

MONTANA WHOLESALE FOOD LICENSING GUIDE



MONTANA
FOOD & CONSUMER
SAFETY PROGRAM

Department of Public Health and Human Services
Food and Consumer Safety Section
1400 Broadway Street – Room C214
Helena, MT 59620-2951
Telephone: 406-444-2837
Web: <https://dphhs.mt.gov/publichealth/fcss>

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The purpose of this document is to help prospective applicants comply with local, state and federal requirements for a wholesale food business. This document provides basic information on how to obtain a license to sell or serve foods at the wholesale level.

There are five steps that should be followed to obtain a license as a wholesale food establishment:

1. CONTACT LOCAL HEALTH OFFICIAL TO DETERMINE WHETHER A LICENSE IS REQUIRED
2. SUBMIT FOOD FACILITY PLAN TO LOCAL HEALTH OFFICIAL
3. SUBMIT WHOLESALE FOOD REVIEW FORM TO STATE OR LOCAL OFFICIAL
4. SCHEDULE PRE-LICENSING INSPECTION WITH LOCAL HEALTH OFFICIAL
5. REGISTER BUSINESS WITH FDA

1. DETERMINE WHETHER A LICENSE IS REQUIRED

Wholesaling is providing food for human consumption that is not directly sold or distributed to the consumer. In other words, wholesaling is food sold or distributed to retailers (Montana Code Annotated (MCA) 50-57-102(11)(a)).

TABLE 1

Table 1 summarizes exemptions to wholesale food licensing by the Montana Department of Health and Human Services, but are likely subject to licensing by another state agency, such as the Montana Department of Livestock or Montana Department of Agriculture:

<ul style="list-style-type: none">• Milk and milk product manufacturers• Raw and unprocessed fruits and vegetables• Meat packing plants• Meat slaughterhouses	<ul style="list-style-type: none">• Most foods with at least 2 percent or greater <u>cooked</u> meat, poultry by total product weight• Most foods with at least 3 percent or greater <u>raw</u> meat, poultry by total product weight
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For more information on what agency has jurisdictional authority over food products, please see the document titled “Food Jurisdiction Guide” at the following web link: <https://dphhs.mt.gov/publichealth/FCSS/WholesaleFoodEstablishments>

For answers to specific licensing questions, please contact your local sanitarian or the State of Montana Department of Public Health and Human Services (DPHHS) Food and Consumer Safety Section (FCSS) at telephone number: 406-444-2837.

Frequently Asked Questions (Q) and Answers (A)

Q: If I only sell or distribute food directly to consumers, do I need a wholesale food license?

A: No, but you will likely need a retail food license, which may be obtained through your local sanitarian.

Q: If I sell or distribute food to grocery stores or other businesses, do I need a wholesale food license?

A: Yes, but there are exceptions, as indicated in Table 1.

Q: If I sell or distribute food to grocery stores AND consumers, do I need a wholesale food license?

A: Yes, but again, there are exceptions. If selling or distributing food directly to consumers, you may also need a retail food license, depending on the type of food sold or served and where the activity takes place.

Q: If the food contains at least the percentage of meat or poultry stated in Table 1, do I need a wholesale food license?

A: Probably not, depending on the type of food being processed or stored, but you will likely need a different license from a state or federal agency (see Department of Livestock contact below).

NOTE: All closed-face sandwiches (food between two or more bread pieces) are DPHHS-FCSS/FDA regulated products, regardless of beef, poultry, pork or other meat content percentage. This status may seem odd, but is legal precedent set by courts.

In most cases, if the food being processed or stored contains at least 2 percent cooked or at least 3 percent raw meat, poultry by total product weight, please contact:

State of Montana Department of Livestock
Meat and Poultry Inspection Division
P.O. Box 202001
Helena, Montana 59620-2001
Telephone: 406-444-5202
E-mail: livemail@mt.gov

Q: What is a processed food?

A: Processing involves many activities, but most are described Table 2.

TABLE 2
PROCESSING ACTIVITIES

<ul style="list-style-type: none"> • Assembling • Baking • Bottling • Brewing • Canning • Coating • Cooking • Cutting • Distilling • Drying • Extracting 	<ul style="list-style-type: none"> • Fermentation • Freezing • Grinding • Heating or re-heating • Infusing • Mixing • Packaging substances • Pickling • Smoking • Stuffing • Other food processing
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TABLE 3
PROCESSED FOOD EXAMPLES

<ul style="list-style-type: none"> • Baked goods • Beer • Cider • Coffee beans-roasted • Fruits-cut or dried • Herbs-cut or dried • Ice for human consumption 	<ul style="list-style-type: none"> • Salad mix • Salsa • Spices and spice rubs • Tea • Vegetables cut, dried, etc. • Water for human consumption • Other processed food products
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2. SUBMIT FACILITY PLAN TO LOCAL HEALTH OFFICIAL

Whenever a wholesale food establishment is constructed, remodeled or converted for use, written plans and specifications must be submitted to local sanitarian for review and approval. Check with the local sanitarian to see if a plan review fee is charged for the service.

Q: A wholesale food license is needed. What now?

A: Submit facility plan to the local sanitarian for their review and approval. The purpose of the facility plan is to ensure the business meets the physical requirements needed to produce safe food. A facility plan must include at least the following in Table 4.

TABLE 4
FACILITY PLAN MINIMUMS

• Drawn to scale with an overhead configuration, if possible
• Legible labels, descriptions and wording on the plan
• Layout and arrangement of facility with at least: plumbing, ventilation, handwashing facilities, dishwashing facilities, food equipment and fixtures
• Construction material description for floors, walls and ceilings (i.e. ceramic tile, stainless steel, etc.)
• Type and model of food equipment and fixtures
• Water supply source (i.e. municipality name or Public Water Supply number from State of Montana Department of Environmental Quality)
• Wastewater/sewage system description (municipal, on-site system, holding tank or other system)

Food equipment and utensils must meet standards specified by the NSF International (formerly National Sanitation Foundation). Business operators should look for NSF stamps or labels on equipment, fixtures and utensils. Homemade food processing equipment is not recommended, especially for high-risk food processing and packaging.

Some local health departments may charge a fee for the plan review and have additional requirements.

Q: What construction materials may be used in the facility?

A: On the last page of this document in Table 9 is a listing of allowed materials for different functions.

3. SUBMIT WHOLESALE FOOD REVIEW FORM

To help determine what food safety steps may be needed for the proposed business, a food processing plan and food packaging labeling examples must be submitted to FCSS for review OR in rare cases, your local sanitarian.

The form and product packaging labels or bulk invoices will be reviewed by FCSS for violations of the applicable state/federal rules. If violations are found during the review process, the proposed business will be afforded the opportunity to correct or sufficiently address the deviations in question. A satisfactory review report from FCSS or your local sanitarian is needed before issuance of a wholesale food license to operate.

In the overwhelming number of cases, FCSS will review the form that you submit on behalf of the local sanitarian to maintain equal application of the rules and codes across the state and country.

Q: The facility plan was given to the local sanitarian. What now?

A: Complete and submit the wholesale food review form. You can download a wholesale food review form at the web link below or contact your local sanitarian:

[Montana Wholesale Food weblink](#)

PROCESS AUTHORITY NOTE: Some foods or processing activities are considered higher risk for transmission of foodborne illness and may have to be assessed by a process authority BEFORE submitting your review form for review.

The process authority will issue written findings in what is commonly referred to as a “process authority letter.” This means your food process might require the supervision of a qualified individual and/or specialized training. Food manufacturers who plan to package certain foods in hermetically sealed containers are one example of processors who must obtain a process authority letter.

The State of Montana recognizes all process authorities listed with the Association of Food and Drug Officials (AFDO). Please use the process authority in Table 5, website link below, or directly visit the AFDO webpage, if you need a process authority letter:

[AFDO Process Authority weblink](#)

TABLE 5
PROCESS AUTHORITY

Dr. Girish Ganjyal, Food Processing Specialist Washington State University 106 FSHN Building P.O. Box 646376 Pullman, WA 99164-6376 Telephone 509-335-5613 <u>Email link</u> <u>Website link</u>

Q: What is a higher risk food or processing activity?

A: This question is best answered by consulting with the local sanitarian or state official.

However, certain foods in hermetically sealed containers, reduced oxygen packaging, low-acid foods and acidified foods are often cited as being higher risk for transmission of foodborne illness. The reason a consultation is often needed is because food under one condition may be safe, but under another may be riskier in transmitting a foodborne illness. Higher risk foods or processing activities usually involve canning or bottling operations or foods containing animal products, but this is not always the case.

Q: The review form is completed. What next?

A: Create food packaging label examples. Packaged and re-packaged food containers must be labeled. Labeling can be a complex issue. However, food labels must at least have the following four pieces of information:

TABLE 6
FOOD LABELING MINIMUMS

● Name of food product (known as the statement of identity)
● Net weight or liquid volume of product in United States units of measure AND metric units of measure
● Ingredient list in order of quantity or predominance from greatest to least by weight
● Name and address of product manufacturer, distributor or packer

Please use the weblinks below for more information of food labeling.

[Montana consumer commodity labeling guide](#)

[Montana bulk commodity labeling guide](#)

[FDA consumer commodity labeling guide](#)

[FDA consumer commodity labeling course](#) (FREE, online). Course takes about one hour.

Health and Nutrition Claims

Food and dietary supplement manufacturers are strongly urged to be aware of making any health or nutrition claims that may render their products being regulated as drugs, rather than food. Any labels, advertisements, promotional material, or any other representations disseminated in any manner or by any means is subject to regulations regarding unsubstantiated health and nutrition claims, including business websites. Contact the Montana Wholesale Food program for more information on this topic.

Suspect claims are evaluated for compliance on an individual basis. Manufacturers are especially cautioned about associating their products with any treatment, mitigation or prevention of diseases.

Examples of such claims are:

Reduces diabetes symptoms

Prevents some types of cancer

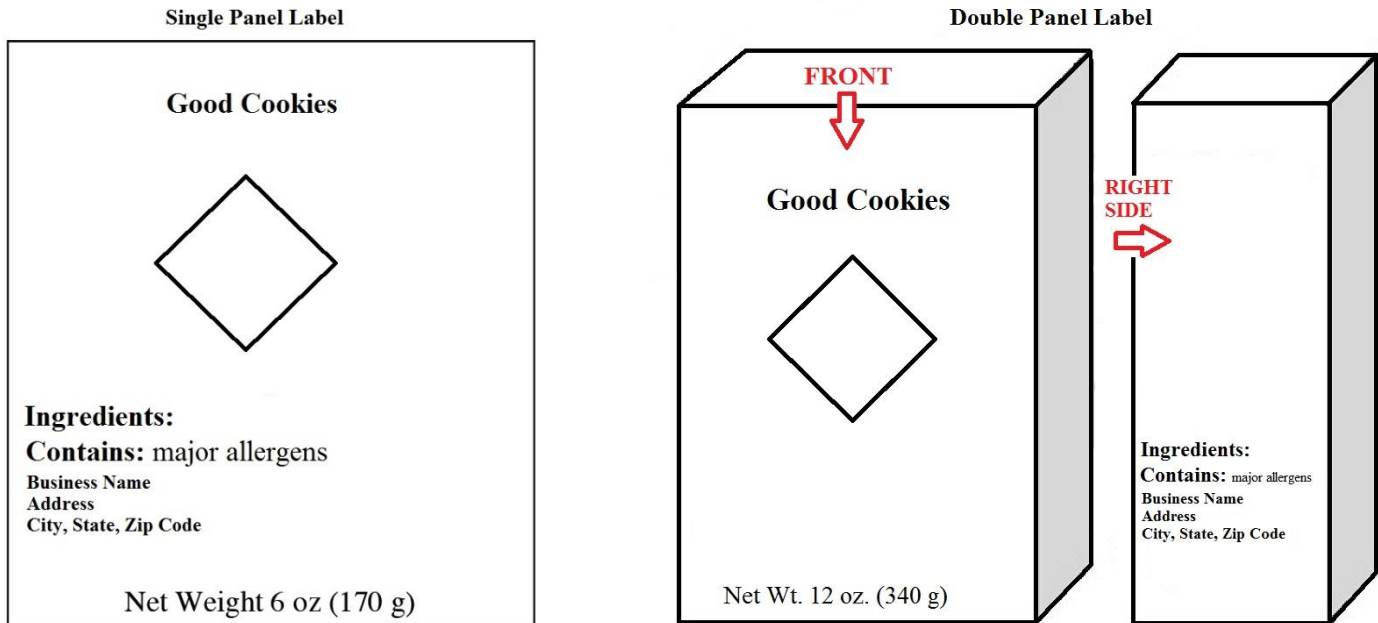
Relives symptoms associated with Crohn's disease, ulcerative colitis, and stomach ulcers

Contains antimicrobial healing properties helping to support overall immune system functions

Kills viruses that cause influenza, herpes, measles, hepatitis C, SARS, AIDS, and other illness

Reduces inflammation

Labeling Examples



Q: Where do I send the review form?

A: The state (FCSS) in almost all cases. FCSS will issue a review report of findings regarding the review form. A satisfactory review report is needed for issuance of a license to operate.

Please submit completed "WHOLESALE FOOD REVIEW FORM" to:

DPHHS-FCSS

P.O. Box 202951

Helena, Montana 59620-2951

Telephone: 406-444-2837

E-mail: hhsfcs@mt.gov

4. SCHEDULE PRE-LICENSING INSPECTION WITH LOCAL HEALTH OFFICIAL

A wholesale food establishment license application is available through your local sanitarian. Check with your local sanitarian for local and state fees.

Q: The review report was satisfactory and the business is ready. What next?

A: Contact your local sanitarian and schedule a pre-licensing inspection.

The local sanitarian must conduct a pre-licensing inspection and approve the license application before DPHHS issues a license to operate. A license to operate will not be granted if there are any rule violations written on the pre-licensing inspection report. Licenses are renewed on an annual basis near the end of the calendar year.

The pre-licensing inspection should be scheduled as closely to the date of opening as possible, but should also allow enough time for correction of deficiencies. All license applications and fees must be submitted before or during the pre-licensing inspection. Check with your local sanitarian for details on when fees should be submitted.

5. FDA REGISTRATION

Most wholesale food establishments must register with FDA, in accordance with the federal Bioterrorism Act of 2002. Wholesale establishments in which their primary function is selling food directly to consumers are exempt from registration under the federal code (21 CFR 1.226).

Registration on-line is easy, free and should take less than 30 minutes at the webpage address below:

<http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/ucm2006831.htm>

ALERT: Some businesses charge money for registering establishments with FDA. However, registration is free from FDA.

Q: Why do I have to register with the FDA?

A: For facilities that meet the criteria, the Bioterrorism Act of 2002 requires registration for compliance with the law.

TABLE 7
LICENSING RESOURCES

Local Sanitarian Information	Montana Food and Consumer Safety Section
Weblink Telephone: 406-444-2837	Weblink Telephone: 406-444-2837

TABLE 8
WHOLESALE FOOD LICENSE CHECKLIST

Step 1. DETERMINE WHETHER A LICENSE IS REQUIRED
Contacted local sanitarian
Contacted state Food and Consumer Safety Section (FCSS)
Step 2. SUBMIT FOOD FACILITY PLAN
Completed Food Facility Plan
Submitted Food Facility Plan to local sanitarian
Step 3. SUBMIT FOOD REVIEW FORM
Completed "WHOLESALE FOOD REVIEW FORM" from FCSS, including:
List of food suppliers
Written description of how the food is delivered to the facility
Written description of how the food is stored until it is processed
List of ingredients for foods being processed
Written description of how foods will be processed and with what equipment
Written description of how the food will be packaged
List of allergens in the facility and what equipment is used to process allergens
Written description of how food will be stored until being shipped
Written description of how and when equipment is cleaned and sanitized
Written description of how and when facility is cleaned (floor, walls, ceiling, etc.)
Distribution information about food (where will the food be shipped)
Transportation provider for food (contract carrier, fleet vehicle, etc.)
Written description of water source
Completed food labeling examples
Submitted food labeling examples to FCSS
Submitted "WHOLESALE FOOD REVIEW FORM" to FCSS
Obtained satisfactory review report from FCSS for food processing plan and labeling examples
Step 4. SCHEDULE PRE-LICENSING INSPECTION
Completed wholesale food business application
Contacted local sanitarian for pre-licensing inspection
Paid applicable fees
Step 5. FDA REGISTRATION
Registered business with FDA (if not specifically exempted from registering in 21 CFR 1.226)

TABLE 9
ALLOWED AND UNALLOWED BUILDING MATERIALS

Establishment Area	Floor						Basecove					Wall				Ceiling			
	Rubber	Ceramic Tile/Quarry Tile	Epoxy Resin	Coved Ceramic/Quarry Tile	Vinyl Screed	Stainless Steel	Commercial Rubber Base Cove for rubber flooring	Stainless Steel	Ceramic Tile	Fiberglass Reinforced Panel	Epoxy-painted Concrete Block	Painted Drywall	Metal—Non-galvanized	Painted Drywall	Vinyl-coated Acoustic Tile	Open joists and rafters			
Food process/prep	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U			
Cooking/Baking	●	A	●	A	—	A	●	A	A	U	●	U	●	A	A	U			
Dishwashing	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U			
Handwashing station	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U			
Walk-in cooler/freezer	U	A	●	A	A	A	U	—	—	—	—	—	—	—	—	—			
Buffet	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U			
Server station for food	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	U			
Bar service	●	A	●	A	—	A	●	A	A	A	A	●	●	A	A	*			
Dry food storage	●	A	●	A	—	A	●	A	A	A	A	A	●	A	A	▼			
Janitorial station	●	A	●	A	—	A	●	A	A	A	A	U	●	A	A	●			
Worker toilet room	●	A	●	A	—	A	●	A	A	A	A	A	A	A	A	U			

A	=	Allowed
U	=	Unallowed
●	=	Seek approval from regulatory authority prior to installation
—	=	Not applicable, must meet NSF International (formerly National Sanitation Foundation) standards
*	=	Sealed joists, rafters and beams may be approved to accommodate for aesthetics
▼	=	Allowed for unopened containers of food, beverages and single-service food items