



The purpose of this document is to help applicants obtain a satisfactory Wholesale Food Review Report in a timely manner. A satisfactory review report is needed before the local regulatory authority can conduct a pre-licensing inspection for issuance of a wholesale food license. Authority for this review is under Montana Code Annotated 50-57-103 (1) (a).

|                                  |  |  |  |
|----------------------------------|--|--|--|
| <b>Return completed form to:</b> | <b>Montana Wholesale Food Program</b><br>1400 Broadway Street, C-214<br>P.O. Box 202951<br>Helena, MT 59620-2951 | <b>Telephone: 406.444.2837</b><br><b>Fax: 406.444.5055</b><br><b>E-mail: hhsfcs@mt.gov</b> | OFFICE USE<br>Request ID _____<br><br>Contact ID _____ |
|----------------------------------|--|--|--|

## GENERAL INFORMATION

|                                     |   |                |  |
|-------------------------------------|---|----------------|--|
| Firm Name                           | Plant name (site of production/warehouse) |                |  |
| Firm mailing address                | Plant address                             |                |  |
| Firm city                           | Plant city                                |                |  |
| Firm state and zip code             | Plant county                              |                |  |
| Contact person and title<br>Mr. Ms. | Contact telephone                         | Contact e-mail |  |

Firm operates as a:

|                 |             |             |     |             |
|-----------------|-------------|-------------|-----|-------------|
| Sole proprietor | Partnership | Cooperative | LLC | Corporation |
|-----------------|-------------|-------------|-----|-------------|

Firm partner or officer information:

| Name | Title | Address, city, state, zip code |
|------|-------|--------------------------------|
|      |       |                                |
|      |       |                                |
|      |       |                                |

If firm is not in Montana, provide contact information of individual residing in Montana who is authorized to receive and accept service of summons and legal notices:

| Name | Title | Address, city, state, zip code |
|------|-------|--------------------------------|
|      |       |                                |

Proposed product(s) to be reviewed (mark all that apply):

|      |                    |
|------|--------------------|
| Food | Dietary supplement |
|------|--------------------|

**CERTIFICATION STATEMENT:** I certify the information provided on this form is true and correct.

| Write or print name and title of certifier | Signature of certifier (type name for e-signature) | Date of certification |
|--|--|-----------------------|
|  |  |                       |



**Sub-ingredients** (skip this section, if not applicable)

List all sub-ingredients for ingredients in product. Sub-ingredients are ingredients within the ingredients. For example, if one of the product ingredients is mayonnaise, the sub-ingredients must be listed within parentheses on the ingredient label as: “*Mayonnaise (soybean oil, water, whole eggs, vinegar, salt, sugar, lemon juice, natural flavors)*.” If your product does not have sub-ingredients, skip this section of the form.

| Ingredient | Sub-ingredients |
|------------|-----------------|
|            |                 |
|            |                 |
|            |                 |
|            |                 |

**Special Processing Questions and Answers** (skip this section, if not applicable)

**Question:** If I am canning food that will not be refrigerated, is there another step for this review?

**Answer:** Yes. The applicant is required to obtain a process authority assessment letter BEFORE sending in this review form.

**Question:** How do I get a process authority assessment letter?

**Answer:** Process authorities are located throughout the United States, usually in major academic institutions. The Montana Wholesale Food Program has links to process authorities posted on its website at:  
<https://dphhs.mt.gov/publichealth/FCSS/WholesaleFoodEstablishments>

**Question:** What will the process authority require?

**Answer:** The proposed product is being submitted for testing purposes. Follow their directions for submitting your product to them.

**Question:** Why is my product being tested?

**Answer:** The product is being tested for safety reasons related to controlling botulism toxin formation, *Listeria* bacteria proliferation, establishing control parameters for those potential hazards, and determine which legal rules apply to the product.

**Question:** How long does it take to obtain a process authority letter?

**Answer:** Usually, 2-4 weeks from day of shipping product to process authority for assessment.

**Question:** What should I do with my process authority letter after it is received?

**Answer:** Send a copy of it with this review form using the contact information on page one of this form.

**Question:** Are there terms of which I should be aware of before the process authority letters is received?

**Answer:** Yes. Please read the list of terms on the next page.

| Term                          | Definition (with examples)  |
|-------------------------------|---|
| Acidified food                | A low-acid food to which a type of acid or acidic food is added to obtain a final hydrogen ion concentration (pH) of 4.6 or below.<br>For example, sauces, salsas and dressings are types of acidified foods.   |
| Low-acid food                 | Food with a hydrogen ion concentration (pH) of greater than 4.6 AND water activity (water available for microbial growth activities) greater than 0.85.<br>For example, canned tuna fish and canned peas are low-acid foods. The term “low-acid” means the food is low in acidity. The term also means the food is higher on the pH scale (greater than pH 4.6).<br>To summarize, low-acid food has two primary attributes: <ol style="list-style-type: none"> <li>1. pH level greater than 4.6</li> <li>2. Water activity level greater than 0.85</li> </ol> |
| Hermetically sealed container | A vessel for food designed to prevent the entry of microorganisms, and in the case of low-acid foods, maintains the sterility of its contents after processing. In other words, the container is air-tight. For example, canned food, many bottled foods with lids and retort plastic pouches.  |

**Question:** Why should I be aware of these processing types?

**Answer:** Acidified foods and low-acid foods require greater scrutiny than other foods during review and processing because of their potential to transmit serious foodborne illnesses. This is especially true when these foods are in hermetically sealed containers or packaged in oil, which is another type of reduced oxygen packaging.

Therefore, these foods are subject to regulations specified in Title 21 of the Code and Federal Regulations, Parts 113 (thermally processed low-acid foods packaged in hermetically sealed containers) and 114 (acidified foods).

Under these regulations, the United States Food and Drug Administration (FDA) requires certain acidified food and low-acid food processors to register the firm, file product processes, successfully complete processing training, keep processing records and use certain equipment.

**Question:** Is special training required for canning unrefrigerated foods?

**Answer:** Yes, for foods that the process authority deems to be acidified or low-acid canned foods. However, high-acid canned foods, such as many jams and jellies, are not subject to special training because of their low water activity levels, resulting from the high amount of sugars in the product. An exception to this statement exist for pepper jellies: visible pepper particle sizes will require testing. Acidified and low-acid canned food operators are required to successfully complete a Better Process Control School, or work directly under the supervision of someone who has successfully completed the Better Process Control School.

**Question:** What options are there to meet the special training requirements?

**Answer:** Acidified and low-acid canned food operators are required to successfully complete a Better Process Control School, or work directly under a supervisor who has successfully completed a Better Process Control School.

## Special Processing Requirements

If the firm is:

1. Processing low-acid foods for storage in hermetically sealed containers that are heat treated to enable the product to not require mechanical refrigeration; **AND/OR**
2. An acidified food processor that stores food in containers that do not require mechanical refrigeration

You must:

1. Have written proof that a supervisor has successfully completed a Better Process Control School for that activity;
2. **Submit with this review form a copy of the supervisor’s Better Process Control School certificate;**
3. Possess a process authority letter from a qualified and recognized process authority;
4. **Submit with this review form a copy of the process authority letter;**
5. Register your product and process with the FDA within 10 days of initial production.

FDA firm registration is on the web: <http://www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/default.htm>

## Water Supply

**Instructions:** provide details about the water supply system used to process the food.

|  |  |
|--|--|
| <b>Water Supply</b><br>(municipal, non-municipal, public, private) |  |
| <b>Water Treatment</b><br>(reverse osmosis, carbon filter, etc.)   |  |

## Processing Checklist

**Instructions:** check all boxes next to the processing type that apply to the product. NOTE: For the purposes of food safety, carbonated soft drinks and carbonated beverages are not considered acidified foods.

| Check | Processing type   | Product examples  | Check | Processing type                           | Product examples   |
|-------|---|---|-------|---|--|
|       | <b>Acidified food</b> —decreasing pH of food by <b>adding acidic ingredients</b> , such as vinegar (acetic acid), citric acid, etc. | Salsa, dressing, sauces, vegetables, etc.   |       | Distilling                                | Whisky, vodka, etc.  |
|       | <b>Low-acid foods in hermetically sealed containers</b> (metal cans, glass bottles, retort pouches, etc.)                           | Vegetables, mushrooms, fish, etc., in metal cans or glass containers with lids                |       | Fermenting                                | Beer, wine, pickles, bean paste, kombucha, kimchi, etc.                                    |
|       | <b>High-acid foods in hermetically sealed containers</b> (metal cans, glass bottles, retort pouches, etc.)                          | Jams, jellies, etc., in metal cans or glass containers with lids                              |       | Freezing                                  | Beverage ice, vegetables, food storage, food cooling, etc.                                 |
|       | Assembling  | Sandwiches on two or more pieces of bread, salad mix, etc.                                    |       | Grinding                                  | Milling flours, grains, coffee, tea, etc.  |
|       | Baking  | Bread, rolls, beef, poultry, etc.   |       | Infusing with oils                        | Garlic in oil, onions in oil or other ingredients in oil mixtures                          |
|       | Bottling  | Drinking water, fruit juices, vegetable juices and other foods in glass or plastic containers |       | Mixing                                    | Potato salad, macaroni salad, coleslaw, seafood salad, cut salad greens, soups, teas, etc. |
|       | Canning   | Fruits, vegetables (acidified, low-acid foods, high-acid foods).                              |       | Refrigerating (cold holding temperatures) | Salsa, dressing, sandwiches, etc.  |
|       | Carbonating (adding carbon dioxide gas to food)   | Soda, beer, etc.  |       | Re-packaging                              | Spices, vegetables, previously packaged foods, etc.  |
|       | Cooking   | Boiling pasta, boiling potatoes, heating beef, heating poultry, heating eggs, soups, etc.     |       | Roasting                                  | Coffee beans, tea leaves, etc.   |
|       | Cooling   | Hot food being cooled to cold temperatures  |       | Smoking                                   | Fish or other foods for preservation or flavoring  |
|       | Cutting   | Slicing fruits, vegetables, beef, poultry, etc.   |       | Other processing type                     |  |
|       | Dehydrating   | Fruits, vegetables, etc.  |       | Other processing type                     |  |

## Processing Details

**Instructions:** in the box to the right, describe how the product will be handled at each step in the food chain. Submit additional pages, if needed.

|  |  |
|--|--|
| <p><b>Food ingredient suppliers</b><br/>Supplier name, city, state;<br/>types of food</p>  |  |
| <p><b>Food packaging suppliers</b><br/>Supplier name, city, state;<br/>types of packaging material</p>   |  |
| <p><b>Food transport <u>to</u> firm</b><br/>How and who will transport<br/>food; e.g. firm fleet vehicle,<br/>contract carrier, personal<br/>vehicle, etc.</p>   |  |
| <p><b>Ingredient storage facilities</b><br/>Refrigerator, freezer, dry<br/>goods; location</p>   |  |
| <p><b>Food processing</b><br/>Basic food preparation<br/>techniques and procedures:<br/><b>Include times and<br/>temperatures</b> (baking,<br/>cooking, cooling)<br/>Also describe basic<br/>techniques, such as mixing,<br/>cutting, slicing, etc.</p>  |  |
| <p><b>Food packaging and<br/>labeling procedures</b><br/>Describe how food will be<br/>packaged, including types of<br/>lids and containers.<br/>Also, describe how label will<br/>be secured to the package;<br/>e.g. adhesive or other<br/>method)</p> |  |
| <p><b>Product storage facilities</b><br/>Where and how finished food<br/>product will be stored;<br/>refrigerator, freezer, dry<br/>goods.</p>   |  |
| <p><b>Food transport <u>from</u> firm</b><br/>How and who will transport<br/>food from the firm to<br/>recipient; e.g. contract<br/>carrier, personal vehicle, etc.</p>  |  |

## Ingredients

All operators who wish to add unusual or uncommon ingredients to food are strongly urged to check whether the proposed ingredient is allowed in regular food. Allowed ingredients usually are included in the following categories:

1. Conventional food (widely consumed in the U.S. prior to January 1, 1958 without known detrimental effects)
2. Approved additives (listed in 21 CFR 172)
3. Generally recognized as safe (GRAS) (listed in 21 CFR 182).

For more information on allowable food ingredients, a guidance document is available from the Montana Wholesale Food Program.

## Marketing

**Instructions:** check "Yes" or "No" in appropriate box

| Comment   | Yes | No |
|---|-----|----|
| The product will be sold directly to consumers at manufacturing site (retail) |     |    |
| The product will be sold to retailers or other merchants (wholesale)          |     |    |
| The product will be sold using the internet (worldwide web)                   |     |    |
| The product will be sold <b>ONLY</b> in Montana                               |     |    |
| The product will be marketed as ready-to-eat                                  |     |    |

## FOOD PACKAGING LABEL INFORMATION

### Commodity Packaging

**Instructions:** check "Yes" or "No" in appropriate box

| Comment   | Yes | No |
|---|-----|----|
| Product packaged for use by individual consumer (consumer commodity)            |     |    |
| Product packaged <b>ONLY</b> for use by retailer or wholesaler (bulk commodity) |     |    |

### Consumer Packaging Labels

**Instructions:** For each consumer product to be processed, provide one label example for review with this form. The label should be in marketplace form in size, shape and description.

Food labels must at least have four pieces of information, which are detailed in the table below.

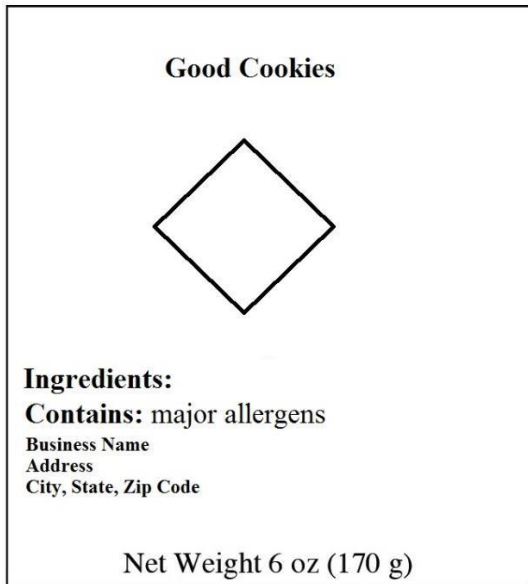
**Food Labeling Minimum Requirements Table**

|  |
|--|
| 1. <b>Product name</b> (known as the statement of identity)  |
| 2. <b>Name and address of product manufacturer</b> , distributor or packer                                     |
| 3. <b>Ingredient list</b> in order of quantity or predominance from greatest to least by weight                |
| 4. <b>Net weight</b> or liquid volume of product in United States units of measure AND metric units of measure |

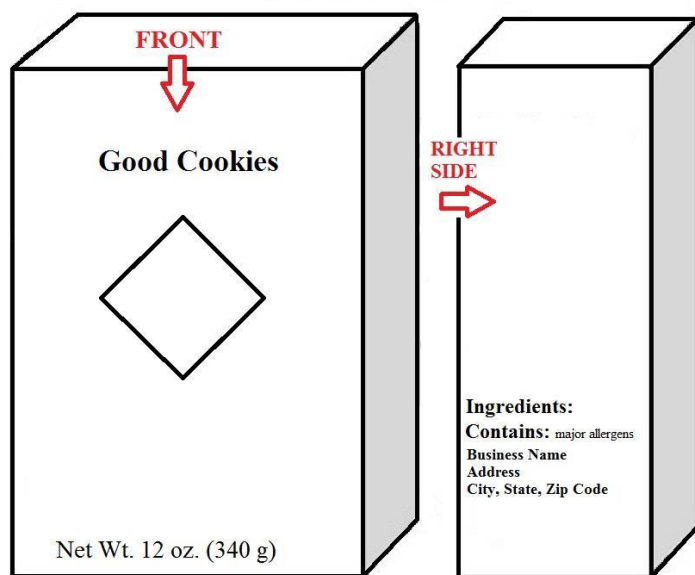
NOTE: all major allergens must be declared on the label or the product will be subject to recall.

**Major allergens are: crustacean shellfish (crab, lobster, shrimp, etc.), eggs, fish, milk, peanuts, soy, tree nuts and wheat.**

Single Panel Label



Double Panel Label



## Special labeling

**Instructions:** check “Yes” or “No” in appropriate box

| Comment  | Yes | No |
|--|-----|----|
| The product will be labeled “Keep Refrigerated.”               |     |    |
| The product will be labeled with a “Best by” or “Use by” date. |     |    |

## Product Labeling Resources

Web links to food labeling information:

[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.

## Nutrition Facts Panels

Firms whose annual gross food sales are at or greater than \$50,001, **or** have total food and non-food sales of at or greater than \$500,001 must provide a “Nutrition Facts” panel on consumer packages.

Firms that voluntarily provide nutrition labeling must also follow applicable regulations. In addition, small firms under the annual income levels stated above that make health or nutrition claims must provide nutrition label panels on consumer packages, in accordance with 21 CFR 101.9 (j).

## 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

Relieves 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

## SANITATION INFORMATION

**Instructions:** in the box to the right, describe how food-contact surfaces, floors, walls, ceilings, equipment and fixtures will be cleaned and sanitized. Submit additional pages, if needed.

|  |  |
|--|--|
| <p><b>Cleaning substances used on food-contact surfaces</b><br/>(e.g. detergent, soap, chlorine, phosphoric acid, hot water, etc.)</p>                         |  |
| <p><b>Equipment and utensils used during cleaning</b><br/>(e.g. wiping cloth, sink, air gun, etc.)</p>   |  |
| <p><b>How food-contact surfaces will be cleaned</b><br/>Describe cleaning process for food-contact surfaces, including utensils and equipment</p>              |  |
| <p><b>Cleaning frequency of food-contact surfaces</b><br/>Describe how often food-contact surfaces will be cleaned and sanitized (time: hours, days, etc.)</p> |  |



## DRINKING WATER BOTTLERS

Prior to issuance of a license to operate, bottlers of drinking water must obtain water from either:

1. A community public water system approved by the Montana Department of Environmental Quality Water Quality Division;  
**OR**
2. A separate, independent system that complies with statutes governing public water supplies

**NOTE: Drinking water bottlers are required to put production dates on containers.** Each package from a batch or segment of a continuous production run of bottled drinking water must be identified by a production code. The production code must identify a particular batch or segment and the day of production.

New drinking water bottlers not utilizing a regulated or municipal water supplier should contact the Montana Department of Environmental Quality to inquire about whether their water supply can meet or exceed public drinking water standards. In addition, the Montana Department of Natural Resources and Conservation should also be contacted about water rights. These items and other issues should be examined prior to applying for a wholesale food license.

### CONTACT INFORMATION

|  |   |
|--|---|
| <b>Montana Department of Environmental Quality</b><br>Permitting and Compliance Division<br>Telephone 406.444.4323<br>Public Water Supply/Subdivisions Bureau (plan review)<br>Public Water Supply Services Section (operator certification) | <b>Montana Department of Natural Resources and Conservation</b><br>Water Rights Bureau<br>1424 9th Avenue<br>P.O. Box 201601<br>Helena, MT 59620-1601<br>Telephone: 406. 444.6601 |
|--|---|

### REVIEW FORM FINAL CHECKLIST

|  |   |
|--|---|
|  | Completed “ <b>GENERAL INFORMATION</b> ” section  |
|  | Signed and dated “ <b>CERTIFICATION STATEMENT</b> ”   |
|  | Provided “ <b>Product Name</b> ”  |
|  | Identified “ <b>Product Phase</b> ”   |
|  | Provided all food “ <b>Ingredient names</b> ”   |
|  | Provided all food “ <b>Sub-ingredients</b> ”  |
|  | Completed “Processing Checklist”  |
|  | Provided “Processing Details”   |
|  | For special processing: provide copy of process school certificate  |
|  | For special processing: provide trained supervisor information  |
|  | For special processing: provide copy of process authority letter, if applicable   |
|  | Provided one actual label for each proposed food product  |
|  | Completed “ <b>SANITATION INFORMATION</b> ” section   |
|  | For drinking water bottlers: followed the special requirements for water source and container labeling  |
|  | Submit information to:<br><b>Montana Wholesale Food Program</b><br><b>1400 Broadway Street, C-214</b><br><b>P.O. Box 202951</b><br><b>Helena, MT 59620-2951</b><br><b>Telephone: 406.444.2837</b><br><b>Fax: 406.444.5055</b><br><b>E-mail: hhsfcs@mt.gov</b> |