

BECOMING A WHOLESALE FOOD MANUFACTURER – EXPLANATION OF REQUIREMENTS

A ***Wholesale Food Manufacturing Establishment*** is defined in 50-57-102, **Montana Codes Annotated (MCA)** as a facility and the facility's buildings or structures used to manufacture or prepare food for human consumption at wholesale. Please note that if the packaged food product you are proposing to produce for wholesale distribution contains greater than 3% raw or 2% cooked meat or poultry, licensing may be required by the Department of Livestock. Be sure to contact them at (406) 444-5202. For other packaged food, approval of the Food & Consumer Safety Section (FCSS) is required prior to licensing, and FCSS must issue the license.

In order to become a licensed wholesale food manufacturer, authorized to process and package food for public distribution, there are 5 steps a new applicant (person or corporation) must complete. They are shown below.

- a) **Apply for a license** (including license fee and application form), and pay any plan review fee which may be required by the county in which the facility is to be located.
- b) **Facility Plan** -- Obtain approval of the plans and specifications prior to construction, including layout plans, water source, sewage disposal, and other structural information. (See Part 1.)
- c) **Process Plan** -- Obtain approval of product ingredients, processing information, packaging, storage, distribution, labeling etc., from FCSS. FDA standards are used for review. (See Part 2.)
- d) **Pass a preliminary inspection** by the local health authority prior to commencing operations of food processing, packaging, sales or distribution.
- e) **Register with FDA**—Beginning on December 12, 2003, all domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption, must register with FDA. This can be easily accomplished by accessing the FDA website at <http://www.fda.gov/Food/FoodDefense/Bioterrorism/FoodFacilityRegistration/default.htm>.

The Montana Food Manufacturing Administrative Rules (ARM Title 37, Chapter 110, Subchapter 3) require that plans and specifications be submitted to FCSS and approved, prior to the construction of any food manufacturing establishment. You will also need to check with the local sanitarian. It is generally recommended that 2 copies of plans be submitted, one for the local health authority, and one for forwarding to FCSS. This includes building plans, food ingredients, processes used, containers, labels, and distribution plans. Additional copies of the building plans may be needed for State Building Codes Bureau, Liquor Division, or other state and local authorities.

If you already have a licensed food facility (a Bakery endorsement- F-4, or a Restaurant endorsement-F-1, for example), you may already process and package some types of food for onsite (retail) sale at your facility, but if you intend to wholesale the products for retail sale elsewhere, it is required that you obtain a separate food manufacturers license. The procedure is the same, except you do not need to submit facility construction plans. There is an additional license and fee required if you intend to operate both a retail and wholesale establishment on the same premises. Contact the county sanitarian for information.

This guide document is intended to assist new applicants in the process of obtaining approval of their proposal prior to the start of construction, as required by state law. Separate guides are available for Water Bottlers and Beverage Bottlers, this guide is intended for conventional food manufacturers. If you have questions or if you need a copy of the above noted administrative rule, or other documents, please contact the local sanitarian or call FCSS at 444-2408 or 444-5306. If you prefer, we will also respond to e-mail requests, at: hreid@mt.gov or you may visit our website at www.fcss.mt.gov.

Food Manufacturing or Commercial Processing Facilities must comply with the following rules, statutes and federal regulations:

50-57-101 MCA et.seq., Licensing of Wholesale Food and Drug Manufacturing Establishments (Montana Codes Annotated)

ARM 37.110.301 et. seq., FOOD MANUFACTURING ESTABLISHMENTS (Administrative Rules of Montana)

ARM 37.110.101 FOOD STANDARDS (FDA Standards adopted in Montana by reference) – which includes the following:

21 CFR 110 GOOD MANUFACTURING PRACTICE
21 CFR 101 FOOD LABELING
21 CFR 130-180 FOOD STANDARDS-GENERAL
21 CFR 180-186 INGREDIENTS RECOGNIZED AS SAFE
21 CFR 189 INGREDIENTS PROHIBITED FROM USE IN FOOD

PLAN COMPONENTS NEEDED FOR REVIEW & APPROVAL

PART 1 -- FACILITY PLANS

- 1) **AREA PLAN** -- Provide a scaled drawing of the area showing the processing facility building, neighboring facilities, surrounding grounds, roadways, parking areas, lot dimensions, and surface types. The designated sewage treatment area, well location, and other improvements. Give name and address of proposed facility and the owner/operator names.
- 2) **PROCESSING FACILITY LAYOUT PLAN** – Provide a scaled drawing (usually ¼ " = 1 foot) of the interior of the building showing room types and dimensions, locations for all equipment, and equipment types. A separate schedule of processing equipment and fixtures, manufacturer name and model numbers is also needed, so it may be easier to number the list and show the corresponding number on the plan. Equipment (refrigerators, peelers, steamers, utensil washing units, freezers, etc.) must be commercial grade and approved for the use intended. Home-type refrigerators, dispensers, and dishwashers, are not allowed.
- 3) **FINISH SCHEDULE** -- Part of the LAYOUT PLAN is a finish schedule. The final finish materials for the various rooms in the facility should be listed, including floors walls, counter tops, ceilings, storage bins, auger conduits, and food contact surfaces. This finish schedule should include the rooms for storage of raw materials, ingredients, food container storage, container closure storage, and finished packaged food storage.
- 4) **VENTILATION** -- Provide information on all required mechanical ventilation whether exhaust (*restrooms, dish machines, broasters, fryers, steamers and cooking units which generate smoke, steam or airborne grease require exhaust ventilation) or incoming filtered air. Food processing areas and food-container fill areas often require filtration of the air coming into these areas, and usually require "separation" from other facility operations. Separation may be provided by air curtains, walls, enclosures, etc., to protect packaged foods from airborne dust, insects, or fumes. Such features should be shown on the plans.
- 5) **PLUMBING PLAN** – Submit a plumbing plan showing locations of floor drains, water lines, sewer lines, water heaters, toilets, sumps and other water or sewer-connected units. Be sure to include anti-back siphonage or back-flow prevention devices on all ice machines, sinks, dishwashers, dipper wells, peelers, hose bibs, toilets, and processing equipment.
- 6) Specify the source of water supply and sewage treatment: if not municipal, provide a detailed plan layout, either on a separate plan or on the facility layout plan.
- 7) Provide information on proposed garbage/solid waste storage containers, collection schedule, collectors identity, and disposal site (name or location).
- 8) Show details of toilet facilities including numbers of fixtures. Ventilation and self-closing doors are required. Restrooms used by employees must have hot and cold running water, soap dispenser, single use towels, exhaust venting, waste basket, and appropriate fixtures. Mops, cleaning chemicals and supplies must have separate storage. No restroom door may open directly into the food prep or container-fill area.
- 9) Show locations of all sinks on layout plan, including utensil sinks, prep sinks, handwash facilities in the processing room,

and mop sinks. A separate mop sink, outside the food prep rooms is required in all new construction.

- 10) Provide details for equipment cleaning procedures. They can be shown on the plan, or on a separate schedule. The procedure for sanitizing food contact equipment and utensils must be specified also. If manual utensil washing is planned, a 3-compartment sink with adequately sized drain boards is required, unless it can be shown that all food-contact surfaces can be cleaned and sanitized and effective bactericidal treatment can be demonstrated by an average plate count per utensil or surface examined of not more than 100 colonies. If mechanical sanitizing is used for utensils, a commercial grade machine is required—make, model number and description of the units is required.
- 11) Indicate areas used for storage of employees' personal items, food ingredients storage, food container and closure storage areas, and location of storage of cleaning compounds, disinfectants and other chemicals.
- 12) Provide a list of all foods to be prepared, processed, packaged or sold. All plans must be on substantial paper, must be clear legible and must include all finish schedules, cleaning procedures and other items listed above.

PART 2 -- PROCESSING SCHEDULES

- 13) **PROCESS DESCRIPTION** -- For all food processing proposals, a process description is required to be submitted with the plans, or soon after, so that the procedures can be reviewed. The process description includes complete ingredient listing, processing methods, packaging information, container and closure information, sales or distribution information (wholesale, mail order sales, electronic mail, interstate, etc.). A Manufacturing Checklist must be submitted for each food or class of foods to be manufactured, or the information may be included in a separate report. These forms include the process description and label exhibits to be attached for review. All such material is kept confidential except to personnel of the health department or FDA.
- 14) **LOW RISK FOODS** -For low risk foods which are naturally acid (with a pH of 4.5 or below), or which are well below the 0.85 water activity level, the process description in the Manufacturing Checklist is sufficient. A separate process schedule is not required. These foods include high acid jams, jellies, preserves, fruit butters, dried foods with a water activity level of 0.85 or below, dry flour, baking mixes, spice mixes, pancake mixes, dried soup mixes, and foods which are to be stored, distributed and sold under refrigeration.
- 15) **MODERATE AND HIGH RISK FOODS** -- Some foods are not always below 4.6 in pH, or below 0.85 water activity and may be subject to risk of developing botulinum toxin if packed in hermetically sealed containers. Foods which usually or commonly have a pH at or above 4.6 or water activity above 0.85, or to which acid is added to obtain a pH below 4.6 are **Low Acid Foods** or **Acidified Foods**. It is not acceptable to process and pack such foods for sale to the public in hermetically sealed containers, whether acidity is increased in processing or not. **FDA registration and a Federal Process Schedule approved by a qualified process authority must first be filed with the Montana Food and Drug Program and the FDA. In addition, a responsible person on-site must have completed an FDA sanctioned training program for Acidified or Low-Acid Food processing. (See 21 CFR 114.10).** Examples include fermented foods, soft drinks, salsa (made from tomatoes, onions, etc.), salad dressings, condiments, vinegar herb mixes, herbal oils, canned vegetables, baked beans, pickles, pickled foods, canned salmon, canned bean dip, canned clam chowder, or any other hermetically sealed low-acid food intended to be shelf stable at room temperature. Any such foods found for sale in the market place or at a farmers market which have been produced without an approved process schedule are subject to seizure and destruction.
- 16) Baked goods and preserves may be sold to the public at farmers markets or by non-profit groups at bake sales, without having been produced under license or approval by the department. Unprocessed farm products may also be sold at farmers markets or roadside stands. This includes fruit, potatoes, unprocessed vegetables, unprocessed fruit, unshucked corn, beans, unshelled peas and other similar raw agricultural products that are not potentially hazardous. No license is required. All other processed foods, including milk products, cheese, meat, poultry, sauerkraut, pickles, or home made

processed food of any kind are regulated. They may be sold at farm markets only if produced in a licensed facility and if adequate refrigeration is provided for transportation and for display at the farmers market.

- 17) Any questions or inquiries regarding the preparation of plans or processing schedules may be directed to the local county sanitarian or to the Food & Consumer Safety Section, DPHHS, in Helena at (406) 444-2408 or 444-5306.
- 19) The necessary forms are available from the local county sanitarian or the Food & Consumer Safety Section, DPHHS on our webpage at www.fcsc.mt.gov or by phone in Helena at (406) 444-2408 or 444-5306.
- 20) It is important that you have your plans approved prior to construction. If not, retro-fitting or expensive changes may be necessary.