[Publication Instructions: Replace entire current existing rule with the following new text.]

COLORADO DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT

Division of Environmental Health and Sustainability

COLORADO WHOLESALE FOOD, INDUSTRIAL HEMP, AND SHELLFISH REGULATIONS

6 CCR 1010-21

Adopted by the Board of Health on February 17, 2021; effective, April 14, 2021.

21.1 Authority

This regulation is adopted pursuant to Sections 25-4-1805, 25-5-420(1), and 25-5-426(1), Colorado Revised Statute (C.R.S.) and is consistent with the requirements of the State Administrative Procedure Act, Section 24-4-101, *et seq.*, C.R.S.

21.2 Scope and Purpose

A. This regulation shall be applied for the protection of public health by ensuring that the premises or places wherein manufactured foods and industrial hemp products are produced, manufactured, packed, processed, prepared, treated, packaged, transported, or held for distribution are in accordance with the "Pure Food and Drug Law", Section 25-5-401 *et seq.*, C.R.S. and the "Shellfish Dealer Certification Act," Section 25-4-1801 *et seq.*, C.R.S.

B. This regulation shall govern the registration of wholesale food manufacturers. Along with the powers and duties delineated in Section 25-4-420 *et seq.*, C.R.S., Section 25-5-426(3), C.R.S., provides the department the power and duty:

1. To grant or refuse to grant registration pursuant to Section 25-5-426(4), C.R.S. and to grant or refuse to grant the annual renewal of a registration;

2. To deny, suspend, or revoke a registration;

3. To issue a certificate of free sale; and

4. To review any records of a wholesale food manufacturer or storage facility necessary to verify compliance with the provisions of Section 25-5-426, C.R.S.

C. This regulation does not apply to:

1. Retail food establishments governed by the *Colorado Retail Food Establishment Regulations*, 6 CCR 1010-2;

2. Facilities or conditions governed by the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4;

3. Entities engaged in the business of possessing, cultivating, dispensing, transferring, transporting, or testing Medical Marijuana or Retail Marijuana governed by the *Colorado Marijuana Rules*, 1 CCR 212-3;

4. The cultivation of industrial hemp governed by the *Rules Pertaining to the Administration and Enforcement of the Industrial Hemp Regulatory Program Act*, 8 CCR 1203-23;

5. Entities that are manufacturing intermediate or finished hemp products from the fibrous material of the plant that are not intended for human consumption. These products include, but are not limited to, cordage, paper, fuel, textiles, bedding, insulation, construction materials, compost materials, and industrial materials;

6. Entities that are manufacturing industrial hemp-derived smokable products, inhalable products, over-the-counter drugs, drugs, or medical devices; and

7. Testing performed by a certified laboratory in accordance with the *Hemp Testing Laboratory Certification*, 5 CCR 1005-5.

D. Nothing in this rule shall be construed to limit the department's statutory authority under the "Pure Food and Drug Law", Section 25-5-401 et seq., C.R.S., the "Shellfish Dealer Certification Act," Section 25-4-1801 et seq., C.R.S., or Section 25-1.5-102, C.R.S.

21.3 Applicability

A. This rule establishes registration requirements for wholesale food and industrial hemp product manufacturers, Section 25-5-426, C.R.S., and certification requirements for wholesale food manufacturers who are also shellfish dealers, Section 25-4-1801 *et seq.*, C.R.S.

1. This regulation establishes the allowance that industrial hemp manufacturers [as defined in 21.4(A)(16)] shall adhere to for the production of industrial hemp products and unfinished industrial hemp products in the State of Colorado.

2. These regulatory requirements do not infer conformance with federal laws and the allowance for manufacturing, sale, and distribution of industrial hemp products and unfinished industrial hemp products to other states or countries.

B. This rule incorporates by reference the Code of Federal Regulations addressing Food for Human Consumption and the national shellfish sanitation standards.

C. Pursuant to section 21.6, this rule incorporates by reference 21 Code of Federal Regulations (C.F.R.) 100-111, 113-170, and 172-190 (April 1, 2017).

D. This rule establishes enforcement standards for wholesale food manufacturers pursuant to Sections 25-1.5-102(1)(c), 25-5-406 and 25-5-420, C.R.S., and enforcement standards for wholesale food manufacturers who are also shellfish dealers pursuant to Section 25-4-1810, C.R.S.

21.4 Definitions

A. For the purpose of these rules and regulations, unless otherwise specified herein:

1. Approved Source means:

   a. A product from a wholesale food manufacturer, industrial hemp manufacturer, or a storage facility registered with the department in accordance with Section 25-5-426, C.R.S, or

   b. Generally Recognized As Safe (GRAS), or

   c. Hemp seed, hemp seed co-products, or hemp-seed by-products, or

   d. Industrial hemp or hemp products from a state that has an established and approved industrial hemp program, or

   e. Industrial hemp or hemp products from a country that inspects or regulates hemp under a food safety program or equivalent criteria to ensure safety for human consumption.

2. Broad spectrum means industrial hemp products that contain multiple cannabinoids and no more than 0.01% total THC.

3. Cannabinoids means a class of lipophilic molecules that are naturally occurring in industrial hemp.

4. Certified laboratory means a public or private laboratory or testing facility certified by the department to perform testing on industrial hemp and industrial hemp products or a testing facility licensed by the Marijuana Enforcement Division.

5. Certificate of Analysis means an official document issued by a certified laboratory or testing facility that shows results of scientific tests performed on a product.

6. Cosmetics means articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance or an article intended for use as a component of any such articles; except that such term does not include soap.

7. Dealer or Shellfish Dealer means a person to whom certification is issued for the activities of shell stock shipper, shucker-packer, repacker, reshipper, depuration processor, or wet storage.

8. Delta-9 tetrahydrocannabinols (THC) or delta-9 THC has the same meaning as "tetrahydrocannabinols" as set forth in Section 27-80-203 (24), C.R.S. Delta-9 THC is the primary psychoactive component of cannabis. For the purposes of these regulations, the terms "Delta-9 THC" and "THC" are interchangeable.

9. Department means the Colorado Department of Public Health and Environment.

10. Dietary supplement means a product taken by mouth that contains a dietary ingredient or a new dietary ingredient intended to supplement the diet.

11. Full spectrum means an industrial hemp product that contains all phytochemicals naturally found in the plant, trace cannabinoids, terpenes, and essential oils, with no more than 0.3% total THC.

12. Generally Recognized As Safe (GRAS) means any substance that is intentionally added to food which is a food additive, that is subject to premarket review by FDA, unless the substance is generally recognized, among qualified experts, as having been adequately shown to be safe under the conditions of its intended use, or unless the use of the substance is otherwise excepted from the definitions of food additive.

13. Herb means any plant with leaves, seeds, or flowers used as a flavoring, food, food additive, or dietary supplement ingredient.

14. Industrial hemp or hemp means the plant Cannabis sativa L. and any part of the plant, including the seeds, all derivatives, extracts, cannabinoids, isomers, acids, salts, and salts of isomers, whether growing or not, with a Delta-9 tetrahydrocannabinol concentration of no more than 0.3% on a dry-weight basis.

15. Industrial hemp extract means an unfinished industrial hemp product or industrial hemp product produced through a solvent or non-solvent based industrial hemp manufacturing process, including but not limited to oils, distillates, resins, and isolates.

16. Industrial hemp manufacturer means a facility that manufactures, produces, packs, processes (extracts), treats, packages, or holds/warehouses industrial hemp products and unfinished industrial hemp products.

17. Industrial hemp product means finished products containing industrial hemp that is for human use or consumption and:

    a. Is a cosmetic as defined in 25-5-402(6) C.R.S.; or

    b. Is a dietary supplement as defined in 25-5-426(2)(b) C.R.S.; or

    c. Is a food as defined in 25-5-402(11) C.R.S.;

    d. Is a food additive as defined in 25-5-402(12) C.R.S.;

    e. Contains any part of the hemp plant, including naturally occurring cannabinoids, compounds, concentrates, extracts, isolates, resins, or derivatives;

    f. Contains a Delta-9 THC concentration of no more than 0.3%, and

    g. Is not a drug as defined in 25-5-402(9) C.R.S.

18. Labeling means a display of written, printed, or graphic matter upon a food, food ingredient container, or package and includes product inserts, and other promotional materials including digital communications.

19. Law means applicable local, state, and federal statutes, regulations and ordinances.

20. Packaging means any type of container, wrapping, or other type of vessel intended to protect both food or dietary supplements from damage, contamination, spoilage, pest attacks, and tampering, during transport, storage, and sale.

21. THC means tetrahydrocannabinol.

22. THCA means tetrahydrocannabinolic acid.

23. Total THC means the sum of the percentage by weight of THCA multiplied by 0.877 plus the percentage by weight of THC [i.e., (% THCA x 0.877) + % THC].

24. Unfinished industrial hemp product means an oil, concentrate or other substance that has a total THC concentration above 0.3% and less than or equal to 5.0%, is not for consumer use or distribution, must be sold or transferred between registered industrial hemp manufacturers, or certified laboratories, and will undergo further refinement or processing into an industrial hemp product.

25. Wholesale food manufacturer means a facility that manufactures, produces, packs, processes, treats, packages, transports, or holds human food, including dietary supplements. These terms include storage facilities. These terms include shellfish dealers when the wholesale food manufacturer is also a shellfish dealer.

21.5 Wholesale Food Manufacturer and Shellfish Dealer Requirements

A. Wholesale food manufacturing facilities in Colorado must be registered in accordance with Section 25-5-426(4), C.R.S.

1. The owner of any wholesale food manufacturer must submit to the department an application each year for registration, along with applicable application and registration fees, using forms provided by the department.

2. The owner of any wholesale food manufacturer must also submit to the department complete and accurate information about the facility's operation and business size, using forms provided by the department.

B. Wholesale food manufacturers who are also shellfish dealers in Colorado must also be certified in accordance with Section 25-4-1805, C.R.S.

1. Any person desiring to do business as a shellfish dealer must apply for and obtain a valid certification issued by the department.

2. Shellfish dealers must report to the department, in the form and manner required by the department, any change in the information provided in the dealer's application or in such reports previously submitted, within thirty days of such change.

21.6 Incorporation by Reference

A. The department shall utilize material incorporated by reference as appropriate to assure that wholesale food manufacturers comply with the "Pure Food and Drug Law", and wholesale food manufacturers who are also shellfish dealers comply with the "Shellfish Dealer Certification Act."

1. 21 C.F.R. 100-190 (April 1, 2017) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the reference material.

2. U.S. Department of Health and Human Services, Public Health Service/Food and Drug Administration, *National Shellfish Sanitation Program Guide for the Control of Molluscan Shellfish Model Ordinance* (2015 Revision) is hereby incorporated by reference into this rule. Such incorporation, however, excludes later amendments to or editions of the reference material.

B. Any provision included or incorporated herein by reference which conflicts with the Colorado Revised Statutes, including but not limited to Section 25-5-401 et seq., C.R.S., Section 25-4-1801 *et seq.*, C.R.S., and Section 25-1.5-102, C.R.S., shall be null and void. These regulations do not incorporate by reference:

1. 21 C.F.R. 112, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*.

2. 21 C.F.R. 171, *Food Additive Petitions*.

C. The incorporated material is available for public inspection during regular business hours at:

Division of Environmental Health and Sustainability
Colorado Department of Public Health and Environment
4300 Cherry Creek Drive South
Denver, Colorado 80246-1530

Pursuant to 24-4-103(12.5)(V)(b), C.R.S., the agency shall provide certified copies of the material incorporated at cost upon request or shall provide the requestor with information on how to obtain a certified copy of the material incorporated by reference from the agency of the United States, this state, another state, or the organization or association originally issuing the code, standard, guideline or rule.

D. The incorporated materials are available at:

https://www.ecfr.gov/cgi-bin/text-idx?SID=2029b930ffb25f468e235e6ec9a86dea&mc=true&tpl=/ecfrbrowse/Title21/21tab_02.tpl

21.7 Industrial Hemp Processing and Manufacturing Requirements

A. Oils, concentrates or other substances that are above 5.0% total THC must undergo further refinement or processing by the original registered industrial hemp manufacturer to meet the definition of a finished industrial hemp product or unfinished industrial hemp product.

B. Prior to manufacturing, packaging, or distributing an industrial hemp product or an unfinished industrial hemp product, a business shall:

1. Be registered with the department;

2. Obtain any necessary local licenses, registrations, and approvals;

3. Ensure all types of industrial hemp products and unfinished industrial hemp products, packaging, and labeling meet the requirements established within this regulation; and

4. Have conspicuously posted all applicable documentation in accordance with the law.

C. Industrial hemp manufacturing facilities shall maintain physical and operational separation from any marijuana-related facility, including separate entrances and exits.

D. All standard operating procedures and scheduled processes performed in the facility are limited to those approved by the appropriate regulatory authority.

E. Ingredients

1. All ingredients must come from an approved source;

2. All industrial hemp ingredients or industrial hemp extract shall be clearly identified to allow for appropriate traceability. Identification includes:

a. Name of ingredient;

b. Identifying batch or lot number from original package;

c. Date the ingredient was manufactured;

d. Date the ingredient was received at the facility; and

e. Expiration, re-test, or use-by date.

3. Spoiled, unwholesome, adulterated, vermin-infested or insect-infested ingredients are not allowed into the facility and shall be:

a. Removed immediately from the premises and properly disposed; or

b. Placed in a quarantine area temporarily until proper disposal if:

(1) Not practicable to remove immediately; or

(2) Required to be collected by a local or state regulatory agency for examination or testing.

F. Testing

1. Effective July 1, 2021, analytical testing shall be performed by a certified laboratory in accordance with the department's State Public Health Laboratory, Disease Control and Public Health Response Division's, *Hemp Testing Laboratory Certification*, 5 CCR 1005-5.

2. In order for a food, food additive, dietary supplement, or cosmetic to contain industrial hemp, the manufacturer shall be able to demonstrate the following purity and potency:

   a. The use of parts of the industrial hemp plant, other than seed and its derivatives (e.g., hulled hemp seed, hemp seed protein powder, hemp seed oil) shall have laboratory test results indicating conforming levels of THC and total THC.

   b. The manufacturer shall document that the industrial hemp product does not contain more than 0.3% total THC.

3. Additional Testing Standards: Industrial hemp manufacturers are responsible for ensuring testing requirements listed in subparagraphs 21.7(F)(5)(a-e) are met and maintaining certificates of analysis on any regulated industrial hemp products they produce or transfer to ensure safety on all lots or batches for human consumption. The testing requirements contained in this regulation are the minimum required and approved testing standards.

4. All certificates of analysis provided as documentation of conformance with the established testing requirements shall be furnished from a certified industrial hemp testing laboratory or a licensed retail marijuana testing laboratory.

   a. Any exceedance of the contaminant action limits presented in section 21.7(F)(5)(a-e) shall be reported to the department by the industrial hemp manufacturer within 48 hours of receipt of the analytical testing results.

5. Permissible Levels of Contaminants: If an industrial hemp product is found to have a contaminant in levels exceeding those established as permissible under this regulation, then it shall be considered to have failed contaminant testing. Notwithstanding the permissible levels established in this regulation, the department reserves the right to determine, upon good cause and reasonable grounds that a particular product presents a risk to public health or safety and therefore shall be considered to have failed a contaminant test.

a. Microbials (Bacteria and Fungus)

Substance	**Action Limits** Per gram (g), unless otherwise indicated
Salmonella spp.	Absent in 25 g
–Shiga-toxin producing Escherichia coli (STEC) - Bacteria	Absent in 25 g
Total coliforms	< 10^2 cfu/g
Total aerobic plate count	< 10^4 cfu/g
Total yeast and mold	< 10^3 cfu/g

b. Mycotoxins

Substance	**Action Limits** Parts per billion (ppb)
Aflatoxins (B1, B2, G1, and G2)	< 20 (total of B1 + B2 + G1 + G2)
Aflatoxin B1	< 5
Ochratoxin	< 5

c. Pesticides

The following pesticides are not allowed in finished hemp products or unfinished hemp products. The following table establishes the Limits of Quantification (LOQ) for laboratory verification.

Substance (pesticides)	**Limits of Quantification** Parts per million (ppm)	
	Product Type	
	Dried Hemp	Industrial Hemp Extract
Abamectin	0.1	0.25
Acephate	0.02	0.05
Acequinocyl	0.03	*
Acetamiprid	0.1	0.05
Aldicarb	1	0.5
Allethrin	0.2	0.1

Substance (pesticides)	**Limits of Quantification** Parts per million (ppm)	
	Product Type	
	Dried Hemp	Industrial Hemp Extract
Atrazine	0.025	*
Azadirachtin	1	0.5
Azoxystrobin	0.02	0.01
Benzovindiflupyr	0.02	0.01
Bifenazate	0.02	0.01
Bifenthrin	1	*
Boscalid	0.02	0.01
Buprofezin	0.02	*
Carbaryl	0.05	0.025
Carbofuran	0.02	0.01
Chlorantraniliprole	0.02	*
Chlorphenapyr	0.05	1.5
Chlorpyrifos	0.04	0.5
Clofentezine	0.02	0.01
Clothianidin	0.05	0.025
Coumaphos	0.02	0.01
Cyantraniliprole	0.02	0.01
Cyfluthrin	0.2	*
Cypermethrin	0.3	*
Cyprodinil	0.25	0.01
Daminozide	0.1	*
Deltamethrin	0.5	*
Diazinon	0.02	*
Dichlorvos	0.1	0.05
Dimethoate	0.02	0.01

Substance (pesticides)	**Limits of Quantification** Parts per million (ppm)	
	Product Type	
	Dried Hemp	Industrial Hemp Extract
Dimethomorph	0.05	*
Dinotefuran	0.1	0.05
Diuron	0.125	*
Dodemorph	0.05	*
Endosulfan sulfate	0.05	2.5
Endosulfan-alpha	0.2	2.5
Endosulfan-beta	0.05	2.5
Ethoprophos	0.02	0.01
Etofenprox	0.05	*
Etoxazole	0.02	*
Etridiazole	0.03	0.15
Fenhexamid	0.125	*
Fenoxycarb	0.02	0.01
Fenpyroximate	0.02	*
Fensulfothion	0.02	0.01
Fenthion	0.02	0.01
Fenvalerate	0.1	*
Fipronil	0.06	0.01
Flonicamid	0.05	0.025
Fludioxonil	0.02	0.01
Fluopyram	0.02	0.01
Hexythiazox	0.01	*
Imazalil	0.05	0.01
Imidacloprid	0.02	0.01
Iprodione	1	0.50

Substance (pesticides)	**Limits of Quantification** Parts per million (ppm)	
	Product Type	
	Dried Hemp	Industrial Hemp Extract
Kinoprene	0.50	1.25
Kresoxim-methyl	0.02	0.15
(Lambda) Cyhalothrin	0.25	*
Malathion	0.02	0.01
Metalaxyl	0.02	0.01
Methiocarb	0.02	0.01
Methomyl	0.05	0.025
Methoprene	2	*
Mevinphos	0.05	0.025
MGK-264	0.05	*
Myclobutanil	0.02	0.01
Naled	0.1	*
Novaluron	0.05	0.025
Oxamyl	3.0	1.5
Paclobutrazol	0.02	0.01
Parathion-methyl	0.05	*
Permethrin	0.5	*
Phenothrin	0.05	*
Phosmet	0.02	*
Piperonyl butoxide	0.2	1.25
Pirimicarb	0.02	0.01
Prallethrin	0.05	*
Propiconazole	0.1	*
Propoxur	0.02	0.01
Pyraclostrobin	0.02	0.01

Substance (pesticides)	**Limits of Quantification** Parts per million (ppm)	
	Product Type	
	Dried Hemp	Industrial Hemp Extract
Pyrethrins	0.05	*
Pyridaben	0.05	0.02
Pyriproxyfen	0.010	*
Quintozene	0.02	*
Resmethrin	0.1	0.05
Spinetoram	0.02	0.01
Spinosad	0.1	0.01
Spirodiclofen	0.25	*
Spiromesifen	3	*
Spirotetramat	0.02	0.01
Spiroxamine	0.1	*
Tebuconazole	0.05	0.01
Tebufenozide	0.02	0.01
Teflubenzuron	0.05	0.025
Tetrachlorvinphos	0.02	0.01
Tetramethrin	0.1	*
Thiabendazole	0.020	*
Thiacloprid	0.02	0.01
Thiamethoxam	0.02	0.01
Thiophanate-methyl	0.05	*
Trifloxystrobin	0.02	0.01

* Note: LOQ not available or established.

d. Heavy Metals

Substance	Action Limits (extracts, foods, dietary supplements) Parts per million (ppm)
Arsenic	< 1.5
Cadmium	< 0.5
Lead	< 0.5
Mercury	< 1.5

e. Residual Solvents

Substance	Action Limits (solvent based industrial hemp extracts) Parts per million (ppm)
Acetone	< 1,000
Benzene*	<2
Butanes	< 1,000
Ethanol	< 1,000
Ethyl Acetate	< 1,000
Heptanes	< 1,000
Hexane	< 60
Isopropyl Alcohol	< 1,000
Methanol	< 600
Pentane	< 1,000
Propane	< 1,000
Toluene*	< 180
Total Xylenes (m, p, o-xylenes)*	< 430
Any other solvent not permitted for use	None detected

* Note: These solvents are not approved for use. Due to their possible presence in the solvents approved for use, limits have been listed here accordingly.

G. Packaging and Labeling Requirements

1. Effective July 1, 2021, packaging and labeling shall be performed in accordance with the department's labeling requirements for industrial hemp food and dietary supplement products listed in sections 21.7(G)(2–6).

2. Product packaging shall be food-grade or GRAS and labeling shall be performed in accordance with 21 C.F.R. 101, subparts A–G and the department's labeling requirements for hemp food products, which includes:

   a. Product Identity Statement (in bold type) which indicates the common or usual name of the food ingredient;

   b. Identify in milligrams the total THC content per serving and total THC content per individual finished product package;

   c. Manufacturing address or a qualifying phrase which states the firm's relation to the product (e.g., "manufactured for" or "distributed by");

   d. Net Weight Statement placed as a distinct item parallel to the base of the package in the bottom third of the principal display panel; and

   e. List of ingredients, in descending order of predominance by weight:

      (1) Identify industrial hemp as an ingredient; and

      (2) Identify each isolated cannabinoid as an ingredient and the amount labeled in milligrams or when using a broad or full spectrum product, label the total amount in milligrams.

3. Allergens shall be clearly identified and listed separately.

4. A code or numbering system that identifies the date and location of manufacturing and packaging is required for tracking and assisting in recalls or trace forward/trace back efforts.

5. Health claims for hemp or hemp-derived ingredients must be qualified and must follow Federal Trade Commission (FTC) and FDA regulations and guidance, including marketing materials and electronic communications. A manufacturer, distributor, or seller of an industrial hemp product shall not include on the label of the product, or publish or disseminate in marketing or electronic communications, any claims that the industrial hemp product can, or is intended to, diagnose, cure, mitigate, treat, or prevent disease.

6. The label of a cosmetic product shall bear a warning statement whenever necessary or appropriate to prevent a health hazard that may be associated with the product. This applies to qualified claims on products as well as ingredients, aerosol products, deodorant products, foaming detergent bath products, coal tar hair dyes, sun-tanning and sunscreen products. Cosmetic packaging must be suitable for the intended purpose. Additional cosmetic labeling requirements are listed in 21 C.F.R. 701, subparts A-C, incorporated by reference pursuant to section 21.6.

H. Record Keeping

1. For all facilities, the following records shall be maintained, as required herein:

    a. Certificates of analysis;

    b. Batch production records;

    c. Recalled product information;

    d. Source of ingredients; and

    e. Other records as required by the department (e.g., ingredient records, corrective action logs, mock recall documents, calibration records, as applicable).

2. For all facilities, records shall:

    a. Be kept as original records, true copies (such as photocopies, pictures, scanned copies, microfilm, microfiche, or other accurate reproductions of the original record(s), or electronic records;

    b. Contain the actual values and observations obtained during monitoring and, as appropriate, during verification activities;

    c. Be accurate, indelible, and legible;

    d. Be created concurrently with performance of the activity documented;

    e. Be as detailed as necessary to provide history of work performed; and include:

        (1) Information adequate to identify the plant or facility (e.g., the name and, when necessary, location of the plant or facility);

        (2) The date and time of the activity documented, when appropriate;

        (3) The signature or initials of the person performing the activity; and

        (4) The identity of the product and the lot code, when appropriate.

3. Record retention for all food, food additive, and cosmetic manufacturing facilities:

    a. Records shall be retained at the plant or facility for at least 2 years after the date they were prepared.

4. Record retention for dietary supplement facilities:

a. Records shall be kept for one year past the shelf life date, if the shelf life dating is used, or two years beyond the date of distribution of the last batch of dietary supplements associated with those records.

I. Recalls

1. Industrial hemp product processing and manufacturing facilities shall establish a written recall plan in accordance with 21 C.F.R. 117.139, *Recall Plan*, that includes procedures that describe the steps to be taken, and assign responsibility for taking those steps, to perform the following actions as appropriate to the facility:

a. Directly notify the direct consignees of the food being recalled, including how to return or dispose of the affected product;

b. Notify the public about any hazard presented by the product when appropriate to protect public health;

c. Conduct effectiveness checks to verify that the recall is carried out; and

d. Appropriately dispose of recalled product (e.g., through reprocessing or reworking as appropriate, or diverting to a use that does not present a safety concern, or destroying the product).

J. Transportation

1. Transfer of industrial hemp or unfinished industrial hemp product shall be conducted in accordance with the law.

2. Industrial hemp, unfinished industrial hemp products, and industrial hemp products shall be transported in a manner where they will be protected from adulteration, allergen cross-contact, environmental contamination and any other hazards.

K. Waste Management

1. Industrial hemp-derived THC shall be diluted to a concentration less than 0.3%, converted, or disposed of in accordance with the department's Hazardous and Waste Management Division's *Marijuana and Marijuana-Related Waste Disposal* Compliance Bulletin.

2. Facility owner/operator is responsible to secure and limit access to industrial hemp-derived THC with a concentration greater than 0.3%.

21.8 Enforcement

A. 1. Wholesale food manufacturers that fail to submit a complete and accurate annual application for registration, or fail to remit fees in accordance with Section 25-5-426(4), C.R.S., are not considered an approved source for introduction of manufactured food into retail commerce.

2. Wholesale food manufacturers who are also shellfish dealers that fail to submit a complete and accurate annual application for certification are not considered an approved source for introduction of shellfish into retail commerce.

B. Adulterated or misbranded food, including food from unapproved sources, may be embargoed in accordance with Section 25-5-406, C.R.S.

C. In accordance with Section 25-1.5-102(1)(c), C.R.S., the department may require wholesale food manufacturers, including wholesale food manufacturers who are also shellfish dealers, to recall adulterated or misbranded food in order to investigate and control the causes of epidemic and communicable diseases affecting public health.

D. Pursuant to Sections 25-4-1810 and 25-5-420, C.R.S., if the department has reasonable cause to believe a violation of this regulation has occurred and immediate enforcement is necessary, it may issue a cease-and-desist order, which shall set forth the provisions alleged to have been violated, the facts constituting the violation, and the requirement that all violating actions immediately cease.

1. At any time after service of the order to cease and desist by certified mail, the person for whom such order was served may request a hearing to determine whether such violation has occurred. Such hearing will be conducted in conformance with the provisions of article 4 of title 24, C.R.S. and shall be determined promptly.

E. To the extent and manner authorized by law, the department may issue letters of admonition or may deny, suspend, refuse to renew, restrict, or revoke any wholesale food manufacturer registration or any shellfish dealer certification if the wholesale food manufacturer or wholesale food manufacturer who is also a shellfish dealer has:

1. Refused or failed to comply with any provision of this regulation or any lawful order of the department;

2. Had an equivalent certification or registration denied, revoked, or suspended by another authority, including but not limited to another state, or the U.S. Food and Drug Administration;

3. Refused to provide the department with reasonable, complete, and accurate information when requested by the department; or

4. Falsified any information submitted to the department.

F. In addition to the requirements herein, when the department determines that a wholesale food manufacturer who is also a shellfish dealer’s activity constitutes a major public health threat, the department shall cooperate with other authorities pursuant to Section 25-4-1805(5), C.R.S