

OFFICE OF THE SECRETARY OF STATE
TOBIAS READ
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MICHAEL KAPLAN
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 603
DEPARTMENT OF AGRICULTURE

FILED

11/20/2025 4:03 PM
ARCHIVES DIVISION
SECRETARY OF STATE

FILING CAPTION: Miscellaneous updates to hemp rules

LAST DAY AND TIME TO OFFER COMMENT TO AGENCY: 12/30/2025 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: DaNette Wernette
503-986-4652
rulemaking@oda.oregon.gov

635 Capitol ST NE
Salem, OR 97301

Filed By:
Sunny Summers
Rules Coordinator

HEARING(S)

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

DATE: 12/16/2025

TIME: 9:00 AM - 9:30 AM

OFFICER: Sunny Summers

REMOTE HEARING DETAILS

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

PHONE NUMBER: 503-446-4951

CONFERENCE ID: 2121607688742

SPECIAL INSTRUCTIONS:

Meeting ID: 212 160 768 874 2

Passcode: Da7FP7c3

+1 503-446-4951,,807277064#

NEED FOR THE RULE(S)

The proposed updates to the Oregon Hemp Program rules are necessary to clarify existing requirements, improve regulatory consistency, and enhance public and environmental safety. The Department has identified areas where additional guidance and updates are needed to align with statutory changes, industry practices, and federal expectations.

The rule revisions provide clearer standards for licensing, testing, recordkeeping, and compliance to ensure that hemp production and processing in Oregon continue to meet quality and safety expectations. Updates also strengthen safeguards intended to prevent diversion, protect consumers, and support lawful market development.

These updates are needed to maintain an effective, transparent regulatory framework that supports a viable hemp industry while ensuring compliance with Oregon law and federal hemp program requirements.

DOCUMENTS RELIED UPON, AND WHERE THEY ARE AVAILABLE

- ORS 571.260-571.348; OHA Division 333 Chapter 007; OLCC Division 845, Chapter 26; OLIS Website
 - Exhibits A & B, attached.
 - 7 USC 1639o: Definitions Text from Title 7- Agriculture Chapter 38 – Distribution and Marketing of Agricultural Products, Subchapter VII – Hemp Production, Statutory Notes and Related Subsidiaries; Interstate Commerce, November 17, 2025 - <https://uscode.house.gov/statviewer.htm?volume=132&page=4914>
 - FDA Q3C – Tables and List Guidance for Industry, p5, Table 1 - <https://www.fda.gov/media/71737/download> (June 2017 version)
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STATEMENT IDENTIFYING HOW ADOPTION OF RULE(S) WILL AFFECT RACIAL EQUITY IN THIS STATE

The adoption of these rules is not anticipated to have a disparate impact on any racial or ethnic group in Oregon. The amendments primarily clarify existing requirements and strengthen safety and compliance provisions within the hemp program. These changes apply uniformly to all licensees and applicants, regardless of race or ethnicity.

FISCAL AND ECONOMIC IMPACT:

The proposed rule amendments are not expected to result in a significant fiscal impact to the Department, other state agencies, or units of local government. The Department will administer the updated rules within existing resources.

For hemp licensees and applicants, the amendments may result in modest costs associated with meeting enhanced safety, testing, or recordkeeping requirements. These costs are expected to be offset by the benefits of clearer standards, reduced regulatory uncertainty, and improved market confidence in Oregon hemp products.

The proposed rules are anticipated to have a neutral to positive economic effect on the hemp industry by supporting program integrity, ensuring compliance with state and federal law, and promoting consumer and public trust. Clearer requirements may also reduce enforcement costs and improve overall program efficiency.

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) Identify any state agencies, units of local government, and members of the public likely to be economically affected by the rule(s):

The proposed rules primarily affect individuals and businesses engaged in the production, processing, and vending of hemp and hemp products. No direct economic impact is anticipated for other state agencies or units of local government. Members of the public are unlikely to experience a measurable economic effect as a result of these rule changes.

(2) Effect on small businesses:

(a) Estimate the number and type of small businesses subject to the rule(s):

Most hemp licensees in Oregon qualify as small businesses. ODA estimates that the majority of approximately 729 licensed growers, handlers, and vendors are small-scale operations.

(b) Describe the expected reporting, recordkeeping, and administrative activities and cost required to comply with the rule(s):

The amendments clarify existing recordkeeping and reporting requirements and establish additional documentation standards related to product testing, traceability, and facility safety. These activities are consistent with current industry practices and are not expected to result in substantial new administrative burdens. Any associated costs are

anticipated to be minimal and related primarily to staff time for maintaining records or submitting required documentation.

(c) Estimate the cost of professional services, equipment, supplies, labor, and increased administration required to comply with the rule(s):

Some small businesses may incur modest costs associated with enhanced safety or testing requirements, such as laboratory fees, facility improvements, or employee training. These costs will vary depending on the scale of operations and existing compliance infrastructure. Overall, costs are expected to be limited and offset by the benefits of clearer regulatory expectations, improved market access, and reduced risk of noncompliance.

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

ODA actively sought input from small businesses throughout the rule development process. Outreach included informal discussions with licensed hemp growers, handlers, and vendors, as well as participation by small business representatives in a Rules Advisory Committee convened to review and provide feedback on the proposed amendments.

WAS AN ADMINISTRATIVE RULE ADVISORY COMMITTEE CONSULTED? YES

RULES PROPOSED:

603-048-0010, 603-048-0100, 603-048-0125, 603-048-0126, 603-048-0127, 603-048-0128, 603-048-0150, 603-048-0151, 603-048-0175, 603-048-0200, 603-048-0225, 603-048-0300, 603-048-0400, 603-048-0500, 603-048-0540, 603-048-0550, 603-048-0600, 603-048-0630, 603-048-0636, 603-048-0640, 603-048-0650, 603-048-0800, 603-048-1000, 603-048-1500, 603-048-1600, 603-048-2300, 603-048-2305, 603-048-2310, 603-048-2320, 603-048-2330, 603-048-2342, 603-048-2350, 603-048-2450, 603-048-2480, 603-048-2500, 603-048-3220, 603-048-3230, 603-048-3240, 603-048-3250, 603-048-3260, 603-048-3280

AMEND: 603-048-0010

RULE SUMMARY: Updates list of definitions

CHANGES TO RULE:

603-048-0010

Definitions ¶¶

The following definitions apply to OAR 603-048-0010 through 603-048-2500 unless the context requires otherwise.¶¶

(1) "Adult use cannabis item" has the meaning given that term in ORS 475C.009.¶¶

(2) "Agricultural hemp seed"¶¶

(a) means Cannabis seed:¶¶

(A) That is sold to or intended to be sold to licensed growers for planting; or¶¶

(B) That remains in an unprocessed or partially processed condition that is capable of germination. (b) does not mean Cannabis seed produced from a marijuana plant.¶¶

(b) ~~d~~Does not mean Cannabis seed produced from a marijuana plant.¶¶

(3) "Agricultural hemp seed producer" means a person who produces agricultural hemp seed or processes industrial hemp into agricultural hemp seed.¶¶

(4) "Barrier" may include but is not limited to a man-made or natural feature, such as a row of trees or hedges, creek, or ditch which encloses, separates, or demarcates a space.¶¶

(5) "Cannabis" means the plant species Cannabis sativa and in these rules refers to all forms of the plant regardless of THC content.¶¶

(56) "Cannabis Tracking System" or "CTS" means the OLCC's system for tracking the transfer of marijuana items.¶¶

(67) "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.¶¶

(78) "Consumption" means ingestion, inhalation or topical application to the skin or hair.¶¶

(89) "Contiguous" for purposes of describing a production area means a single, uninterrupted geographical area where all parts of the production area are adjacent and connected to each other without any land, structure, or barrier separating any part of the production area. Up to eight feet of open tractor road is allowed within the production area.¶

(10) "Conviction" or "convicted" means any plea of guilty or nolo contendere, or any finding of guilt, except when the finding of guilt is subsequently overturned on appeal, pardoned, or expunged. A conviction is expunged when the conviction is removed from the individual's criminal history record and there are no legal disabilities or restrictions associated with the expunged conviction, other than the fact that the conviction may be used for sentencing purposes for subsequent convictions. In addition, where an individual is allowed to withdraw an original plea of guilty or nolo contendere and enter a plea of guilty and the case is subsequently dismissed, the individual is no longer considered to have a conviction.¶

(911) "Crop" means industrial hemp grown under a single license.¶

(102) "Cut microgreen" means microgreens that have been cut such that the root is fully removed from the remainder of the plant. The remainder of the plant is the cut microgreen.¶

(143) "Days" means calendar days unless otherwise specified in rule.¶

(124) "Department" means the Oregon Department of Agriculture.¶

(135) "Grower" means a person, joint venture or cooperative that produces industrial hemp and includes a person growing for research purposes.¶

(146) "Grow site" means one contiguous lot, parcel, or tract of land used to produce or intended to produce industrial hemp.¶

(157) "Flowering" means a hemp plant that has formed a mass of pistils measuring greater than two centimeters wide at its widest point.¶

(18) "Handler" means a person, joint venture or cooperative that:¶

(a) receives industrial hemp for processing into industrial hemp commodities, products, or agricultural hemp seed;¶

(b) processes industrial hemp commodities or products into hemp items; or¶

(c) trims industrial hemp; or¶

(d) packages hemp items.¶

(169) "Handling site" means one contiguous lot, parcel, or tract of land used to process or intended to process industrial hemp.¶

(1720) "Harvest" includes cutting of the cannabis plant such that the plant is no longer growing or removing part or all of the plant from the growing medium for the purpose of processing, storing, transfer or sale. Harvest does not include sampling for purposes of testing under OAR 603-048-0600, removal of all or part of the cannabis plant due to mold, pest, disease, or minimal pruning or removal of cannabis plants in the course of normal agricultural practices such as removing male plants.¶

(218) "Harvest Lot":¶

(a) Means a quantity of Cannabis of the same variety or strain harvested in a distinct timeframe that is:¶

(A) Grown in one ~~contiguous~~ production area within a grow site; or¶

(B) Grown in a ~~portion of one production area or within~~ portions of one ~~contiguous~~ production area within a grow site.¶

(b) Does not include a quantity of cannabis grown in noncontiguous ~~production areas~~.¶

(1922) "Harvest Lot Identifier" means a unique numerical identifier that begins with the name of the grow site, then the year of harvest, and then a unique number to identify the harvest lot. If a harvest lot is subsequently split into one or more lots for purposes of testing in OAR 603-048-2300 to 603-048-2480 or for purposes of retesting in accordance with OAR 603-048-0630(3), a unique letter shall be added to the end of the original harvest lot identifier to identify the split lots.¶

(203) "Hemp" means industrial hemp and these terms are used interchangeably.¶

(244) "Hemp Item" has the meaning provided in OAR 603-048-2310.¶

(225) "Immature hemp plant" means a ~~cannabis~~ hemp plant that is not flowering.¶

(236) "Immature plant lot" means a quantity of immature hemp plants tested, transferred or sold as one unit.¶

(247) "Immature plant lot identifier" means a unique numerical identifier that begins with the name of the grow site, then the year of production, and then a unique number to identify the immature plant lot. If an immature plant lot is subsequently split into one or more lots for purposes of testing, a unique letter shall be added to the end of the original immature plant lot identifier to identify the split lots.¶

(258) "Industrial hemp":¶

(a) Means the plant species Cannabis sativa, and any part of that plant whether growing or not including the seeds thereof, that contain an average total tetrahydrocannabinol concentration that does not exceed 0.3 percent on a dry weight basis.¶

(b) Includes, but is not limited to:¶

- (A) Industrial hemp that has been minimally preserved, for purposes of transfer or storage including chopping, separating, or drying;¶
- (B) Microgreens; and¶
- (C) Agricultural hemp seed.¶
- (c) Does not mean:¶
- (A) Industrial hemp commodities or products; or¶
- (B) Marijuana, as that is defined in ORS 475C.009 including but not limited to Cannabis seed produced by a marijuana plant.¶
- (269) Industrial Hemp Commodity or Product:¶
- (a) Means an item processed containing any industrial hemp or containing any chemical compounds derived from industrial hemp, including CBD derived from industrial hemp.¶
- (b) Includes:¶
- (A) Hemp concentrates or extracts as defined in OAR 603-048-2310;¶
- (B) Hemp edible as defined in OAR 603-048-2310;¶
- (C) Hemp tincture as defined in OAR 603-048-2310;¶
- (D) Hemp topical as defined in OAR 603-048-2310;¶
- (E) Hemp transdermal patch as defined in OAR 603-048-2310;¶
- (F) Industrial hemp processed through retting or other processing such that it is suitable fiber for textiles, rope, paper, hempcrete, or other building or fiber materials;¶
- (G) Industrial hemp seed processed such that it is incapable of germination and processed such that is suitable for human consumption;¶
- (H) Industrial hemp seed pressed or otherwise processed into oil;¶
- (I) Cut microgreens¶
- (c) Does not include:¶
- (A) Industrial hemp that has not been processed in any form;¶
- (B) Industrial hemp that has been minimally prepared for purposes of transfer or storage including chopping, separating, or drying;¶
- (C) Agricultural hemp seed or any Cannabis seed produced by a marijuana plant.¶
- (2730) "Industrial hemp for human consumption" has the meaning in OAR 603-048-2310.¶
- (2831) "Kief" means the resinous trichomes of hemp that accumulate or fall off when hemp flowers are sifted through a mesh screen or sieve.¶
- (329) "Key participant" means any person listed on an application for a license and:¶
- (a) If an applicant or key participant is a limited partnership, each general partner in the limited partnership;¶
- (b) If an applicant or key participant is a general partnership, each general partner in the general partnership;¶
- (c) If an applicant or key participant is a manager-managed limited liability company, each manager of the limited liability company as those terms are defined in ORS 63.001;¶
- (d) If an applicant or key participant is a corporation, each person with executive managerial control in a corporation. A person with executive managerial control includes, but is not limited to, any officer of the corporation;¶
- (e) Any individual or legal entity with an ownership interest in the applicant or a key participant;¶
- (f) If an applicant or key participant is a member-managed limited liability company, any individual or legal entity who holds or controls a direct or indirect interest of 20 percent or more in the applicant.¶
- (g) Any principal investigator of an applicant for a research grower license.¶
- (303) "Laboratory" means a laboratory that is licensed by the OLCC under ORS 475C.548 and accredited by the Oregon Health Authority under ORS 475C.560.¶
- (314) "Land Use Compatibility Statement (LUCS) is a document that is submitted to a city or county official to confirm whether a proposed activity or permit is consistent with local government land use regulations.¶
- (35) "License" means a license issued by the Department under ORS 571.281 and these rules.¶
- (326) "Licensed research grower" means a person licensed to produce hemp for research purposes only pursuant to OAR 603-048-0126.¶
- (337) "Licensee" means a grower, handler, agricultural hemp seed producer, licensed research grower, vendor or other person licensed under ORS 571.281 or these rules.¶
- (348) "Mature hemp plant" means a cannabis hemp plant that is not an immature hemp plant flowering.¶
- (359) "Microgreens" means seedling or small shoots of industrial hemp that have grown less than three inches in height from where the plant emerges from the soil or other growing medium to the tip of the plant greenery.¶
- (3640) "OLCC" means the Oregon Liquor and Cannabis Commission.¶
- (3741) "Ownership interest":¶
- (a) Includes any person or legal entity that exercises control over, or is entitled to exercise control over, the business. Control over the business includes but is not limited to the authority to enter a contract or similar

obligations on behalf of the business.¶¶

(b) Includes any individual or legal entity owning the real or personal property of the proposed licensed site unless the owner of the property has given control over the property to another party via a lease or rental agreement or similar agreement.¶¶

(c) Does not include an employee acting under the direction of the owner or other non-executive employees such as farm, field, or shift managers that do not make financial planning decisions and that do not vote or exercise control of the business.¶¶

~~(3842)~~ "Planting" or the action "plants" means placing a seed, cutting, or plant in the ground or other media for the purpose of growing, or being in possession of any such seed, cutting, or plant.¶¶

~~(439)~~ "Principal investigator" means an individual, ~~employed~~ retained by the applicant or licensee, who is primarily responsible for a hemp research project implemented or intended to be implemented under a research grower license.¶¶

~~(404)~~ "Process" means the processing, compounding, or conversion of industrial hemp into industrial hemp commodities or products or agricultural hemp seed. It also means further processing, compounding or conversion of industrial hemp commodities or products into hemp items. Process includes the basic preparation of commodities or products, the alteration of a commodity or product into another, and preservation and packaging techniques. Processing does not include minimal preparation of hemp for purposes of transfer or storage including chopping, separating, or drying.¶¶

~~(41)~~ "Production area" means a contiguous area at a grow site where industrial hemp is produced or is intended to be produced and may include a field, greenhouse, or other building.¶¶

~~(425)~~ "Process lot identifier" means a unique numerical identifier that begins with the last seven numbers of the handler's license number or the name of the handler, then the year of processing, and then a unique number to identify the process lot.¶¶

~~(43)~~ "Produce" means the planting, cultivation, growing, or harvesting of industrial hemp.¶¶

~~(446)~~ "Process lot" means:¶¶

(a) Any amount of hemp concentrate or extract of the same type and processed at the same time using the same extraction methods, standard operating procedures and batches from the same or different harvest lots; or¶¶

(b) Any amount of hemp cannabinoid products of the same type and processed at the same time using the same ingredients, standard operating procedures and batches from the same or different harvest lots or process lots of cannabinoid concentrate or extract.¶¶

~~(457)~~ "Produce" means the planting, cultivation, growing, or harvesting of industrial hemp.¶¶

~~(48)~~ "Production area" means a contiguous area at a grow site or proposed grow site where industrial hemp is produced or is intended to be produced and may include a field, greenhouse, raised bed, or other structure.¶¶

~~(49)~~ "Retest" or "Retesting" means the laboratory process of retesting a retained file sample for THC content after the sample failed initial testing for THC content under OAR 603-048-0600. A retest does not include or permit taking a new sample from the harvest lot.¶¶

~~(4650)~~ "Seed lot" means a quantity of cannabis seeds tested, transferred, or sold as one unit.¶¶

~~(4751)~~ "Seed lot identifier" means a unique numerical identifier that begins with the name of the grow site, then the year of production, and then a unique number to identify the seed lot identifier. If a seed lot is subsequently split into one or more lots for purposes of testing, a unique letter shall be added to the end of the original seed lot identifier to identify the split lots.¶¶

~~(4852)~~ "Structure" means any wall, door, building (including but not limited to greenhouses or hoop houses), fencing, or barrier which encloses, separates, or demarcates a space.¶¶

~~(53)~~ "Tetrahydrocannabinol" or "THC" means tetrahydrocannabinol and has the same meaning as delta-9 THC unless otherwise specified in the rule.¶¶

~~(549)~~ "These rules" means OAR 603-048-0010 to 603-048-2500.¶¶

~~(505)~~ "THCA" means (6aR,10aR)-1-hydroxy-6,6,9-trimethyl-3-pentyl-6a,7,8,10a-tetrahydro-6H-benzo[c]chromene-2-carboxylic acid, Chemical Abstracts Service Number 23978-85-.¶¶

~~(516)~~ "Total THC" means the sum of the concentration or mass of delta-9-THCA multiplied by 0.877 plus the concentration or mass of delta-9-THC.¶¶

~~(527)~~ "Trim" or "trimming" means the preparation or manicure of industrial hemp into usable hemp for retail sale.¶¶

~~(538)~~ "Unit of sale" means an amount of a hemp item commonly packaged for transfer or sale to a consumer or capable of being packaged for transfer or sale to a consumer.¶¶

~~(59)~~ "Vendor" means a person, including a retailer or wholesaler, that stores, transfers, or sells industrial hemp or hemp items for resale to another person, including to other vendors, wholesalers or consumers.¶¶

~~(5460)~~ "Vendor site" means a location or online domain where a vendor stores, transfers, offers for sale, or sells industrial hemp or hemp items.

Statutory/Other Authority: ORS 561.90, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

AMEND: 603-048-0100

RULE SUMMARY: Updates general licensing requirements

CHANGES TO RULE:

603-048-0100

Licensing, generally ¶

(1) Industrial hemp is an agricultural product subject to regulation by the Department.¶

(2) Only a licensee may sell, store, receive or transfer industrial hemp, except as provided in ORS 475C.305, ORS 571.266 and this rule.¶

(a) Laboratories are not required to be licensed with the Department to sample, test, or transfer or store industrial hemp for sampling and testing purposes; and¶

(b) Seed testing facilities with a registered seed technologist registered by the Society of Commercial Seed Technologist or certified seed analyst certified by the Association of Official Seed Analysts are not required to be licensed with the Department to sample, test, treat, or transfer or store industrial hemp seed or seedlings for sampling and testing purposes.¶

(c) A license is not required to transport or ship hemp or hemp products produced in accordance with 7 USC 1639 (<https://uscode.house.gov/statviewer.htm?volume=132&page=4914>), et seq. through the state.¶

(3) Licenses.¶

(a) Apply only to the individual or legal entity identified on an application that is approved and location listed by the Department.~~issued license~~¶

(b) Are a personal privilege and may not be transferred.¶

(c) May not be sold or transferred.¶

(4) For transfers and sales within Oregon, a licensee may only sell or transfer industrial hemp or agricultural hemp seed to:¶

(a) Another licensee; or¶

(b) An OLCC licensee in accordance with ORS 571.336, ORS 571.337, and rules adopted thereunder.¶

~~(5) A grower may not transfer or sell a growing mature hemp plant unless it has passed preharvest testing in accordance with OAR 603-048-0600.~~¶

~~(6) Restriction on industrial hemp product sales:~~¶

(a) For the purposes of this section, "consumer" means a person who purchases, acquires, owns, holds or uses industrial hemp products other than for the purpose of resale.¶

(b) A licensee may not ~~sell~~transfer, sell, or offer for sale an industrial hemp product that contains more than 0.3 percent total THC to a consumer unless the licensee is licensed as a retailer by OLCC.~~¶~~

~~(7, as provided in ORS 475C.257.~~¶

(c) Each unit of sale transferred, sold, or offered for sale is in violation of this rule is a separate violation.¶

(d) Beginning on January 1, 2026 a handler must adhere to Hemp Registry requirements in OAR Chapter 845, Division 26.¶

(6) Licensure and compliance with these rules does not protect a person from possible criminal prosecution under state or federal law or other sanctions by other governmental entities.

Statutory/Other Authority: ORS 561.190, ORS 571.260 - 571.348, 571.005, 475C.257

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-0125

RULE SUMMARY: Updates grower license requirements

CHANGES TO RULE:

603-048-0125

Grower Licensure

(1) Only a grower licensed with the Department may produce industrial hemp except as exempted in OAR 603-048-0100.¶

(2) Industrial hemp may only be produced at grow sites and within production areas included on the grower license except as exempted in OAR 603-048-0100.¶

(3) A licensed grower may use any propagation method, including planting seeds from, or starts, or the use of clones or cuttings, to produce industrial hemp.¶

(4) The Department shall make available to licensed growers information that identifies licensed agricultural hemp seed producers from whom growers may purchase agricultural hemp seed.¶

(5) Each grow site or production area identified by the Department that is not included on the grower license is a separate violation of section (2) of this rule.¶

(6) A licensed grower may trim industrial hemp produced by the grower without a handler license conduct the following activities only if the grower:¶

(a) Trims at the licensed grow site where the industrial hemp was produced;¶

(b) Submits to the Department prior to beginning any trimming activities a valid approved by the Department to do so: trim, manufacture kief, or make pre-rolls, per 603-048-0128.¶

(7)(a) A grower may only apply pesticides to ind-use compatibility statement (LUCS) stating that trimming is permitted signtrial hemp or hemp items that are included byon the local county or government with jurisdiction over the grow site; and¶

(c) Complies with all requirements applicable to handlers for the production of usable hemp.¶

(7) A licensed grower may manufacture kief from industrial hemp produced by the grower without a handler license only if the grower:¶

(a) Manufactures the kief at the licensed grow site where the industrial hemp was produced; Hemp Program's guide list or approved by the Environmental Protection Agency for use on industrial hemp.¶

(b) A grower must comply with all applicable laws and rules regulating pesticides.¶

(b8) Submits to the Department prior to beginning any kief-related activities a valid land use compatibility statement (LUCS) stating that kief manufacture is permitted signed by the local county or government with jurisdiction over the grow site;¶

(c) Complies with all requirements and restrictions applicable to handlers for the production of hemp products and commodities and all requirements and restrictions OLCC imposes on producale or transfer of growing immature hemp plants are only permitted as follows:¶

(a) The person making the sale or transfer must be a licensed grower and hold a valid ODA nursery license issued under ORS 475.065 for manufacturing kief in OAR Chapter 845, Division 25571.055;¶

(b) The person receiving the sale or transfer must be a licensed grower; and¶

(dc) Complies with all applicable testing requirements for kief in The licensees must comply with OAR 603-048-230500 to and 603-048-205500.¶

(89) For a grow site that proposes or is licensed to trim or manufacture kief, if the Department receives written notification from the jurisdiction where a proposed grow site or licensed grow site is located that the LUCS is invalid or is no longer valid, the Department may require the applicant or licensee to obtain a new LUCS. If a new LUCS is not submitted, the Department may deny or revoke the license. If the LUCS submitted states that the proposed land use is prohibited in the applicable zone or otherwise fails to demonstrate that the proposed activity is permitted, the Department shall revoke or deny the license.¶

(9) (a) A grower may only apply pesticides to industrial hemp or hemp items that are included on the Hemp Program's guide list or approved by the Environmental Protection Agency for use on industrial hemp.¶

(b) A grower must comply with all applicable laws and rules regulating pesticides. Sale or transfer of growing mature hemp plants are only permitted as follows:¶

(a) The person making the sale or transfer must be a licensed grower and hold a valid ODA nursery license issued under ORS 571.055;¶

(b) The plants must have passed preharvest testing in accordance with OAR 603-048-0600; and¶

(c) The licensees must comply with OAR 603-048-0500 and 603-048-0550¶

Note: The Hemp Program's guide list for pesticides is available from the Department.

Statutory/Other Authority: ORS 561.190, ORS 569.445, ORS 571.260 - 571.348, ORS 633.511-633.996

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-0126

RULE SUMMARY: Updates pre-registration violations

CHANGES TO RULE:

603-048-0126

Pre-Registration Violations

(1)(a) Except as provided in paragraph (b) of this subsection, if a person plants an industrial hemp crop or commits a violation of ORS 571.260 to 571.348 prior to applying for a grower license, the Department shall refuse to issue a license to the person.¶¶

(b) If the crop described in paragraph (a) of this subsection is removed and the Department determines that the violation is resolved, the person described in paragraph (a) of this subsection may apply for a license under ORS 571.281. The crop must be disposed of in accordance with OAR 603-048-0640 within 14 calendar days of the Department's notification to the person, unless the Department grants an extension in writing.¶¶

(2) If a person plants an industrial hemp crop or commits a violation of ORS 571.260 to 571.348 prior to being issued a grower license under ORS 571.281, the Department shall:¶¶

(a)(A) Prioritize the person's industrial hemp crop for inspection under ORS 571.281 (7), if the person planted the industrial hemp crop as described in this subsection; and¶¶

(B) Require the person to enter into a corrective action plan as described in OAR 603-048-0800(6) with the Department; or¶¶

(b) Refuse to issue a license to the person if the Department determines that a corrective action plan is insufficient to address the violation.¶¶

(3) If the person described in section (2) of this rule does not enter into a corrective action plan pursuant to OAR 603-048-0800(6), the Department may not issue a license to the person under ORS 571.281.¶¶

(4) If the person described in section (2) of this rule refuses to permit or cooperate as described in OAR 603-048-0650(3) with a pre-licensure inspection or a pre-licensure sampling for THC content as described in OAR 603-048-0200(9) or refuses to obtain pre-licensure pre-harvest testing as requested by the Department, the Department may refuse to issue a license to the person under ORS 571.281.¶¶

(5) Planting an industrial hemp crop for the purposes of this rule includes ~~the planting of~~ growing cannabis plants at the same location a person identifies as a proposed grow site in a grower application unless the cannabis plants are permitted under ORS 475C.305, ORS 571.266, a license issued pursuant to ORS 475C.065, or a medical marijuana grow site registered under ORS 475C.792.

Statutory/Other Authority: ORS 561.190, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

RULE SUMMARY: Updates grower research license requirements

CHANGES TO RULE:

603-048-0127

Grower Research License

- (1) ~~Beginning on January 1, 2022, a~~ A person proposing to grow hemp for research purposes only may apply for a research grower license.¶¶
- (2) All of the provisions regarding growers in these rules apply to licensed research growers except as explicitly exempted or provided otherwise in this rule.¶¶
- (a) When submitting an application for a research grower license, the applicant must include the address of research facilities where cannabis from the licensed grow site may be stored, handled, tested, or otherwise researched.¶¶
- (b) When submitting an application for a research grower license, the applicant must submit the following:¶¶
- (A) A written research plan that identifies the purpose of the research for conducting the research. The plan must identify the amount of cannabis intended to be grown. It must also identify how the applicant will ensure the plants and plant material remains at the grow site and prevent the material from entering the commercial marketplace.¶¶
- (B) A written destruction plan that identifies when and how an applicant will timely dispose of plants grown under the license.¶¶
- (C) If co-located with an industrial hemp grow, meet requirements established in OAR 603-048-0520.¶¶
- (D) Any other information pertinent to the research specifically requested by the Department.¶¶
- (c) An applicant for a research grower license must submit the fee for a grower license in OAR 603-48-0700(1)(a) with its application but is not required to submit a fee for a grow site license. The applicant must identify every grow site in the application.¶¶
- (d) A licensed research grower is not required to conduct preharvest testing in accordance with OAR 603-048-0600 except as required for transfers.¶¶
- (e) A licensed research grow site or research facility may not be co-located with a medical marijuana grow site registered under ORS 475C.792 or marijuana producer licensed under ORS 475C.065.¶¶
- (3) A licensed research grower must:¶¶
- (a) Except as permitted in section 4 of this rule, ensure that all cannabis, and all parts thereof, grown under the license remains at the licensed grow site, research facility listed on the application, or laboratory and that the cannabis does not enter the commercial marketplace or used by a consumer.¶¶
- (b) Dispose in accordance with OAR 603-048-0640 all cannabis, and all parts thereof, grown under the license in the grower's possession within 30 days of completing research activities on the cannabis and prior to the termination of the license.¶¶
- (4) Sale and Transfers.¶¶
- (a) A licensed research grower may not sell or transfer any cannabis, or parts thereof, grown under the research grower license to any other person or otherwise allow the cannabis to enter the commercial marketplace, be used by a consumer, or leave the licensed grow site or research facility listed on the application, except as explicitly permitted in this rule.¶¶
- (b) A licensed research grower may send samples of cannabis, or parts thereof, grown under the research grower license to a laboratory for testing.¶¶
- (c) A licensed research grower may sell or transfer cannabis, or parts thereof, grown under the research grower license to a licensed grower if the cannabis has passed pre-harvest testing in accordance with OAR 603-048-0600 prior to transfer.¶¶
- (d) A licensed research grower may sell or transfer cannabis, or parts thereof, grown under the research grower license to another licensed research grower.¶¶
- (5) The Department must deny an application for a research grower license and revoke a research grower licensee if the proposed or licensed grow site or research facility is co-located with a medical marijuana grow site registered under ORS 475C.792 or a marijuana producer licensed under ORS 475C.065.¶¶
- (6) The following are Class 1 violations:¶¶
- (a) Failing to comply with any part of this rule.¶¶
- (b) Failing to comply with a written research plan.¶¶
- (c) Failing to comply with a written destruction plan.¶¶
- (d) Failing to comply with any condition placed on the license by the Department.¶¶
- (e) Failing to comply with a Department order.¶¶
- (7) The Department may impose conditions on the grower research license that the Department determines

necessary to be consistent with ORS 571.260 to ORS 571.348 or these rules or to ensure that cannabis does not enter the chain of commerce.

Statutory/Other Authority: ORS 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

ADOPT: 603-048-0128

RULE SUMMARY: Creates grower endorsements

CHANGES TO RULE:

603-048-0128

Grower Endorsements

(1) A licensed grower may trim industrial hemp produced by the grower without a handler license only if the grower:¶

(a) Trims at the licensed grow site where the industrial hemp was produced;¶

(b) Submits to the Department prior to beginning any trimming activities a valid LUCS stating that trimming is not prohibited signed by the local county or government with jurisdiction over the grow site; and¶

(c) Complies with all requirements applicable to handlers for the production of usable hemp.¶

(2) A licensed grower may manufacture kief from industrial hemp produced by the grower without a handler license only if the grower:¶

(a) Manufactures the kief at the licensed grow site where the industrial hemp was produced;¶

(b) Submits to the Department prior to beginning any kief-related activities a valid LUCS stating (LUCS) stating that kief manufacture is not prohibited signed by the local county or government with jurisdiction over the grow site;¶

(c) Complies with all requirements and restrictions applicable to handlers for the production of hemp products and commodities and all requirements and restrictions OLCC imposes on producers licensed under ORS 475.065 for manufacturing kief in OAR Chapter 845, Divisions 25 and 26; and¶

(d) Complies with all applicable testing requirements for kief in OAR 603-048-2300 to 603-048-2500.¶

(3) A licensed grower may manufacture hemp pre-rolls without a handler license only if under the following circumstances:¶

(a) The pre-roll consists of only dried hemp leaves and flowers, an unflavored rolling paper and a filter or tip.¶

(b) The grower manufactures the pre-rolls at the licensed grow site where the industrial hemp used for the pre-roll was produced;¶

(c) The grower submits to the Department prior to beginning any pre-roll-related activities a LUCS stating that pre-roll manufacture is not prohibited signed by the local county or government with jurisdiction over the grow site;¶

(d) The grower complies with all requirements and restrictions applicable to handlers for the production of hemp products and commodities and all requirements and restrictions OLCC imposes on producers licensed under ORS 475.065 for manufacturing pre-rolls in OAR Chapter 845, Divisions 25 and 26; and¶

(e) Complies with all applicable testing requirements for pre-rolls in OAR 603-048-2300 to 603-048-2500.¶

(4) For a grow site that proposes or is licensed to trim industrial hemp, manufacture kief, or manufacture pre-rolls, if the Department receives written notification from the jurisdiction where a proposed grow site or licensed grow site is located that the LUCS is invalid or is no longer valid, the Department may require the applicant or licensee to obtain a new LUCS. If a new LUCS is not submitted, the Department may deny or revoke the license. If the LUCS submitted states that the proposed land use is prohibited in the applicable zone or otherwise fails to demonstrate that the proposed activity is permitted, the Department shall revoke or deny the license.¶

(5) The Department may suspend or revoke an existing endorsement if the handler does not comply with rules pertaining to that endorsement.

Statutory/Other Authority: ORS 561.191, 571.260 - 571.348

Statutes/Other Implemented: 571.260 - 571.348

AMEND: 603-048-0150

RULE SUMMARY: Updates handler licensure requirements

CHANGES TO RULE:

603-048-0150

Handler Licensure

(1) Only a handler licensed with the Department may process industrial hemp or further process a hemp item.¶

~~(2) Industrial hemp may only be processed at handling sites included, except as otherwise permitted under these rules.¶~~

~~(2) A handler may only process industrial hemp, commodities, or products as identified on an approved LUCS and as approved only by the handler's license. A hemp handling license must be obtained from the Department. This requirement becomes effective on July 1, 2026.¶~~

~~(3) Industrial hemp may only be processed at the sites indicated on the handler's license. A handler must obtain a separate license for each handling site.¶~~

~~(3) Handling sites may not be moved or relocated.¶~~

~~(4) Beginning on January 1, 2026 a handler must adhere to Hemp Registry requirements in OAR Chapter 845, Division 26.¶~~

~~(5) Handler Licensure by Reciprocity. A marijuana processor licensed under ORS 475C.085 with a hemp endorsement as described in OAR 845-025-3210 from the OLCC may be licensed by reciprocity with the Department as a handler in accordance with OAR 603-048-0225(5). A marijuana processor licensed by reciprocity:¶~~

~~(a) Is deemed to be in compliance with the recordkeeping requirements in OAR 603-048-0500 if the marijuana processor tracks all industrial hemp and industrial hemp products and commodities in the Cannabis Tracking System as required by OAR Chapter 845, Division 25.¶~~

~~(b) Is deemed to be in compliance with testing requirements for hemp items if the marijuana processor tests all hemp items as required in OAR Chapter 845, Division 25.~~

Statutory/Other Authority: ORS 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

ADOPT: 603-048-0151

RULE SUMMARY: Creates handler endorsements

CHANGES TO RULE:

603-048-0151

Handler Endorsements

(1) For licenses issued on or after June 31, 2026, a handler may only process hemp edibles, hemp topicals, hemp concentrates, or hemp extracts if the handler has a current endorsement from the Department for that type of processing activity. Endorsements types are:

(a) Hemp edible;

(b) Hemp topical;

(c) Hemp concentrate; and

(d) Hemp extract.

(2) To request an endorsement, an applicant must submit the documents as described in section 3 of this rule with the applicant's initial handler application or at any time following licensure with a change form.

(3) To apply for an endorsement, a handler applicant or handler licensee must submit:

(a) A form prescribed by the Department that identifies the proposed endorsements;

(b) A land use compatibility statement showing that any proposed handler endorsements are not prohibited uses; and

(c) For application for an extraction endorsement and if required by the local governing body for other endorsement types, proof of passing inspection of extraction equipment by a professional engineer and a certificate of occupancy from the local governing body.

(4) A handling site may have multiple endorsements.

(5) For the purposes of endorsements, any hemp cannabinoid product that is intended to be consumed or ingested orally or applied in the mouth is considered a hemp edible.

(6) The Department may deny a handler's request for an endorsement or suspend or revoke an existing endorsement if the handler cannot or does not comply with rules pertaining to that endorsement.

(7) The Department may cancel an endorsement or handler license if the license is found to be exercising endorsement privileges without having been approved for that endorsement or continuing to exercise that endorsement after receiving notice that the landowner or local governing body has revoked permission to do so.

(8) Violations. Processing without the required endorsement is a Class I violation.

Statutory/Other Authority: ORS 561.191, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

AMEND: 603-048-0175

RULE SUMMARY: Updates vendor site license requirements

CHANGES TO RULE:

603-048-0175

Vendor Site License

(1) Effective July 1, 2024, a vendor must have a license with the Department under these rules for each vendor site prior to storing, transferring, offering for sale, or selling industrial hemp or hemp items to consumers in Oregon except:¶

(a) A license is not required if the person only facilitates the sale or transfer by connecting buyers and sellers and the person does not store the industrial hemp or hemp items at any time.¶

(b) A licensed grower, handler, or agricultural hemp seed producer is not required to be licensed with the Department as a vendor site to store, transfer, or sell industrial hemp or hemp items the licensee produced or processed if the licensee first notifies the Department of the location where the industrial hemp or hemp items are stored, transferred, or sold in the license application or on another form provided by the Department.¶

(c) A license is not required for a vendor site licensed by OLCC under ORS 475C.065, 475C.085, 475C.093, or 475C.097.¶

(d) A license is not required for a person who only transports industrial hemp or hemp items and does not store the industrial hemp or hemp items at any time other than as necessary for transportation or delivery.¶

(2) A vendor site license is effective the day the Department issues the license and expires annually on June 30. Fees are not prorated.¶

(3) A vendor site license applies only to the vendor site identified on the license. ~~A vendor; each address~~ must obtain a separate license ~~for each vendor site~~. Vendor sites may not be moved or relocated.¶

(4) For an online vendor, a vendor site license may apply to all webpages that are part of the second level domain name.¶

(45) Each unlicensed vendor site identified by the Department is a separate violation of section (1) of this rule.¶

(6) Beginning on January 1, 2026 a vendor must adhere to Hemp Registry requirements in OAR Chapter 845, Division 26.¶

(7) In addition to record keeping requirements of 603-048-0500, at the point of sale to a consumer and until three years after a product is out of inventory, a vendor must have immediately available for viewing a copy of certificate of analysis for each hemp product showing passing full compliance testing.

Statutory/Other Authority: ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.263, 571.269, 571.281

AMEND: 603-048-0200

RULE SUMMARY: Updates grower licensure applications and review requirements

CHANGES TO RULE:

603-048-0200

Grower Licensure Applications and Review ¶¶

(1) Licenses are valid for a one-year term beginning on January 1 of each calendar year. Licenses granted after January 1 are effective on the date issued.¶¶

(a) An applicant must submit, and the Department must receive, a complete application and applicable fees by no later than May 31 of the calendar year for any grower license.¶¶

(b) An applicant may submit a grower application late if received by the Department by no later than July 31 and submitted with the late fee for each grow site application identified in OAR 603-048-0700.¶¶

(c) An applicant is not subject to the May 31 deadline if the applicant has purchased land with an active grower license. No new production areas or grow sites other than those included in the original license may be added or moved after May 31 unless submitted with the late fee identified in OAR 603-048-0700 for each new grow site before July 31.¶¶

(2) The Department shall review and act on applications in the order they are received. An individual is not licensed with the Department until the Department has approved the license and notified the applicant of licensure.¶¶

(3) To apply for a grower license, an applicant must submit to the Department:¶¶

(a) A complete grower license application on a form provided by the Department;¶¶

(b) A complete grow site application on a form provided by the Department for each proposed grow site;¶¶

(c) All applicable fees as described in OAR 603-048-0700; and¶¶

(d) Consent to a criminal records check by fingerprint identification for the applicant or if the applicant is a legal entity, submit a consent for every key participant in the applicant entity in accordance with ORS 181A.195, ORS 181A.200 and OAR chapter 125, division 7 and the Department's directives. To complete the criminal records check, the Department may require additional information, documents, or action including, but not limited to, fingerprint identification, proof of identity, or additional criminal, judicial, or other background information at any time. Consent for a criminal records check is required only if the applicant or key participant has not passed a criminal records check with the Department in the previous two licensing years or if otherwise required by the Department. The Department may, in its discretion, require a criminal records check at any time.¶¶

(e) An informed consent form prescribed by the Department if the applicant is not the owner of the premises where the grow site will be located. The consent form:¶¶

(A) Is valid for only the grower or growers named on the consent form.¶¶

(B) Must be signed by the owner of the premises or the property owner's legal representative for the grow site and must not have been terminated.¶¶

(f) Documentation of lawful participation in a pilot program prior to December 20, 2018, if the applicant or any key participant is disqualified due to a felony conviction relating to a controlled substance within the last ten years from the date of application but asserts the convicted individual was growing hemp lawfully under a pilot program authorized by Section 7606 of the Agricultural Act of 2014 before December 20, 2018.¶¶

(g) Any other documents or information requested by the Department.¶¶

(4) A person seeking to produce or process agricultural hemp seed must separately apply for and obtain an agricultural hemp seed producer license as described in OAR 603-048-0300.¶¶

(5) A grower license application must include the following information:¶¶

(a) The name, legal type of applicant (individual, corporation, etc.).¶¶

(b) Contact information for the applicant.¶¶

(c) For business entities, principal place of business for licensee, Oregon Secretary of State registry number, names of all key participants, employer identification number, and contact information, including phone number and e-mail of all key participants;¶¶

(d) A primary contact person who the Department can contact to arrange for onsite inspections or for questions regarding the application or license and contact information (phone number, email) for the primary contact person.¶¶

(e) The address of each grow site;¶¶

(f) Other information specified by the Department in the application, including but not limited to:¶¶

(A) The intended use of the industrial hemp (flower, seed, and/or fiber); and¶¶

(B) The intended number of acres or square feet to be cultivated.¶¶

(g) Any other information or forms required by the Department.¶¶

- (h) For each proposed grow site location, a completed grow site application form with the following information:¶
- (A) The address of the grow site;¶
 - (B) A grow site map that identifies:¶
 - (i) All points of ingress or egress to the property, including roads;¶
 - (ii) All structures or buildings;¶
 - (iii) For any structures or buildings where hemp will be grown, any rooms, walls, doors, and windows in those structures;¶
 - (iv) All production areas using clear boundaries and any barriers or structures within or between production areas.¶
 - (C) Information for each ~~non-contiguous~~ production area, as described in subsection (C) and (D) of this rule.¶
 - (D) If in the production area is a field:¶
 - (i) The global positioning system (GPS) coordinates provided in decimal of degrees and taken at the approximate center of the growing field; ~~and~~¶
 - (ii) The number of square feet or acres of each cultivated field; ~~and~~¶
 - (iii) ~~A map of the grow site showing clear boundaries of the production area;~~¶
 - (E) If in the production areas is a greenhouse or other building:¶
 - (i) The global positioning system (GPS) coordinates provided in decimal of degrees and taken at the approximate center of the greenhouse or other building; ~~and~~¶
 - (ii) The approximate dimension or square feet of the greenhouse or other building; ~~and~~¶
 - (iii) ~~A map of the grow site showing clear boundaries of each production area.~~¶
 - (6)-(a) To add a grow site or a production area to an existing grower license during the licensed calendar year, the licensed grower must:¶
 - (A) For additions submitted by May 31 of the license year, submit a complete grow site application form or change form and change fee identified in OAR 603-048-0700 to the Department.¶
 - (B) For additions submitted after May 31 but no later than July 31, submit a complete grow site application form or change form and a late fee identified in OAR 603-048-0700 for each grow site application.¶
 - (b) A grower may request that the Department remove a grow site or productions area at any time without a fee. The Department may approve or deny the request. Grow sites and production areas may not be moved or relocated.¶
 - (c) A grow site or production area may not be added after July 31.¶
 - (7) Renewal Application.¶
 - (a) A person with a current valid license may apply for a renewal license by ~~submitting a complete renewal~~ applying as described in subsection (3) and (5) of this rule, submitting an application on a form provided by the Department.¶
 - (b) The Department must receive the complete renewal application and all applicable fees ~~described in OAR 603-048-0700~~ by no later than December 1 of the current license year.¶
 - (c) All application requirements for an initial license apply to a renewal application.¶
 - (d) The Department shall deny an applicant for a renewal if the applicant fails to report the information required in OAR 603-048-0400(7). An application received after December 1 will be treated as an initial application.¶
 - (8) In addition to the requirements in sections (3) to (7), all applicants must acknowledge and agree in the application that:¶
 - (a) Any information provided to the Department may be publicly disclosed and may be provided to law enforcement agencies without notice to the applicant or licensee;¶
 - (b) The Department, or its designee, may enter any field, facility or greenhouse used for the production or handling of industrial hemp or agricultural hemp seed and may take samples of industrial hemp or agricultural hemp seed as necessary for the administration of the Department's laws.¶
 - (c) All fees lawfully due to the Department will be timely paid.¶
 - (d) The information provided is true and correct and that applicant's signature is an attestation of that fact.¶
 - (9) The Department, in its discretion, may require an inspection of the grow site prior to licensure. The inspection may include sampling for THC testing. The Department, in its discretion, may require an applicant to conduct pre-harvest testing on any cannabis present at the grow site prior to licensure and submit passing test results to the Department.¶
 - (10) Incomplete Applications.¶
 - (a) If an applicant does not provide all information or documentation required by rule or pay the applicable fee, the Department shall reject the application as incomplete.¶
 - (b) If an application is illegible or is substantially incomplete, the Department may summarily reject the application as incomplete. If an applicant fails to provide all information or documentation required, the Department may notify the applicant of the missing information or documentation and allow the applicant 15 days to submit the

missing information or documentation. If the applicant fails to timely submit all the missing information or documentation, the Department shall reject the application as incomplete.¶

(c) The Department may verify the information submitted, verify any accompanying documentation submitted with an application, or request additional information, documentation, or attestation from the applicant to ensure compliance with ORS 571.260 to ORS 571.348. If an applicant fails to timely submit information, documentation, criminal history check, or attestation requested by the Department, the Department shall reject the application as incomplete.¶

(d) An applicant whose application is rejected as incomplete may reapply until May 31 of the calendar year or July 31 with the late fee identified in OAR 603-048-0700. If the individual reapplies by May 31 of the calendar year or July 31 with the late fee identified in OAR 603-048-0700, the application fee may be applied to a new application. An applicant who reapplies after May 31 shall be denied unless they apply by July 31 and submit the late fee identified in OAR 603-048-0700.¶

(11) Denial.¶

(a) The Department must deny an initial or renewal grow site and grower application if:¶

(A) The applicant fails to satisfy any of the requirements for initial licensure.¶

(B) The applicant or any key participant has been convicted of a felony relating to a controlled substance within the last ten years from the date of application unless the conviction also occurred before December 20, 2018, the convicted individual was growing hemp lawfully under a pilot program authorized by Section 7606 of the Agricultural Act of 2014 before December 20, 2018, and documentation of the participation is submitted with the application.¶

(C) The applicant or any key participant plants an industrial hemp crop or commits a violation of ORS 571.260 to ORS 571.348 prior to applying for a grower license unless:¶

(i) the applicant disposes the industrial hemp crop in accordance with OAR 603-048-0640 within 14 days of the Department's notification to the applicant, unless the Department grants an extension in writing; and¶

(ii) the Department determines the violation is resolved.¶

(D) Required to deny under OAR 603-048-0126.¶

(E) The applicant or any key participant materially falsifies any information or documentation submitted in or with an application.¶

(F) Any production areas identified in the application are within the boundaries of another licensed hemp grow site, a licensed recreational marijuana premises, or a plot at a medical marijuana grow site.¶

(G) The applicant or licensee has outstanding civil penalties and is not making payments consistent with a repayment plan agreed upon by the Department.¶

(b) The Department may deny an initial or renewal grow site or grower application if:¶

(A) The applicant or any key participant violated or has a history of noncompliance with:¶

(i) A provision of ORS 571.260 to ORS 571.348;¶

(ii) A rule adopted under a provision of ORS 571.260 to ORS 571.348;¶

(iii) An order issued by the Department pursuant to a provision of ORS 571.260 to ORS 571.348 or a rule adopted thereunder, including a detention order;¶

(iv) Any statutory law or Department rule related to agricultural activities other than industrial hemp operations.¶

(B) The application, or material submitted with or to supplement the application, contains false, misleading, or incorrect information;¶

(C) The applicant is a legal entity that is required to be registered with the Oregon Secretary of State but does not have an active registration;¶

(D) The owner of the proposed grow site or the property owner's legal representative notifies the Department in writing that they have withdrawn consent for applicant to produce hemp at the proposed grow site location; or¶

(E) The applicant, or any key participant, has a history of noncompliance with OLCC statutes or rules regarding the prohibition on the unregulated commerce of marijuana items including but not limited to any violation or disciplinary action under ORS 475C.185 or OAR 845-025-8590(2)(e).¶

(F) Issuing the license would be a violation of or inconsistent with the Agriculture Improvement Act of 2018 (P.L. 115-334) or 7 CFR Part 990.¶

(G) The applicant fails to complete pre-harvest testing in accordance with OAR 603-048-0600 upon Department request, cannabis at the proposed grow site fails pre-harvest testing, or any cannabis at the proposed grow site exceeds 0.3 percent total THC and is not otherwise permitted by ORS 475C.305 or under a license issued under ORS 475C.¶

(12) Ineligibility based on past noncompliance.¶

(a) A grower, and all key participants, is ineligible for a grower license for a period of five years if the grower commits three of any of the violations below over a five-year-period:¶

(A) the grower produces cannabis that exceeds 1.0 percent THC on a dry weight basis;¶

(B) the grower fails to provide a legal description of land on which the grower produces hemp;¶

(C) the grower fails to obtain a license under these rules prior to producing hemp.¶

(b) Only for the purposes of determining ineligibility under subsection (a) of this rule:¶

(A) A grower shall accrue a maximum of one violation per year.¶

(B) The period of ineligibility begins on the date that the last violation is found in a final order by the Department.¶

(c) A grower, and all key participants, is ineligible for a grower license for a period of two year from the date a final order is entered revoking the grower's license, except for final orders issued pursuant to subsection (a) of this rule where the ineligibility period of five years.¶

(d) A grower or key participant whose application is denied under OAR 603-048-0126(1)(a) or section (11)((b), (B), or (E) of this rule, is ineligible for a period of two year from the date a final order is entered denying the grower's license, except for final orders issued pursuant to subsection (a) of this rule where the ineligibility period is five years.¶

(e) A grower or key participant ineligible under this rule may not apply or reapply for a grower license during the period of ineligibility.¶

(f) The Department must deny any grower application submitted by a person ineligible under this rule and shall revoke the license of a person who is ineligible under this rule.¶

(g) Nothing in this rule prevents the Department from assessing multiple violations or from taking other action to revoke or deny a license or impose civil penalties.¶

(13) The Department may place an application on hold if the applicant, licensee, ~~or~~ any key participant, or the proposed grow site is currently under investigation for violation of ORS 571.260 to 571.348, these rules, other cannabis laws or statutes, or pending a disciplinary action with the Department,¶

(14) The Department may not issue a license to an applicant that is a legal entity if it is required to be registered with the Oregon Secretary of State but does not have an active registration.

Statutory/Other Authority: ORS 561.120, 561.200, 561.275, 561.190, 569.445, ORS 571.260-571.348, 633.511-633.996

Statutes/Other Implemented: ORS 571.260-571.348

RULE SUMMARY: Updates handler applications and review requirements

CHANGES TO RULE:

603-048-0225

Handler Applications and Review

- (1) Licenses are valid for a one-year term beginning on January 1 of each calendar year. Licenses granted after January 1 are effective on the date issued.¶
- (2) Renewal Application. A person with a current valid license may apply for a renewal license by submitting a complete renewal application and renewal fee to the Department by no later than December 1 of the current license year. All application requirements for an initial license apply to an application for renewing a license.¶
- (3) The Department shall review and act on applications in the order they are received. An individual is not licensed with the Department until the Department has approved the license and notified the licensee of licensure.¶
- (4) To apply for a handler license, an applicant must submit to the Department:¶
 - (a) A complete application to the Department on forms provided by the Department; and¶
 - (b) All applicable fees as described in OAR 603-048-0700.¶
- (5) A person seeking to produce or process agricultural hemp seed must separately apply for and obtain an agricultural hemp seed producer licensure as described in OAR 603-048-0300.¶
- (6) An application for a handler licensure must:¶
 - (a) Include all the following information:¶
 - (A) The name, legal type of applicant (individual, corporation, etc.), Oregon Secretary of State business registry number for if legal entity required to be registered, and contact information of the applicant;¶
 - (B) The name and address of applicant's handling site;¶
 - (C) A primary contact person who the Department can contact to arrange for onsite inspections or for questions regarding the application or license and contact information (phone number, email) for the primary contact person.¶
 - (D) Other information for purposes of studying the growth, cultivation, and marketing of industrial hemp as specified by the Department in the application.¶
 - (b) Include a completed copy of the Department land use compatibility statement (LUCS) for each hemp operation location signed by the local county or government.¶
 - (c) An informed consent form prescribed by the Department if the applicant is not the owner of the premises where the handling site will be located. The consent form:¶
 - (A) Is valid for only the applicant(s) named on the consent form.¶
 - (B) Must be signed by the owner of the premises or the property owner's legal representative for the handler site and must not have been terminated.¶
 - (d) Include any other information or forms required by the Department.¶
- (7) In addition to the requirements in sections (4) to (6), all applicants for licensure must acknowledge and agree that:¶
 - (a) Any information provided to the Department may be publicly disclosed and may be provided to law enforcement agencies without notice to the applicant or licensee;¶
 - (b) The Department, or its designee, may enter any facility used for processing and may take samples of industrial hemp, agricultural hemp seed, or industrial hemp products or commodities as necessary for the administration of the Department's laws.¶
 - (c) All fees lawfully due to the Department will be timely paid.¶
 - (d) Licensure and compliance with these industrial hemp rules may not protect a person from possible criminal prosecution under federal law or other sanctions by federal entities, or from possible criminal prosecution under the laws of other states.¶
- (8) The Department, in its discretion, may require an inspection of the handling site prior to issuing a license.¶
- (9) Incomplete Applications.¶
 - (a) If an applicant does not provide all of the information or documentation required in rule or otherwise required by the Department of this rule or pay the applicable fee, the Department shall reject the application as incomplete.¶
 - (b) If an application is illegible or is substantially incomplete, the Department may summarily reject the application as incomplete. If an applicant fails to provide all of the information required, the Department may notify the applicant of the missing information and allow the applicant 15 days to submit the missing information.¶
 - (c) The Department may verify the information submitted, verify any accompanying documentation submitted with an application, or request additional information, documentation, or attestation from the applicant to ensure

compliance with ORS 571.260 to ORS 571.348 and these rules. If an applicant fails to timely submit information, documentation, or attestation requested by the Department, the Department shall reject the application as incomplete.¶¶

(d) An applicant whose application is rejected as incomplete may reapply at any time. If the individual reapplies within the year, the application fee may be applied to a new application.¶¶

(10) Denial.¶¶

(a) The Department must deny an initial or renewal application if:¶¶

(A) The LUCS submitted states that the proposed land use is prohibited in the applicable zone or the LUCS fails to demonstrate that the proposed license activity is permitted; or¶¶

(B) The applicant fails to satisfy any of the requirements for initial licensure.¶¶

(b) The Department may deny an initial or renewal application if:¶¶

(A) The applicant violated or has a history of noncompliance with:¶¶

(i) A provision of ORS 571.260 to ORS 571.348;¶¶

(ii) A rule adopted under a provision of ORS 571.260 to ORS 571.348;¶¶

(iii) An order issued by the Department pursuant to a provision of ORS 571.260 to ORS 571.348 or a rule adopted thereunder, including a detainment order;¶¶

(iv) Any statutory law or Department rule related to agricultural activities other than industrial hemp operations.¶¶

(v) State or federal laws related to the unlawful manufacture, delivery, export or import of marijuana.¶¶

(B) The application, or documents submitted with the application, contains false, misleading, or incorrect information; ~~or~~¶¶

(C) The applicant is a legal entity that is required to be registered with the Oregon Secretary of State but does not have an active registration.¶¶

(D) The applicant, ~~or any key participant~~ individual member of applicant, has a history of noncompliance with OLCC statutes or rules regarding the prohibition on the unregulated commerce of marijuana including but not limited to any violation or disciplinary action under ORS 475C.185 or OAR 845-025-8590(2)(e).¶¶

(E) There is cannabis plant material at the proposed handling site that:¶¶

(i) Exceeds 3 percent total THC a dry weight basis calculated in accordance with OAR 333-064-0100(4) that is not otherwise permitted by ORS 475A.305 or under a license issued by OLCC under ORS 475C.¶¶

(ii) Exceeds permissible possession limits under ORS 475A.305 and is not otherwise authorized under a license issued by OLCC under ORS 475C.¶¶

(11) Licensure by Reciprocity. A marijuana processor licensed under ORS 475C.085 with a hemp endorsement as described in OAR 845-025-3210 from the OLCC may apply for a handler license by submitting to the Department:¶¶

(a) A complete reciprocity handler licensure application on forms provided by the Department;¶¶

(b) A copy of the marijuana processor's current license and hemp endorsement;¶¶

(c) All applicable fees as described in OAR 603-048-0700; and¶¶

(d) Any other forms or documents required by the Department.¶¶

(12) Ineligibility based on past noncompliance.¶¶

(a) A handler is ineligible for a handler license for a period of two year from the date a final order is entered revoking the handler's license.¶¶

(b) A handler whose application is denied under section (10)(b)(A), (B), or (D) of this rule is ineligible for a period of two year from the date a final order is entered denying the handler's license.¶¶

(c) A handler ineligible under this rule may not apply or reapply for a handler license during the period of ineligibility.¶¶

(d) The Department must deny any handler application submitted by a person ineligible under this rule and shall revoke the license of a person who is ineligible under this rule.¶¶

(13) The Department may place an application on hold if the applicant ~~or~~ licensee, or proposed site is currently under investigation for violation of ORS 571.260 to 571.348 or these rules ~~or~~, pending a disciplinary action with the Department, or under investigation for violating a state or federal law related to the unlawful manufacture, delivery, export or import of marijuana.¶¶

(14) If the Department receives written notification from the jurisdiction where a proposed handling site or licensed handling site is located that the LUCS is invalid or is no longer valid, the Department may require the applicant or licensee to obtain a new LUCS. If a new LUCS is not submitted, the Department may deny or revoke the license. If the LUCS submitted states that the proposed land use is prohibited in the applicable zone or otherwise fails to demonstrate that the proposed licensed activity is permitted, the Department shall revoke or deny the license.¶¶

(15) The Department may not issue a license to an applicant that is a legal entity that is required to be registered with the Oregon Secretary of State but does not have an active registration.¶¶

(16) The applicant or licensee has outstanding civil penalties and is not making payments consistent with a

repayment plan agreed upon by the Department.

Statutory/Other Authority: ORS 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

AMEND: 603-048-0300

RULE SUMMARY: Updates agricultural hemp seed producer license application and review requirements

CHANGES TO RULE:

603-048-0300

Agricultural Hemp Seed Producer License Application and Review

- (1) Only a grower licensed with the Department may produce agricultural hemp seed. Only a handler licensed with the Department may process agricultural hemp seed. An applicant may apply for a grower or handler license at the same time the applicant applies for a license as an agricultural hemp seed producer.¶¶
- (2) A licensed grower or handler seeking to produce or process agricultural hemp seed must obtain an agricultural hemp seed producer license unless:¶¶
 - (a) A licensed grower retains agricultural hemp seed only for the purpose of personally propagating industrial hemp for the grower's own use in future years;¶¶
 - (b) A licensed grower renders all Cannabis seeds produced such that they are incapable of germination; or¶¶
 - (c) A licensed handler processes agricultural hemp seed in such a manner that the seeds are incapable of germination.¶¶
- (3) An application to produce agricultural hemp seed must include all of the following information:¶¶
 - (a) The name, legal type of applicant (individual, corporation, etc.), Oregon Secretary of State business registry number if a legal entity required to be registered, and contact information of the applicant;¶¶
 - (b) The name and address of the applicant's agricultural hemp seed operation(s);¶¶
 - (c) If industrial hemp is grown in a field:¶¶
 - (A) The global positioning system (GPS) coordinates provided in decimal of degrees and taken at the approximate center of the growing field;¶¶
 - (B) The number of square feet or acres of each cultivated field; and¶¶
 - (C) A map of the grow site showing clear boundaries of the production area;¶¶
 - (d) If industrial hemp is grown in a greenhouse or other building:¶¶
 - (A) The global positioning system (GPS) coordinates provided in decimal of degrees and taken at the approximate center of the greenhouse or other building;¶¶
 - (B) The approximate dimension or square feet of the greenhouse or other building; and¶¶
 - (C) A map of the grow site showing clear boundaries of the production area.¶¶
 - (e) Other information for purposes of studying the growth, cultivation, and marketing of industrial hemp as specified by the Department in the application.¶¶
 - (f) Any other information or forms required by the Department.¶¶
- (4) An application to process agricultural hemp seed must include all of the following information:¶¶
 - (a) The name legal type of applicant (individual, corporation, etc.) and contact information of the applicant;¶¶
 - (b) The name and address of applicant's facility used for processing industrial hemp agricultural seed.¶¶
 - (c) Other information for purposes of studying the growth, cultivation, and marketing of industrial hemp as specified by the Department in the application.¶¶
 - (d) Any other information, documents or forms required by the Department.¶¶
- (5) A licensed grower may retain agricultural hemp seed without an agricultural hemp seed producer license for the purpose of personally propagating industrial hemp in future years, except that a licensed grower may not:¶¶
 - (a) Retain seed from a harvest lot for future planting that failed pre-harvest THC testing as described in OAR 603-048-0600 and 603-048-0630.¶¶
 - (b) Sell or transfer agricultural hemp seed for the purpose of planting without first obtaining an agricultural hemp seed producer license.¶¶
- (6) An applicant for licensure must acknowledge and agree that:¶¶
 - (a) Any information provided to the Department may be publicly disclosed and may be provided to law enforcement agencies without notice to the applicant or licensee;¶¶
 - (b) The Department may enter any field, facility, greenhouse, or other building used for the production or processing of industrial hemp and may take samples of industrial hemp, industrial hemp commodities or products, or agricultural hemp seed as necessary for the administration of the Department's laws.¶¶
 - (c) All fees lawfully due to the Department will be timely paid.¶¶
 - (d) The information provided is true and correct and that applicant's signature is an attestation of that fact.¶¶
 - (e) Licensure and compliance with industrial hemp rules does not protect a person from possible criminal prosecution under federal law or other sanctions by federal entities.¶¶
- (7) Renewal Application.¶¶
 - (a) A person with a current valid license may apply for a renewal license by submitting a complete renewal application on a form provided by the Department. The renewal application must include:¶¶

- (A) Updated contact information for the applicant and all key participants, as applicable if applicant is applying for a grower license;¶
- (B) Any other information required by the Department.¶
- (b) The Department must receive the complete renewal application described in OAR 603-048-0700 by no later than December 1 of the current license year.¶
- (c) All application requirements for an initial license apply to a renewal application except as specifically identified in this rule.¶
- (8) The Department, in its discretion, may require an inspection of the grow site prior to licensure. The inspection may include sampling for THC testing as described in ORS 571.281 or OAR 603-048-8010.¶
- (9) Incomplete Applications.¶
- (a) If an applicant does not provide all of the information required by rule or otherwise required by the Department or pay the applicable fee, the Department shall reject the application as incomplete.¶
- (b) If an application is illegible or is substantially incomplete, the Department may summarily reject the application as incomplete. If an applicant fails to provide all of the information required, the Department may notify the applicant of the missing information and allow the applicant 15 days to submit the missing information.¶
- (c) The Department may verify the information submitted, verify any accompanying documentation submitted with an application, or request additional information, documentation, or attestation from the applicant to ensure compliance with ORS 571.260 to ORS 571.348 ~~(as amended by OL 2021, Ch. 542)~~ and these rules. If an applicant fails to submit information, documentation, or attestation requested by the Department, the Department shall reject the application as incomplete.¶
- (d) An applicant whose application is rejected as incomplete may reapply at any time. If the individual reapplies within the year, the application fee may be applied to a new application.¶
- (10) Denial.¶
- (a) The Department must deny an initial or renewal application if the applicant is not licensed as a grower or handler.¶
- (b) The Department may deny an initial or renewal application if:¶
- (A) The applicant or key participant violated or has a history of noncompliance with:¶
- (i) A provision of ORS 571.260 to ORS 571.348;¶
- (ii) A rule adopted under a provision of ORS 571.260 to ORS 571.348 ;¶
- (iii) An order issued by the Department pursuant to a provision of ORS 571.260 to ORS 571.348 a rule adopted thereunder, including a detention order; or¶
- (iv) Any statutory law or Department rule related to agricultural activities other than industrial hemp operations.¶
- (B) The application, or documents submitted with the application, contains false, misleading, or incorrect information;¶
- (C) The applicant is a legal entity that is required to be registered with the Oregon Secretary of State but does not have an active registration; or¶
- (D) The applicant, or any key participant, has a history of noncompliance with OLCC statutes or rules regarding the prohibition on the unregulated commerce of marijuana including but not limited to any violation or disciplinary action under ORS 475C.185 or OAR 845-025-8590(2)(e).¶
- (11) Licenses are valid for a one-year term beginning January 1 of each calendar year. Licenses granted after January 1 are effective on the date issued.¶
- (12) Ineligibility based on past noncompliance.¶
- (a) An industrial hemp seed producer, and all key participants, is ineligible for an industrial hemp seed producer license for a period of one year from the date a final order is entered revoking the license.¶
- (b) An industrial hemp seed producer or key participant whose application is denied under section (10)(b)(A), (B), or (D) of this rule is ineligible for a period of two year from the date a final order is entered denying the license.¶
- (c) An industrial hemp seed producer or key participant ineligible under this rule may not apply or reapply for an industrial hemp seed producer license during the period of ineligibility.¶
- (d) The Department must deny any industrial hemp seed producer application submitted by a person ineligible under this rule and shall revoke the license of a person who is ineligible under this rule.¶
- (13) The Department may not issue a license to an applicant that is a legal entity required to be registered with the Oregon Secretary of State but does not have an active registration.¶
- (14) The applicant or licensee has outstanding civil penalties and is not making payments consistent with a repayment plan agreed upon by the Department.

Statutory/Other Authority: ORS 561.120, 561.200, 561.275, 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

RULE SUMMARY: Updates reporting requirements

CHANGES TO RULE:

603-048-0400

Reporting Requirements

- (1) A licensee must immediately report, within 48 hours, the theft or loss of industrial hemp or hemp items to the Department. A licensee must provide a copy of the police report of such a theft to the Department or the police report number of such a theft upon the Department's request. A vendor is not required to report shrinkage of industrial hemp or hemp items.¶
- (2) An applicant or licensee must report to the Department in writing within 10 days of the following:¶
 - (a) A disciplinary proceeding or enforcement action by another government entity that may affect the applicant or licensee's business;¶
 - (b) Permanent closure of a grow site, research facility, vendor site or handling site. The applicant or licensee is responsible for all activities at a grow site, research facility, vendor site or handling site until the date the Department is notified of a permanent site closure in accordance with OAR 603-048-0800(1).¶
 - (c) Any felony arrest or conviction of the ~~grower~~ applicant or grower licensee or ~~if~~ of a legal entity, any key participant, relating to a controlled substance or the unlawful manufacture, delivery, export or import of marijuana.¶
 - (d) On a form provided by the Department and changes to the name, address, e-mail or telephone number of the licensee, primary contact person, or any key participant within 10 days of the change;¶
 - (e) On a form provided by the Department, the removal of a production area and the addition of a production area at a grow site prior to producing at a new production area ~~not licensed with the Department~~. The grower must comply with OAR 603-048-0200(6)(a) prior to producing at a production area ~~not licensed with the Department~~. previously identified to the Department in the current license year.¶
 - (f) Any and all licensed production areas that the licensee decides not to plant with industrial hemp or does not plant with industrial hemp during the licensing year.¶
- (3) Changes in Business Structure or Ownership. A licensee that proposes to change its business structure or ownership structure must submit a complete Change in Business or Ownership on a form provided by the Department to the Department, and receive written approval by the Department, prior to making such a change.¶
 - (a) The Department shall approve the change if the change would not result in an initial or renewal application denial or revocation under these rules.¶
 - (b) If the licensee proceeds with the change without an approved Change in Business or Ownership form, the licensee must surrender the license in writing or the Department shall revoke the license.¶
 - (c) The Department may refuse to accept a Change in Business or Ownership form for a change in business structure or financial interest if the licensee is expiring in less than 90 days, the licensee is under investigation by the Department, or has been issued a Notice by the Department following an alleged violation and the alleged violation has not been resolved.¶
 - (d) If a licensee has a change in ownership that is 51% or greater, a new application and application fees must be submitted. The Department shall process the application in accordance with these rules, notwithstanding 603-048-0200(1) except that no new production areas or grow sites other than those included in the original license may be added or moved after May 31 unless otherwise permitted by OAR 603-048-0200(6)(a).¶
 - (e) A licensed grower must submit with the Change in Business or Ownership consent for a criminal background check for any new licensee or key participant in the licensed business in accordance with OAR 603-048-0200(43)(d).¶
- (4) Licensees must pay the change fee described in OAR 603-048-0700 for each change form submitted under section (2)(b),(d),(e) or (3)(a)) of this rule.¶
- (5) Growers must ensure that all laboratory THC test results for all harvest lots are timely reported to the Department and that any failed test report is immediately reported to the Department as required by these rules.¶
- (6) By December 1 of the current license year:¶
 - (a) Growers shall report to the Department on forms provided by the Department:¶
 - (A) Amount of industrial hemp planted (in acres or square feet);¶
 - (B) Amount of industrial hemp harvested;¶
 - (C) Any other information as specified on the forms by the Department.¶
 - (b) Handlers shall report to the Department on forms provided by the Department:¶
 - (A) Type of industrial hemp commodities and products produced;¶
 - (B) The amount of industrial hemp commodities and products produced per type; and¶

(C) Any other information as specified on the forms by the Department.¶¶

(7) Growers shall report hemp crop acreage to the United States Department of Agriculture Farm Service Agency in accordance with 7 CFR 990.7 the following information:¶¶

(a) Street address and geospatial location for each production area;¶¶

(b) Acreage dedicated to the production of hemp or greenhouse or indoor square footage dedicated to hemp; and¶¶

(c) Department grower license number.¶¶

(8) Growers must submit at least one of the following reports to the Department for each production area ~~register~~ identified with the Department or at the grow site by no later than December 1 of the license year. Submission by December 1 does not excuse failure to comply with any other applicable deadline.¶¶

(a) Report of decision not to plant the production area during the license year as described in section (2)(f) of this rule.¶¶

(b) Test report as described in OAR 603-048-0600.¶¶

(c) Waste and disposal form as described in OAR 603-048-0640.¶¶

(d) Loss report as described in section (1) of this rule.¶¶

(e) Permanent closure report as described in section (2)(a) of this rule.¶¶

(f) Notification to the Department that crop is still growing in the production area.¶¶

(9) For purposes of this rule, "permanent closure" means that the grow site, research facility ~~or a~~, handling site, or vendor site will not be used for licensed activities for the remainder of the licensed year. Licensed activities include any form of producing, including possession of any live plants or germination of seeds, any form of processing, and any storage of industrial hemp or hemp products and commodities.¶¶

(10) For the purposes of this rule, "shrinkage" means the loss of inventory due to circumstances such as shoplifting, fraud, employee theft, and administrative error.

Statutory/Other Authority: ORS 561.190, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-0500

RULE SUMMARY: Updates record keeping requirements

CHANGES TO RULE:

603-048-0500

Record Keeping Requirements ¶¶

- (1) Licensees must maintain records required under these rules for ~~not less than~~ at least three (3) years after the ~~total disposition~~ there is no remaining inventory of each harvest, seed, immature plant, or process lot, as identified by unique identifier assigned pursuant to this rule.¶¶
- (2) For purposes of identifying industrial hemp and industrial hemp products and commodities for record keeping:¶¶
- (a) Growers must assign each harvest lot of industrial hemp produced by the grower a harvest lot identifier as that term is defined in 603-048-0010.¶¶
- (b) Growers must assign each seed lot produced by the grower a seed lot identifier as that term is identified in OAR 603-048-0010.¶¶
- (c) Growers must assign immature plant lot transferred or sold by the grower an immature plant lot identifier as that term is identified in OAR 603-048-0010.¶¶
- (d) Handlers must assign a process lot identifier as that term is defined in 603-048-0010 to any hemp items made by the handler.¶¶
- (e) Licensees must assign a unique identifier to each lot of industrial hemp, industrial hemp for human consumption, and hemp items received from outside Oregon.¶¶
- (3) Grower Recordkeeping. A grower must create and maintain records for all industrial hemp planted or produced that includes the following information:¶¶
- (a) The harvest lot, seed lot, and immature plant lot identifier as applicable;¶¶
- (b) Grow site and production area identifiers;¶¶
- (c) Date of harvest if applicable;¶¶
- (d) Any and all sampling and testing documentation from preharvest testing;¶¶
- (e) Documentation of any production area not planted during the licensing year and documentation of reporting to the Department in accordance with OAR 603-048-0400(2)(f).¶¶
- (f) For cannabis waste and all other cannabis disposal:¶¶
- (A) Documentation of disposal, including photos or videos, as required in OAR 603-048-0640; and¶¶
- (B) Documentation of required reports to the Department as required in OAR 603-048-0640.¶¶
- (4)(a) Industrial Hemp Recordkeeping. A licensee must create and maintain records for each harvest lot, seed lot, or immature plant lot, or portion thereof, of industrial hemp that includes the following information:¶¶
- (A) The name and address of the person(s) transferring the lot to the licensee or receiving the lot from the licensee.¶¶
- (B) The hemp or marijuana license number of the person(s) transferring or receiving the lot. If the lot is received from or transferred to outside of Oregon, include the hemp or marijuana outside-state license number of the person(s) transferring or receiving.¶¶
- (C) The harvest lot, seed lot, or immature plant lot identifier for each lot received or transferred;¶¶
- (D) The date of receipt or transfer;¶¶
- (E) The amount of industrial hemp (plants, material, seeds) received or transferred in pounds;¶¶
- (F) All test reports for each lot received or transferred;¶¶
- (G) If transferred to an OLCC licensee(s), the UID number(s), as that term is defined in OAR 845-025-1015, assigned to the harvest lot(s).¶¶
- (b) The requirements of section (4)(a) of this rules does not apply to sale or transfers of immature plants to a consumer.¶¶
- (5) Recordkeeping for Industrial Hemp for Human Consumption and Hemp Items.-¶¶
- (a) A licensee must create and maintain records for the receipt or transfer of each process lot, or portion thereof, of industrial hemp for human consumption and hemp items that include the following information:¶¶
- (A) The name and address of the person(s) transferring the industrial hemp for human consumption or hemp items to the licensee or receiving the industrial hemp for human consumption or hemp items from the licensee.¶¶
- (B) The hemp or marijuana license number of the person(s) transferring or receiving the process lot. If the process lot is received from or transferred to outside of Oregon, include the hemp or marijuana outside-state license number of the person transferring or receiving.¶¶
- (C) The process lot identifier or unique identifier for the industrial hemp for human consumption and hemp items received or transferred.¶¶

- (D) The date of receipt or transfer;¶
 - (E) The amount in units or pounds received or transferred;¶
 - (F) All test reports for the industrial hemp for human consumption and hemp items received or transferred;¶
 - (G) If transferred to an OLCC licensee, the UID number(s), as that term is defined in OAR 845-025-1015, assigned to industrial hemp for human consumption and hemp items transferred.¶
 - (b) The requirements of section (5)(a) of this rule does not apply to sale or transfers from a licensee to a consumer.¶
 - (c) A licensee must create and maintain records for each process lot, or portion thereof, of industrial hemp for human consumption and hemp items that are disposed. The records must include the process lot identifier, the date of disposal, reason for disposal, and the amount disposed.¶
 - (6) Handler Recordkeeping. A handler must create and maintain disposition information for each harvest lot and process lot of industrial hemp, industrial hemp for human consumption and hemp items, or portion thereof received or transferred that includes the following information:¶
 - (a)-Whether the industrial hemp, industrial hemp for human consumption, or hemp items was transferred without processing;¶
 - (b) If processed:¶
 - (A) The process lot identifier;¶
 - (B) The method of processing;¶
 - (C) The type of hemp item created from the industrial hemp, industrial hemp for human consumption, or hemp item; and¶
 - (D) The amount in units or pounds of the hemp item created.¶
 - (7) A licensee must provide, upon the Department's request, records relating to the operation of the licensed business or any key participant in the licensed business, including but not limited to records required to be maintained by the legal entity under ORS 60.771, 63.771, 65.771 67.150, 70.050 or other applicable laws within 12 business days from date of email or after date delivered by certified mail.¶
 - (8) It is a separate violation for each harvest or process lot, or portion thereof, that a licensee fails to create or maintain records as required by this rule. In addition, each failure to comply with an obligation described under this rule is a separate violation for each harvest or process lot, or portion thereof.
- Statutory/Other Authority: ORS 561.190, ORS 571.260-571.348
- Statutes/Other Implemented: ORS 571.260-571.348

AMEND: 603-048-0540

RULE SUMMARY: Updates industrial hemp drying and storage requirements

CHANGES TO RULE:

603-048-0540

Industrial Hemp Drying and Storage Requirements

(1) When drying or storing industrial hemp, licensees must label each harvest lot with the following information:¶

(a) The license number of the grower that produced the harvest lot;¶

(b) The harvest lot identifier; and¶

(c) The date the harvest lot was harvested.¶

(2) The pre-harvest test results for each drying or stored harvest lot must be readily available at the drying or storage location and produced upon request.¶

(3) A licensee may only dry or store industrial hemp in locations identified on the grow site application or on a change form submitted to the Department identifying where industrial hemp will be dried or stored.

Statutory/Other Authority: ORS 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

AMEND: 603-048-0550

RULE SUMMARY: Updates transport documentation requirements

CHANGES TO RULE:

603-048-0550

Transport Documentation Requirements

(1) When transporting industrial hemp or agricultural hemp seed, licensees must ensure a copy of the following documents accompanies the industrial hemp or agricultural hemp seed:¶¶

(a) A copy of the hemp grower license;¶¶

(b) A copy of the invoice or bill of lading that includes the originating location and destination and contact information of buyer and seller if applicable; and¶¶

(c) A copy of the pre-harvest test results issued by a laboratory under OAR 603-048-0600 and sampling documentation required under OAR 603-048-0600 that corresponds to the harvest lot(s) in transit as identified by harvest lot identifier.¶¶

(2) "Industrial hemp commodities" for the purpose of this rule means industrial hemp items that are not, or are not yet, packaged for retail sale.¶¶

(3) When transporting industrial hemp commodities, licensees must ensure a copy of the following documents accompanies the industrial hemp commodities:¶¶

(a) A copy of the hemp license of the transferor and recipient, if applicable;¶¶

(b) A copy of the invoice or bill of lading that includes the originating location and destination and contact information of buyer and seller if applicable;¶¶

(4) When transporting industrial hemp for human consumption or hemp items, licensees must ensure a copy of test results required under OAR 603-048-2300 accompanies the industrial hemp for human consumption or hemp items.

Statutory/Other Authority: ORS 561.190, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-0600

RULE SUMMARY: Updates pre-harvest sampling and testing for tetrahydrocannabinol

CHANGES TO RULE:

603-048-0600

Pre-Harvest Sampling and Testing for Tetrahydrocannabinol

(1) A grower may not:

- (a) Harvest a harvest lot until it has been sampled in accordance with these rules.
- (b) Transfer or sell a harvest lot until it has passed testing in accordance with these rules.
- (c) Conduct repeat preharvest sampling and testing on a harvest lot that has failed testing under this rule except as expressly permitted in OAR 603-048-0630.

(2) Required Sampling and Testing:

- (a) A grower must ensure that the grower's entire crop is timely sampled and tested according to these rules.
 - (b) Harvest lots must be sampled and tested separately and may not be combined. At the discretion of the grower, industrial hemp grown in a ~~contiguous field or growing~~ single production area may be subdivided into separate harvest lots for sampling and testing consistent with these rules. A subdivided production area must still meet the definition of a production area. Sampling must be conducted and testing must be reported using the harvest lot identifier described in OAR 603-048-0500(2).
 - (c) A grower must arrange for and ensure the sampling of a harvest lot no more than 30 days prior to harvest for the purpose of ensuring that the harvest lot does not exceed permissible THC concentration levels on a dry weight basis. Harvest must be complete within the applicable time period for sampling or the grower must arrange for additional sampling of the unharvested cannabis in accordance with these rules.
 - (d) If a purpose of the harvest lot is to produce flower, the grower must arrange for sampling such that flowers are present at the time of sampling. In this case, only plants with flowers shall be sampled.
 - (e) The grower or authorized representative must provide the sampler with unrestricted and unobstructed access to all hemp and other cannabis plants whether growing or harvested and all lands, buildings, and other structures used for cultivation, handling, and storage of all hemp and Cannabis and all other locations listed in the grower's license.
 - (f) During a scheduled sampling, the grower, person in charge of the grow site, or an authorized representative of the grower shall be present at the grow site.
- (3) All sampling and testing must be performed by the Department or a laboratory.
- (4) If a grower uses a laboratory to perform testing and sampling the grower must ensure that the laboratory:
- (a) Retains all documentation of sampling and testing for at least three years and can provide such documentation to the Department upon request.
 - (b) Complies with ~~sample or matrix spike recovery requirements~~ laboratory control sample recovery and Relative Percent Difference requirements ~~as described in Exhibit B in OAR 333-064-0100.~~
 - (c) Conducts sampling and testing in accordance with these rules.
 - (d) Can demonstrate that its limit of quantification (LOQ) for THC is at or below 0.315 percent THC.
 - (e) Requires all laboratory staff conducting sampling to complete annual sampling training with the Department prior to conducting sampling.
 - (f) Tests for and reports the total THC content of the harvest lot calculated in accordance with OAR 333-064-0100(4).

(5) To request sampling and testing, prior to sampling a grower must submit to the laboratory, or the Department, a completed sampling request form provided by the Department that includes:

- (a) A written sampling request for THC analysis for each harvest lot, as identified by the harvest lot identifier, for which the grower is requesting sampling and testing and the total number of harvest lots to be sampled and tested;
- (b) A description of the location of the production area of each harvest lot, as identified by the harvest lot identifier, including the GPS coordinates or address of the harvest lot; and
- (c) A written description and visual depiction of each harvest lot to be sampled and tested such that the production area for each harvest lot is apparent from a visual inspection of the premises and easily discernible from other harvest lots.

(6) Sampling of a harvest lot must:

- (a) Occur after the laboratory or Department personnel fully complete the sampling form provided by the Department onsite at the production area.
- (b) Produce a sample that is representative of the harvest lot.
- (c) Be conducted:
- (A) In accordance with the Department's Sampling Protocol prescribed in Exhibit A and incorporated by

reference.¶

(B) Such that a sufficient sample size is taken and retained for analysis of all requested tests, any requested retest, and any quality control performed by the testing laboratory for these tests.¶

(7) A grower must ensure that:¶

(a) The laboratory conducts testing according to the Department's Testing Protocol prescribed in Exhibit B and incorporated by reference.¶

(b) The laboratory reports all test results electronically to the Department at HempTestReports@oda.oregon.gov using the forms provided by or approved by the Department or via an online portal operated by the Department, and include for each sample tested:¶

(A) Grower's name and license number;¶

(B) Harvest lot identifier;¶

(C) Sample date;¶

(D) Testing date;¶

(E) Total THC percentage to the second decimal point only calculated in accordance with OAR 333-064-0100(4);¶

(F) The laboratory's measurement of uncertainty for THC testing of industrial hemp. Measurement of uncertainty means the parameter, associated with the result of the measurement, that characterizes the dispersion of the values that could reasonably be attributed to the particular quantity subject to measurement;¶

(G) Clear identification of the harvest lot by harvest lot identifier that corresponds to the sample and the location of the corresponding harvest lot's production area;¶

(H) Copy of grower's sampling request form required in section (5) of this rule; and¶

(I) Copy of the completed sampling form required in section (6) of this rule.¶

(c) The laboratory reports all results from testing conducted under this rule to the United States Department of Agriculture. The test results report must contain the following information:¶

(A) Grower's license number;¶

(B) Grower's name;¶

(C) Business address of the grower;¶

(D) Harvest lot identifier¶

(E) Name of the laboratory¶

(F) Date of the test and report¶

(G) Whether it is a retest;¶

(H) Test result.¶

(d) If a sample fails testing a grower must ensure that:¶

(A) The laboratory sends the failed test report electronically to the Department at HempTestReports@oda.oregon.gov using the forms provided or approved by the Department or via an online portal operated by the Department within 24 hours of the failed test report.¶

(B) The laboratory sends failed test reports to the grower who requested the testing using the forms provided or approved by the Department within 24 hours of the failed test report.¶

(C) The grower complies with OAR 603-048-0630.¶

(8) A sample fails testing when the application of the measurement of uncertainty to the amount of total THC of the sample calculated in accordance with OAR 333-064-0100(4) reported by a laboratory produces a distribution or range that does not include 0.3 percent or less on a dry weight basis. A laboratory's measurement of uncertainty may not exceed 10 percent of the measured value. If the sample from a harvest lot fails required THC testing under these rules the harvest lot corresponding to the sample fails required THC testing.¶

(9) A sample passes testing when the application of the measurement of uncertainty to the amount of total THC of the sample calculated in accordance with OAR 333-064-0100(4) reported by a laboratory produces a distribution or range that includes 0.3 percent or less on a dry weight basis and the harvest lot was sampled and tested in compliance with these rules. If the sample of the harvest lot passes THC testing under these rules, the harvest lot corresponding to the sample passes required THC testing.¶

(10) Upon receipt of a failed test report:¶

(a) The grower must immediately clearly label or place signage on the harvest lot that it failed testing.¶

(b) The grower must immediately detain the harvest lot at the grow site and may not sell, harvest, transfer, or process the harvest lot.¶

(c) The grower may not move the harvest lot from the grow site or allow the harvest lot to be removed from the grow site without written permission from the Department.¶

(d) If the harvest lot has not been harvested, the grower may continue normal agricultural processes to maintain the viability of the harvest lot, but may not harvest without written permission from the Department.¶

(e) If the harvest lot has been harvested, the grower must immediately segregate the failed harvest lots from any other harvest lots. If the failed harvest lot has been commingled, all cannabis commingled with a failed harvest lot must be detained and is subject to all of the requirements, including required disposal, of the failed harvest lot.¶

(11) For any harvest lot that fails testing, unless the harvest lot passes testing upon resampling or retesting in accordance with OAR 603-048-0630, the grower must dispose of the harvest lot, including all parts of the cannabis plants including the stalk and seed, in accordance with OAR 603-048-0640:¶¶

(a) Within fourteen (14) days of the failed test report if no resampling or retesting in accordance with these rules is sought unless extended by the Department in writing; or¶¶

(b) Within fourteen (14) days of any failed test report from any resampling, or retesting completed in accordance with these rules unless extended by the Department in writing.¶¶

(12) Invalid Sampling or Testing:¶¶

(a) It is the grower's obligation to demonstrate and maintain documentation that each harvest lot was sampled and tested in accordance with these rules and passes THC testing required by these rules.¶¶

(b) Sampling or testing that does not meet all of the requirements and standards of these rules is invalid. The harvest lot corresponding to an invalid sampling or invalid testing fails to satisfy the required THC testing under these rules.¶¶

(c) The Department may detain, seize, embargo, and dispose of the harvest lot that fails THC testing under this rule or that was invalidly sampled or tested as provided under OAR 603-048-0900.¶¶

(13) The Department may, at its discretion, agree to conduct sampling and testing for a licensed grower. Prior to conducting the sampling and testing the grower must pay fees as described in OAR 603-048-0700 for each harvest lot requested to be sampled and tested.¶¶

(14) In addition to the testing required by this section the Department may inspect any industrial hemp and sample for testing for THC content. The Department may detain, seize, embargo, and dispose of any industrial hemp that fails THC testing as described in section (9) of this rule.¶¶

(15) All laboratories conducting sampling or testing must be registered with the United States Drug Enforcement Agency in accordance with 21 USC 823(f) unless the United States Department of Agriculture issues written guidance or amends the federal rules to extend or waive this requirement.

Statutory/Other Authority: ORS 561.120, 561.200, 561.275, 561.190, ORS 571.260-571.348

Statutes/Other Implemented: ORS 571.260-571.348

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.



Exhibit A: Sampling Protocol Hemp Pre-Harvest Testing

To be valid pre-harvest THC sampling and testing required under OAR Chapter 603, Division 48, all sampling must be conducted as described in this Protocol.¹

A. General Sampling Requirements

1. Sampling may only be performed by the Department or a laboratory licensed by the Oregon Liquor Control Commission (OLCC) under ORS 475B.560 and accredited by the Oregon Health Authority (OHA) pursuant to ORS 475B.565 [hereinafter, “Laboratory”].²
2. All sampling must be performed by personnel employed by a Laboratory [hereinafter, “sampler”] and in accordance with OAR 603-048-0600 and this Protocol. Samplers must complete annual sampling training with the Department before sampling.
3. The Laboratory must follow chain of custody procedures consistent OAR 333-064-0100(2) and be documented to record the collection, transport, and receipt of samples by the Department or Laboratory. Laboratory must maintain records for each harvest lot as identified by harvest lot identifier.
4. Sampling must produce a representative sample of the harvest lot.
5. The Laboratory must avoid contamination of the non-sampled material with sample containers that are free of analytes of interest and appropriate for the analysis requested.
6. The Laboratory shall only sample plants with flowers when a purpose of the harvest lot is to produce flower. If no flowering plants are present, the Laboratory shall reschedule the sampling for a later date when flowering plants are present.

¹ The definitions in OAR 603-048-0010 unless the context indicates otherwise.

² Note that the sampling of industrial hemp for pre-harvest THC concentration itself is not accredited by OHA.



7. The Laboratory must obtain a sufficient sample size to provide sufficient material to conduct all requested tests, any requested retest, and any quality control performed by the testing laboratory.

B. Initiating a Sampling Request

1. The Laboratory must receive a complete Hemp Sampling and Testing Request Form prior to sampling. The Laboratory must receive a new and separate “Harvest Lot Sampling Request Description” for each “Harvest Lot” to be sampled.
2. The Laboratory must complete the Hemp On-Site Sampling Form. The Laboratory must complete a new and separate “Harvest Lot On-Site Sampling Description” for each Harvest Lot to be sampled.
3. A “Harvest Lot” means:
 - a. Means a quantity of cannabis of the same variety or strain harvested within a distinct timeframe that is:
 - A. Grown in one production area within a grow site; or
 - B. Grown in a portion or portions of one production area within a grow site.
 - b. Does not include cannabis grown in noncontiguous fields or noncontiguous growing areas.
4. Prior to beginning the sampling procedure, the sampler shall:
 - a. Survey the site to identify the conditions to determine the appropriate sampling procedure as described in this Protocol.
 - b. Visually establish the homogeneity of the harvest lot to establish the plants growing are of the same variety or strain.
 - c. Verify the description of the location of the production area of each harvest lot in the Hemp Sampling and Testing Request Form matches the location of the harvest lot to be sampled (including the GPS coordinates or the address of the harvest lot, and the written description and visual depiction of the harvest lot).

C. Survey and Sample Collection

1. The sample pattern must ensure that all parts of the harvest lot are adequately



and proportionately represented in the plants inspected and sampled.

2. The sampler must use a sawtooth pattern when sampling the harvest lot. Two (2) sawtooth patterns are provided below. The approved sampler must choose one of the patterns most suitable for the field to be sampled. (Figure 1 and 2).

The sampler must walk at right angles to the row of plants. The sampler must sample according to the pattern to the extent possible but may deviate from the pattern as necessary to account for particular physical growing conditions and to ensure that all parts of the harvest lot are adequately and proportionately sampled to produce a representative sample.

- a. A sample shall be obtained from flowering tops when flowering tops are present, and shall be approximately five to eight inches in length from the main stem (that includes the leaves and flowers), the terminal bud (that occurs at the end of a stem) or central cola (cut stem that could develop into a bud).³ Samplers should avoid sampling dead, diseased, or mechanically injured plants.
 - b. A sample shall consist of no more than one sample per plant, randomly chosen from the harvest lot. Place each sample in a paper bag.
 - c. Since they are a measure of the entire harvest lot, all samples from the harvest lot may be collected into a single bag.
 - d. Samplers should avoid collecting too many samples from the borders of the harvest lot.
3. Sample Size:
 - a. **The sample size must be at least 4 ounces, which is the minimum amount necessary for laboratory tests and file samples.**
 - b. Each composite sample should consist of a maximum 30 plant heads of about five to eight inches.
 - c. For greenhouses, small fields, or when sampling from a known number of plants, the Hypergeometric Table 1 below should be used.

³ See note on harvest lots intended for flower production in the General Sampling Requirements.



Table 1. Hypergeometric Table for Random Sampling

For greenhouses, small fields or when sampling from a known number of plants, plants may be sampled follows:

Total number of plants:	Randomly select this number of plants to sample:
1-13	Sample all plants
14-15	13
16-17	14
18-19	15
20-22	16
23-25	17
26-28	18
29-32	19
33-38	20
39-44	21
45-53	22
54-65	23
66-82	24
83-108	25
109-157	26
158-271	27
272-885	28
886-200,000	29

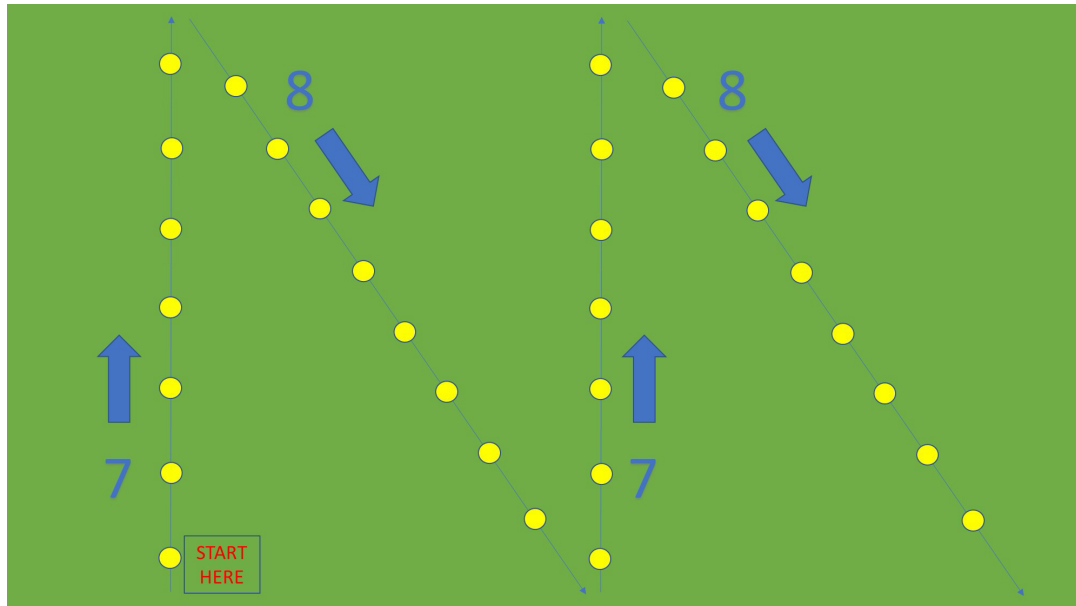


Figure 1. This is a typical sawtooth survey pattern starting in the lower “left” corner of the field. The yellow dots indicate the approximate locations to collect samples.

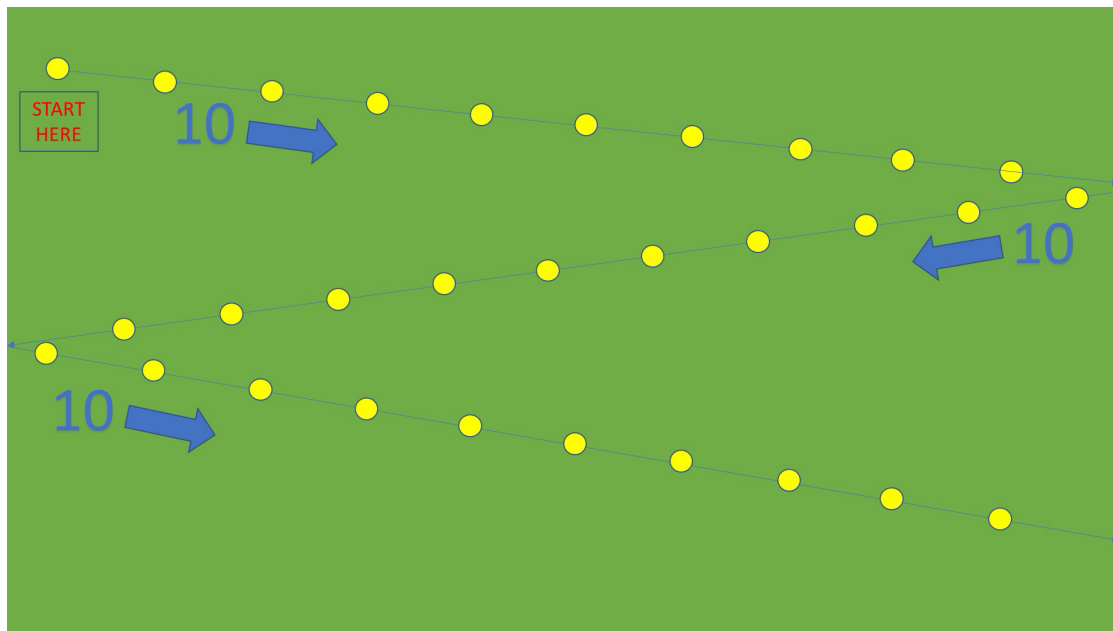


Figure 2. This is another typical sawtooth survey pattern starting in the top “left” corner of the field. The yellow dots indicate the approximate locations to collect samples.



D. Reporting and Recordkeeping Requirements

1. The Laboratory shall record data for all samples collected on the appropriate forms for sample collection. All records must clearly identify the harvest lots by harvest lot identifier.
2. The Laboratory shall submit a copy of the following forms for each Harvest Lot with the samples when submitting for testing.
 - a. Hemp Sampling and Testing Request Form
 - b. Hemp On-Site Sampling Form
3. The Laboratory shall maintain standard operating procedures (SOP) that accurately reflect current sampling procedures.
 - a. The SOP shall be readily accessible to all pertinent personnel and provided to ODA upon request.
 - b. The SOP shall clearly indicate the effective date of the document, the revision number, and the signature of the approving authority.
 - c. The sampling SOP shall use these protocols as minimum requirements and must include additional detail specific to laboratory procedures. Any changes, including use of a selected option, shall be documented and included on the sampling form. In cases where the published method has been modified or where the referenced method is ambiguous or provides insufficient detail, these changes or clarifications shall be clearly described.
 - d. All documents shall be controlled and retained in accordance with the TNI Standards as defined in in OAR 333-064-0025(52).
4. When procuring the sample, the Laboratory must create a Chain of Custody form that includes, but is not limited to, the information set out below. All sampling report forms must be signed by the sampler.
 - a. Sampler's name
 - b. Laboratory License Number
 - c. Grower license number
 - d. Field ID/Name and Harvest Lot Identifier
 - e. Sampling Date/Time
 - f. Custody transfer signatures



- g. Custody Transfer Dates/Times
- 5. The Laboratory shall provide to ODA upon request any and all records associated with the sampling, including SOPs, chain of custody forms, quality checks, etc.

E. Preparation of the Composite Sample

1. The Laboratory shall close the paper bag for collection and seal in a manner to show evidence of tampering. On the sample bag, record Field Name and the harvest lot identifier, date of sampling, sampler's signature, license growername.
2. The Laboratory must have detailed procedures on maintaining custody and sample integrity during transport. These procedures should take into consideration controlling temperature and other environmental factors.
3. Composite samples must always be identified by labeling or marking the sample container to associate them with the harvest lot from which they originated.
4. The Laboratory must submit the composite sample to the testing laboratory in its entirety.
5. The Laboratory shall submit a copy of all of the following forms with the samples when submitting for testing:
 - a. Hemp Sampling and Testing Request Form - Completed by grower;
 - b. Hemp On-Site Sampling Form- Completed by Laboratory

F. Equipment and Supplies

1. Forms (including extra sample request forms)
2. Paper bags for samples
3. Permanent pens for marking on paper sample bags
4. Pruning shears for collecting foliar samples
5. Single-use Coveralls
6. Gloves, disposable
7. Boots or booties (waterproof recommended)



8. Rain gear (recommended)
9. Boxes for storing sample equipment and samples
10. Bleach, 10% solution or other acceptable surface disinfectant for cleaning tools or boots between fields
11. Clipboard
12. Clicker to count the number of samples collected (optional)

G. Sanitation

1. Park vehicle on pavement or on designated roads within the field.
2. Clean collection tools with an appropriate disinfectant after finishing all sample collections within the field.
3. Dispose of coveralls and gloves in an appropriate receptacle before leaving the field or in a designated receptacle in the vehicle. Ensure that single-use coveralls are appropriately cleaned prior to next use and are not contaminated by used coveralls.
4. Field sampling equipment must be certified clean prior to use by the Laboratory.

H. Resampling

1. A Laboratory may resample a Harvest Lot upon receipt of a completed Sampling and Testing Request Form from a grower that indicates the request is for “Remediation Resampling.”
2. A Laboratory shall conduct any such resampling in accordance with all applicable rules and this protocol.

References

- USDA APHIS National Seed Health Service. 2001. Reference manual B: Seed health testing and phytosanitary field inspection methods manual. Version dated 2/27/2001, USDA APHIS NSHS, Beltsville, MD, 56 pp.
https://www.aphis.usda.gov/sites/default/files/Ref-Man-B_0.pdf
- OAR Chapter 603, Division 48



Exhibit B: Testing Protocol

Hemp Pre-Harvest Testing

To be sufficient to meet the requirement for pre-harvest THC sampling and testing under OAR Chapter 603, Division 48, testing must be conducted as described in this Protocol.¹

A. Testing Requirements

1. Testing may only be performed by a laboratory licensed by the Oregon Liquor Control Commission (OLCC) under ORS 475B.560 and accredited by the Oregon Health Authority (OHA) pursuant to ORS 475B.565 to sample and test for tetrahydrocannabinol (THC) content (hereinafter, Laboratory)² or the Oregon Department of Agriculture (ODA).
2. All testing must be performed by personnel employed by a Laboratory and in accordance with OAR 603-048-0600 and this Protocol.
3. The Laboratory must follow chain of custody procedures consistent with OAR 333-064-0100(2) and be documented to record the collection, transport, and receipt of samples by the Laboratory.
4. Testing must be conducted in compliance with OAR 333-064-0100(3) – (7) except that the Laboratory need not test or report CBD values.
5. The Laboratory must perform testing under their Quality Management system as defined by their ORELAP accreditation.
6. The Laboratory must perform testing in a manner that avoids contamination of the non-sampled material with sample containers that

¹ The definitions in OAR 603-048-0010 unless the context indicates otherwise.

² Note that the sampling of industrial hemp for pre-harvest THC concentration itself is not accredited by OHA.



are free of analytes of interest and appropriate for the analyses requested.

7. The Laboratory shall calculate total THC (meaning the molar sum of THC and THCA) percentage on a dry weight basis calculated in accordance with OAR 333-064-0100(4).
8. The Laboratory must estimate and report the measurement of uncertainty (MU) with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

B. Initiating a Testing Request

1. The Laboratory must receive a complete Industrial Hemp Sampling and Testing Request Form prior to testing. The Laboratory must receive a new and separate “Harvest Lot Sampling Request Description” for each Harvest Lot to be tested.
2. The Laboratory must receive a complete Industrial Hemp On-Site Sampling Form prior to testing. The Laboratory must receive a new and separate “Harvest Lot On-Site Sampling Description” for each Harvest Lot to be tested.
3. A “Harvest Lot” means:
 - a. Means cannabis of the same variety or strain harvested in a distinct timeframe that is:
 - i. Grown in one production area within a grow site; or
 - ii. Grown in a portion or portions of one production area within a grow site.
 - b. Does not include cannabis grown in noncontiguous fields or noncontiguous growing areas.

C. Sample Preparation Requirements

1. The Laboratory shall dry all of the leaf and flower of the sample (not obvious stem and seeds).
2. After drying, the Laboratory shall pulverize and sieve the sample using



mesh size 1 mm as described in United Nations Office on Drugs and Crime: Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products. ISBN 978-92-1-148242-3. The Laboratory shall blend and homogenize the sieved material.

3. The Laboratory shall determine the dry weight of the sieved material.
4. The Laboratory shall divide the sieved, blended and homogenized sample into two portions: the test portion and the retained file sample. The Laboratory shall store the retained file sample in a freezer until needed. The retained file sample must be of sufficient material to conduct any requested retest and any quality control performed by the testing Laboratory.

D. Retesting Requirements

1. The Laboratory shall retest a Harvest Lot upon receipt of a completed Request for Retest from a grower. “Retest” or “Retesting” means the laboratory process of retesting a retained file sample for THC content after the sample failed initial testing for THC content. A retest does not include or permit taking a new sample from the harvest lot.
2. The Laboratory shall forward the retained file sample to another Laboratory or to the ODA upon receipt of a completed Request for Retest from the grower requesting that the sample be forwarded. The Laboratory shall:
 - a. Use packaging appropriate for secure transport.
 - b. Protect the sample from moisture and temperature extremes.
 - c. Include all documentation with the sample.
 - d. Forward the sample by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody is accounted for to protect its integrity.

E. Testing After Resampling

1. The Laboratory may test a Harvest Lot after a valid resampling in



accordance with OAR 603-048-0630.

2. The Laboratory shall conduct testing after a resampling like any other testing in accordance with this Protocol.
3. The Laboratory shall report the test results as described in Part F of the Protocol, but shall indicate that the result is pursuant to resampling.

F. Reporting and Recordkeeping Requirements

1. All documentation of sampling and testing must be retained by the Laboratory for at least three years and be provided to the Department upon request. All records must clearly identify the harvest lots by harvest lot identifier.
2. The Laboratory shall make Standard Operating Procedure (SOPs) readily accessible to all pertinent personnel and provided to the Department upon request.
3. All documents shall be controlled and retained in accordance with the TNI Standard as defined in in OAR 333-064-0025(52).
4. When testing or forwarding the sample, the Laboratory must create and use a Chain of Custody form that minimally includes the information set out below.
 - a. Laboratory name
 - b. Grower registration number
 - c. Analyst's name
 - d. Laboratory License Number
 - e. Field ID/Name and Harvest Lot Identifier
 - f. Testing Date/Time
 - g. Custody transfer signatures
 - h. Custody Transfer Dates/Times
5. The Laboratory must estimate and report the measurement of uncertainty (MU) with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty. Measurement of uncertainty means the parameter, associated with the result of the measurement, that



characterizes the dispersion of the values that could reasonable be attributed to the particular quantity subject to measurement.

6. The Laboratory shall provide to the Department upon request analytical data and any records associated with test results reported, including SOPs, chain of custody forms, quality checks, MU determination, etc.
7. The Laboratory shall report percentage of total THC in the sample on a dry weight basis to exactly two significant figures.
8. The Laboratory shall report whether the sample passes testing. A sample passes testing when the application of the measurement of uncertainty to the amount of total THC of the sample calculated in accordance with OAR 333-064-0100(4) reported by a laboratory produces a distribution or range that includes 0.3 percent or less on a dry weight basis and the harvest lot was sampled and tested in compliance with these rules.
9. The Laboratory shall report all test results electronically to the Department at HempTestReports@oda.state.or.us using the forms provided or approved by the Department, and include for each sample tested:
 - a. Grower's name and registration number;
 - b. Sample date;
 - c. Sample size by weight;
 - d. Testing date;
 - e. Total THC percentage to exactly two significant figures calculated in accordance with OAR 333-064-0100(4) and whether the sample passed testing;
 - f. The Laboratory's uncertainty level for THC testing of cannabis;
 - g. The harvest lot identifier that corresponds to the sample and the location of the corresponding harvest lot;
 - h. Copy of grower's sampling request form corresponding to the harvest lot;
 - i. Copy of the completed sampling form corresponding to the harvest lot; and



- j. Signature of the laboratory analyst.
- 10. The Laboratory shall send any failed test report electronically to the Department at HempTestReports@oda.state.or.us using the forms provided or approved by the Department **within 24 hours of the failed test.**
- 11. The Laboratory shall send completed copies of the Sampling and Request Form and the On-Site Sampling Form corresponding to the Harvest Lot with each test report.
- 12. The laboratory shall report all test results, except for interim mid-season testing conducted for monitoring THC content during the growth cycle and not for pre-harvest testing, to the United States Department of Agriculture. The test results report must contain the following information:
 - a. Grower's license number;
 - b. Grower's name;
 - c. Business address of the grower;
 - d. Harvest lot identifier
 - e. Name of the laboratory and if applicable, the DEA registration number of the laboratory;
 - f. Date of the test and report;
 - g. Whether it is a retest;
 - h. Test result including whether the lot passed testing.

AMEND: 603-048-0630

RULE SUMMARY: Updates failed pre-harvest testing; retesting requirements

CHANGES TO RULE:

603-048-0630

Failed Pre-Harvest Testing; Retesting

(1) If a sample tested under OAR 603-048-0600 fails an initial test, a grower may pursue retesting at the grower's own cost pursuant to sections (2) and (3) of this rule.¶

(2) Retesting of Failed Samples. If a sample tested under OAR 603-048-0600 fails an initial test, the laboratory that did the testing, or the Department if the Department did the testing, may retest the sample pursuant to the Testing Protocol, Exhibit B. If the sample passes, the sample must be retested by another laboratory or the Department and again pass testing to confirm the result in order for the harvest lot to pass testing.¶

(a) If a grower wishes to have a sample retested, the grower must request a retest within ~~seven (7)~~ 10 business days from the date the notice of the failed test was sent to the grower. The retest must be completed within 30 calendar days from the date the retest was requested.¶

(b) To request retesting, the grower must provide the laboratory, or the Department, with the following on a form provided by the Department:¶

(A) A written request for retesting for each sample the grower requests be retested; and¶

(B) Notification that the sample is being retested because of the failed test and the failed test results.¶

(c) If a grower has requested a retest in accordance with subsection (2)(a) and (b) of this rule and the sample passes upon retest, the grower has seven (7) days from the date the notice of the passed test is sent to request that another laboratory, or the Department, retest the remaining file sample and confirm that the sample meets requirements established in OAR 603-048-0600. The initial laboratory must coordinate with the second laboratory or the Department to provide the remaining file sample for retesting. The retesting must be completed within 30 days from the date the retesting was requested.¶

(d) If a grower has requested an initial or secondary retest and the test report indicates that the sample failed testing as described in OAR 603-048-0600(8) the sample fails testing and no further testing is permitted under this subsection.¶

(e) Reporting:¶

(A) A grower must report electronically to the Department within 24 hours, at

HempTestReports@oda.oregon.gov using the forms provided or approved by the Department, or via an online portal operated by the Department, any initial or secondary request for retest of a sample.¶

(B) A grower must ensure that a laboratory reports electronically to the Department within 24 hours, at HempTestReports@oda.oregon.gov using the forms provided or approved by the Department, or via an online portal operated by the Department, the testing results of the initial or secondary retest.¶

(3) Resampling Production Area. If a sample tested under OAR 603-048-0600 fails an initial test, a grower may seek resampling and retesting of the production area if:¶

(a) The original plants in the production area associated with the failed test remain standing and growing in the production area.¶

(b) The grower requests the resampling within seven (7) days from the date the notice of the failed test was sent to the grower.¶

(c) The grower subdivides the production area into separate harvest lots for resampling and retesting if the initial test reported that the production area exceeds 1.0 percent total THC on a dry weight basis.¶

(d) The grower properly identifies the subdivided harvest lots in accordance with OAR 603-048-0500 if required to subdivide under section (3)(c) of this rule.¶

(e) The grower provides the laboratory or the Department with the following on a form provided by the Department:¶

(A) A written request for resampling for each harvest lot the grower requests be resampled that includes all of the information required in OAR 603-048-0600 for initial sampling; and¶

(B) Notification that the harvest lot is being resampled because of the failed test and the failed test results.¶

(f) The resampling occurs within ten (10) days of the request for resampling and the test results are reported within 30 days of the request for resampling.¶

(4) If the harvest lot fails testing after resampling conducted under section (3) of this rule, the grower may pursue retesting pursuant to section (2) of this rule, but may not pursue resampling under section (3) of this rule.¶

(5) Reporting:¶

(a) A grower must report electronically to the Department within 24 hours, at HempTestReports@oda.oregon.gov using the form provided or approved by the Department, or via an online portal operated by the Department any requests for resampling under this subsection.¶

- (b) A grower must ensure that the laboratory reports electronically to the Department within 24 hours, at HempTestReports@oda.oregon.gov using the forms provided or approved by the Department, or via an online portal operated by the Department, the testing results of any resampling under this subsection.¶¶
- (6) The Department may detain, seize, embargo the harvest lot corresponding to a sample, as provided under ORS 561.605 to 561.620 and subject to the provisions of ORS Chapter 183, if the sample failed a test under OAR 603-048-0600.¶¶
- (7) The Department may detain, seize, embargo, and dispose of the harvest lot corresponding to a sample, as provided under ORS 561.605 to 561.620 and subject to the provisions of ORS Chapter 183, if the sample:¶¶
- (a) Was not sampled and tested in compliance with all of the requirements and standards of these rules;¶¶
- (b) Fails a test under OAR 603-048-0600 to 603-048-0630.¶¶
- (8) If a sample passes the first and second retest described in section (2)(c) of this rule, the sample and corresponding harvest lot satisfies THC testing required by these rules and is released from the restrictions in OAR 603-048-0600(10).¶¶
- (9) If a sample passes testing after resampling conducted under section (3) of this rule, the sample and corresponding harvest lot satisfies THC testing required by these rules and is released from the restrictions in OAR 603-048-0600(10). Any harvest lots that are not retested or that fail testing after resampling, the grower must dispose of in accordance with OAR 603-048-0640.¶¶
- (10) If the amount of the harvest lot material collected for purposes of sampling is not sufficient to allow for the first and second retesting described in section (2)(c) of this rule, the sample and corresponding harvest lot fails to satisfy these rules.¶¶
- (11) The grower must ensure that any additional testing is reported by the laboratory to the United States Department of Agriculture. The test results report must contain the following information:¶¶
- (a) Grower's license number;¶¶
- (b) Grower's name;¶¶
- (c) Business address of the grower;¶¶
- (d) Harvest lot identifier¶¶
- (e) Name of the laboratory¶¶
- (f) Date of the test and report¶¶
- (g) Whether it is a retest;¶¶
- (h) Test result.
- Statutory/Other Authority: ORS 561.190, ORS 561.605-561.620, ORS 571.260-571.348
- Statutes/Other Implemented: ORS 571.260-571.348

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.



Exhibit B: Testing Protocol

Hemp Pre-Harvest Testing

To be sufficient to meet the requirement for pre-harvest THC sampling and testing under OAR Chapter 603, Division 48, testing must be conducted as described in this Protocol.¹

A. Testing Requirements

1. Testing may only be performed by a laboratory licensed by the Oregon Liquor Control Commission (OLCC) under ORS 475B.560 and accredited by the Oregon Health Authority (OHA) pursuant to ORS 475B.565 to sample and test for tetrahydrocannabinol (THC) content (hereinafter, Laboratory)² or the Oregon Department of Agriculture (ODA).
2. All testing must be performed by personnel employed by a Laboratory and in accordance with OAR 603-048-0600 and this Protocol.
3. The Laboratory must follow chain of custody procedures consistent with OAR 333-064-0100(2) and be documented to record the collection, transport, and receipt of samples by the Laboratory.
4. Testing must be conducted in compliance with OAR 333-064-0100(3) – (7) except that the Laboratory need not test or report CBD values.
5. The Laboratory must perform testing under their Quality Management system as defined by their ORELAP accreditation.
6. The Laboratory must perform testing in a manner that avoids contamination of the non-sampled material with sample containers that

¹ The definitions in OAR 603-048-0010 unless the context indicates otherwise.

² Note that the sampling of industrial hemp for pre-harvest THC concentration itself is not accredited by OHA.



are free of analytes of interest and appropriate for the analyses requested.

7. The Laboratory shall calculate total THC (meaning the molar sum of THC and THCA) percentage on a dry weight basis calculated in accordance with OAR 333-064-0100(4).
8. The Laboratory must estimate and report the measurement of uncertainty (MU) with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty.

B. Initiating a Testing Request

1. The Laboratory must receive a complete Industrial Hemp Sampling and Testing Request Form prior to testing. The Laboratory must receive a new and separate “Harvest Lot Sampling Request Description” for each Harvest Lot to be tested.
2. The Laboratory must receive a complete Industrial Hemp On-Site Sampling Form prior to testing. The Laboratory must receive a new and separate “Harvest Lot On-Site Sampling Description” for each Harvest Lot to be tested.
3. A “Harvest Lot” means:
 - a. Means cannabis of the same variety or strain harvested in a distinct timeframe that is:
 - i. Grown in one production area within a grow site; or
 - ii. Grown in a portion or portions of one production area within a grow site.
 - b. Does not include cannabis grown in noncontiguous fields or noncontiguous growing areas.

C. Sample Preparation Requirements

1. The Laboratory shall dry all of the leaf and flower of the sample (not obvious stem and seeds).
2. After drying, the Laboratory shall pulverize and sieve the sample using



mesh size 1 mm as described in United Nations Office on Drugs and Crime: Recommended Methods for the Identification and Analysis of Cannabis and Cannabis Products. ISBN 978-92-1-148242-3. The Laboratory shall blend and homogenize the sieved material.

3. The Laboratory shall determine the dry weight of the sieved material.
4. The Laboratory shall divide the sieved, blended and homogenized sample into two portions: the test portion and the retained file sample. The Laboratory shall store the retained file sample in a freezer until needed. The retained file sample must be of sufficient material to conduct any requested retest and any quality control performed by the testing Laboratory.

D. Retesting Requirements

1. The Laboratory shall retest a Harvest Lot upon receipt of a completed Request for Retest from a grower. “Retest” or “Retesting” means the laboratory process of retesting a retained file sample for THC content after the sample failed initial testing for THC content. A retest does not include or permit taking a new sample from the harvest lot.
2. The Laboratory shall forward the retained file sample to another Laboratory or to the ODA upon receipt of a completed Request for Retest from the grower requesting that the sample be forwarded. The Laboratory shall:
 - a. Use packaging appropriate for secure transport.
 - b. Protect the sample from moisture and temperature extremes.
 - c. Include all documentation with the sample.
 - d. Forward the sample by the most expedient, secure, and legal means to ensure that the sample continues to be representative of the harvest lot sampled and the chain of custody is accounted for to protect its integrity.

E. Testing After Resampling

1. The Laboratory may test a Harvest Lot after a valid resampling in



accordance with OAR 603-048-0630.

2. The Laboratory shall conduct testing after a resampling like any other testing in accordance with this Protocol.
3. The Laboratory shall report the test results as described in Part F of the Protocol, but shall indicate that the result is pursuant to resampling.

F. Reporting and Recordkeeping Requirements

1. All documentation of sampling and testing must be retained by the Laboratory for at least three years and be provided to the Department upon request. All records must clearly identify the harvest lots by harvest lot identifier.
2. The Laboratory shall make Standard Operating Procedure (SOPs) readily accessible to all pertinent personnel and provided to the Department upon request.
3. All documents shall be controlled and retained in accordance with the TNI Standard as defined in in OAR 333-064-0025(52).
4. When testing or forwarding the sample, the Laboratory must create and use a Chain of Custody form that minimally includes the information set out below.
 - a. Laboratory name
 - b. Grower registration number
 - c. Analyst's name
 - d. Laboratory License Number
 - e. Field ID/Name and Harvest Lot Identifier
 - f. Testing Date/Time
 - g. Custody transfer signatures
 - h. Custody Transfer Dates/Times
5. The Laboratory must estimate and report the measurement of uncertainty (MU) with test results. Laboratories shall use appropriate, validated methods and procedures for all testing activities and evaluate measurement of uncertainty. Measurement of uncertainty means the parameter, associated with the result of the measurement, that



characterizes the dispersion of the values that could reasonable be attributed to the particular quantity subject to measurement.

6. The Laboratory shall provide to the Department upon request analytical data and any records associated with test results reported, including SOPs, chain of custody forms, quality checks, MU determination, etc.
7. The Laboratory shall report percentage of total THC in the sample on a dry weight basis to exactly two significant figures.
8. The Laboratory shall report whether the sample passes testing. A sample passes testing when the application of the measurement of uncertainty to the amount of total THC of the sample calculated in accordance with OAR 333-064-0100(4) reported by a laboratory produces a distribution or range that includes 0.3 percent or less on a dry weight basis and the harvest lot was sampled and tested in compliance with these rules.
9. The Laboratory shall report all test results electronically to the Department at HempTestReports@oda.state.or.us using the forms provided or approved by the Department, and include for each sample tested:
 - a. Grower's name and registration number;
 - b. Sample date;
 - c. Sample size by weight;
 - d. Testing date;
 - e. Total THC percentage to exactly two significant figures calculated in accordance with OAR 333-064-0100(4) and whether the sample passed testing;
 - f. The Laboratory's uncertainty level for THC testing of cannabis;
 - g. The harvest lot identifier that corresponds to the sample and the location of the corresponding harvest lot;
 - h. Copy of grower's sampling request form corresponding to the harvest lot;
 - i. Copy of the completed sampling form corresponding to the harvest lot; and



- j. Signature of the laboratory analyst.
- 10. The Laboratory shall send any failed test report electronically to the Department at HempTestReports@oda.state.or.us using the forms provided or approved by the Department **within 24 hours of the failed test.**
- 11. The Laboratory shall send completed copies of the Sampling and Request Form and the On-Site Sampling Form corresponding to the Harvest Lot with each test report.
- 12. The laboratory shall report all test results, except for interim mid-season testing conducted for monitoring THC content during the growth cycle and not for pre-harvest testing, to the United States Department of Agriculture. The test results report must contain the following information:
 - a. Grower's license number;
 - b. Grower's name;
 - c. Business address of the grower;
 - d. Harvest lot identifier
 - e. Name of the laboratory and if applicable, the DEA registration number of the laboratory;
 - f. Date of the test and report;
 - g. Whether it is a retest;
 - h. Test result including whether the lot passed testing.

AMEND: 603-048-0636

RULE SUMMARY: Updates hemp microgreens requirements

CHANGES TO RULE:

603-048-0636

Hemp Microgreens

~~Effective March 1, 2024.~~

(1) Notwithstanding OAR 603-048-0600, a grower is not required to pre-harvest sample and test cut microgreens prior to transfer or sale.

(2) Notwithstanding OAR 603-048-2300 to 603-048-2480, growers and handlers are not required to test cut microgreens under ORS 571.330. Cut microgreens are a part of industrial hemp that are exempt from ORS 571.330.

(3) The Department may sample and test any growing microgreens crop and any cut microgreens.

(4) The Department may require that a licensee in possession of cut microgreens conduct testing under OAR 603-048-0600 or OAR 603-048-2300 to 603-048-2480 at the expense of the licensee.

(5) Cut microgreens are subject to all other requirements for industrial hemp as identified in these rules.

(6) The Department may detain and dispose of any microgreens or cut microgreens if they contain an average total tetrahydrocannabinol concentration that exceeds 0.3 percent on a dry weight basis.

(7) A grower may only produce microgreens via germination from agricultural hemp seed.

(8) A licensee may not dry microgreens prior to sale to a consumer.

Statutory/Other Authority: ORS 571.263, 571.272, 571.330, 571.339

Statutes/Other Implemented: ORS 571.263, 571.330

CHANGES TO RULE:

603-048-0640

Cannabis Waste and Cannabis Disposal

(1) For the purposes of this rule, "cannabis waste" includes cannabis grown at the grower's licensed grow site or under a grower's license that the licensee determines has lost its market value due to mold, pest, disease, or that the licensee otherwise does not intend to store, process, transfer, or sell. This includes removal of male plants, as detailed in section (5) of this rule. "Cannabis waste" does not include minimal amounts of cannabis pruned or removed from cannabis plants in the course of normal agricultural practices ~~such as removing male plants.~~¶

(2) A licensee must comply with the following when disposing of cannabis that fails testing or resampling under OAR 603-048-0600 to 603-048-0635 or if the licensee is otherwise ordered by the Department to dispose of cannabis plants.¶

(a) The licensee must request approval from the Department at least seven (7) calendar days prior to the date of proposed disposal of plants, on a form provided by the Department that includes the following information:¶

(A) Proposed date of disposal;¶

(B) Amount of plants to be disposed;¶

(C) Proposed method of disposal; and¶

(D) Grow site, production area, and harvest lots from which plants are proposed to be disposed.¶

(b) The licensee must permit Department staff, or the Department's designee, to observe the destruction if required by the Department.¶

(c) The licensee must have written Department approval prior to beginning disposal.¶

(d) The licensee must ensure that timely disposal occurs after Department approval is received.¶

(e) The licensee must document the disposal as follows:¶

(A) Photograph the disposal such that the destruction of each separate production area or harvest lot is identifiable. Documentation must include photos of the separate production areas or harvest lots before and after the disposal method is applied. The photos must depict all parts of the subject production area or harvest lots. Alternatively, the licensee may video the destruction if the video satisfies the requirements described for the photographs.¶

(B) The licensee must maintain the photos and video required in subsection (A) for at least three years from the date of disposal and provide immediately to the Department upon request.¶

(e) Within seven (7) calendar days of completing disposal, the licensee must submit a disposal report on a form provided by the Department that includes but is not limited to the following information:¶

(A) Date of disposal;¶

(B) Amount of plants disposed;¶

(C) Method of disposal; and¶

(D) Grow site, production area, and harvest lots from which plants were disposed.¶

(3) A licensee who determines that any portion of the cannabis grown at the grow site is cannabis waste must:¶

(a) Request approval from the Department within 14 days of the determination and at least seven (7) days prior to the date of proposed disposal using a form provided by the Department that includes the following information:¶

(A) Proposed date of disposal¶

(B) Amount of cannabis waste to be disposed¶

(C) Proposed method of disposal¶

(D) Grow site, production area, and harvest lots from which the cannabis waste derives from.¶

(E) Description of the reason why the cannabis is waste (disease, mold, etc.)¶

(b) Comply with all of the requirements in section (2)(b)-(e) of this rule¶

(4) To dispose of cannabis waste or cannabis that fails pre-harvest testing as described in OAR 603-048-0600 to 603-048-0635 such that destruction is required or when otherwise ordered by the Department to dispose of cannabis, the licensee must render the cannabis waste or cannabis into a non-retrievable or non-ingestible form. Licensee may use any of the following methods for disposal as consistent with other local, state, and federal laws or regulations:¶

(a) Plowing under¶

(b) Mulching/composting¶

(c) Disking¶

(d) Brush mower/chopper¶

(e) Burning¶

(5) If immediate culling of male plants is necessary, a licensee must email to hemp@oda.oregon.gov to notify the

Department that the culling activity is to occur prior to removing the affected plants. The license must comply with all of the requirements in section (2)(b)(d), & (e) of this rule.[¶]

(6) It is a Class 1 violation to fail to comply with any provision of this rule.

Statutory/Other Authority: ORS 561.190, ORS 569.445, ORS 571.260 - 571.348, ORS 633.511-633.996

Statutes/Other Implemented: ORS 571.260 - 571.315

AMEND: 603-048-0650

RULE SUMMARY: Updates industrial hemp inspection and record review requirements

CHANGES TO RULE:

603-048-0650

Industrial Hemp Inspection and Record Reviews ¶¶

(1) The Department, as it deems necessary in the enforcement and carrying out its laws may, during normal business hours, inspect premises, machinery, equipment, and facilities of licensees ~~and, inspect any crop during any growth phase or after harvested crop, and sample for analysis, and inspect any industrial hemp products or commodities~~ and sample for analysis.¶¶

(2) Upon not less than three (3) days' notice, the Department may subject licensee records to inspection or audit during normal business hours. The Department may make an inspection or audit for the purpose of ensuring compliance with:¶¶

(a) A provision of ORS 571.260 to 571.348;¶¶

(b) A rule adopted under a provision of ORS 571.260 to 571.348; or¶¶

(c) An order issued by the Department pursuant to a provision of ORS 571.260 to 571.348 or rule adopted under a provision of ORS 571.260 to 571.348, including a detainment order.¶¶

(3) A licensee must permit Department staff, or its designee, to inspect and access all parts of the licensed grow site, handling site, vendor site, research facility equipment, facilities, and any area where cannabis is grown, stored, sold or processed pursuant to the license and cooperate with such an inspection. Failure to permit or cooperate with an inspection includes, but is not limited to:¶¶

(a) Failing to appear at a licensed site or facility within a reasonable period of time after being notified of an on-site inspection.¶¶

(b) After reasonable notice of an onsite inspection, failing to appoint a licensee representative knowledgeable about operations at the site or facility to be available to the Department staff, or its designee, during an inspection.¶¶

(c) Failing to timely respond to Department staff, or its designee, communications to set up a time for inspection.¶¶

(d) Refusing to grant access to all areas of the licensed site or facility.¶¶

(e) Failing to maintain safe conditions at a site or facility, such that the Department or its designee cannot reasonably and safely inspect the site or facility. Failing to maintain safe conditions may include allowing unrestrained animals on the grow site or maintaining hazards or other dangerous conditions on the site or facility.¶¶

(f) Failure to provide to the Department, upon request, information concerning compliance with these rules.¶¶

(g) Failure to provide confirmation, upon request by the Department or its designee, of the presence or absence of hazards or dangerous conditions at a site or facility.¶¶

(h) Ending an inspection or engaging in aggressive or confrontational behavior that requires Department staff or its designee to end an inspection prior to the Department or its designee finishing all inspection tasks and duties.¶¶

(i) Failing to permit the Department or its designee to conduct sampling for the purposes of testing under these rules.

Statutory/Other Authority: ORS 561.120, 561.200, 561.275, 561.190, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

RULE SUMMARY: Updates enforcement and civil penalty for industrial hemp law violations

CHANGES TO RULE:

603-048-0800

Enforcement and Civil Penalty for Industrial Hemp Law Violation

(1) A licensee is responsible for:¶

(a) All activities that occur at the grow site, research facility, vendor site or handling site and for ensuring that all activities at the site comply with ORS 571.260 to 571.348 and these rules. If a licensee no longer is operating at a grow site, research facility, vendor site or handling site, the licensee must notify the Department as described in OAR 603-048-0400(2)(b).¶

(b) Any act or omission of a licensee representative in violation of these rules or any provision of ORS 571.260 to 571.348.¶

(2) In addition to any other liability or penalty provided by law, the Department may impose a civil penalty not to exceed \$2,500 on any person who violates any provision of ORS 571.260 to 571.348, a rule adopted pursuant thereto, or order issued by the Department under ORS 571.260 to 571.348 or a rule adopted pursuant thereto, including a detainment order.¶

(3) The Department shall issue a written notice to the person being assessed the penalty consistent with ORS Ch. 183. Any contested case to contest the civil penalty will be conducted pursuant to ORS Ch. 183. Each violation may be considered a separate and distinct offense.¶

(4) Subject to the provisions of ORS Ch. 183,¶

(a) the Department may revoke a license issued under these rules if the licensee violates:¶

(aA) A provision of ORS 571.260 to 571.348;¶

(bB) A rule adopted under a provision of ORS 571.260 to 571.348;¶

(cC) An order issued by the Department for violation of a provision of ORS 571.260 to 571.348 or any rule adopted thereunder including a detainment order;¶

(dD) Any statutory law or Department rule related to agricultural activities other than industrial hemp operations.¶

(b) the Department may deny, revoke or suspend a license if:¶

(A) An applicant, licensee or an individual listed on the application violates state or federal laws related to the unlawful manufacture, possession, delivery, export or import of marijuana or¶

(B) applicant's proposed or licensee's grow site or handling site is a location where unlawful manufacture, possession, delivery, export or import of marijuana occurred.¶

(C) Any cannabis at the proposed or licensed grow site or handling site exceeds 0.3 percent total THC and is not otherwise permitted by ORS 475C.305 or under a license issued under ORS 475C.¶

(D) Any finished hemp items at the proposed or licensed grow site or handling site exceed the permissible concentrations in OAR 845-026-0400.¶

(E) Any industrial hemp commodities at the proposed or licensed grow site or handling site exceed five percent total THC and is not otherwise permitted by ORS 475C.305 or under a license issued under ORS 475C.¶

(5) Subject to the provisions of ORS Ch. 183, the Department may revoke a license for any reason that the Department may deny an initial or renewal application.¶

(6) Subject to the provisions of ORS Ch. 183, the Department must revoke a license if:¶

(a) A grower licensee or a key participant is convicted of a felony relating to a controlled substance within the last ten years unless the convicted individual was growing hemp lawfully under a pilot program authorized by Section 7606 of the Agricultural Act of 2014 before December 20, 2018 if the conviction also occurred before December 20, 2018;¶

(b) A licensed research grow site or research facility is co-located with a medical marijuana grow site registered under ORS 475C.792 or marijuana producer licensed under ORS 475C.065.¶

(7) Corrective Action Plans.¶

(a) If the Department identifies violations by a licensee, the Department in writing may require a licensee to enter a corrective action plan as an alternative or in addition to disciplinary action.¶

(b) The licensee must submit a corrective action plan to the Department within 10 days of receiving the Department's written directive to submit a corrective action plan.¶

(c) The licensee must correct all identified violations by the deadline established by the Department. Licensee may request a longer time period to correct violations in the corrective action plan.¶

(d) The Department shall review and determine if the proposed corrective action plan is acceptable. The corrective action plan must include all elements required by the Department in writing.¶

(A) If the corrective action plan is not acceptable, the Department shall notify the licensee in writing which

provisions in the Department finds unacceptable.¶

(B) Licensee shall submit a revised corrective action plan to the Department within 10 days of receiving the Department's notification. The Department shall review the revised plan in accordance with this rule. If the plan is still unacceptable, the Department may take the actions described in subsection (e) of this rule.¶

(e) If the licensee fails to submit a corrective action plan, fails to comply with any deadline in subsection (7) of this rule or other deadline established by the Department for the corrective action plan process, or fails to timely correct all identified violations, the Department may take action to revoke or deny licensee's license or impose civil penalties.

Statutory/Other Authority: ORS 561.190, 569.445, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-1000

RULE SUMMARY: Updates violations and penalties

CHANGES TO RULE:

603-048-1000

Violations and Penalties ¶¶

- (1) The Department may impose a civil penalty not to exceed \$2,500 on a person for violating:¶¶
- (a) A provision of ORS 571.260 to ORS 571.348;¶¶
 - (b) A rule adopted under a provision of ORS 571.260 to ORS 571.348; or¶¶
 - (c) An order issued by the Department pursuant to a provision of ORS 571.260 to ORS 571.348, or a rule adopted thereunder, including a detainment order.¶¶
- (2) The Department may impose a civil penalty based on the classification of the violation. The civil penalty amount for each classification is as follows:¶¶
- (a) Class 1 violation, \$2,500;¶¶
 - (b) Class 2 violation, \$1000;¶¶
 - (c) Class 3 violation, \$500.¶¶
- (3) The civil penalty amount for each classification are guidelines. If the Department finds one or more mitigating or aggravating circumstances, it may assess a lesser or greater amount.¶¶
- (4) Common violations are classified as follows:¶¶
- (a) Class 1 violations include:¶¶
- (A) Failing to obtain a license with the Department when required under ORS 571.260-571.348 or rules adopted thereunder except as otherwise specified in this rule for vendor site licenses;¶¶
 - (B) Producing cannabis at a grow site not included on the grower license.¶¶
 - (C) Providing any false or misleading information or documentation to the Department or providing false or misleading information or documentation to a laboratory when requesting required testing under these rules;¶¶
 - (D) Falsifying information or records required to be maintained by the Department or submitted to the Department;¶¶
 - (E) Failing to test a hemp item in accordance with OAR 603-048-2300 through 603-048-2480;¶¶
 - (F) Failing to test a harvest lot in accordance with these rules;¶¶
 - (G) Altering or falsifying a laboratory test report or result;¶¶
 - (H) Selling or ~~attempting~~ offering to sell a hemp item that fails to meet testing requirements or has not been tested as required by OAR 603-048-2000 through 603-048-2480;¶¶
 - (I) Selling, transferring, receiving, ~~attempting~~ offering to transfer, sell, or receive, processing or attempting to process a harvest lot that:¶¶
- (i) Has not been sampled and tested in accordance with these rules;¶¶
 - (ii) Failed testing under OAR 603-048-0600 and did not otherwise pass testing under OAR 603-048-0630 to 603-048-0630;¶¶
 - (iii) Was invalidly tested as described in OAR 603-048-0600.¶¶
- (J) Growing or handling cannabis with total THC calculated in accordance with OAR 333-064-0100(4) that exceeds 3 percent on a dry weight basis.¶¶
- (K) Failing to ensure cannabis, industrial hemp, or industrial hemp commodity or product, or any portion thereof, that is subject to a detainment, embargo, seizure, or destruction order complies with the order as described in OAR 603-048-0900(4).¶¶
- (L) Failing to timely dispose of cannabis as described in OAR 603-048-0640.¶¶
- (M) Failing to permit Department staff, or its designee, to inspect and access all parts of the licensed or proposed grow site, handling site, vendor site, equipment, facilities, and any area where cannabis is grown, handled, or stored pursuant to a license or failing to cooperate with any such inspection in accordance with OAR 603-048-0650(3).¶¶
- (N) Failing to timely report cannabis waste or disposal in accordance with OAR 603-048-0640.¶¶
- (O) Failing to comply with a Department order.¶¶
- (P) Repeat violations of Class 2 or Class 3 violations.¶¶
- (Q) Any other violation of ORS 571.260 to ORS 571.348 or these rules that may cause an immediate threat to the public health or safety.¶¶
- (R) Failing to provide an accurate legal description of land where hemp is produced.¶¶
- (S) The third or subsequent instance of failing to obtain a vendor site license when required by these rules.¶¶
- (T) The presence of cannabis with total THC calculated in accordance with OAR 333-064-0100(4) that exceeds 3 percent on a dry weight basis at a grow site or handling site that is not otherwise permitted by ORS 475A.305 or

under a license issued by OLCC under ORS 475C.

(b) Class 2 violations include, but are not limited to:

(A) Failing to ensure test reports for the THC content of each harvest lot is timely reported to the Department as required by 603-048-0400.

(B) Failing upon request to timely provide the Department with laboratory test results that verify compliance with these rules.

(C) Failing to identify each ~~non-contiguous~~ production area where cannabis is produced including failing to submit a change form and applicable fee with the Department identifying any additional production areas not identified in the licensee's application.

(D) The second instance of failing to obtain a vendor site license when required by these rules.

(E) Any other uncategorized violation.

(F) Repeat violations of Class 3 violations.

(c) Class 3 violations include but are not limited to:

(A) Failure to keep or provide information or records as required by the Department;

(B) Growing or handling hemp with total THC calculated in accordance with OAR 333-064-0100(4) that fails testing as described in OAR 603-048-0600 but does not exceed 3 percent total THC;

(C) Failing to ensure failed test results of a hemp item are reported to the Department within 24 hours as required by OAR 603-048-2300.

(D) The first instance of failing to obtain a vendor site license when required by these rules.

(5) In addition to the penalty described in subsection (1) of this rule, the Department may impose a civil penalty not to exceed \$10,000 against a licensed grower if the Department determines that the licensee produced cannabis on a licensed grow site that contains an average tetrahydrocannabinol concentration of at least 10 percent on a dry weight basis.

Statutory/Other Authority: ORS 561.120, 561.200, 561.275, 561.190, ORS 571.260 - 571.348

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-1500

RULE SUMMARY: Updates retail sale requirements and restrictions

CHANGES TO RULE:

603-048-1500

Retail Sale Requirements; Restrictions

- (1) For the purposes of this rule, "consumer" means a person who purchases, acquires, owns, holds or uses an industrial hemp commodity or products other than for the purpose of resale.¶
- (2) A person may not sell, transfer or deliver to a consumer an industrial hemp commodity or product that contains cannabinoids and is intended for human consumption unless:¶
- (a) If it is a hemp item, the hemp item has been tested in accordance with ORS 571.330 and OAR 603-048-2300 to 603-048-2500;¶
- (b) If the hemp commodity or product is intended for human consumption by ingestion, the hemp commodity or product was processed in a facility licensed by the State Department under ORS 616.695 to 616.755 or in a facility in another state or jurisdiction that meets requirements substantially similar to requirements established under ORS 616.695 to 616.755;¶
- (c) The person obtains and maintains documentation of the results of any testing required under these rules;¶
- (d) If the industrial hemp commodity or product is sold to a person under 21 years of age or any representations are made to the consumer about the concentration of delta-8-tetrahydrocannabinol, the results of the testing required under this subsection demonstrate the concentration of delta-8-tetrahydrocannabinol;¶
- (e) The industrial hemp commodity or product does not contain more than 0.3 percent tetrahydrocannabinol or the concentration of tetrahydrocannabinol allowed under federal law, whichever is greater; and¶
- (f) The industrial hemp commodity or product does not exceed the concentration of adult use cannabinoids ~~established as defined by~~ in OAR 845-026-0100, and established in OAR 845-026-0300, and OAR 845-026-0400.¶
- (3)~~(a)~~ The testing required under this rule may be conducted only by:¶
- ~~(a)~~A A laboratory licensed by the ~~e~~Commission under ORS 475C.548 and accredited by the authority under ORS 475C.560; or¶
- ~~(b)~~B If the industrial hemp commodity or product was processed outside of this state, a laboratory accredited to the same or more stringent standards as a laboratory described in paragraph ~~(a)~~ A of this subsection.¶
- (b) A laboratory is considered accredited to the same or more stringent standards as a laboratory described in paragraph (a)(A) of this subsection if the laboratory is accredited under TNI Standards to perform analyses on environmental samples for the matrices implicated for the testing conducted, including but not limited to pesticides, cannabinoids, potency, mycotoxins, microbiology, residual solvents, and heavy metals.¶
- (4) A person may not sell or deliver an adult use cannabis item as defined by OAR 845-026-0100 and OAR 845-026-0300 to a person under 21 years of age.¶
- (5) Restriction on industrial hemp product sales: A person may not sell an industrial hemp product that contains more than 0.3 percent total THC to a consumer unless licensed as a retailer by OLCC as defined in ORS 475C.257.¶
- (6) Compliance with these rules does not protect a person from possible criminal prosecution under federal law or other sanctions by federal entities.¶
- (7) Each unit of sale of hemp item or lot of industrial hemp for human consumption sold, transferred, or delivered in violation of these rules is a separate violation.
- Statutory/Other Authority: ORS 561.190
- Statutes/Other Implemented: ORS 571.300-571.348

AMEND: 603-048-1600

RULE SUMMARY: Updates prohibitions on adulteration

CHANGES TO RULE:

603-048-1600

Prohibitions on Adulteration

- (1) A licensee may not supply, transfer, or sell adulterated industrial hemp for human consumption or hemp items.¶¶
- (2) A licensee may not treat or otherwise adulterate hemp or a hemp item with any chemical, biologically active drug, plant, substance, including nicotine, or other compound that has the effect or intent of altering the usable hemp's color, appearance, weight or smell.¶¶
- (3) "Adulterated" means to make industrial hemp for human consumption or a hemp item impure by adding or applying foreign or inferior ingredients or substances, including but not limited if the hemp or hemp item:¶¶
 - (a) In the Department's judgment, bears or contains any poisonous or deleterious substance in a quantity rendering it injurious in a manner that may pose a risk to human health, including but not limited to tobacco or nicotine;¶¶
 - (b) Bears or contains any added poisonous or deleterious substance exceeding a safe tolerance if such tolerance has been established;¶¶
 - (c) Consists in whole or in part of any filthy, putrid, or decomposed substance, or otherwise is unfit for human consumption;¶¶
 - (d) Is processed, prepared, packaged, or is held under improper time-temperature conditions or under other conditions increasing the probability of contamination with excessive microorganisms or physical contaminants;¶¶
 - (e) Is processed, prepared, packaged, or held under insanitary conditions increasing the probability of contamination or cross-contamination;¶¶
 - (f) Is held or packaged in containers composed, in whole or in part, of any poisonous or deleterious substance rendering the contents potentially injurious to health;¶¶
 - (g) Any substance has been substituted wholly or in part therefor;¶¶
 - (h) Damage or inferiority has been concealed in any manner; or¶¶
 - (i) Any substance has been added thereto or mixed or packaged therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is;¶¶
 - (j) Is treated with a pesticide that is not on the Hemp Program's guide list or approved by the EPA for use on industrial hemp.¶¶
- (4) The Department may request or require a licensee to recall any industrial hemp for human consumption or hemp item that the licensee has sold or transferred that does not meet the minimum standards established by these rules, including but not limited to when there is evidence that:¶¶
 - (a) Pesticides were used in the production of industrial hemp in violation of these rules, ORS chapter 634 or OAR chapter 603, division 57.¶¶
 - (b) The industrial hemp for human consumption or a hemp item is adulterated, contaminated, may pose a risk to public health and safety, or is otherwise unfit for human use, consumption, or application.¶¶
 - (c) The industrial hemp for human consumption or hemp item does not meet testing requirements of these rules.¶¶
- (5) In addition to the actions above, the Department may initiate an action to detain, seize, embargo or dispose of hemp or hemp items if it does not meet the minimum standards established in these rules and as described in section (4) of this rule in accordance with OAR 603-048-0900.¶¶
- (6) Each harvest or process lot of industrial hemp for human consumption and each unit of sale of hemp item supplied, transferred, or sold in violation of this rule is a separate violation.

Statutory/Other Authority: ORS 571.263, 571.281

Statutes/Other Implemented: ORS 561.605-561.630, 571.272, 571.281, 571.309, 571.330, 571.339

AMEND: 603-048-2300

RULE SUMMARY: Updates requirements for testing of industrial hemp for human consumption and hemp items

CHANGES TO RULE:

603-048-2300

Testing of Industrial Hemp for Human Consumption and Hemp Items

- (1) A grower or handler may not sell, or offer for sale or transfer industrial hemp for human consumption or a hemp item unless it is first tested by a laboratory as required by these rules.¶
- (2) Violations of these rules may result in the suspension or revocation of a licensee's license or the imposition of civil penalties, or both. Violations include:¶
- (a) Failure to test industrial hemp for human consumption or a hemp item in accordance with these rules;¶
- (b) Selling, ~~transferring~~, ~~for attempting to sell~~ sale, or transferring industrial hemp for human consumption or a hemp item that ~~fails to meet~~ has not been ~~testing requirements~~ tested or does not pass testing required by these rules;¶
- (c) Failure to maintain a copy of all required test reports as required by OAR 603-048-0500; and¶
- (d) Failure to report failed test results to the Department electronically to HempTestReports@oda.oregon.gov using the forms provided by the Department within 24 hours after receipt of failed result.¶
- (e) Altering or falsifying a laboratory test report or result.¶
- (3) These rules require industrial hemp for human consumption and hemp items to be sampled, tested, and reported in a manner consistent with the Authority's marijuana sampling and testing rules in OAR 333-007-0300 to 333-007-0500 and OAR 333-064. In applying those rules:¶
- (a) Industrial hemp for human consumption and hemp items are treated as their marijuana equivalents as described in OAR 603-048-2310;¶
- (b) References to "licensee or registrant" or "processor or processing site" should be read as "grower" or "handler";¶
- (c) References to "Authority or the Commission" should be read as "Department"; and¶
- (d) References to "consumer or patient" should be read as "consumer" as that is defined in OAR 603-048-2310.¶
- (4) To be sufficient to meet the requirement for testing under these rules, a licensed grower or handler must ensure through a testing agreement or contract with the laboratory that the laboratory:¶
- (a) Samples industrial hemp for human consumption and hemp items according to OAR 333-007-0360 and OAR 333-064-0100;¶
- (b) Tests industrial hemp for human consumption and hemp items according to OAR 333-007-0390 to 333-007-0450 and 333-064-0100;¶
- (c) Keeps records in accordance with OAR 333-064-0100.¶
- (d) Reports all failed tests to the Department electronically to HempTestReports@oda.oregon.gov using the forms provided by the Department consistent with reporting requirements under OAR 333-064-0110;¶
- (e) Provides the licensee with test reports that meet the requirements in OAR 333-064-0110.¶
- (f) Provides test reports that clearly identify the process lot identifier.¶
- (g) Meets the proficiency testing requirements in OAR 333-064-0120.¶
- (h) Can demonstrate that its limit of quantification (LOQ) for THC is at or below 0.3 percent THC.¶
- ~~(5) Each~~ (5) Each unit of sale of hemp item or lot of industrial hemp for human consumption sold, transferred, or attempted to be sold or transferred in violation of these rules is a separate violation.¶
- (6) The requirement to contract with a laboratory under Subsection (4) of this rule does not apply to hemp items manufactured outside the state of Oregon.

Statutory/Other Authority: ORS 561.190, 571.263, 571.281, 571.285, 571.322, 571.330

Statutes/Other Implemented: 571.322, 571.330, ORS 571.333, 571.336, 571.337, 571.339, 571.348

AMEND: 603-048-2305

RULE SUMMARY: Updates purpose of OAR 603-048-2300 to 603-048-2500

CHANGES TO RULE:

603-048-2305

Purpose

(1) The purpose of OAR 603-048-2300 to 603-048-2500 is to establish minimum testing standards for industrial hemp for human consumption and hemp items.¶¶

(2) All references to OAR Chapter 333, Division 7 refer to the rules in effect as of ~~March 31, 2022~~November 19, 2025.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.285, ORS 571.322, ORS 571.330, ORS 571.337

Statutes/Other Implemented: ORS 571.322, ORS 571.330, ORS 571.337, ORS 571.333, ORS 571.336, ORS 571.339, ORS 571.348

AMEND: 603-048-2310

RULE SUMMARY: Updates testing definitions

CHANGES TO RULE:

603-048-2310

Definitions ¶¶

The following definitions apply to OAR 603-048-2300 to OAR 603-048-3280 unless the context provides otherwise.¶¶

- (1) "Added substance" means any component or ingredient added to usable hemp, cannabinoid concentrate or cannabinoid extract during or after processing that is present in the finished hemp cannabinoid product, including but not limited to flavors, non-cannabis derived terpenes, and any substances used to change the viscosity or consistency of the cannabinoid product.¶¶
- (2) "Adult use cannabinoid" includes, but is not limited to, tetrahydrocannabinols, tetrahydrocannabinolic acids that are artificially or naturally derived, delta-8-tetrahydrocannabinol, delta-9-tetrahydrocannabinol, the optical isomers of delta-8-tetrahydrocannabinol or delta-9 tetrahydrocannabinol and any artificially derived cannabinoid that is reasonably determined to have an intoxicating effect.¶¶
- (3)(a) "Artificially derived cannabinoid" means a chemical substance that is created by a chemical reaction that changes the molecular structure of any chemical substance derived from the plant Cannabis family Cannabaceae.¶¶
- (b) "Artificially derived cannabinoid" does not include:¶¶
- (A) A naturally occurring chemical substance that is separated from the plant Cannabis family Cannabaceae by a chemical or mechanical extraction process;¶¶
- (B) Cannabinoids that are produced by decarboxylation from a naturally occurring cannabinoid acid without the use of a chemical catalyst; or¶¶
- (C) Any other chemical substance identified by the Commission, in consultation with the Authority and the Department of Agriculture, by rule.¶¶
- (4) "Authority" means the Oregon Health Authority.¶¶
- (5) "Batch" means:¶¶
- (a) A quantity of hemp, usable hemp or hemp stalk from a harvest lot; or¶¶
- (b) A quantity of hemp-¶¶
- (6) "Biomass" is any harvested cannabis that has not been further processed into a product.¶¶
- concentrate or extract or hemp cannabinoid product from a process lot.¶¶
- ~~(67)~~ "Cannabinoid" means any of the chemical compounds that are the active constituents of the cannabis plant.¶¶
- ~~(78)~~ "Cannabinoid capsule"¶¶
- (a) Means a small, soluble pill, tablet, or container that contains liquid or powdered hemp cannabinoid product, hemp concentrate, or hemp extract and is intended for human ingestion.¶¶
- (b) For sampling and testing purposes is equivalent to a cannabinoid capsule as that is defined in OAR 333-007-0310.¶¶
- (c) Does not mean a cannabinoid suppository.¶¶
- ~~(89)~~ "Cannabis Tracking System" or "CTS" means the Commission's system for tracking the transfer of hemp and marijuana items and other information as authorized by ORS 475C.177, ORS 571.336 and 571.337.¶¶
- ~~(910)~~ "CBD" means cannabidiol, Chemical Abstracts Service Number 13956-29-1.¶¶
- ~~(101)~~ "CBDA" means cannabidiolic acid, Chemical Abstracts Service Number 1244-58-2.¶¶
- ~~(112)~~ "Chain of custody procedures" means procedures employed by laboratory personnel using a chain of custody form to record the possession of samples from the time of sampling through the retention time specified by the Department.¶¶
- ~~(123)~~ "Commission" means the Oregon Liquor and Cannabis Commission.¶¶
- ~~(134)~~ "Consumer" includes:¶¶
- (a) A person who purchases, acquires, owns, holds or uses hemp items other than for the purpose of resale; and¶¶
- (b) A person who purchases, receives, or otherwise uses hemp items who is not a licensed hemp handler, licensed hemp vendor, or a marijuana processor, wholesaler or retailer licensed by the Commission.¶¶
- ~~(145)~~ "Consumption" means ingestion, inhalation, or topical application to the skin or hair.¶¶
- ~~(156)~~ "Duplicate sample" means sample increments taken in an identical manner to sample increments taken from the primary sample and representative of the same hemp item being sampled that is prepared and analyzed separately from the primary sample.¶¶
- ~~(167)~~ "Finished hemp concentrate or extract" means a hemp concentrate or extract that is in its final form ready for packaging for sale or transfer to a consumer.¶¶

(178) "Finished cannabinoid hemp product" means a cannabinoid hemp product that is in its final form ready for packaging for sale or transfer to a consumer and includes all ingredients whether or not the ingredients contain cannabinoids.¶¶

(189) "Food" means a raw, cooked, or processed edible substance, or ingredient used or intended for use or for sale in whole or in part for human consumption, chewing gum and includes beverages.¶¶

(1920) "Hemp cannabinoid product":¶¶

(a) Means a hemp edible or any other product intended for human consumption including a hemp topical or hemp transdermal patch, that contains cannabinoids from industrial hemp or the dried leaves or flowers of hemp; or¶¶

(b) Usable hemp, hemp extracts and hemp concentrates that have been combined with an added substance.¶¶

(c) Cannabinoid hemp product does not include usable hemp by itself, hemp stalk by itself, a hemp concentrate or extract by itself, hemp seed incapable of germination by itself, or other products derived only from hemp seeds incapable of germination that may include other non-hemp ingredients.¶¶

(d) For sampling and testing purposes is equivalent to a cannabinoid product as that is defined in OAR 333-007-0310.¶¶

(201) "Hemp concentrate or extract":¶¶

~~(a) Means a substance obtained by separating cannabinoids from industrial hemp leaves, flowers, or stalk by a mechanical, chemical or other process.~~
marijuana by:¶¶

(a) A mechanical extraction process:¶¶

(b) A chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol or ethanol; or¶¶

(c) A chemical extraction process using the solvent carbon dioxide, provided that the process does not involve the use of high heat or pressure.¶¶

(d) For sampling and testing purposes is equivalent to a cannabinoid concentrate or edible as that is defined in OAR 333-007-0310.¶¶

(22) "Hemp Extract" means a substance obtained by separating cannabinoids from marijuana by:¶¶

(a) A chemical extraction process using a hydrocarbon-based solvent, such as butane, hexane, or propane;¶¶

(b) A chemical extraction process using the solvent carbon dioxide, if the process uses high heat or pressure.¶¶

~~(b)~~ (c) For sampling and testing purposes is equivalent to a cannabinoid concentrate or edible as that is defined in OAR 333-007-0310.¶¶

(213) "Hemp edible":¶¶

(a) Means a food or potable liquid into which industrial hemp, a hemp concentrate, a hemp extract, or the dried leaves or flowers of hemp have been incorporated.¶¶

(b) Does not mean hemp seed incapable of germination by itself or other products derived only from hemp seeds incapable of germination that may include other non-hemp ingredients.¶¶

(c) For sampling and testing purposes is equivalent to a cannabinoid edible as that is defined in OAR 333-007-0310.¶¶

(224) "Hemp item":¶¶

(a) Means usable hemp, hemp stalk, a hemp cannabinoid product, or a hemp concentrate or extract.¶¶

(b) For sampling and testing purposes is equivalent to a marijuana item as that is defined in OAR 333-007-0310.¶¶

(235) "Hemp stalk":¶¶

(a) Means the stalk of industrial hemp intended for human consumption.¶¶

(b) For sampling and testing purposes is equivalent to usable marijuana as that is defined in OAR 333-007-0310.¶¶

(246) "Hemp suppository" means a small soluble container designed to melt at body temperature within a body cavity other than the mouth, especially the rectum or vagina, containing a hemp cannabinoid product, concentrate, or extract.¶¶

(257) "Hemp tincture":¶¶

(a) Means a liquid hemp cannabinoid product packaged in a container of four (4) fluid ounces or less that consists of either:¶¶

(A) A non-potable solution of at least 25 percent non-denatured alcohol, in addition to a hemp concentrate, hemp extract, or usable hemp and perhaps other ingredients intended for human consumption that is exempt from the Liquor Control Act under ORS 471.035; or¶¶

(B) A non-potable solution comprised of glycerin, plant-based oil, or concentrated syrup; hemp concentrate or extract or usable hemp, and perhaps other ingredients that does not contain any added sweeteners and is intended for human consumption or ingestion.¶¶

(b) For sampling and testing purposes is equivalent to a cannabinoid tincture as that is defined in OAR 333-007-0310.¶¶

(268) "Hemp topical":¶¶

(a) Means a substance intended to be applied to skin or hair that contains a hemp cannabinoid product, hemp concentrate or extract and for purposes of testing includes a hemp transdermal patch.¶¶

(b) For sampling and testing purposes is equivalent to a cannabinoid topical as that is defined in OAR 333-007-0310.¶

(279) "Hemp transdermal patch":¶

(a) Means an adhesive substance applied to human skin that contains a hemp cannabinoid product, hemp concentrate or extract for absorption into the bloodstream.¶

(b) For sampling and testing purposes is equivalent to a cannabinoid transdermal patch as that is defined in OAR 333-007-0310.¶

(2830) "High heat" means a temperature exceeding 180 degrees Fahrenheit.¶

(2931) "Homogeneous" means a hemp cannabinoid product, hemp concentrate or extract has uniform composition and properties throughout each process lot.¶

(302) "Industrial hemp-derived vapor item" means an industrial hemp concentrate or industrial hemp extract, as those terms are defined in ORS 571.269, whether alone or combined with other substances, that is intended for use in an inhalant delivery system.¶

(313) "Industrial hemp for human consumption"¶

(a) Means industrial hemp that is intended to be processed into a hemp item.¶

(b) For sampling and testing purposes is equivalent to marijuana as that is defined in OAR 333-007-0310.¶

(324) "Inhalant delivery system" has the meaning given that term in ORS 431A.175.¶

(335) "Marijuana testing rules" means Authority testing rules for marijuana items found in OAR Chapter 333, Divisions 7 and 64, and all referenced tables and exhibits.¶

(346) "ORELAP" means the Oregon Environmental Laboratory Accreditation Program administered by the Authority pursuant to ORS 438.605 to 438.620.¶

(357) "Process lot" means:¶

(a) Any amount of hemp concentrate or extract of the same type and processed using the same extraction methods, standard operating procedures and batches from the same or a different harvest lot; or¶

(b) Any amount of a hemp cannabinoid product of the same type and processed using the same ingredients, standard operating procedures and batches from the same or a different harvest lot or process lot of hemp concentrate or extract.¶

(368) "Relative percentage difference" or "RPD" means the comparison of two quantities while taking into account the size of what is being compared as calculated under OAR 333-064-0100.¶

(379) "Relative standard deviation" or "RSD" means the standard deviation expressed as a percentage of the mean recovery as calculated under OAR 333-064-0100.¶

(3840) "Remediation":¶

(a) Means a process or technique applied to a hemp item to remove heavy metals, pesticides or solvents.¶

(b) Does not include dilution.¶

(3941) "Replicate Sample" means a sample in addition to the primary and duplicate samples that consists of the same number of increments taken in the same manner as the primary and duplicate samples.¶

(402) "Sample" means an amount of a hemp item or hemp collected by laboratory personnel from a grower or handler and provided to a laboratory for testing.¶

(413) "Sample increment" means an amount of a hemp item or hemp collected by laboratory personnel from a grower or handler that may be combined into a sample for purposes of testing.¶

(424) "Standard operating procedure" means a written set of instructions or procedures using the same ingredients, methods and steps to create a single type of industrial hemp item or hemp-derived vapor item.¶

(435) "Sterilization" means the removal of all microorganisms and other pathogens from a hemp item by treating it with approved chemicals or subjecting it to high heat or other process.¶

(446) "Test batch" means a group of samples from a batch submitted collectively to a laboratory for testing purposes.¶

(457) "Texture" means the feel, appearance, or consistency of a hemp item.¶

(468) "THC" means tetrahydrocannabinol and has the same Chemical Abstracts Service Number as delta-9 THC.¶

(479) "THCA" means tetrahydrocannabinolic acid, Chemical Abstracts Service Number 23978-85-0.¶

(4850) "These rules" means OAR 603-048-2300 through 603-048-2503280.¶

(4951) "TNI" means The NELAC (National Environmental Laboratory Accreditation Conference) Institute, a voluntary organization of state and federal environmental officials and interest groups purposed primarily to establish consensus standards for accrediting environmental laboratories.¶

(50) "TNI EL Standards" means the adopted 2009 TNI Environmental Lab Standards (© 2009 The NELAC Institute), which describe the elements of laboratory accreditation developed and established by the consensus principles of TNI and that meet the approval requirements of TNI procedures and policies Standards has the same meaning as defined in OAR 333-064-0025(52). Details regarding standards are available at www.nelac-institute.org.¶

(512) "Unit of sale" means an amount of a hemp item commonly packaged for transfer or sale to a consumer or

capable of being packaged for transfer or sale to a consumer.¶¶

(523) "Usable hemp"¶¶

(a) Means the flowers and leaves of industrial hemp intended for human consumption that does not fall within meaning hemp concentrate or extract, hemp edible, or hemp cannabinoid product.¶¶

(b) Includes, for purposes of these rules, pre-rolled hemp as long as the pre-roll consists of only dried hemp leaves and flowers, an unflavored rolling paper and a filter or tip.¶¶

(c) For sampling and testing purposes is equivalent to usable marijuana as that is defined in OAR 333-007-0310.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330, ORS 571.337

Statutes/Other Implemented: ORS 571.260 - 571.348

AMEND: 603-048-2320

RULE SUMMARY: Updates compliance testing requirements for industrial hemp for human consumptions and usable hemp

CHANGES TO RULE:

603-048-2320

Compliance Testing Requirements for Industrial Hemp for Human Consumption and Usable Hemp

A grower or handler must have every batch of industrial hemp for human consumption, usable hemp, and hemp stalks, tested as required and in the same manner as marijuana under OAR 333-007-0320 prior to sale, transfer, or offering for sale or transfer.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330

Statutes/Other Implemented: ORS 571.330, ORS 571.339

AMEND: 603-048-2330

RULE SUMMARY: Updates compliance testing requirements for hemp concentrate or extract

CHANGES TO RULE:

603-048-2330

Compliance Testing Requirements for Hemp Concentrate or Extract

(1) A handler must have every process lot of a hemp concentrate or extract, including kief, intended for use by a handler to make a hemp cannabinoid product tested in the same manner as a cannabinoid concentrate or extract under OAR 333-007-0330(2) prior to sale, or transfer, ~~except for a hemp extract or concentrate that meets the criteria in section (5) of this rule~~ offering for sale, or transfer.¶

(2) A handler must have every process lot of a finished hemp concentrate or extract, including kief, tested in the same manner as a finished cannabinoid concentrate or extract under OAR 333-007-0330(1) prior to sale, transfer, or offering for sale or transfer.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330

Statutes/Other Implemented: ORS 571.330, ORS 571.339

AMEND: 603-048-2342

RULE SUMMARY: Updates compliance testing requirements for industrial hemp-derived vapor items

CHANGES TO RULE:

603-048-2342

Compliance Testing Requirements for Industrial Hemp-Derived Vapor Items

A handler must ensure that every process lot of an industrial hemp-derived vapor item for use by a consumer is tested as described in OAR 333-007-0342 prior to sale, transfer, or offering for sale or transfer.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330

Statutes/Other Implemented: ORS 571.263, ORS 571.281, ORS 571.330

AMEND: 603-048-2350

RULE SUMMARY: Specifies location of applicable rules

CHANGES TO RULE:

603-048-2350

Batch Requirements for Compliance Testing

- (1) Usable hemp. A handler must separate each harvest lot of usable hemp and industrial hemp intended for human consumption into no larger than 50.0 pound batches.¶
- (2) Hemp concentrates or extracts:¶
 - (a) A process lot of a hemp concentrate or extract is considered a batch.¶
 - (b) A batch of hemp concentrate or extract must be produced using a standard operating procedure and result in one finished hemp concentrate or extract that is uniform in texture and form.¶
- (3) Hemp Cannabinoid products.¶
 - (a) A handler must separate process lots into not larger than 35,000 unit of sale batches.¶
 - (b) A batch of a hemp cannabinoid product must be produced using a standard operating procedure and result in a finished hemp cannabinoid product that is uniform in potency, texture, and weight. A standard operating procedure may use different flavors or colors in a batch if the different flavors or colors:¶
 - (A) Are substituted for one another at a 1:1 ratio; and¶
 - (B) Do not affect the potency, texture, or weight of the finished hemp cannabinoid product.¶
 - (c) If a hemp cannabinoid product is or may be sold in different quantities in a unit of sale, then the process lot shall be sampled based on the smallest unit of sale for the purposes of sampling and testing. All proposed units of sales must meet the Commission's concentration limit rules found in ~~Chapter 845, division 26~~ OAR 845-026-0400.¶
- (4) Industrial hemp-derived vapor items¶
 - (a) A process lot of an industrial hemp-derived vapor item is considered a batch.¶
 - (b) A batch of an industrial hemp-derived vapor item must be made from a standard operating procedure and result in one final industrial hemp-derived vapor item that is uniform in flavor, texture, and form.¶
- (5) A handler must assign each batch a process lot identifier as described in OAR 603-048-0500 and that process lot identifier must be:¶
 - (a) Provided to the individual responsible for taking samples; and¶
 - (b) Included on the batch label as required in OAR 603-048-2380.¶
- (6) A handler may not reuse a process lot identifier.¶
- (7) For the purposes of this rule, "flavor" means:¶
 - (a) The essential oil or essence which contains the flavoring constituents derived from a spice, fruit, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material.¶
 - (b) Any substance, the function of which is to impart flavor, which is not derived from a spice, fruit juice, vegetable, vegetable juice, herb, root, leaf, or similar plant material.¶
 - (c) Flavor does not include flavoring constituents derived from the cannabis plant.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330

Statutes/Other Implemented: ORS 571.263, ORS 571.281, ORS 571.330

AMEND: 603-048-2450

RULE SUMMARY: Updates requirements for failed test samples

CHANGES TO RULE:

603-048-2450

Failed Test Samples ¶¶

(1) If a sample or a duplicate sample (collectively referred to as "sample" for the purposes of this rule) fails any initial test, the laboratory that did the testing may reanalyze the sample. The laboratory that did the initial test may not subcontract the reanalysis. If a primary sample or a duplicate sample fails, both must be reanalyzed. If the sample passes, another laboratory must resample the batch and confirm that result in order for the batch to pass testing.¶¶

(a) If a grower or handler wishes to have a sample reanalyzed, the grower or handler must request a reanalysis within seven (7) calendar days from the date the laboratory sent notice of the failed test to the grower or handler. The reanalysis must be completed by the laboratory within 30 calendar days from the date the reanalysis was requested.¶¶

(b) If a grower or handler has requested a reanalysis in accordance with subsection (1)(a) of this rule and the sample passes, the handler has seven (7) calendar days from the date the laboratory sent notice of the passed test to request that another laboratory resample the batch and confirm the passed test result. The retesting must be completed by the second laboratory within 30 calendar days from the date the retesting was requested.¶¶

(c) A grower or handler must inform the Department within 24 hours, of the following, electronically to HempTestReports@oda.oregon.gov using the forms provided the Department:¶¶

(A) A request for reanalysis of a sample;¶¶

(B) The testing results of the reanalysis;¶¶

(C) A request for retesting; and¶¶

(D) The results of retesting.¶¶

(2) If a sample fails a test or a reanalysis under section (1) of this rule, the batch:¶¶

(a) May be remediated or sterilized according to the requirements of OAR 333-007-0450 for their marijuana equivalents as described in OAR 603-048-2310; or¶¶

(b) Must be destroyed as required by OAR 333-007-0450 in a manner specified by the Department if the batch is not or cannot be remediated or sterilized under OAR 333-007-0450 or fails testing as described in OAR 333-007-0450.¶¶

(3) If a grower or handler is permitted to remediate or sterilize under this rule, the grower or handler must provide notice to the Department of the handler's intent to remediate or sterilize.¶¶

(4) A grower or handler must inform a laboratory prior to samples being taken that the batch has failed a test and is being retested after undergoing remediation or sterilization.¶¶

(5) A grower or handler must, as applicable:¶¶

(a) Have detailed procedures for sterilization processes to remove microbiological contaminants and for reducing the concentration of solvents.¶¶

(b) Document all sampling, testing, sterilization, remediation and destruction that are a result of failing a test under these rules.¶¶

(c) A grower or handler must report failed test results to the Department within 24 hours of receipt of the failed test report electronically to HempTestReports@oda.oregon.gov using the forms provided by the Department.¶¶

(6) If a batch fails a test under these rules, the grower or handler must:¶¶

(a) Must store, and segregate, label, and in the batch in a secure area and label the batch clearly to indicate it has failed a test and the label must include a test batch number.¶¶

(b) May not remove the batch from the registered premises licensed grow or handling site without permission from the Department in accordance with OAR 333-007-0450.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.319, ORS 571.330

Statutes/Other Implemented: ORS 571.263, ORS 571.281, ORS 571.319, ORS 571.330

AMEND: 603-048-2480

RULE SUMMARY: Updates when additional testing may be required

CHANGES TO RULE:

603-048-2480

Additional Testing ¶¶

(1) The Department may require a licensee to submit samples identified by the Department to a laboratory of the licensee's choosing to be tested in order to determine whether a licensee is in compliance with OAR 603-048-2300 through 603-048-2500 or any other rule of the Department, and may require additional testing that is not required by these rules.¶¶

(2) To be sufficient to meet the requirement for audit testing under this rule, a licensee must ensure, through a testing agreement or contract, that the laboratory conducting the testing complies with these rules, to the extent they are applicable, and if conducting testing not required by these rules, may only use Authority approved methods.¶¶

(3) The Department may establish a process for the random testing of hemp items for microbiological contaminants.¶¶

(4) Any testing ordered under this rule must be paid for by the licensee.¶¶

(5) The Department may obtain a hemp item from a person at any time and have it tested to ensure compliance with these rules and OAR chapter 333, division 7, or to protect the public health and safety.¶¶

(6) The department may inspect biomass or processed industrial hemp that is stored at a location for which a license is issued under this section.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330

Statutes/Other Implemented: ORS 571.263, ORS 571.281, ORS 571.330

AMEND: 603-048-2500

RULE SUMMARY: Updates requirements for quality control and research and development testing

CHANGES TO RULE:

603-048-2500

Quality Control and Research and Development Testing

- (1) A person may request that a laboratory conduct testing for the purpose of assuring quality control or for research and development, except as provided in section (23) of this rule.¶
- (2) A person must ensure that relevant information regarding the licensee or manufacturer of the item is provided to the laboratory conducting the test in accordance with OAR 603-048-2315.¶
- (3) A person may not request that a laboratory conduct pesticide testing on industrial hemp or hemp items for the purpose of quality control, research and development, or any purpose other than compliance testing. A pesticide test on industrial hemp or hemp items is considered by the Department to be a compliance test. Test results may be used by the Department, including the Department's Pesticide Program, for enforcement of state pesticide laws and rules.¶
- (4) A person that submits industrial hemp or hemp items for quality control or research and development testing is not subject to OAR 603-048-2320 to 603-048-2470.¶
- (5) A laboratory result from a quality control or research and development test cannot be used as a compliance test result and industrial hemp or a hemp item that has only undergone a quality control or research and development test may not be transferred ~~or sold,~~ sold, or attempted to be sold or transferred unless the hemp item has also passed required compliance testing.¶
- (6) Licensees must maintain and retain all quality control and research and development test results for at least two years and provide copies of such results upon request to the Department.

Statutory/Other Authority: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330, 571.339

Statutes/Other Implemented: ORS 561.190, ORS 571.263, ORS 571.281, ORS 571.330, 571.339

ADOPT: 603-048-3220

RULE SUMMARY: Creates general handler requirements

CHANGES TO RULE:

603-048-3220

General Handler Requirements

(1) A handler must:

(a) Beginning January 1, 2026, register hemp items in accordance with OAR 845-026-6100 and comply with OAR 845-026-6100 through 845-026-6120.

(b) Use equipment, counters, and surfaces for processing that are food-grade and do not react adversely with any solvent being used.

(c) Have counters and surface areas that are constructed in a manner that reduce the potential for development of microbials, molds, and fungi and that can be easily cleaned.

(d) Maintain the licensed facility in a manner that is free from conditions which may result in contamination and that is suitable to facilitate safe and sanitary operations for product preparation purposes.

(2) A handler may not process, possess, transfer or sell a hemp item that contains Dimethyl Sulfoxide (DMSO).

(3) A handler may not treat or otherwise adulterate a cannabinoid product, concentrate, or extract with any additive or substance that would increase potency, toxicity, or addictive potential, or that would create an unsafe combination with other psychoactive substances. Prohibited additives or substances include but are not limited to nicotine, caffeine, polyethylene glycol, or any chemicals that increase carcinogenicity or cardiac effects.

(4) A handler must ensure every process lot of a finished cannabinoid concentrate or extract or finished cannabinoid product, as those terms are defined in OAR 333-007-0310, is uniform in potency, texture, and weight per unit of sale.

Statutory/Other Authority: ORS 561.190, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

ADOPT: 603-048-3230

RULE SUMMARY: Creates requirements for handler policies and procedures

CHANGES TO RULE:

603-048-3230

Handler Policies and Procedures

A handler must create, maintain, and follow written, detailed standard policies and procedures that include but are not limited to:¶

- (1) Instructions for making each hemp cannabinoid concentrate, extract, or product.¶
- (2) The ingredients and the amount of each ingredient for each process lot;¶
- (3) The process for making each product;¶
- (4) The number of servings in a process lot;¶
- (5) The intended cannabinoid concentration per serving and in a unit of sale of the product;¶
- (6) The process for making each process lot homogeneous;¶
- (7) If processing a hemp concentrate or extract:¶
 - (a) Conducting necessary safety checks prior to commencing processing;¶
 - (b) Purging any solvent or other unwanted components from a hemp concentrate or extract;¶
- (8) Procedures for cleaning all equipment, counters, and surfaces thoroughly;¶
- (9) Procedures for preventing growth of pathogenic organisms and toxin formation;¶
- (10) Proper handling and storage of any solvent, gas, or other chemical used in processing or on the licensed premises in accordance with material safety data sheets and any other applicable laws;¶
- (11) Proper disposal of any waste produced during processing in accordance with all applicable local, state and federal laws, rules, and regulations;¶
- (12) Quality control procedures designed to maximize safety and minimize potential product contamination;¶
- (13) Appropriate use of any necessary safety or sanitary equipment; and¶
- (14) Emergency procedures to be followed in case of a fire, chemical spill, or other emergency.¶
- (15) Violations. A first-time violation of this rule is a Class III violation.

Statutory/Other Authority: ORS 561.191, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

ADOPT: 603-048-3240

RULE SUMMARY: Creates handler training requirements

CHANGES TO RULE:

603-048-3240

Handler Training Requirements

(1) A handler must have documented a comprehensive training program that includes, at a minimum, the following topics:¶

(a) The standard operating policies and procedures;¶

(b) The hazards presented by all solvents or other chemicals used in processing and on the licensed premises as described in the material safety data sheet for each solvent or chemical; and¶

(c) Applicable Department statutes and rules.¶

(2) At the time of hire and prior to engaging in any processing, and once yearly thereafter, each employee involved in processing must be trained in accordance with the handler's training program. Documentation of applicable training provided, including training date(s) and material covered, must be maintained by the license for all employees for three (3) years after their employment.¶

(3) Violations. A first-time violation of this rule is a Class III violation.

Statutory/Other Authority: ORS 561.191, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

ADOPT: 603-048-3250

RULE SUMMARY: Creates handler requirements for hemp edible endorsement

CHANGES TO RULE:

603-048-3250

Handler Requirements for Hemp Edible Endorsement

(1) A hemp edible handler or a handler which makes a hemp concentrate or extract that will be used in an edible may only process in a food establishment licensed by the Department and must comply with the applicable provisions of OAR chapter 603, divisions 21, 24, 25, and 28.

(2) A hemp edible handler may not:

(a) Engage in processing in a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited service restaurant, single-event temporary restaurant as defined in ORS 624.

(b) Process food intended for commercial sale that does not contain cannabinoids, at the handling site; or

(c) Use a hemp concentrate or extract to process food unless that concentrate or extract was processed by a licensee in a food establishment licensed by the Department in compliance with the applicable provisions of OAR chapter 603, divisions 21, 24, 25, and 28.

(3) Violations. A violation of section (1) of this rule is a Class I violation. All other first-time violations of rule are Class III violations.

Statutory/Other Authority: ORS 561.191, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

RULE SUMMARY: Creates handler requirements for hemp concentrate and extracts

CHANGES TO RULE:

603-048-3260

Handler Requirements for Hemp Concentrate and Extract

(1) Hemp Concentrates or Extracts. A handler with a hemp concentrate or extract endorsement:

(a) May not use Class I solvents as those are classified in the Federal Drug Administration Guidance, Table I, published in the Federal Register on December 24, 1997 (62 FR 67377, <https://www.fda.gov/media/71737/download>).

(b) Must:

(A) Only use a hydrocarbon-based solvent that is at least 99 percent purity.

(B) Only use a non-hydrocarbon-based solvent that is food-grade.

(C) Work in an environment with proper ventilation, controlling all sources of ignition where a flammable atmosphere is or may be present.

(D) Use only potable water and ice made from potable water in processing OAR 603-025-0020(8).

(E) If making a concentrate or extract that will be used in a hemp edible, be endorsed as a hemp edible handler OAR 603-048-3030.

(2) Hemp Extracts. A handler with an endorsement to make hemp extracts:

(a) May not use pressurized canned flammable fuel, including but not limited to butane and other fuels intended for use in camp stoves, handheld torch devices, refillable cigarette lighters, and similar consumer products.

(b) Prior to licensure or renewal the applicant must:

(A) Provide proof in a form and manner specified by the Department that the site proposed to be licensed has received a Certificate of Occupancy for the intended use issued by the appropriate local building official or fire marshal;

(B) Must list all equipment used in extraction and, if applicable, provide proof that equipment and process has been inspected by a certified mechanical or electrical engineer.

(c) Must:

(A) Process in a fully enclosed room clearly designated on the current premises map of the handling site.

(B) Process, if using hydrocarbon solvents, in a room with equipment, including all electrical installations that meet the requirements of the Oregon Structural Specialty Code, related Oregon Specialty Codes and the Oregon Fire Code.

(C) Use a professional grade closed loop extraction system designed to recover the solvents and built to codes of recognized and generally accepted good engineering standards, such as those of:

(i) American National Standards Institute (ANSI);

(ii) Underwriters Laboratories (UL); or

(iii) The American Society for Testing and Materials (ASTM).

(D) If using carbon dioxide in processing, use a professional grade closed loop carbon dioxide gas extraction system where every vessel is rated to a minimum of six hundred pounds per square inch.

(E) For extraction system engineering services, including but not limited to consultation on and design of extraction systems or components of extraction systems, use the services of a professional engineer registered with the Oregon State Board of Examiners for Engineering and Land Surveying, unless an exemption under ORS 672.060 applies.

(F) Have an emergency eye-wash station in any room in which extract is being processed.

(G) Have all applicable material safety data sheets readily available to personnel working for the handler.

(H) If subject to inspection by local and state fire officials, maintain the premises' Certificate of Occupancy at intervals specified by the fire official.

(3) Hemp Concentrates. A handler with an endorsement to make hemp concentrates:

(a) May not:

(A) Use denatured alcohol.

(B) If using carbon dioxide, apply high heat or pressure.

(b) Must only use or store dry ice in a well-ventilated room to prevent against the accumulation of dangerous levels of carbon dioxide.

(c) May use:

(A) A mechanical extraction process; or

(B) A chemical extraction process using a nonhydrocarbon-based or other solvent, such as water, vegetable glycerin, vegetable oils, animal fats, isopropyl alcohol, or ethanol.

(4) Violations. A violation of this rule is a Class I violation.

Statutory/Other Authority: ORS 561.191, 571.263, 571.281(9)

Statutes/Other Implemented: ORS 571.260-571.348

RULE ATTACHMENTS MAY NOT SHOW CHANGES. PLEASE CONTACT AGENCY REGARDING CHANGES.

Q3C — Tables and List Guidance for Industry

**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**[June 2017]
ICH**

Revision 3

Q3C — Tables and List

Guidance for Industry

Additional copies are available from:

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druginfo@fda.hhs.gov

<http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/default.htm>

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Center for Biologics Evaluation and Research
Food and Drug Administration*

*10903 New Hampshire Ave., Bldg. 71, Room 3128
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Phone: 800-835-4709 or 240-402-8010

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**U.S. Department of Health and Human Services
Food and Drug Administration
Center for Drug Evaluation and Research (CDER)
Center for Biologics Evaluation and Research (CBER)**

**[June 2017]
ICH**

Revision 3

Q3C — Tables and List Guidance for Industry¹

This guidance represents the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA office responsible for this guidance as listed on the title page.

I. INTRODUCTION

This is the companion document for the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) guidance for industry *Q3C Impurities: Residual Solvents*, which makes recommendations as to what amounts of residual solvents are considered safe in pharmaceuticals.

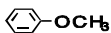



This document may be updated if proposals for change are submitted to the ICH Secretariat for consideration by the ICH Q3C Expert Working Group (EWG). If the EWG supports the proposal for change, the proposal will be submitted to the ICH Assembly for endorsement. Any proposals that are endorsed by the ICH Assembly will be announced through a notice in the *Federal Register* prior to the updating of this document. The guidance was revised in November 2003 to reflect updated recommendations for N-Methylpyrrolidone and Tetrahydrofuran, in February 2012 to reflect an updated recommendation for cumene, and in October 2016 to reflect updated recommendations for Triethylamine and Methylisobutylketone.

In general, FDA's guidance documents do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidances means that something is suggested or recommended, but not required.


¹ This document was developed within the Expert Working Group (Quality) of the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH) and has been subject to consultation by the regulatory parties, in accordance with the ICH process. This document was endorsed by the ICH Steering Committee at *Step 4* of the ICH process in July 1997. At *Step 4* of the process, the final draft is recommended for adoption to the regulatory agencies. This guidance was published in the *Federal Register* on December 24, 1997 (62 FR 67377), and is applicable to drug and biological products.

² The information included for Methylisobutylketone reflects that included in the *Revision of PDE Information for Methylisobutylketone*, which reached *Step 4* in November 2016 and was subsequently incorporated into the core guidance.








II. LIST OF SOLVENTS INCLUDED IN THE Q3C GUIDANCE

Solvent	Other Names	Structure	Class
Acetic acid	Ethanoic acid	CH_3COOH	Class 3
Acetone	2-Propanone Propan-2-one	CH_3COCH_3	Class 3
Acetonitrile		CH_3CN	Class 2
Anisole	Methoxybenzene		Class 3
Benzene	Benzol		Class 1
1-Butanol	n-Butylalcohol Butan-1-ol	$\text{CH}_3(\text{CH}_2)_3\text{OH}$	Class 3
2-Butanol	sec-Butylalcohol Butan-2-ol	$\text{CH}_3\text{CH}_2\text{CH}(\text{OH})\text{CH}_3$	Class 3
Butylacetate	Acetic acid butyl ester	$\text{CH}_3\text{COO}(\text{CH}_2)_3\text{CH}_3$	Class 3
tert-Butylmethylether	2-Methoxy-2-methyl-propane	$(\text{CH}_3)_3\text{COCH}_3$	Class 3
Carbon tetrachloride	Tetrachloromethane	CCl_4	Class 1
Chlorobenzene			Class 2
Chloroform	Trichloromethane	CHCl_3	Class 2
Cumene	Isopropylbenzene (1-Methyl)ethylbenzene	$\text{C}_6\text{H}_5\text{-CH}(\text{CH}_3)_2$	Class 2
Cyclohexane	Hexamethylene		Class 2
1,2-Dichloroethane	sym-Dichloroethane Ethylene dichloride Ethylene chloride	$\text{CH}_2\text{ClCH}_2\text{Cl}$	Class 1
1,1-Dichloroethene	1,1-Dichloroethylene Vinylidene chloride	$\text{H}_2\text{C=CCl}_2$	Class 1
1,2-Dichloroethene	1,2-Dichloroethylene Acetylene dichloride	ClHC=CHCl	Class 2

Contains Nonbinding Recommendations

Dichloromethane	Methylene chloride	CH_2Cl_2	Class 2
1,2-Dimethoxyethane	Ethyleneglycol dimethylether Monoglyme Dimethyl Cellosolve	$\text{H}_3\text{COCH}_2\text{CH}_2\text{OCH}_3$	Class 2
N,N-Dimethylacetamide	DMA	$\text{CH}_3\text{CON}(\text{CH}_3)_2$	Class 2
N,N-Dimethylformamide	DMF	$\text{HCON}(\text{CH}_3)_2$	Class 2
Dimethyl sulfoxide	Methylsulfinylmethane Methyl sulfoxide DMSO	$(\text{CH}_3)_2\text{SO}$	Class 3
1,4-Dioxane	p-Dioxane [1,4]Dioxane		Class 2
Ethanol	Ethyl alcohol	$\text{CH}_3\text{CH}_2\text{OH}$	Class 3
2-Ethoxyethanol	Cellosolve	$\text{CH}_3\text{CH}_2\text{OCH}_2\text{CH}_2\text{OH}$	Class 2
Ethyl acetate	Acetic acid ethylester	$\text{CH}_3\text{COOCH}_2\text{CH}_3$	Class 3
Ethyleneglycol	1,2-Dihydroxyethane 1,2-Ethanediol	$\text{HOCH}_2\text{CH}_2\text{OH}$	Class 2
Ethylether	Diethylether Ethoxyethane 1,1'-Oxybisethane	$\text{CH}_3\text{CH}_2\text{OCH}_2\text{CH}_3$	Class 3
Ethyl formate	Formic acid ethylester	$\text{HCOOCH}_2\text{CH}_3$	Class 3
Formamide	Methanamide	HCONH_2	Class 2
Formic acid		HCOOH	Class 3
Heptane	n-Heptane	$\text{CH}_3(\text{CH}_2)_5\text{CH}_3$	Class 3
Hexane	n-Hexane	$\text{CH}_3(\text{CH}_2)_4\text{CH}_3$	Class 2
Isobutyl acetate	Acetic acid isobutylester	$\text{CH}_3\text{COOCH}_2\text{CH}(\text{CH}_3)_2$	Class 3
Isopropyl acetate	Acetic acid isopropylester	$\text{CH}_3\text{COOCH}(\text{CH}_3)_2$	Class 3
Methanol	Methyl alcohol	CH_3OH	Class 2
2-Methoxyethanol	Methyl Cellosolve	$\text{CH}_3\text{OCH}_2\text{CH}_2\text{OH}$	Class 2
Methyl acetate	Acetic acid methylester	$\text{CH}_3\text{COOCH}_3$	Class 3
3-Methyl-1-butanol	Isoamyl alcohol Isopentyl alcohol 3-Methylbutan-1-ol	$(\text{CH}_3)_2\text{CHCH}_2\text{CH}_2\text{OH}$	Class 3

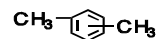
Contains Nonbinding Recommendations

Methylbutyl ketone	2-Hexanone Hexan-2-one	$\text{CH}_3(\text{CH}_2)_3\text{COCH}_3$	Class 2
Methylcyclohexane	Cyclohexylmethane		Class 2
Methylethyl ketone	2-Butanone MEK Butan-2-one	$\text{CH}_3\text{CH}_2\text{COCH}_3$	Class 3
Methylisobutyl ketone	4-Methylpentan-2-one 4-Methyl-2-pentanone MIBK	$\text{CH}_3\text{COCH}_2\text{CH}(\text{CH}_3)_2$	Class 2
2-Methyl-1-propanol	Isobutyl alcohol 2-Methylpropan-1-ol	$(\text{CH}_3)_2\text{CHCH}_2\text{OH}$	Class 3
N-Methylpyrrolidone	1-Methylpyrrolidin-2-one 1-Methyl-2-pyrrolidinone		Class 2
Nitromethane		CH_3NO_2	Class 2
Pentane	<u>n</u> -Pentane	$\text{CH}_3(\text{CH}_2)_3\text{CH}_3$	Class 3
1-Pentanol	Amyl alcohol Pentan-1-ol Pentyl alcohol	$\text{CH}_3(\text{CH}_2)_3\text{CH}_2\text{OH}$	Class 3
1-Propanol	Propan-1-ol Propyl alcohol	$\text{CH}_3\text{CH}_2\text{CH}_2\text{OH}$	Class 3
2-Propanol	Propan-2-ol Isopropyl alcohol	$(\text{CH}_3)_2\text{CHOH}$	Class 3
Propyl acetate	Acetic acid propyl ester	$\text{CH}_3\text{COOCH}_2\text{CH}_2\text{CH}_3$	Class 3
Pyridine			Class 2
Sulfolane	Tetrahydrothiophene 1,1-dioxide		Class 2
Tetrahydrofuran	Tetramethylene oxide Oxacyclopentane		Class 2
Tetralin	1,2,3,4-Tetrahydro-naphthalene		Class 2
Toluene	Methylbenzene		Class 2
1,1,1-Trichloroethane	Methylchloroform	CH_3CCl_3	Class 1
1,1,2-Trichloroethene	Trichloroethene	$\text{HClC}=\text{CCl}_2$	Class 2
Triethylamine	N,N-Diethylethanamine	$\text{N}(\text{CH}_2\text{CH}_3)_3$	Class 3

Contains Nonbinding Recommendations

Xylene¹

Dimethylbenzene
Xylol



Class 2

¹Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethylbenzene.

III. SOLVENTS GROUPED BY CLASS

Solvents in Class 1 (Table 1) should not be employed in the manufacture of drug substances, excipients, and drug products because of their unacceptable toxicity or their deleterious environmental effect. However, if their use is unavoidable in order to produce a drug product with a significant therapeutic advance, then their levels should be restricted as shown in Table 1, unless otherwise justified. The solvent 1,1,1-Trichloroethane is included in Table 1 because it is an environmental hazard. The stated limit of 1,500 ppm is based on a review of the safety data.

Table 1. – Class 1 Solvents in Pharmaceutical Products (Solvents That Should Be Avoided)

Solvent	Concentration Limit (ppm)	Concern
Benzene	2	Carcinogen
Carbon tetrachloride	4	Toxic and environmental hazard
1,2-Dichloroethane	5	Toxic
1,1-Dichloroethene	8	Toxic
1,1,1-Trichloroethane	1,500	Environmental hazard

Contains Nonbinding Recommendations

Solvents in Class 2 (Table 2) should be limited in pharmaceutical products because of their inherent toxicity. PDEs are given to the nearest 0.1 mg/day, and concentrations are given to the nearest 10 ppm. The stated values do not reflect the necessary analytical precision of determination. Precision should be determined as part of the validation of the method.

Table 2. – Class 2 Solvents in Pharmaceutical Products

Solvent	PDE (mg/day)	Concentration Limit (ppm)
Acetonitrile	4.1	410
Chlorobenzene	3.6	360
Chloroform	0.6	60
Cyclohexane	38.8	3,880
Cumene	0.7	70
1,2-Dichloroethene	18.7	1,870
Dichloromethane	6.0	600
1,2-Dimethoxyethane	1.0	100
N,N-Dimethylacetamide	10.9	1,090
N,N-Dimethylformamide	8.8	880
1,4-Dioxane	3.8	380
2-Ethoxyethanol	1.6	160
Ethyleneglycol	6.2	620
Formamide	2.2	220
Hexane	2.9	290
Methanol	30.0	3,000
2-Methoxyethanol	0.5	50
Methylbutyl ketone	0.5	50
Methylcyclohexane	11.8	1,180
Methylisobutylketone ²	45	4,500
N-Methylpyrrolidone	5.3	530
Nitromethane	0.5	50
Pyridine	2.0	200
Sulfolane	1.6	160
Tetrahydrofuran	7.2	720
Tetralin	1.0	100

² The information included for Methylisobutylketone reflects that included in the *Revision of PDE Information for Methylisobutylketone*, which reached *Step 4* in November 2016 and was subsequently incorporated into the core guidance.

Contains Nonbinding Recommendations

Toluene	8.9	890
1,1,2-Trichloroethene	0.8	80
Xylene ¹	21.7	2,170

¹Usually 60% m-xylene, 14% p-xylene, 9% o-xylene with 17% ethylbenzene.

Solvents in Class 3 (Table 3) may be regarded as less toxic and of lower risk to human health. Class 3 includes no solvent known as a human health hazard at levels normally accepted in pharmaceuticals. However, there are no long-term toxicity or carcinogenicity studies for many of the solvents in Class 3. Available data indicate that they are less toxic in acute or short-term studies and negative in genotoxicity studies. It is considered that amounts of these residual solvents of 50 mg per day or less (corresponding to 5,000 ppm or 0.5 percent under Option 1) would be acceptable without justification. Higher amounts may also be acceptable provided they are realistic in relation to manufacturing capability and good manufacturing practice (GMP).

Table 3. – Class 3 Solvents Which Should Be Limited by GMP or Other Quality-Based Requirements

Acetic acid	Heptane
Acetone	Isobutylacetate
Anisole	Isopropylacetate
1-Butanol	Methylacetate
2-Butanol	3-Methyl-1-butanol
Butylacetate	Methylethylketone
<i>tert</i> -Butylmethylether	2-Methyl-1-propanol
Dimethylsulfoxide	Pentane
Ethanol	1-Pentanol
Ethylacetate	1-Propanol
Ethylether	2-Propanol
Ethylformate	Propylacetate
Formic acid	Triethylamine ³

³ The information included for Triethylamine reflects that included in the *Revision of PDE Information for Triethylamine*, which reached *Step 4* in November 2016 and was subsequently incorporated into the core guidance.

Contains Nonbinding Recommendations

The solvents listed in Table 4 may also be of interest to manufacturers of excipients, drug substances, or drug products. However, no adequate toxicological data on which to base a PDE were found. Manufacturers should supply justification for residual levels of these solvents in pharmaceutical products.

Table 4. – Solvents for Which No Adequate Toxicological Data Were Found

1,1-Diethoxypropane	Methylisopropylketone
1,1-Dimethoxymethane	Methyltetrahydrofuran
2,2-Dimethoxypropane	Petroleumether
Isooctane	Trichloroacetic acid
Isopropylether	Trifluoroacetic acid

ADOPT: 603-048-3280

RULE SUMMARY: Creates requirements for hemp topical handler

CHANGES TO RULE:

603-048-3280

Hemp Topical Handler

(1) A handler with a hemp topical endorsement may not process in a location that is operating as a restaurant, seasonal temporary restaurant, intermittent temporary restaurant, limited service restaurant or single-event temporary restaurant as defined in ORS 624.¶

(2) Violations. A violation of this rule is a Class II violation.

Statutory/Other Authority: ORS 561.191, 571.263, 571.005, 571.336, 571.263

Statutes/Other Implemented: ORS 571.260-571.348