

Chapter 16-171 WAC
HEMP EXTRACT CERTIFICATION

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WAC

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WAC 16-171-100 Hemp extract certification—Purpose. The purpose of this chapter is to:

(1) Establish requirements for new hemp extract certification applications and renewals.

(2) Establish an inspection criteria and a rating system that will be used to determine whether a hemp extract certification applicant is in compliance with chapters 69.07 and 15.130 RCW, and regulations adopted thereunder, including Title 21 C.F.R.

(3) Identify steps leading to enforcement actions by the department.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-100, filed 6/7/22, effective 7/8/22.]

WAC 16-171-110 Hemp extract—Definitions. (1) Definitions for terms used in this chapter may be found in chapters 69.07 and 15.130 RCW, and Title 21 C.F.R. as adopted in WAC 16-167-050, unless otherwise provided in this chapter.

(2) For the purposes of this chapter, the following definitions apply:

(a) **"Adequate"** means that which is needed to accomplish the intended purpose in keeping with good public health practice.

(b) **"Adulterate"** has the same meaning as provided in RCW 15.130.200 except that the department does not consider hemp extract itself to be adulterated when produced in compliance with RCW 69.07.220 and these rules for use as a food ingredient in another state that allows its use as a food ingredient.

(c) **"Certification criteria violation"** means any violation of the inspection criteria that must be met prior to the issuance of a hemp extract certification.

(d) **"Critical violation"** means a violation of the inspection criteria that results in hemp extract adulteration or that has the potential to contribute to conditions resulting in such adulteration.

(e) **"Department"** means the Washington state department of agriculture (WSDA).

(f) **"Director"** means the director of the department.

(g) **"Facility or hemp extract facility"** means any premise, plant, building, room, area, or facility which processes, prepares, or handles hemp for production of hemp extract for use as a food ingredient in another state that allows its use as a food ingredient.

(h) **"Hemp"** has the same meaning as provided for in RCW 15.140.020 and means the plant *Cannabis sativa L.* and any part of the plant, including the seeds thereof and all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not,

with a delta-9 tetrahydrocannabinol concentration of not more than 0.3 percent on a dry weight basis.

(i) "**Hemp extract**" means a substance or compound intended for human ingestion that is derived from, or made by, manufacturing hemp. The term does not include hemp seeds or hemp seed-derived ingredients that are generally recognized as safe by the United States Food and Drug Administration.

(j) "**Hemp extract certification**" means a certification issued by the department to a hemp extract facility manufacturing hemp extract for export to other states, which certifies the hemp extract facility's compliance with Washington state's inspection and sanitation requirements.

(k) "**Hemp processor**" has the same meaning as provided for in RCW 15.140.020, and means a person who takes possession of raw hemp material with the intent to modify, package, or sell a transitional or finished hemp product.

(l) "**Sanitize**" means to adequately treat hemp extract contact surfaces by a process that is effective in destroying vegetative cells of microorganisms of public health significance, and in substantially reducing numbers of other undesirable microorganisms, but without adversely affecting the product or its safety for the consumer.

(m) "**Significant violation**" means any violation of the inspection criteria not deemed to be a critical violation as described in WAC 16-171-140.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-110, filed 6/7/22, effective 7/8/22.]

WAC 16-171-120 Hemp extract facility certification—New application and renewals—Inspection criteria. To qualify for a new hemp extract certification issued under chapter 69.07 RCW, the Washington Food Processing Act, a hemp processor must first make an application to the department. After the department receives a complete application, the department will inspect the facility. The facility must be in compliance with the following requirements prior to issuance of a certification:

(1) The applicant must submit an application that includes:

(a) The full name of the applicant and the location of the hemp extraction facility where the applicant intends to operate, and if the applicant is an entity, the full name of each officer, managing member, or other responsible individuals;

(b) The principal business address of the applicant in the state and elsewhere and the name of a person domiciled in this state authorized to receive and accept service of summons of legal notices of all kinds for the applicant; and

(c) The type of hemp extracts to be processed, the method of manufacturing, and any other necessary information to make an evaluation.

(2) A hemp processor holding a hemp extract certification must apply for renewal of the certification annually.

(3) The appropriate fee must accompany the application submitted to the department, as follows:

(a) For new applications, the fee is \$1,400.

(b) For a new certification inspection, the fee is \$3,000.

(c) For renewal applications, the fee is \$1,500.

(4) The hemp extract facility must be in substantial compliance with inspection criteria as described in WAC 16-171-150(2). Refer to WAC 16-171-140 for the inspection and certification criteria and WAC 16-171-130 for definitions of certain inspection criteria. For the purposes of certification, a hemp extract facility may incur a one-point debit of a licensing criteria that has sliding scale.

(5) To renew a certification, a hemp extract manufacturer must submit a renewal application and fees before the manufacturer's current certification expires. If the department has received receipt of a submitted renewal application and fees before the certification expiration date, the time period of the prior certification extends until the department either issues the renewed certification or denies the renewal application. If a manufacturer does not timely submit a renewal application or fees, the prior certification expires upon the expiration date.

(6) Upon the approval of the application by the director the applicant shall be issued a new or renewal certification.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-120, filed 6/7/22, effective 7/8/22.]

WAC 16-171-130 Hemp extract certification—Inspection criteria definitions. This section provides definitions for certain criteria the department will use when conducting inspections to determine if a hemp extract facility complies with inspection criteria and good manufacturing practices for hemp extract certification. The complete set of inspection criteria is set forth in WAC 16-171-140.

(1) **"Clean and adequate protective clothing and hair restraints"** means the clothing, or the outside layer of clothing, which can occasionally or incidentally contact hemp extract, either directly or indirectly, is:

(a) Clean at the start of the work shift; and

(b) Changed when the clothing becomes so soiled during the course of the work shift that contamination of hemp extract, hemp extract packaging or hemp extract contact surfaces becomes imminent; and

(c) Suitable to the specific hemp extract manufacturing operation for protection against the contamination of hemp extract, hemp extract packaging, and hemp extract contact surfaces; and

(d) Clean and effective hair restraints, such as hairnets, or beard nets if appropriate, are worn for the protection of hemp extract from contamination. Hats, caps, scarves or other head cover are acceptable if the hair is properly contained to protect hemp extract from contamination. Hair spray and/or tying back the hair in pony-tails, etc., are not considered effective hair restraints.

(2) **"Adequate washing and sanitizing of hands as necessary"** means washing and sanitizing hands thoroughly to protect against contamination of hemp extract from undesirable microorganisms in an adequate hand wash facility by:

Using proper handwashing methods which consist of:

(a) Applying soap to hands;

(b) Using warm water;

(c) Scrubbing hands thoroughly;

(d) Rinsing and drying hands using methods that prevent hemp extract contamination;

(e) Washing hands before beginning work, after each absence from the work station, and any time hands become soiled or contaminated; and

(f) Sanitizing hands when appropriate in addition to, but not in place of, the proper handwashing methods.

(3) **"Garments and personal belongings stored appropriately; not a source of contamination"** means personal belongings and garments, either personal or supplied by the hemp extract facility, are stored or kept separately from hemp extract manufacturing, handling and storage operations such as in an area, locker, cupboard, or other closeable unit that is dedicated to the storing or hanging of personal belongings and clothing so not to become a source of contamination to hemp extract, hemp extract packaging or hemp extract contact surfaces; and

No hemp extract, packaging materials, utensils or equipment used in the hemp extract manufacturing operation are kept, stored or commingled with personal belongings or garments.

(4) **"Processes separated as required"** means there is a separation of processes for the purpose of reducing potential contamination in hemp extract manufacturing operations where contamination is likely to occur. One or more of the following means may accomplish this:

- (a) Location;
- (b) Time;
- (c) Partition;
- (d) Air flow;
- (e) Enclosed systems; or
- (f) Other effective method.

(5) **"Adequate light"** means lighting is provided in handwashing, dressing and locker rooms, toilet rooms and in all areas where hemp extract is examined, manufactured or equipment is cleaned. Shatter resistant light bulbs or fixtures are to be used to protect against hemp contamination.

(6) **"Detergents, sanitizers and toxic materials properly identified"** means:

(a) Labeling any container containing detergent, sanitizer, or toxic material with the:

- (i) Product name;
- (ii) Chemical description;
- (iii) Directions for use;
- (iv) Any required precautionary and warning statements;
- (v) First-aid instructions;
- (vi) Name and address of the manufacturer or distributor; and
- (vii) Any other additional information required by the federal Environmental Protection Agency or other laws or rules; and

(b) Small transport or use containers for detergents, sanitizers, or toxic materials are used only under the following conditions:

(i) The contents are properly identified on the container. Labeling the container with the common name is acceptable if the original storage container is on hand and properly identified;

(ii) No hemp extract container is used as a container for detergents, sanitizers, or toxic materials;

(iii) No container used for detergents, sanitizers, or toxic materials, is used as a hemp extract container.

(7) **"Product contact surfaces clean and maintained in a sanitary condition, cleaned and sanitized prior to each use or as essential"** means:

(a) Product contact surfaces of equipment, utensils, containers and other articles used in the manufacturing of hemp extract, when its

continued use is apparent, are cleaned as frequently as necessary to protect against contamination of hemp extract;

(b) Hemp extract residues are removed from product contact surfaces frequently enough to prevent residues from becoming unwholesome or unfit for food, decomposed, filthy, putrid, or injurious to health; and

(c) The hemp extract product contact surfaces are sanitized prior to use and after cleaning as necessary.

(8) **"Product contact surfaces clean and maintained in a sanitary condition, cleaned and sanitized prior to each use or as essential: Critical violation"** means it is a critical violation if a hemp extract product contacts a surface that is not sanitized after cleaning or prior to use. Product contact surfaces that become contaminated, but are cleaned and sanitized prior to use, are not considered a critical violation.

(9) **"Nonproduct contact surfaces of equipment cleaned and maintained in a sanitary condition"** means nonproduct contact surfaces of equipment are kept reasonably free from dirt, old hemp extract residues, foreign material, dust, mold, mildew, slime and other accumulations that occur because of day-to-day hemp extract manufacturing operations.

(10) **"In-use hemp contact equipment and utensils appropriately stored: Protected from contamination between uses"** means the utensils used in the manufacturing of hemp, such as knives, scrapers, scoops, shovels, cutters, and other hand tools and equipment, are placed or stored in a manner to prevent hemp extract contact surfaces from being contaminated with filth. Filth includes, but is not limited to, nonpathogenic microorganisms, unsuitable toxic chemicals, and microscopic physical contaminants.

Storage and placement of utensils or equipment in the following manner is considered inappropriate storage:

(a) In contact with the floor, dirty equipment frames, other insanitary nonhemp extract contact surfaces;

(b) In contact with containers of nonpotable water (other than sterilizing solutions); and

(c) In contact with other contaminants.

(11) **"In-use hemp contact equipment and utensils appropriately stored: Protected from contamination between uses: Critical violation"** means that it is a critical violation when a utensil or piece of equipment is or has been stored in a manner that it becomes obviously contaminated with filth and its continued use is apparent.

Utensils and equipment that become contaminated are not considered a critical violation if the utensils and equipment are cleaned and sanitized prior to the next use.

(12) **"Water supply - Safe and of sanitary quality"** means the water supply used in the manufacturing of hemp is potable from an approved source and is monitored in accordance with applicable laws and rules with current satisfactory water tests as applicable. Water from an approved source and monitored in accordance with applicable laws and rules means:

(a) Hemp extract facilities with 25 or more employees and operating 60 days or more annually comply with the state department of health, division of drinking water requirements for a Group A water system (chapter 246-290 WAC).

(b) Hemp extract facilities with less than 25 employees or operating less than 60 days annually, comply with the state department of health, division of drinking water requirements for a Group B water

system (chapter 246-291 WAC) unless connected to a Group A public water system.

(c) Private water supplies must meet the department of health, division of drinking water requirements for a Group B water system (chapter 246-291 WAC) with respect to monitoring for bacteriological properties. When water is incorporated into the product, chemical and physical properties must also be monitored.

(13) **"Current satisfactory water test"** means for water obtained from other than a municipal system, analysis verifying the bacteriological, physical and chemical safety of the water has been conducted according to appropriate Group A or B water system monitoring schedules and that reports of analysis are on file at the manufacturing facility and available for review by the department during routine facility inspection.

(14) **"No cross connections, no back siphonage"** means there is no backflow from or cross connection between piping systems that discharge waste water sewage and piping systems that carry water for hemp extract manufacturing. This includes any cross connection between a potable water system and a nonpotable system.

(15) **"Adequate floor drains and plumbing to convey wastes and sewage from the manufacturing facility, into approved sewage disposal system"** means:

(a) Plumbing is designed, sized, installed and maintained in accordance with applicable state and local plumbing codes so that sewage and liquid disposable waste is readily conveyed from the plant;

(b) Floor drainage is sufficient to prevent excessive pooling of water or other disposable waste;

(c) Plumbing and drains do not provide a source of contamination to hemp or hemp extract, potable water, hemp extract contact surfaces or hemp extract packaging material or create any insanitary condition; and

(d) Sewage is disposed into a municipal sewer system or other system approved by a federal, state or local agency having jurisdiction.

(16) **"Adequate, readily accessible toilet facilities"** means a hemp extract facility provides its employees with toilet facilities that are located within a reasonable distance to the work area, and are maintained in accordance with local zoning ordinances.

(a) Toilet facilities are located on the premises of a hemp extract facility.

(b) If the hemp extract facility shares space in a multiple building complex, toilet facilities are located within the complex and within a reasonable distance from the work area.

(c) Outhouses, chemical toilets, or other nonflushing toilets may not be used.

(17) **"Toilets clean, in good repair, not opening directly into process areas, self-closing doors"** means toilet rooms are kept clean, free of trash and litter, in good repair and all toilet room doors are self-closing and do not open directly into a hemp extract manufacturing area.

(18) **"Handwash facilities adequate and convenient, with hot and cold or tempered water"** means employees and visitors in a hemp extract facility have access to one or more handwashing facilities with hot, cold, or tempered running water, and there is at least one handwash facility located in each restroom and one in the hemp extract manufacturing area in a convenient location for use when hands become soiled.

(19) **"Hemp extract protected from contamination in storage"** means hemp and hemp extract is stored under conditions that protect against physical, chemical and microbial contamination, as well as against deterioration of the hemp extract and the container.

(20) **"Hemp extract protected from contamination in storage: Critical violation"** means it is a critical violation when a storage situation allows potential contamination of products.

(21) **"Packaging material properly handled and stored"** means packaging material is protected from potential sources of contamination during handling and storage. This includes, but is not limited to:

(a) Boxes, liners, and other primary containers are stored off floors or other insanitary surfaces;

(b) Top containers in a nested stack of lined or primary containers are inverted or otherwise protected;

(c) All single service containers, caps, roll stock, liner jars, bottles, jugs, and other preformed containers are stored in closed sanitary tubes, wrappings, boxes or cartons prior to use;

(d) The forming, make-up or other package assembly is conducted in a manner that prevents contamination;

(e) The handling of packaging material and containers prior to filling or wrapping is conducted as not to expose them to contamination by dust, foreign material, or other contaminants.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-130, filed 6/7/22, effective 7/8/22.]

WAC 16-171-140 Hemp extract facility—Inspection criteria. The following table identifies:

(1) Inspection criteria and whether each criterion also represents a certification requirement;

(2) Whether a violation is critical; and

(3) The debit value for each significant violation.

	Criteria Item-Critical*	Debit Value	Certification Requirement?
1	Hemp extract products free from adulteration.	C	Yes
2	Persons with apparent infections or communicable diseases properly restricted.	C	Yes
3	Adequate washing and sanitizing of hands as necessary, gloves used in food handling sanitary conditions.	C	Yes
4	Product contact surfaces clean and maintained in a sanitary condition; cleaned and sanitized prior to each use or as essential.	C	Yes
5	In use hemp contact equipment and utensils appropriately stored; protected from contamination between uses.	C	No
6	Water used is safe and of adequate sanitary quality; from approved source.	C	Yes
7	No cross connections; no back-siphonage.	C	Yes
8	Hot and cold water, under pressure, in areas where foods are processed or equipment washed.	C	Yes
9	Adequate, readily accessible toilet facilities provided.	C	Yes
10	No evidence of human defecation or urination about the premises.	C	Yes
11	Handwash facilities adequate and convenient, including hot and cold or tempered water.	C	Yes
12	Hemp protected from contamination in storage.	C	No

Criteria Item-Critical*		Debit Value	Certification Requirement?
* A critical violation results in an establishment not being in substantial compliance.			
Criteria Item-Significant		Debit Value	Certification Requirement?
1	Jewelry, watches other personal items not a source of contamination.	1	No
2	Clean and adequate protective clothing and hair restraints.	1-2	No
3	Use of tobacco, eating and drinking of food and beverages and gum chewing restricted to appropriate areas.	1	No
4	Garments and personal belongings stored appropriately, not a source of potential contamination.	2	No
5	Employee work procedures preclude contamination.	1-2	No
6	Grounds: Free from pest attractions, breeding places, harborage, excessive dust and other contaminants.	1	No
7	Suitable size and location, construction including walls, floors, ceiling, counters, shelving, other fixtures, smooth, readily cleanable and in good repair.	1-5	Yes
8	Processes separated as required.	1-2	Yes
9	No operations in domestic living or sleeping quarters (including domestic kitchens).	0	Yes
10	Adequate light.	1-2	Yes
11	Lights; glass over food protected; breakproof.	1	No
12	Adequate ventilation to minimize vapors, steams, noxious fumes.	1-2	Yes
13	Drip or condensate from ceiling, fixtures, pipes, ducts not a potential source of contamination.	1-3	No
14	Screened or protected to exclude pests.	1-2	No
15	Building, fixtures, facilities clean; including transport vehicles.	1-5	Yes
16	Detergents, sanitizers, toxic materials safely used and stored.	1-3	No
17	Detergents, sanitizers and toxic materials properly identified.	1-2	No
18	Product contact surfaces clean and maintained in a sanitary condition; cleaned and sanitized prior to each use or as essential.	1-2	No
19	Nonproduct contact surfaces of equipment clean and maintained in a sanitary condition.	1-2	No
20	In use hemp extract contact equipment and utensils appropriately stored; protected from contamination between uses.	1-2	No
21	Effective measures taken to exclude pests from the facility. No harborage/breeding areas.	1-2	No
22	Pesticides safely used and stored.	1-3	No
23	No evidence of rodents, insects, birds or other animals.	1-5	Yes
24	Current satisfactory water supply test.	5	Yes
25	Water supply sufficient in quantity for intended operations.	2	Yes
26	Adequate floor drains and plumbing to convey wastes and sewage from plant.	1-2	Yes
27	Sewage and waste lines protected not a source of contamination.	1-2	Yes
28	Adequate offal, rubbish and waste disposal.	1-2	Yes
29	Toilet facilities clean and in good repair, no direct opening to process area, self-closing door.	1-2	Yes
30	Soap and single service towels or suitable drying devices provided at handwash facilities. Adequate refuse receptacles provided.	1-2	No
31	Readily understandable handwash signs provided at handwash facilities.	1	No

	Criteria Item-Significant	Debit Value	Certification Requirement?
32	Hand dips provided as necessary.	1-2	No
33	Design, material and workmanship durable, readily cleanable and in good repair. Contact surfaces nontoxic and corrosion resistant.	1-3	Yes
34	Design and use preclude contamination with lubricants, fuel, contaminated water, paint, rust, compressed air/gas and other contaminants.	1-3	No
35	Freezers and cold storage units equipped with adequate thermometers.	1	No
36	Incoming raw materials or ingredients are from an approved source, in an obvious sanitary condition. Items inspected on receipt, suitable for intended use, segregated as necessary and properly stored (clean storage containers, facilities, products properly covered), ingredients properly identified; raw materials washed or cleaned as required.	1-5	No
37	No contaminating material used, stored or transported with supplies, ingredients or processed foods.	1-2	No
38	Packing material properly handled and stored.	1	No
39	Cleaning operations - Conducted to minimize contamination.	1-3	No

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-140, filed 6/7/22, effective 7/8/22.]

WAC 16-171-150 Hemp extract facility inspection rating system—Inspection score. (1) A hemp extract facility is evaluated at the completion of an inspection conducted by the department as follows:

(a) A hemp extract facility will be debited the point value assigned to the inspection item listed in WAC 16-171-140 for each violation found during an inspection.

(b) The maximum point value possible is 100.

(c) The sum of the points debited for an inspection are subtracted from the maximum point value of 100. The remaining sum is the facility's score for that inspection.

(d) When the department identifies a critical violation during inspection of a hemp extract facility a failing score of "critical" will be listed unless the violation is satisfactorily corrected during the inspection.

(2) A hemp extract facility is considered in substantial compliance with the inspection criteria if:

(a) No critical violations are found, or if critical violations are found, they are corrected prior to completion of the inspection; or

(b) The facility's inspection score is 90 points or above.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-150, filed 6/7/22, effective 7/8/22.]

WAC 16-171-160 Hemp extract facilities—Basis for enforcement action. (1) The department may issue a notice of correction for:

(a) Hemp extract facilities that score less than 90 points on an inspection; or

(b) Critical violations found during an inspection of a hemp extract facility.

(2) The department may review and consider initiating enforcement action, such as certification suspension, civil penalties, and/or other actions provided in chapter 69.07 or 15.130 RCW when:

(a) Hemp extract facilities score less than 90 points on two separate inspections within a consecutive three-year period; or

(b) Hemp extract facilities fail to correct critical violations during an inspection.

(3) Nothing herein shall prevent the department from:

(a) Choosing not to pursue a case administratively.

(b) Issuing a notice of correction in lieu of pursuing enforcement action.

(c) Negotiating settlement(s) of cases on such terms and for such reasons as it deems appropriate.

[Statutory Authority: RCW 69.07.020 and 69.07.220. WSR 22-13-038, § 16-171-160, filed 6/7/22, effective 7/8/22.]