Specialized Processing Methods
Variance Tools

Operator’s Manual

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Revised September 2015
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Introduction:

The tools provided in this guidance are designed to assist the Michigan Department of Agriculture and Rural Development (MDARD), Food and Dairy Division, local health departments and retail food operators understand and apply for specialized processing methods variances in accordance with the 2009 Michigan Modified Food Code (Food Code). Individuals who have specific questions regarding the variance process should contact the office that licenses and evaluates the retail food operation (either their local health department or MDARD).

What is a Variance?
A "Variance" is a written document issued by the regulatory authority that authorizes and allows a modification or waiver of one or more requirements of the Food Code if, in the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver (2009 Michigan Modified Food Code, Section 8-103.10).

When is a Variance needed?
A "Variance" may be requested when the retail food establishment is not able to meet a section in the Food Code as detailed in the sections 8-103.11 and 8-103.12, or when the retail food establishment conducts an operation that is not addressed by the Food Code as referenced in section 3-502.11.

Are there different types of variances?
Yes, there are specialized processing methods variances and other variances.

Specialized Processing Methods Variances: The Food Code requires a variance request with evidence be submitted to the regulatory authority if a retail food establishment:

- uses an alternative procedure for cooking and chilling hot sauces in a sealed bag, and is unable to meet all the requirements in section 3-502.12(D) (1) and (2), but wants to continue the cook-chill process; or,
- prepares their own yogurt for use as a condiment; or,
- adds enough vinegar to the sushi rice so the rice is not potentially hazardous and prevents the growth of pathogens such as Bacillus cereus even if held at room temperature for the 8-hour shift; or,
- prepares food using a method that is determined by the food licensing agency to require a variance.
- does pickling or fermentation of meat and poultry products.

A separate and specific application process has been developed for Specialized Meat and Poultry Processing Method Variances that involve the curing and smoking of meat and poultry products and can be found at http://www.michigan.gov/mdard/0,4610,7-125-50772_45851_45853-272866--,00.html

Other Variances: The Food Code also requires a variance request be submitted to the regulatory authority if a retail food establishment uses an alternative procedure when the food establishment is not equipped with a service sink, but has an acceptable alternate procedure for
obtaining water for mopping the floors and disposing of wastewater that meets the Food Code and any applicable local, state or federal law.

For more information on variance requests, see 2009 Michigan Modified Food Code, section 8-103.10, Modifications and Waivers, section 8-103.11, Documentation of Proposed Variance and Justification, and section 8-103.12, Conformance with Approved Procedures. If a HACCP plan is required, see section 8-201.13, When a HACCP Plan is Required, and section 8-201.14, Contents of a HACCP Plan, for details.

Who issues or denies Specialized Processing Methods Variances?
A "variance" must be reviewed and allowed by the regulatory authority before the retail food establishment is allowed to waive or modify the requirements of the Food Code, or conduct a food operation that is not addressed in the Food Code. A variance will be granted if upon review and determination by the regulatory authority, a health hazard or nuisance will not result. The regulatory authority reserves the right to withdraw a variance, once granted.


Do I need a variance if our food establishment plans to prepare, package and label sandwiches and other ready-to-eat foods for the gasoline station convenience store down the road?
The business you are describing may categorize your business as a wholesale food processor or limited wholesale food processor. The requirements for food manufacturing are different from retail food sales. Please contact the regulatory agency that licenses your operation (your local health department or MDARD) to discuss your business plan before proceeding.
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Specialized Processing Variance Process Flow Chart

Discuss variance proposal feasibility with licensing and evaluation regulatory agency (LHD or MDARD). A risk assessment may be conducted to determine feasibility.

Obtain Specialized Processing Method Variance Request application

Submit Variance Request application

Regulatory agency begins variance review process

Provide additional information the application reviewer, if requested

Regulatory agency monitors and documents the variance process, in accordance with recipe, flow diagram, HACCP plan, SSOP, and other materials submitted

Variance granted, possibly with conditions

Regulatory agency verifies compliance with HACCP plan
### General Information

**Company Contact**

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<thead>
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<th>Name:</th>
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<td>Address:</td>
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**Contact Person (if different than above)**

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<th>Name:</th>
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<tr>
<td>Title:</td>
<td>Email:</td>
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<tr>
<td>Mailing Address:</td>
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<td>City:</td>
<td>Zip:</td>
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<tr>
<td>Food Establishment License Number:</td>
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</table>

**Cite relevant Michigan Modified Food Code section numbers:**

- [ ]

**Statement of proposed variance:**

- [ ]

**Explain the risk that your proposal may introduce to your food operation and how all relevant public health hazards will be addressed:**

- [ ]

- [ ]

**A similar variance has been issued to another food establishment under the same ownership (please provide a copy of approved variance).**

- [ ]
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Submit the following items as part of the proposal for special processing variance:

1. **Food Product Description**
   - Complete description the proposed food item.
   - Recipe or list of ingredients.
   - Summary description of the process used to prepare food item.
   - Detailed description of the packaging.
   - Detailed description of the method of sale and intended use of the product.
   - Statement of final product’s intended storage conditions.
   - Proposed shelf life and how shelf life was determined.
   - Statement of distribution methods.

2. **General Facility and Specialized Processing Equipment Overview**
   - Provide a detailed floor plan of processing area and entire facility, including all equipment.
   - Indicate other food and non-food operations occurring at the facility.
   - Attach a list of all equipment that will be used to prepare the food item with manufacturer’s specification sheets.
   - If any equipment requires calibration, include the policy for calibration.
   - Indicate details of the water supply and wastewater supply for the facility.

3. **Flow Diagram of Food Processing Steps**
   - Attach a detailed flow diagram from receiving to sale or use.
   - Included descriptions at each step with foods used, employee actions, and areas utilized. Descriptions must include hazards and potential contaminations. (Note: If submitting a HACCP plan, include above requested items in the plan.)

4. **Hazard Analysis Critical Control Point (HACCP) Plan**
   - If required per Food Code or Code of Regulations, submit a HACCP plan. Refer to [www.fda.gov](http://www.fda.gov), keyword: HACCP Guidelines.

5. **Standard Operating Procedures (SOPs)**
   - Submit SOPs for process, including, but not limited to: hand washing; personal hygiene; preventing bare hand contact with ready-to-eat food; employee illness; purchasing food from approved sources; cleaning and sanitizing food contact surfaces; cross-contamination prevention; ware washing; date-marking; using time only (not time and temperature) as a method to control bacterial growth; thawing; cooking; potentially hazardous food; cooling; reheating; hot holding; cold holding; and supervisor and food employee training plan.
   - SOP does need to be provided when the item is addressed specifically by a HACCP plan control point.
   - For additional general SOPs guidance, visit [www.michigan.gov/mdardplanreview](http://www.michigan.gov/mdardplanreview)

6. **Accredited Commercial Lab Analytical Test Results for Validation, if required**
   - Provide any product assessments or scientific studies performed on the food item as required. This is commonly needed for shelf life and determination of whether or not end product is non-TCS (shelf stable packaged foods).

7. **Labeling, if required**
   - Provide a sample of the proposed label and/or packaging that will be used for product
   - Policy for how tracking will be done through lot codes or date codes
   - Refer to MDARD Food Labeling Guide at [www.michigan.gov/foodlabeling](http://www.michigan.gov/foodlabeling)

**NOTE:** If a similar variance request been granted by another agency, please provide proof of variance approval.
Specialized Processing Methods Variance Request Instructions

General Information:
Please fill in the name and vital information of the company as it appears on your food establishment license application.

Cite Relevant Food Code Section Numbers:
Locate the section number in the 2000 Michigan Modified Food Code that applies to your variance. For specialized processing methods variances, use the appropriate description in section 3-502.11 (A-H).

Statement of Proposed Variance:
Clearly tell us in your own words what the Food Code requires and what your alternate plan involves.

Explain the risk that your proposal may introduce to your food operation and how all relevant public health hazards will be addressed:
Clearly explain in your own words the risk involved if the Food Code requirement is not met. After identifying the potential hazards or contamination, explain how you plan to prevent any foodborne illness or adulteration problems from occurring.

Specialized Processing Variance Submission Items:
Please include all submissions, if applicable to your variance request.

1. Food Product Description
   Description of proposed food: What is the identity/name of your food product?
   Menu items and recipes: Provide us a copy of your menu item categories, and recipe for the proposed food with ingredients and preparation steps. Quantities are not required for the recipes, but ingredients should be listed in the order of predominance and should list the step by step procedures.
   Description of process to prepare food: How is food prepared and is the food raw, partially cooked, or fully cooked?
   Description of packaging: Describe in detail.

   Method of sale: Is the food to be sold at retail? Sold at wholesale? Describe where food will be sold and if food will be sold under a separate business.
   Intended use: Is the food intended to be ready-to-eat, re-heated before eating, or used in another way?
   Intended storage of final product: If the food is packaged before sale, is the food to be sold frozen, refrigerated or at room temperature?
   Shelf life: What is proposed shelf life? How was shelf life determined?

2. General Facility and Specialized Processing Equipment Overview
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Provide a current layout of your facility or food preparation/storage/distribution area. Include sinks and specialized processing equipment, doors, other equipment, etc., and demonstrate how the foods flow through the facility. How do you prevent cross contamination?

3. Flow Diagram of Food Processing Steps
If you have not listed the step-by-step procedure for the proposed food in your recipe, draw a diagram of the ingredients and how they are combined to make the finished food product. At each step, describe what the step is, who is responsible, where the step is done, when the step happens, why and how you prevent hazards and contamination.

4. Hazard Analysis Critical Control Point (HACCP) Plan

a. Recordkeeping/Monitoring Log Forms
Your HACCP plan will require recordkeeping. Monitoring log forms are documents that employees use to record critical control points such as time, temperature, pH, water activity, and other values. Log forms also include documented equipment and facility cleaning schedules. For information on log forms, go to http://www.michigan.gov/mdard/0,4610,7-125-50772_45851_61711_61714--- ,00.html

For more information, contact your regulatory agency.

5. Standard Operating Procedures (SOPs)
Provide the following standard operating procedures:

a. Procedures all establishments must submit:
- Handwashing.
- Personal hygiene, including cuts and sores.
- Preventing bare hand contact with ready-to-eat food (gloves, utensils, etc.).
- Employee illness.
- Purchasing food from approved sources.
- Cleaning and sanitizing food contact surfaces.

b. Procedures applicable to your proposed operation that must be submitted:
- Cross-contamination prevention.
- Warewashing.
- Date-marking ready-to-eat, potentially hazardous food.
- Time and temperature control for thawing potentially hazardous food.
- Time and temperature control for cooking potentially hazardous food.
- Time and temperature control for cooling potentially hazardous food.
- Time and temperature control for reheating potentially hazardous food.
- Time and temperature control for hot holding potentially hazardous food.
- Time and temperature control for cold holding potentially hazardous food.
- Other required operational procedures or good retail practices.

For information on how to write SOPs, go to: www.michigan.gov/mdardplanreview
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Additional standard operating procedures such as your company's food employee and supervisory training plan will also be requested for review. Please discuss required SOPs with the jurisdiction reviewing your variance request.

a. Food Employee and Supervisory Training Plan:
   Explain the food safety training and re-training plan for your employees and supervisors who monitor the food preparation.
   http://www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006810.htm

6. Accredited Commercial Lab Analytical Test Results for Initial Validation (Scientific Data), if Required:
   a. Validation is the scientific and technical process for determining that the critical control points and associated critical limits are adequate and sufficient to control the likely hazards. The initial validation of your HACCP plan is the process by which your establishment proves that what is written in the HACCP plan will be effective in preventing, eliminating, or reducing food safety hazards. Validation can be met by gathering evidence that supports your HACCP plan. The data you bring together can come from many sources. Sources can include scientific literature, product testing results, regulatory requirements, and/or industry standards.
   b. If you are manufacturing an acidified or low acid shelf stable food, Title 21 Code of Federal Regulations part 113 (Thermally Processed Low-acid Foods Packaged in Hermetically Sealed Containers) or part 114 (Acidified Foods) require that you have:
      (1) a scheduled process established by qualified persons having expert knowledge; and,
      (2) an operator who has attended a school approved by the Food and Drug Administration.

For more information, visit:

For all other foods, discuss with your regulatory agency and/or determine if your food requires a product assessment and scientific analysis.
http://www.fda.gov/food/foodscienceresearch/safepracticesforfoodprocesses/ucm094159.htm
The product testing data submitted as evidence may consist of characteristics data, microbial testing of finished food product, and/or challenge studies. The type of scientific data required depends on the food product, storage temperature and shelf life, and should be discussed with your food science consultant. Tests conducted must be completed by trained employees and test methods must meet the Food and Drug Administration guidelines such as:

2. Association of Official Analytical Chemists, *Bacteriological Analytical Manual*; or,

c. Characteristics data includes determination of the water activity and pH value of the finished food product.

d. Microbial testing of finished food product tests the food sample only for the presence of spoilage organisms and pathogens specific to the process.

e. Challenge studies involve inoculating the food product with specific test organisms and determining survival of the pathogens in the finished food product.

**Labeling, if Required:**

The label must meet requirements for package foods as specified in 21 CFR part 101, 9 CFR part 317, and subpart N of part 381 of title 9 of the Code of Federal Regulations, and as specified under sections 3-202.17 and 3-202.18 of the food code. For information on labeling, go to: [www.michigan.gov/foodlabeling](http://www.michigan.gov/foodlabeling)

Your regulatory agency (MDARD or your local health department) may review your proposed label for compliance, but does not approve labels.
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Acknowledgements

Local Health Departments

Theodore Dohnal, District Health Department #10
Rene’ Heweitt-Lichota, Macomb County Health Department
Terri Rose, Oakland County Health Department
Kristen Schweighoefer, Washtenaw County Department of Planning and Environment
Elizabeth Suggitt, Luce-Mackinac-Alger-Schoolcraft District Health Department
Deb VandeBunte, Ottawa County Health Department

Industry Partners

James Rennie, Champps Americana
James Conway, Hissho Foods

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Kevin Halfmann, Food Policy Specialist
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James Padden, Regional Supervisor
Sandra Walker, Food Program Manager
Rodney Blanchard, Food Service Specialist
Jeanne Hausler, Food and Dairy Communications