

ARM 37.110.304 INTRODUCTION (1) This subchapter regulates wholesale food establishments, as stated in Title 50, chapter 57, MCA. These rules reflect the most recent scientific information, align the regulations with other states, and correspond to the extent feasible with the retail food rules.

AUTH: 50-57-103, MCA

IMP: 50-57-103, MCA

ARM 37.110.305 INCORPORATION BY REFERENCE (1) The Department of Public Health and Human Services (department) adopts and incorporates by reference the Food and Consumer Safety (FCS) Circular 2-2019 for wholesale food establishments. This publication may be reviewed online at:

<https://dphhs.mt.gov/publichealth/FCSS/WholesaleFoodEstablishments>, or by contacting DPHHS-FCSS, 1400 Broadway Street, Helena, MT 59620. The circular is modeled after the 2015 Montana retail food rule, 2013 U.S. Food and Drug Administration "Food Code," and Montana food standards contained in ARM Title 37, chapter 110, subchapter 1.

AUTH: 50-57-103, MCA

IMP: 50-57-103, MCA

ARM 37.110.306 LICENSES (1) Any person applying to operate a wholesale food establishment must complete and submit a written application for a license on a form provided by the department. License application forms are available through the local health authority in the county where the activity is being proposed.

(2) A license applicant or legal licensee must submit to the regulatory authority properly prepared plans and specifications for review and approval before:

- (a) construction of a new food establishment;
- (b) conversion of an existing structure for use as a food establishment;
- (c) significant remodeling of an existing food establishment, as determined by the regulatory authority;
- (d) significant change in licensing subtype from low-risk food processing to high-risk food processing, as determined by the regulatory authority; or
- (e) a proposed change in legal ownership of an existing food establishment, as determined by the regulatory authority.

(3) Establishment plans and specifications must include, as required by the regulatory authority, the following information to demonstrate conformance with this subchapter:

- (a) intended ingredients, recipes, or products;
- (b) anticipated volume of food to be stored, processed, and sold or served;
- (c) proposed layout, mechanical schematics, construction materials, and finish schedules;
- (d) proposed equipment types, manufacturers, model numbers, locations, dimensions, performance capacities, and installation specifications;
- (e) evidence that standard procedures ensuring compliance with the requirements of this rule are developed or are being developed; and
- (f) other information that may be required by the regulatory authority for the proper review of the proposed construction, conversion, or modification, and procedures for operating a food establishment.

(4) Proposed mobile food establishments, engaged in food processing, especially high-risk processing, must adequately demonstrate to both the department and the local regulatory authority that the business plan can control at

Wholesale Food Rule 2020

least the following factors, prior to issuance of a license for each and every anticipated food-processing site:

- (a) access to sufficient quantity and quality of potable water;
- (b) provision for numbers and location of handwashing stations;
- (c) provision for numbers and location of food worker toilets;
- (d) access to sufficient quantity and quality of wastewater disposal systems;
- (e) control over possible airborne contaminants;
- (f) control over possible ground-based contaminants;
- (g) control over possible vermin access;
- (h) control over proper plumbing for water and wastewater;
- (i) control over operations to prevent water and wastewater freezing; and
- (j) other relevant control items deemed appropriate by the department or

local regulatory authority.

(5) A proposed food manufacturing establishment bottling drinking water in Montana must submit the following to the department and/or local health authority for review and approval:

(a) written test results of the most recent inorganic, volatile organic, organic chemical, and radiological analyses of the water serving the establishment;

(b) written test results for pesticides and synthetic organic chemicals, if the department or local health authority determines such tests are necessary, or if random testing has shown there is or may be contaminants present at levels which may adversely affect public health;

(c) a written description of the water source, water treatment systems, all substances added to the water, and any other documentation required by the department or local health authority to verify that labels and terminology used on product labels conform with applicable law; and

(d) for products labeled "mineral water" or for a label containing the term "mineral water" copies of laboratory testing results of mineral content and total dissolved solids (TDS) of the product, obtained during the last 12 months preceding the license year from an agency approved by the department or another public health agency, to test drinking water.

(6) License applicants and license holders must ensure uniform application of food safety standards and compliant product labels.

(a) Prior to approval of an application for a license, or change in certain license subtypes, the local regulatory authority will require the license applicant to submit to the department, and/or the local regulatory authority, food processing plans and food package labeling examples on a form provided by the department for assessment of compliance with this subchapter, and food standards in applicable subsections of ARM 37.110.101. The assessment will be conducted by either the local regulatory authority or the department, or both.

(b) Pursuant to the requirement in (6), this section addresses who is qualified to conduct food safety evaluations and scientific food studies:

(i) Food processes or packaging methods and scientific challenge studies that need a written safety evaluation must be conducted by a process authority currently listed with the Association of Food and Drug Officials at the time of the compliance assessment stated in (6)(a).

(ii) When a challenge study is proposed, in addition to the requirement in (b)(i), the study must be designed and evaluated by an expert food microbiologist,

and the laboratory in which the study is conducted must be able to demonstrate prior experience in conducting valid scientific challenge studies.

(c) At the conclusion of the pre-licensing assessment done by the department, the department will submit in a timely manner to the local regulatory authority, and license applicant, a written report regarding findings of the pre-licensing assessment, which may be used by the local regulatory authority as a basis for approval or denial of an application for a license. The written report will also suggest to the local regulatory authority to which license subtype the business should be assigned.

(7) All wholesale food establishments must comply with all appropriate building construction standards in 50-60-101, MCA, and all applicable administrative rules as adopted by the Department of Labor and Industry in ARM Title 24, chapter 301 before issuance of a department wholesale food license.

(8) The regulatory authority must conduct one or more pre-licensing inspections to verify that the food establishment is constructed and equipped in accordance with the approved plans and approved modifications of those plans, and is in compliance with law and this subchapter. No license will be issued or permission granted to operate a proposed establishment if any violations of this rule are observed by the regulatory authority during the final onsite pre-licensing inspection. The department will issue a license to the applicant if the final pre-licensing inspection by the regulatory authority reveals that the proposed wholesale food establishment complies with requirements in this subchapter.

(9) No person may operate a wholesale food establishment who does not have a valid license issued by the department. Only a person who complies with the requirements of this subchapter will be entitled to receive or retain such a license. A valid license must be posted in a conspicuous place for viewing at every wholesale food establishment. Food establishments, under this subchapter that also sell or serve to consumers must procure a separate retail food establishment license, unless specifically exempted from licensure under law in Title 50, chapter 50, MCA.

(10) A license issued by the department must be validated by the local health officer of the local board of health with jurisdiction where the establishment is located in accordance with 50-57-208, MCA. Upon refusal to validate a license, the applicant may appeal the decision in accordance with 50-57-209, MCA.

(11) The department may deny or cancel a license, in accordance with 50-57-210, MCA. Prior to license cancellation, the applicant or licensee may submit a correction plan, in accordance with 50-57-211, MCA. A written notice to the applicant or licensee and hearing are required in cases involving license denials or cancellations, in accordance with 50-57-212, MCA.

(12) Whenever a cancellation of a license has become final, the holder of the cancelled license may make written application for a new license.

(13) Obtaining the license referred to in (9) does not relieve the applicant from satisfying applicable requirements from other federal, state, or local agencies. These may include:

- (a) building rule permits and inspections;
- (b) fire and life safety inspections;
- (c) private or public water supply system or sewage treatment systems permits or inspections; and
- (d) occupational health and safety requirements.

Wholesale Food Rule 2020

(14) The local regulatory authority will assign a food establishment to a license type and subtype by assessing food processing procedures, food service, and utilizing the definitions in this subchapter.

(15) At the time of initial licensing and updated as needed, but no less than each licensing year, the regulatory authority will correctly assign a food establishment to one of four categories by evaluating the food processing and service procedures of the food establishment based on the criteria specified in Table 1.

Table 1: Food Establishment Categories

Category A: a food establishment whose point value is less than two must be included in this category.

Category B: a food establishment whose point value is at least two, but not greater than four, must be included in this category.

Category C: a food establishment whose point value equals or exceeds five must be included in this category.

Category D: a food establishment that has been ordered closed by the regulatory authority, or caused a documented foodborne illness outbreak within the previous licensing year must be included in this category.

Food Establishment Point Assignments	
Assignment Factors	Points
Food is not processed at the facility	0
Establishment has annual gross sales in excess of \$1 million	1
Establishment distributes food to other states or nations	1
Establishment provides delivery of ready-to-eat food to consumers	1
Potentially hazardous food (condition control food) are held at the facility for any period of time	1
Establishment provides wild mushrooms or wild plants	1
Establishment distributes food directly to schools, hospitals, elderly care facilities, or to other facilities that serve highly susceptible populations to foodborne illness	4
Food is processed before being distributed, involving activities such as baking, blanching, boiling, chopping, cooking, cutting, dicing, heating, reheating, or slicing, back-sweetening, and the finished food product is considered ready-to-eat	5
Food processed at the facility is classified as an acidified food, fish, or fishery product, low-acid canned food, or juice product	5
Establishment is engaged in sprouting seeds or making ice for human consumption	5
Establishment infuses vegetables or herbs in oil	5
Establishment packages potentially hazardous foods in reduced oxygen packaging or modified atmospheric packaging	5

(16) Botanical substances are those substances not classified in law as food, dietary supplements, drugs, or cosmetics but its use is commonly or usually known by reasonable persons to be an edible product available in commerce.

(a) Botanical substances as determined by the department that are in commerce, such as kratom (*Mitragyna speciosa*), will not be classified as foods, dietary supplements, drugs, or cosmetics if the following conditions apply to product labeling, promotional materials, and advertising:

(i) the information makes no reference to the product being edible; and

(ii) the information makes no health or health-related claims that would render the products unapproved drugs, dietary supplements, or food.

(b) This rule does not waive detainment and condemnation powers given in 50-31-509 and 50-31-510, MCA, for public health and safety purposes regarding adulteration and misbranding.

AUTH: 50-57-103, MCA

IMP: 50-57-103, 50-57-201, 50-57-203, 50-57-208, 50-57-209, 50-57-210, 50-57-211, 50-57-212, 50-57-213, MCA

ARM 37.110.307 INSPECTIONS (1) The local health officer, registered sanitarian, or sanitarian-in-training employed by or contracted with the local board of health must perform an inspection of each wholesale food establishment within the jurisdiction of the local board of health at least once every 12 months. Additional inspections of the food service establishment must be performed as often as necessary for the enforcement of this subchapter.

AUTH: 50-57-103, MCA

IMP: 50-57-103, 50-57-301, MCA

ARM 37.110.313 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES (1) To qualify for reimbursement under 50-57-305, MCA, a local board of health will perform inspections as specified in this subchapter or enter into a written, signed cooperative agreement with the department that establishes the duties and responsibilities of the local board of health and the department consistent with this subchapter.

(2) All local boards of health must meet the following criteria:

(a) At least one sanitarian working with or for the local board of health must receive training from the department in standardized food inspections. The department is responsible for making training and standardization available on a periodic basis.

(b) Reporting of inspection dates must be documented in a manner and frequency approved by the department.

(c) All documentation of enforcement of this subchapter including inspection reports, consumer complaints, illness investigations, plans of correction, issuances of variances, and enforcement actions must be retained for five years and be submitted or otherwise made available to the department upon request.

(3) A failure by the local board of health to meet any or all of its responsibilities under this rule may result in the withholding of funds from the local board reimbursement fund in an amount to be determined by the department.

AUTH: 50-57-103, MCA

IMP: 50-57-103, 50-57-104, 50-57-301, 50-57-305, MCA

37.110.315 CERTIFICATE OF FREE SALE (1) Requirements for issuance of a Certificate of Free Sale (CFS) by the department or local regulatory authority are:

- (a) all certificate applicants must possess a valid wholesale food license;
- (b) a CFS will be issued only for license subtypes listed on the issued license;
- (c) a CFS will only be issued for compliance with general good food manufacturing practices regulated in this subchapter, and not for the specific food manufacturing regulations stated in ARM 37.110.101;
- (d) products for certification must not be under or pending any known embargo, detainment, or litigation by the regulatory authority, U.S. Food and Drug Administration (USFDA), or other enforcement action by health or safety authorities recognized by the department, including local, state, or federal judicial orders;
- (e) prior to issuing a CFS, the certificate applicant will provide to the department or local regulatory authority a signed statement that certifies to the best of their knowledge the products are not pending any known embargo, detainment, or litigation by a local regulatory authority, the department, or USFDA, or local, state, or federal judicial orders;
- (f) certificate applicants that request a CFS must have been inspected by the regulatory authority within the inspection frequency stated in [NEW RULE IV];
- (g) certificate applicants must be in substantial compliance, and not have any uncorrected critical or priority violations of applicable food safety laws and rules;
- (h) a CFS will be issued in a format approved by the department that specifies:
 - (i) plant location where the products were processed;
 - (ii) date the plant was inspected, and found in substantial compliance, without any uncorrected critical or priority violations of applicable food safety laws and rules;
 - (iii) only known facts about the products, and conditions found during the inspection;
 - (iv) the inspection was not conducted to assess compliance with federal good manufacturing practices, only for compliance with Montana wholesale food rules;
 - (v) the issued document is clearly titled "Certificate of Free Sale"; and
 - (vi) the certificate does not imply or express any testimonials regarding product warranty;
- (i) the applicant must provide the department or local regulatory authority with information for a CFS on a form provided and approved by the department;
- (j) certificate applicant must currently be registered with USFDA, if products are shipped out of state, or outside the United States;

Wholesale Food Rule 2020

(k) the CFS will be issued in the order the requests are received, and provided in accordance with department or local regulatory authority resources in the timeliest manner possible; and

(l) the department or local regulatory authority will deliver CFSs by the U.S. Postal Service.

(2) The department or local regulatory authority will not charge a fee for the CFS, unless allowed by law.

(3) The decision by the department or local regulatory authority to deny a CFS may be appealed by the applicant by filing a written notice of appeal to the department or local regulatory authority within 30 days of the date on the written denial. Upon the filing of the notice of appeal, the applicant is entitled to a hearing before the department or local regulatory authority held pursuant to the contested case procedure detailed in the Montana Administrative Procedure Act. If the department or local regulatory authority finds the applicant is entitled to a CFS, the presiding officer of the department will issue written directions about how and when the certificate will be issued.

AUTH: 50-57-103, MCA

IMP: 50-57-103, MCA