kratom products is tested by a third party in accordance with section (3) of this rule and must retain test results records in accordance with section (4) of this rule.

Example 3: Rachael, a registered Oregon kratom processor, purchases unfinished kratom products from Brandon, also a registered Oregon kratom processor. Subsequently, Rachael converts the unfinished kratom products into finished kratom products. Rachael must ensure each batch of finished kratom products is tested by a third party in accordance with section (3) of this rule and retain test results records in accordance with section (4) of this rule.

(c) Notwithstanding subsection (a) of this section, a Kratom processor may satisfy the requirements of section (3) of this rule by retesting kratom products acquired from a registered Oregon kratom processor. If a kratom

processor elects to retest kratom products acquired from another Oregon kratom processor, the kratom processor must retain records of those third-party test results in accordance with section (4) of this rule. A processor that elects to test products that have been previously tested by another Oregon kratom processor under this subsection must test a minimum of 0.5 percent by volume of each finished kratom product formulation or unfinished kratom product from the invoice retained in accordance with section (4) of the rule.

Statutory/Other Authority: Oregon Laws 2022, chapter 41, section 7

Statutes/Other Implemented: Oregon Laws 2022, chapter 41, section 3, Oregon Laws 2022, chapter 41, section 7

ADOPT: 150-475-6030

RULE SUMMARY: Provides guidance to kratom processors on when the Department of Revenue will assess civil penalties for distributing kratom products without registering and how a kratom processor can appeal that penalty.

CHANGES TO RULE:

150-475-6030

Civil Penalties for Unregistered Kratom Processors

(1) The Department of Revenue may impose civil penalties on any person who sells, distributes, or exposes for sale kratom products on a wholesale basis to a retailer without first registering as a Kratom Processor under OAR 150-475-6010.

(2) The following civil penalties will be imposed on a per incident basis for a violation listed in section (1) of this rule.

(a) The department will issue a civil penalty of \$500 for a kratom processor's first violation.

(b) The department will issue a civil penalty of \$1,000 for a kratom processor's second and each subsequent violation.

(3) Each sales invoice or other document indicating a sale of kratom will be considered a separate incident for determining the penalty imposed under subsection (2) of this rule.

(4) If the department assesses a penalty under this administrative rule, the penalty assessment may be appealed as a contested case under ORS chapter 183 within 30 days of the date on the notice of penalty assessment.

Statutory/Other Authority: Oregon Laws 2022, chapter 41, section 7

Statutes/Other Implemented: Oregon Laws 2022, chapter 41, section 3