

BEFORE THE DEPARTMENT OF PUBLIC
HEALTH AND HUMAN SERVICES OF THE
STATE OF MONTANA

In the matter of the adoption of New)	NOTICE OF PUBLIC HEARING ON
Rules I through VI, the amendment of)	PROPOSED ADOPTION,
ARM 37.110.101, and the repeal of)	AMENDMENT, AND
ARM 37.110.301, 37.110.302,)	REPEAL
37.110.303, 37.110.310, 37.110.311,)	
37.110.312, 37.110.318, 37.110.319,)	
37.110.320, 37.110.321, 37.110.323,)	
37.110.330, 37.110.331, 37.110.332,)	
37.110.333, 37.110.340, 37.110.341,)	
37.110.342, 37.110.347, 37.110.348,)	
37.110.350, 37.110.351, 37.110.352,)	
37.110.353, 37.110.354, 37.110.355,)	
37.110.360, 37.110.361, 37.110.362,)	
37.110.363, 37.110.364, 37.110.370,)	
37.110.371, 37.110.801, 37.110.802,)	
37.110.805, and 37.110.810)	
pertaining to wholesale foods and)	
food standards)	

TO: All Concerned Persons

1. On June 13, 2019, at 1:00 p.m., the Department of Public Health and Human Services will hold a public hearing in the auditorium of the Department of Public Health and Human Services Building, 111 North Sanders, Helena, Montana, to consider the proposed adoption, amendment, and repeal of the above-stated rules.

2. The Department of Public Health and Human Services will make reasonable accommodations for persons with disabilities who wish to participate in this rulemaking process or need an alternative accessible format of this notice. If you require an accommodation, contact the Department of Public Health and Human Services no later than 5:00 p.m. on June 4, 2019, to advise us of the nature of the accommodation that you need. Please contact Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; telephone (406) 444-4094; fax (406) 444-9744; or e-mail dphhslegal@mt.gov.

3. The rules as proposed to be adopted provide as follows:

NEW RULE I 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

NEW RULE II 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

NEW RULE III 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 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.

(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 detention 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

NEW RULE IV 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

NEW RULE V 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

NEW RULE VI 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;

(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

4. The rule as proposed to be amended provides as follows, new matter underlined, deleted matter interlined:

37.110.101 FOOD STANDARDS (1) The department adopts by reference the following federal regulations establishing food definitions and standards promulgated by the United States Food and Drug Administration ~~which~~ that are found in the corresponding parts of Title 21 of the Code of Federal Regulations (CFR) as of April 1, ~~2004~~ 2017 and 2018; These standards apply to all food as the term is defined in 50-31-103(15), MCA.

(a)	Color additives	21 CFR 70
(b)	Color additive petitions	21 CFR 71
(c)	Listing of color additives exempt from certification	21 CFR 73
(d)	Listing of color additives subject to certification	21 CFR 74
(e)	Color additive certification	21 CFR 80
(f)	General specifications and general restrictions for provisional color additives for use in foods, drugs and cosmetics	21 CFR 81
(g)	Listing of certified provisionally listed colors and specifications	21 CFR 82
(h)	Dissemination of information on unapproved/new uses for marketed drugs, biologics and devices	21 CFR 99
(i)	General (food for human consumption)	21 CFR 100, Subpart G
(j)	Food labeling	21 CFR 101
(k)	Common or usual name for non-standardized foods	21 CFR 102

(l)	Nutritional quality guidelines for foods	21 CFR 104
(m)	Foods for special dietary use	21 CFR 105
(n)	Infant formula quality control procedures	21 CFR 106
(o)	Infant formula	21 CFR 107
(p)	Emergency permit control	21 CFR 108
(q)	Unavoidable contaminants in food for human consumption and food-packaging material	21 CFR 109
(r)	Current good manufacturing practice in manufacturing, packing or holding human food	21 CFR 110
(s)	Current good manufacturing practice for dietary supplements	21 CFR 111
(t)	Thermally processed low-acid foods packages in hermetically sealed containers	21 CFR 113
(u)	Acidified foods	21 CFR 114
(v)	Shell eggs	21 CFR 115
<u>(w)</u>	<u>Current good manufacturing practice, hazard analysis, and risk-based preventive controls for human food</u>	<u>21 CFR 117</u>
(w) <u>(x)</u>	Hazard analysis and critical control point (HACCP) systems	21 CFR 120
(x) <u>(y)</u>	Fish and fishery products	21 CFR 123
(y) <u>(z)</u>	Processing and bottling of bottled drinking water	21 CFR 129
(z) <u>(aa)</u>	Food standards: general	21 CFR 130
(aa) <u>(ab)</u>	Milk and cream	21 CFR 131
(ab) <u>(ac)</u>	Cheeses and related cheese products	21 CFR 133
(ac) <u>(ad)</u>	Frozen desserts	21 CFR 135
(ad) <u>(ae)</u>	Bakery products	21 CFR 136
(ae) <u>(af)</u>	Cereal fours and related products	21 CFR 137
(af) <u>(ag)</u>	Macaroni and noodle products	21 CFR 139
(ag) <u>(ah)</u>	Canned fruits	21 CFR 145
(ah) <u>(ai)</u>	Canned fruit juices	21 CFR 146
(ai) <u>(aj)</u>	Fruit butters, jellies, preserves, and related products	21 CFR 150
(aj) <u>(ak)</u>	Fruit pies	21 CFR 152
(ak) <u>(al)</u>	Canned vegetables	21 CFR 155

(a) <u>(am)</u>	Vegetable juices	21 CFR 156
(am) <u>(an)</u>	Frozen vegetables	21 CFR 158
(an) <u>(ao)</u>	Eggs and egg products	21 CFR 160
(ao) <u>(ap)</u>	Fish and shellfish	21 CFR 161
(ap) <u>(aq)</u>	Cacao products	21 CFR 163
(aq) <u>(ar)</u>	Tree nut and peanut products	21 CFR 164
(ar) <u>(as)</u>	Beverages	21 CFR 165
(as) <u>(at)</u>	Margarine	21 CFR 166
(at) <u>(au)</u>	Sweeteners and table syrups	21 CFR 168
(au) <u>(av)</u>	Food dressing and flavorings	21 CFR 169
(av) <u>(aw)</u>	Food additives	21 CFR 170
(aw) <u>(ax)</u>	Food additive petitions	21 CFR 171
(ax) <u>(ay)</u>	Food additives permitted for direct addition to food for consumption	21 CFR 172
(ay) <u>(az)</u>	Secondary direct food additives permitted in food for human consumption	21 CFR 173
(az) <u>(ba)</u>	Indirect food additives: general	21 CFR 174
(ba) <u>(bb)</u>	Indirect food additives: adhesives and components of coatings	21 CFR 175
(bb) <u>(bc)</u>	Indirect food additives: paper and paperboard components	21 CFR 176
(bc) <u>(bd)</u>	Indirect food additives: polymers	21 CFR 177
(bd) <u>(be)</u>	Indirect food additives: adjuvants, production aids and sanitizers	21 CFR 178
(be) <u>(bf)</u>	Irradiation in the production, processing, and handling of food	21 CFR 179
(bf) <u>(bg)</u>	Food additives permitted in food on an interim basis or in contact with food pending additional study	21 CFR 180
(bg) <u>(bh)</u>	Prior-sanctioned food ingredients	21 CFR 181
(bh)	Substances generally recognized as safe	21 CFR 182

(bi)		
(bi) (bj)	Direct food substances generally recognized as safe	21 CFR 184
(bj) (bk)	Indirect food substances affirmed as generally recognized as safe	21 CFR 186
(bk) (bl)	Substances prohibited from use in human food	21 CFR 189
(bl) (bm)	Dietary supplements	21 CFR 190

(2) Copies of the federal regulations which were adopted and incorporated by reference under (1) may be obtained, ~~upon payment of copying costs,~~ from the Department of Public Health and Human Services, Food and Consumer Safety Section, 1400 Broadway, P.O. Box 202951, Helena, Montana 59620-2951, phone: (406) 444-2408.

AUTH: 50-31-104, 50-31-108, 51-31-201, MCA
IMP: 50-31-101, 50-31-104, 50-31-203, MCA

5. The department proposes to repeal the following rules:

37.110.301 DEFINITIONS is found on page 37-27281 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.302 PRECONSTRUCTION REVIEW is found on page 37-27283 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.303 PRELIMINARY INSPECTION is found on page 37-27283 of the Administrative Rules of Montana.

AUTH: 50-50-103, 50-50-301, 50-50-302, MCA
IMP: 50-50-103, 50-50-301, 50-50-302, MCA

37.110.310 FOOD SUPPLIES is found on page 37-27287 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.311 MILK AND MILK PRODUCTS is found on page 37-27287 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.312 FROZEN DESSERTS is found on page 37-27287 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.318 SHELLFISH is found on page 37-27291 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.319 MEAT AND MEAT PRODUCTS is found on page 37-27291 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.320 POULTRY AND POULTRY PRODUCTS is found on page 37-27291 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.321 BAKERY PRODUCTS is found on page 37-27291 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.323 EGGS AND EGG PRODUCTS found on page 37-27293 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.330 FOOD PROTECTION is found on page 37-27297 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.331 TEMPERATURE REQUIREMENTS is found on page 37-27297 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.332 FOOD PREPARATION is found on page 37-27298 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.333 FOOD STORAGE found on page 37-27299 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.340 DISPLAY AND SERVICE is found on page 37-27315 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.341 TRANSPORTATION is found on page 37-27315 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.342 TOXIC MATERIALS is found on page 37-27316 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.347 EMPLOYEE REQUIREMENTS is found on page 37-27323 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.348 EQUIPMENT AND UTENSILS: COMPOSITION, PLACEMENT, CLEANING, SANITIZING AND STORAGE is found on page 37-27324 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.350 WATER SUPPLY is found on page 37-27331 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.351 SEWAGE DISPOSAL is found on page 37-27332 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.352 PLUMBING is found on page 37-27332 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.353 TOILET AND LAVATORY FACILITIES is found on page 37-27333 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.354 WASTE DISPOSAL is found on page 37-27334 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.355 VERMIN CONTROL is found on page 37-27335 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.360 FLOORS, WALLS AND CEILINGS is found on page 37-27345 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.361 LIGHTING AND VENTILATION is found on page 37-27347 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.362 DRESSING ROOMS AND LOCKERS is found on page 37-27348 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.363 CLEANING OF PREMISES is found on page 37-27348 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.364 LIVE ANIMALS AND BIRDS: PROHIBITED ON PREMISES is found on page 37-27349 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA
IMP: 50-50-103, MCA

37.110.370 INSPECTIONS is found on page 37-27351 of the Administrative Rules of Montana.

AUTH: 50-50-103, 50-50-305, MCA
IMP: 50-50-301, 50-50-302, 50-50-305, MCA

37.110.371 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES is found on page 37-27352 of the Administrative Rules of Montana.

AUTH: 50-50-305, MCA
IMP: 50-50-305, MCA

37.110.801 DRINKING WATER is found on page 37-27471 of the Administrative Rules of Montana.

AUTH: 50-31-104, 50-31-201, 50-50-103, MCA
IMP: 50-31-104, 50-31-201, 50-50-103, MCA

37.110.802 ICE is found on page 37-27473 of the Administrative Rules of Montana.

AUTH: 50-31-104, 50-31-201, 50-50-103, MCA
IMP: 50-31-104, 50-31-201, 50-50-103, MCA

37.110.805 COMMON CARRIERS is found on page 37-27479 of the Administrative Rules of Montana.

AUTH: 50-50-103, MCA

IMP: 50-50-103, MCA

37.110.810 MINIMUM PERFORMANCE REQUIREMENTS FOR LOCAL HEALTH AUTHORITIES is found on page 37-27487 of the Administrative Rules of Montana.

AUTH: 50-50-305, MCA

IMP: 50-50-305, MCA

6. STATEMENT OF REASONABLE NECESSITY

The Department of Public Health and Human Services (department) is proposing to adopt New Rules I through VI, proposing amendments to ARM 37.110.101, and is proposing to repeal ARM 37.110.301, 37.110.302, 37.110.303, 37.110.310, 37.110.311, 37.110.312, 37.110.318, 37.110.319, 37.110.320, 37.110.321, 37.110.323, 37.110.330, 37.110.331, 37.110.332, 37.110.333, 37.110.340, 37.110.341, 37.110.342, 37.110.347, 37.110.348, 37.110.350, 37.110.351, 37.110.352, 37.110.353, 37.110.354, 37.110.355, 37.11.360, 37.110.361, 37.110.362, 37.110.363, 37.110.364, 37.110.370, 37.110.371, 37.110.801, 37.110.802, 37.110.805, and 37.110.810. These repealed rules will be addressed in the new wholesale food rule and its companion circular.

The department is proposing amendments to the existing Food Manufacturing Establishments subchapter to update the rules to reflect the most recent scientific information, better align the rules with other states, improve uniform application of food safety principles throughout Montana, and comply with 50-57-103(2), MCA. This section of Montana law requires wholesale food rules to correspond as closely as possible with the retail food establishment rules. The substantive changes are described below.

The department is also proposing amendments to the existing food standards subchapter to update the rules to reflect change in federal codes that represent the most recent food standards. The last time these standards were updated was in 2001.

New Rule I

The department is proposing New Rule I because it is necessary to describe the purpose of these rules and when they apply.

New Rule II

The department is proposing New Rule II, which adopts and incorporates by reference the Food and Consumer Safety (FCS) Circular 2-2019 for wholesale food establishments. 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. The proposed circular closely follows the existing retail food establishment rules while also being tailored to the needs of wholesale food establishments.

The circular is divided into eight chapters. Chapter one defines the terms that are used throughout the circular. Chapter two provides standards for management and personnel of wholesale food establishments. Chapter three provides standards for the use, transport, storage, identification, labeling, and preparation of different types of foods. Chapter four provides standards for equipment, utensils, and linen used in the course of operating a wholesale food establishment. Chapter five provides water, plumbing, and waste disposal standards. Chapter six provides physical plant operation standards. Chapter seven provides standards for storage and use of poisonous and toxic materials. Chapter eight provides compliance and enforcement standards, including provisions for variances.

The following is a summary of important changes in the circular compared to the previous rules and the retail food establishment rules.

1-201.10: The definition of "mobile" is further clarified in this section to more easily distinguish between normal transport of food, and a facility engaged in a licensable activity, such as a processing and/or warehousing unit.

2-102.12: Food establishment operators should be aware that a Certified Food Protection Manager is required for certain establishments that meet specific criteria described in section 2-102.12.

3-201.16: Provisions have been written for the safe introduction of wild plants and wild mushrooms into commerce.

3-202.11: This section clarifies safe transport of food where the previous rule was vague or silent regarding this topic.

3-301.11: Food establishment operators should be aware that bare-hand contact is not allowed with ready-to-eat foods (RTE), unless written approval has been given to the legal licensee by the local health authority.

3-302.110: This section was created to address the issue of major food allergens contaminating other food products.

3-404.11: This section was created to clarify the relationship between federal and state food standards, as they apply to specialized, high-risk food processes, such as acidified foods, low-acid canned foods, juice processing, and fish processing.

3-601.13: This section was created to clarify a portion of retail food law that allows wholesale food operators to provide offsite samples to the public, as part of their licensing activities.

4-205.10: This section of the circular clarifies and updates the previous rule of ARM 37.110.348(5) addressing replacement utensils and equipment. The circular provides a firm standard by which operators and regulatory agencies may assess food equipment for its performance suitability in commercial settings versus equipment described for non-commercial use, or custom-made equipment. Variances and waivers are allowed under Circular 8-103.10 for special circumstances, provided they do not conflict and are consistent with precedent set and documented by the department to ensure uniform application of the rules.

5-101.11.02: The department's 2016 nonpublic water circular is referenced in this section to ensure that such water systems are held to the same standard as public systems, serving similar functions.

5-101.13: This section incorporates ARM 37.110.801 regarding drinking water into the circular.

5-101.14: This section incorporates ARM 37.110.802 regarding the use of snow and ice as food, into the circular.

8-102.10: Provisions have been made in this section for ensuring needed food safety requirements are met that are not directly or indirectly addressed in other sections of this subchapter, especially as it applies to high-risk mobile food processing units.

8-103.10: Provisions have been made in this section for granting variances not directly or indirectly addressed in other sections of this circular, provided certain circumstances are met for precedent and notification.

8-402.11: Training of state and local health officials is critical in communicating correct and relevant information to the public, food workers, license applicants, and legal licensees about food safety. Public health agencies have an obligation to provide this training to both state and local health officials to ensure competency and program success in preventing outbreaks and illnesses.

New Rule III

The department is proposing New Rule III, which identifies the process for obtaining a wholesale food establishment license and the requirements that must be met for issuance of the license. The rule is necessary to inform applicants of the information that must be provided to seek a wholesale food establishment license and the process under which applications for a license are evaluated.

New Rule IV

The department is proposing New Rule IV to address the inspection requirements formerly contained in ARM 37.110.370. The new rule is necessary to conform with the department's proposed adoption of Food and Consumer Safety (FCS) Circular 2-2019 for wholesale food establishments.

New Rule V

The department is proposing New Rule V to address the minimum performance requirements for local health authorities formerly contained in ARM 37.110.371. The new rule is necessary to conform with the department's proposed adoption of Food and Consumer Safety (FCS) Circular 2-2019 for wholesale food establishments.

New Rule VI

The department is proposing New Rule VI because there were previously no rules for issuing or denying Certificates of Free Sale. Certificates of Free Sale are used by industry to export goods to foreign nations to assure clients the firm is compliant with United States' food safety laws and rules. The rule specifies the criteria that must be met for the department or local regulatory authority to issue Certificates of Free Sale.

ARM 37.110.101

The department is proposing amendments to ARM 37.110.101 to update 2001 state food standards to the most current federal standards. These revisions are necessary to ensure the rule references the most current federal standards.

ARM 37.110.301, 37.110.302, 37.110.303, 37.110.310, 37.110.311, 37.110.312, 37.110.318, 37.110.319, 37.110.320, 37.110.321, 37.110.323, 37.110.330, 37.110.331, 37.110.332, 37.110.333, 37.110.340, 37.110.341, 37.110.342, 37.110.347, 37.110.348, 37.110.350, 37.110.351, 37.110.352, 37.110.353, 37.110.354, 37.110.355, 37.110.360, 37.110.361, 37.110.362, 37.110.363, 37.110.364, 37.110.370, 37.110.371, 37.110.801, 37.110.802, 37.110.805, and 37.110.810

The department is proposing to repeal these rules because they will be addressed in the wholesale food rule and its companion circular.

Fiscal Impact

These proposed new rules affect approximately 629 licensed wholesale food establishments. There is no anticipated fiscal impact due to this rulemaking.

7. The department intends these proposed adoptions, amendments, and repeals to be effective January 1, 2020.

8. Concerned persons may submit their data, views, or arguments either orally or in writing at the hearing. Written data, views, or arguments may also be submitted to: Gwen Knight, Department of Public Health and Human Services, Office of Legal Affairs, P.O. Box 4210, Helena, Montana, 59604-4210; fax (406) 444-9744; or e-mail dphhslegal@mt.gov, and must be received no later than 5:00 p.m., June 21, 2019.

9. The Office of Legal Affairs, Department of Public Health and Human Services, has been designated to preside over and conduct this hearing.

10. The department maintains a list of interested persons who wish to receive notices of rulemaking actions proposed by this agency. Persons who wish to have their name added to the list shall make a written request that includes the name, e-mail, and mailing address of the person to receive notices and specifies for which program the person wishes to receive notices. Notices will be sent by e-mail unless a mailing preference is noted in the request. Such written request may be mailed or delivered to the contact person in 8 above or may be made by completing a request form at any rules hearing held by the department.

11. The bill sponsor contact requirements of 2-4-302, MCA, do not apply.

12. With regard to the requirements of 2-4-111, MCA, the department has determined that the adoption, amendment, and repeal of the above-referenced rules will not significantly and directly impact small businesses.

/s/ Robert Lishman
Robert Lishman
Rule Reviewer

/s/ Sheila Hogan
Sheila Hogan, Director
Public Health and Human Services

Certified to the Secretary of State May 14, 2019.