



# MONTANA WHOLESALE FOOD REVIEW FORM

Revision date: 10.23.13

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><b>1400 Broadway Street, C-214</b><br><b>P.O. Box 202951</b><br><b>Helena, MT 59620-2951</b> | <b>Telephone: 406.444.2408</b><br><b>Fax: 406.444.5055</b><br><b>E-mail: <a href="mailto:hhsfcs@mt.gov">hhsfcs@mt.gov</a></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.

| Print name and title of certifier | Signature of certifier | 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**

**Question:** What are some definitions of terms for special types of food processing?

**Answer:** The table below defines critical terms of which operators should be aware.

| 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, in this case, greater than 4.6.<br><br>To summarize, low-acid food has two primary attributes:<br>1. pH level greater than 4.6<br>2. Water activity level greater than 0.85 |
| 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.<br><br>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.

**CONTINUED ON NEXT PAGE**

## 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.   |       | Fermenting                                | Beer, wine, pickles, bean paste, 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                |       | Freezing                                  | Beverage ice, vegetables, food storage, food cooling, etc.                                 |
|       | <b>High-acid foods in hermetically sealed containers</b> (metal cans, glass bottles, retort pouches, etc.)                          | Fruit, tomatoes, etc., in metal cans or glass containers with lids                            |       | Grinding                                  | Milling flours, grains, coffee, tea, etc.  |
|       | Assembling  | Sandwiches on two or more pieces of bread, salad mix, etc.                                    |       | Infusing with oils                        | Garlic in oil, onions in oil or other ingredients in oil mixtures                          |
|       | Baking  | Bread, rolls, beef, poultry, etc.   |       | Mixing                                    | Potato salad, macaroni salad, coleslaw, seafood salad, cut salad greens, soups, teas, etc. |
|       | Bottling  | Drinking water, fruit juices, vegetable juices and other foods in glass or plastic containers |       | Refrigerating (cold holding temperatures) | Salsa, dressing, sandwiches, etc.  |
|       | Carbonating (adding carbon dioxide gas to food)   | Soda, beer, etc.  |       | Re-packaging                              | Fruits, 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 process (describe)                  |  |
|       | Dehydrating   | Fruits, vegetables, etc.  |       | Other process (describe)                  |  |
|       | Distilling  | Whisky, vodka, etc.   |       | Other process (describe)                  |  |

## 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 carrier,<br/>personal vehicle, etc.</p>  |  |

**FDA Requirements** (skip this section, if not applicable)

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 food-safety training from an approved processing school; **AND**
2. Registered 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>

**Montana Food Review Requirements** (skip this section, if not applicable)

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. The firm is an acidified food processor that stores food in containers that do not require mechanical refrigeration

You must:

1. **Submit with this review form a copy of the supervisor’s approved processing school certificate; AND**
2. Provide information in the section below

The supervisor who has successfully completed food-safety training from an approved processing school must be in a position with the firm to monitor the food process of interest. Failure to provide this documentation will result in issuance of an unsatisfactory review report.

**NOTE: Documentation from a processing authority is not required if the product is labeled “Keep Refrigerated.”**

| Name, title of supervisor | Process school (s) city, state | Completion date |
|---------------------------|--------------------------------|-----------------|
|                           |                                |                 |

**Marketing**

**Instructions:** check “Yes” or “No” in box to right, as applicable

| 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                               |     |    |

**FOOD PACKAGING LABEL INFORMATION**

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

Packaged and re-packaged food containers must be labeled. Labeling can be a complex issue. However, food labels must at least have four pieces of information, which are detailed in the table below.

**Food Labeling Minimum Requirements Table**

|  |
|--|
| <ol style="list-style-type: none"> <li>1. <b>Product name</b> (known as the statement of identity)</li> <li>2. <b>Name and address of product manufacturer</b>, distributor or packer</li> <li>3. <b>Ingredient list</b> in order of quantity or predominance from greatest to least by weight</li> <li>4. <b>Net weight</b> or liquid volume of product in United States units of measure <b>AND</b> metric units of measure</li> </ol> |
|--|

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.**

Montana Food and Consumer Safety Section highly recommends all food packaging have a production code stamped on the food label, in the event of a product recall.

## Special labeling

**Instructions:** check “Yes” or “No” in box to right, as applicable

| 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

Please visit the United States Food and Drug Administration (FDA) web address for labeling information:

<http://www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm>

A FREE on-line labeling course is also available. The course takes about one hour to complete:

<http://www.accessdata.fda.gov/ORAU/Labeling/>

## NUTRITION LABELING

Firms whose total gross sales for all products—food and non-food—is \$501,000 or less with \$49,000 or less from food sales are exempt from nutrition labeling requirements.

For products that require federal nutrition labeling, computer software is available to assist in creating compliant labels at the following webpage address: <http://extension.usu.edu/foodbiz/htm/nfp/>

In addition, nutrition labeling and other compliance assistance is also available from:

Mission Mountain Food Enterprise Center:

Telephone: 406-676-5901

Web: [http://www.lakecountycdc.org/Production\\_and\\_Processing\\_Assistance](http://www.lakecountycdc.org/Production_and_Processing_Assistance)

**Question:** Where is there more information on labeling examples?

**Answer:** Call the state or visit their webpage for labeling guidelines.

Telephone: 406-444-2408; Food and Consumer Safety Section (FCSS)

Web: <http://www.dphhs.mt.gov/publichealth/fcs/wholesalefood.shtml>

## 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</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.

### 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: provided copy of process school certificate  |
|  | For special processing: provided trained supervisor information  |
|  | 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 all 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: 406.444.2408</b><br><b>Fax: 406.444.5055</b><br><b>E-mail: <a href="mailto:hhsfcs@mt.gov">hhsfcs@mt.gov</a></b> |