Specialized Processing Methods
Variance Tools

Regulator’s Manual

Michigan Department of Agriculture and Rural Development
Food and Dairy Division
MDA-FoodDairyInfo@michigan.gov
www.michigan.gov/foodsafety
800-292-3939

Revised September 2015
# Table of Contents

- Introduction ........................................................................................................... 3
- Specialized Processing Variance Process Flow Chart ........................................... 5
- Variance Granting Procedure Model ..................................................................... 6
- Specialized Processing Methods Variance Application ......................................... 8
- Specialized Processing Methods Variance Request Instructions ........................ 10
- Specialized Processing Methods Reviewer's Checklist ....................................... 14
- Specialized Processing Methods Variance Model Letter ..................................... 18
- Acknowledgements ............................................................................................. 19
Introduction

The tools provided in this guidance are designed to help food regulatory staff from the Michigan Department of Agriculture and Rural Development (MDARD) and local health departments understand the requirements and process for retail food operators to apply for specialized processing methods variances, in accordance with the 2009 U.S. Food and Drug Administration (FDA) Michigan Modified Food Code (Food Code).

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 method variances and other variances.

Specialized Processing Method 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
Specialized Processing Methods Variance Tools
Regulator’s Manual

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 Method 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.
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
Variance Granting Procedure Model

Agency Team:

After discussing the variance request with the MDARD Food Program supervisor (coordinator), local health department area sanitarian and other resources, as needed, MDARD’s variance review and issuance designee may grant a variance that modifies or waives the requirements of the Food Code if a health hazard or nuisance will not result from the variance (Food Code § 8-103).

Review Process/Timeline/Decision Making/Correspondence/Communication:

1. The following items must be included before a variance will be reviewed and given consideration for issuance. The person requesting the variance shall submit a written request to the regulatory agency that licenses your operation (your local health department or MDARD) that provides the following information:
   a. A statement of the proposed variance of the Food Code requirement, citing relevant Food Code section numbers;
   b. An analysis of the rationale for how the potential public health hazards and nuisances addressed by the relevant Food Code sections will be alternatively addressed by the proposal;
   c. A HACCP plan and other relevant attachments when specifically required by the Food Code; and,
   d. A HACCP plan when relevant to the variance requested.

2. Upon receipt, the submission shall be date stamped and reviewed. A written response to the variance request should be processed within 30 days of receipt of completed submittal of information.

   If additional information is required, or assistance from the state consultant or other resources is required, a letter should be sent to the applicant explaining the reason for the delay in issuing or denying the request.

3. A log of the variance requests shall also be maintained by the agency. The log will list the date of submission, name of the applicant, proposed variance request, reason for issuance or denial, and the date variance response letter sent to applicant.

   For uniformity and consistency, all variance responses for operations that have multi-jurisdictional application, such as firms with multiple establishments (e.g. chain stores) or operations common to multiple establishments, will be posted on a variance listserv available to local health departments, MDARD Food Service Program and Food Safety and Inspection Program, and FDA regulators.

4. If the variance review and issuance designee denies a variance, he or she shall notify the requesting party of the decision and the reasons in writing. The variance denial letter template shall include reasons for the denial, the applicant’s right to appeal, and the appeal process. A copy of the letter shall be given to the area sanitarian and placed in the food establishment file.
5. If the variance review and issuance designee recommends acceptance of a variance, he or she shall write a brief memorandum explaining his or her reasons for recommended acceptance.

   a. Specialized Processing Methods variances – Specialized Processing Methods variance requests as referenced in the Food Code, section 3-502.11, may require assistance from MDARD or other knowledgeable resources, to help determine whether the variance should be approved or denied. Upon receipt of feedback from the MDARD consultant or other agencies, the variance review and issuance designee shall keep a record explaining the approval or denial, in case the decision is appealed.

      i. Allowing vinegar and sugar flavored rice for sushi to be kept at room temperature for an 8-hour shift is an example of a specialized processing method variance granted to a food establishment. The amount of vinegar added to their sushi rice mixture rendered the food non-potentially hazardous, and was sufficient to control the growth of pathogens of public health concern such as *Bacillus cereus*.

   b. Other variances – Some variance requests such as emptying wastewater into the toilet in lieu of a service sink may be approved without any discussion with the state agency. Standard variances such as these may be approved by the variance review and issuance designee.

When a variance is granted, the variance review and issuance designee shall notify the applicant by letter. A copy of the variance issuance letter and the original variance request, including information specified in item (1) above, shall be retained in the food establishment records at the departmental office, and a copy of the variance request issuance or denial letter shall be given to the area sanitarian.

The variance issuance letter must include the possibility of withdrawal of the variance if a problem arises, if there is a change in ownership, or if a significant change in the operations occurs.

**Periodic Assessment or Review of Variance**

During routine inspections, the area sanitarian is responsible for assessing the success of the variance in meeting its public health objective. The sanitarian must ensure that a health hazard or nuisance has not resulted from the implementation of the variance.

If a problem arises, the agency may immediately withdraw approval of the variance.

**Withdrawing Approved Variances**

Food establishments that change their menu, operations, equipment, or ownership and impact the variance without properly notifying the area sanitarian must be instructed to resubmit their variance for review. Previously issued variances are void until new variance is granted.

When the department variance and issuance designee withdraws a variance, he or she shall notify the requesting party of the decision and the reasons in writing. The letter shall notify the operator that the variance is revoked. Copies of the letter shall be given to the area sanitarian and placed in the food establishment file.
Specialized Processing Methods Variance Tools
Regulator’s Manual

Specialized Processing Methods Variance Application

General Information

Company Contact

Name: 
Address:    City:    Zip: 

Contact Person (if different than above)

Name: 
Title:    Email: 
Mailing Address: 
City:    Zip: 

Food Establishment License Number: 

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).
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.
   - Include 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 Tools
Regulator’s Manual

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 method 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?
   Statement of Distribution Methods: Describe any special distribution controls needed.
Specialized Processing Methods Variance Tools
Regulator’s Manual

2. General Facility and Specialized Processing Equipment Overview
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.
Specialized Processing Methods Variance Tools
Regulator’s Manual

For information on how to write SOPs, go to: www.michigan.gov/mdardplanreview

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:
   c. 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
   d. 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:
      1. National Advisory Committee on Microbiological Criteria for Food, Parameters for Inoculated Pack/Challenge Study Protocols;
      or,
Specialized Processing Methods Variance Tools
Regulator’s Manual

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

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

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

7. Labeling, if Required:

Your regulatory agency (MDARD or your local health department) may review your proposed label for compliance, but does not approve labels.
# Specialized Processing Methods Reviewer's Checklist

**Establishment Name:**

**Establishment Food License Number:**

**Address:**

<table>
<thead>
<tr>
<th>City</th>
<th>State</th>
<th>Zip</th>
</tr>
</thead>
</table>

**Food Item:**

<table>
<thead>
<tr>
<th>S</th>
<th>N/A</th>
<th>NMI</th>
</tr>
</thead>
</table>

## 1. Food Product Description

- Description of product identity (name, recipe)
- Method of sale (In-house, Retail, Wholesale, Internet/Mail Order)
- Food Process Category (Fully Cooked, Partially Cooked, Raw)
- Intended use of food product (RTE, Reheat before use, Cook before use)
- Description of Packaging
- Storage temperature of finished product
- Shelf Life
- Special Distribution Controls
- Finished Product Potentially Hazardous/Time Temperature Control food Status

**Comments:**

**Information Request Date:**

**Information Received Date:**

## 2. Regulations: Codes & Registrations

- Food Code Specialized Processing method or ROP variance
- 21 CFR part 110 Current GMPs in Manufacturing, Packaging, and Holding of Human Food
- 21 CFR part 113 Thermally Processed Low Acid Foods Packaged in Hermetically Sealed Containers Requirements and Registrations
- 21 CFR part 114 Acidified Foods Requirements and Registrations
- 21 CFR part 120 Juice HACCP (Wholesale Only)
- 21 CFR part 123 Fish and Fishery Products (Wholesale Only)
- Michigan Regulation 569 Smoked Fish
- 21 CFR part 129 Processing and Bottling of Bottled Drinking Water
- FDA Bioterrorism Act registration (Wholesale Only)
- Other (describe):

**Comments:**

**Information Request Date:**

**Information Received Date:**

---

14
### 3. General Facility & Specialized Processing Equipment Overview

<table>
<thead>
<tr>
<th></th>
<th>N/A</th>
<th>NMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Processing area adequate in size, layout and design</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other food and/or nonfood operations conducted on-site</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Well and septic adequate</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equipment suitable for process</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equipment placed to preclude contamination</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equipment being used as intended and according to specifications</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Equipment Calibration schedule</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other concern (describe):</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Information Request Date: Information Received Date:

---

### 4. Flow Diagram of Food Processing Steps

<table>
<thead>
<tr>
<th></th>
<th>N/A</th>
<th>NMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Flow diagram of process from receiving to sale or use</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Description of each step (food, employee, environmental)</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hazards and contamination potentials identified at each step</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other concern (describe):</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Information Request Date: Information Received Date:

---

### 5. HACCP

<table>
<thead>
<tr>
<th></th>
<th>N/A</th>
<th>NMI</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>HACCP as required by Food Code and/or CFRs</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Hazard Analysis Conducted</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CCPs Identified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Critical Limits Identified</td>
<td></td>
</tr>
<tr>
<td></td>
<td>CCPs Monitoring Requirements</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Corrective Actions Established</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Record Keeping Procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Validation/Verification Procedures</td>
<td></td>
</tr>
<tr>
<td></td>
<td>HACCP Plan provided</td>
<td></td>
</tr>
<tr>
<td></td>
<td>Other (describe):</td>
<td></td>
</tr>
</tbody>
</table>

Comments: Information Request Date: Information Received Date:
### 6. Standard Operating Procedures

- General SOPs
- Process specific SOPs
- Record keeping documents as needed (monitoring, cleaning, etc)
- Training Plan
- Other (describe)

Comments:  
Information Request Date: 
Information Received Date:

### 7. Accredited Commercial Lab Analytical Test Results for Validation (as required)

- Aw or water activity
- pH
- Product Assessment
- Microbiological tests for Pathogen of concern
- Challenge Study
- Shelf Life Study
- Other:

Comments:  
Information Request Date: 
Information Received Date:

### 8. Label Review (See MDA reviewer guide)

- Sample label or packaging
- Statement of Identity
- Name and address of responsible party
- Quantity Declaration
- Ingredients List
- Nutrition Facts (if required)
- Sell By Date
- Lot identification (code/date)
- Allergen Labeling
- Other Special Considerations: Bottled Water, Meat Products (USDA)
- Special labeling Instructions

Comments:  
Information Request Date: 
Information Received Date:
<table>
<thead>
<tr>
<th></th>
<th>NA</th>
<th>NM</th>
<th>9. On-Site Evaluation/ Training</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td></td>
<td>Process and Documentation submitted match operation and facilities</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Operator is adequately trained/ certified to conduct proposed food operation</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Other(describe):</td>
</tr>
</tbody>
</table>

**Reviewed by:**

**Date:**

**Agency:**

**On-site Review Date:**

**On-site Reviewer’s Name:**

**Notes:**

____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
____________________________________________________________________________________
Subject: Specialized Processing Method Variance

Dear (Name):

This letter is in regards to the variance requested by your firm to (variance proposal) . Your specialized processing method variance application was received on (date stamped and received).

Your variance request states that you plan to process (describe the product identity, intended use, storage temperature, packaging, shelf life, method of sale, labeling instructions, and the food manufacturing process).

Based on the information you submitted, your variance has been (describe if variance granted, denied, or more information requested for review and determination).

(If variance is granted, include a statement that approval is conditional and “regulatory authority” reserves the right to withdraw a variance approval if the operator deviates from the submitted procedures or problems are noted). If, for any reason, the department finds violations caused by the variance or if your operation deviates from the submitted procedures, we reserve the right to rescind the variance approval.

In accordance with the Administrative Procedures Act, PA 306 of 1969, you are allowed an opportunity for a hearing, upon request.

Please contact our agency at (area code + phone number) if you have any questions.

Sincerely,

Designated variance reviewer, Title

cc:
Acknowledgements

Local Health Departments

Theodore Dohnal, District Health Department #10
Rene’ Heweitt-Lichota, Macomb County Health Department
Terri Rose, Oakland County Health Department
Kristen Schweighoefoer, 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

Michigan Department of Agriculture and Rural Development

Kevin Halfmann, Food Policy Specialist
Laura Hoitenga, Senior Food Field Scientist
Rebecca Krzyzanowski, Food Service Specialist
Jasmine Lincicome, Food Protection Trainer
James Padden, Regional Supervisor
Sandra Walker, Food Program Manager
Rodney Blanchard, Food Service Specialist
Jeanne Hausler, Food and Dairy Communications