

**DEPARTMENT OF PUBLIC HEALTH AND ENVIRONMENT**

**Division of Environmental Health and Sustainability**

**COLORADO WHOLESALE FOOD AND SHELLFISH REGULATIONS**

**6 CCR 1010-21**

*[Editor's Notes follow the text of the rules at the end of this CCR Document.]*

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**Adopted by the Board of Health on August 15, 2018; effective, October 15, 2018**

**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 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, and
  2. Facilities or conditions governed by the *Colorado Milk and Dairy Products Regulations*, 6 CCR 1010-4.
- 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 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.
- B. This rule incorporates by reference the Code of Federal Regulations addressing Food for Human Consumption and the national shellfish sanitation standards.
- C. 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. Department means the Colorado Department of Public Health and Environment.
  - 2. 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.
  - 3. Wholesale food manufacturer or Wholesale food manufacturing facilities 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 CFR 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 CFR 112, *Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption*.
  2. 21 CFR 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 C.R.S. 24-4-103(12.5)(V)(b), 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.colorado.gov/pacific/cdphe/wholesale-food-stakeholder-meetings>

## 21.7 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.

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- 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.

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**Editor's Notes**

**History**

Entire rule eff. 10/15/2018.