



SANDERS COUNTY RETAIL MANUFACTURING FOOD REVIEW FORM

Revision date: 05.20.15

The purpose of this document is to help applicants obtain a satisfactory Retail Manufacturing 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 food license. Authority for this review is under MCA 50-50-103, 201, 203 and ARM 37.110.272.

Return complete d form to:	Sanders County Environmental Health P.O. Box 519 Thompson Falls, MT 59873	Telephone: 406.827-6919 Fax: 406.827.4388 E-mail: ssorenson@co.sanders.mt.us	OFFICE USE Request ID Contact ID
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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 Mr. Ms.	Contact telephone	Contact e-mail

Firm operates as a:

Sole proprietor	Partnership	Cooperative	LLC	Corporation
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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
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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

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. 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. 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. To summarize, low-acid food has two primary attributes: <ol style="list-style-type: none"> 1. pH level greater than 4.6 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. 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.

Water Supply

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

Water Supply (municipal, non-municipal, public, private)	
Water Treatment (reverse osmosis, carbon filter, etc.)	

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
	Acidified food —decreasing pH of food by adding acidic ingredients , such as vinegar (acetic acid), citric acid, etc.	Salsa, dressing, sauces, vegetables, etc.		Fermenting	Beer, wine, pickles, bean paste, etc.
	Low-acid foods in hermetically sealed containers (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.
	High-acid foods in hermetically sealed containers (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>Food ingredient suppliers Supplier name, city, state; types of food</p>	
<p>Food packaging suppliers Supplier name, city, state; types of packaging material</p>	
<p>Food transport to firm How and who will transport food; e.g. firm fleet vehicle, contract carrier, personal vehicle, etc.</p>	
<p>Ingredient storage facilities Refrigerator, freezer, dry goods; location</p>	
<p>Food processing Basic food preparation techniques and procedures: Include times and temperatures (baking, cooking, cooling) Also describe basic techniques, such as mixing, cutting, slicing, etc.</p>	
<p>Food packaging and labeling procedures Describe how food will be packaged, including types of lids and containers. Also, describe how label will be secured to the package; e.g. adhesive or other method)</p>	
<p>Product storage facilities Where and how finished food product will be stored; refrigerator, freezer, dry goods.</p>	
<p>Food transport from firm How and who will transport food from the firm to recipient; e.g. contract carrier, 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 ONLY in Montana		
The product will be marketed as ready-to-eat		

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"> 1. Product name (known as the statement of identity) 2. Name and address of product manufacturer, distributor or packer 3. Ingredient list in order of quantity or predominance from greatest to least by weight 4. Net weight 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.

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/hm/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

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

<p>Montana Department of Environmental Quality Permitting and Compliance Division Telephone 406.444.4323 Public Water Supply/Subdivisions Bureau (plan review) Public Water Supply Services Section (operator certification) Webpage: http://www.deq.mt.gov/pcd/pwsub/default.mcp</p>	<p>Montana Department of Natural Resources and Conservation Water Rights Bureau 1424 9th Avenue P.O. Box 201601 Helena, MT 59620-1601 Telephone: 406. 444.6601 Webpage: http://www.dnrc.mt.gov/wrd/water_rts/</p>
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REVIEW FORM FINAL CHECKLIST

Completed “ GENERAL INFORMATION ” section
Signed and dated “ CERTIFICATION STATEMENT ”
Provided “ Product Name ”
Identified “ Product Phase ”
Provided all food “ Ingredient names ”
Provided all food “ Sub-ingredients ”
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 “ SANITATION INFORMATION ” section
For drinking water bottlers: followed the special requirements for water source and container labeling
Submit all information to: Sanders County Environmental Health PO Box 519 Thompson Falls, MT 59873 Phone: 406-827-6919 Fax: 406-827-4388 Email: ssorenson@co.sanders.mt.us