

SPECIALIZED PROCESSING METHODS

Variance Tools

Operator's Manual



MICHIGAN DEPARTMENT OF AGRICULTURE AND RURAL DEVELOPMENT
FOOD AND DAIRY DIVISION

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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 service 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 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 Standard Operating Procedure (SOP) goes outside of the Food Code and 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.

Specialized Meat and Poultry Processing Method Variances that involve the curing and smoking of meat and poultry products can be found at <http://www.michigan.gov/meatprocessing>.

Specialized Processing Methods Variances: The Food Code requires a **variance request** with evidence be submitted to the regulatory authority.

Food Code - 3-502.11

All require VARIANCE and HACCP

- Smoking for preservation – beef jerky
- Curing – nitrates/nitrites – DQ 10, Prague powder, curing salt

- TCS to Non-TCS with additives – pickling, fermentation, acidification
- Reduced Oxygen packaging – Vacuum packing, canning, bottling
- Custom Processing animals
- Sprouting Seeds
- Anything deemed necessary by regulatory authority

Michigan Specific

- Regulation 569 for smoked fish
 - Packaging for retail
 - Shelf-life extension
 - Cold smoking
- Meat Processing HACCP/Variance Program
 - For "traditional cured" meats
 - No curing above 41°F
 - No fermentation

Identifying Hazards and Control Points for Hazards to provide food safety

- Specific for establishment/process
- Monitoring, Verification, and Validation requirements
- Must keep records and provide those to regulatory authority
- Products subject to recall/seizure/disposition if not following the plan

Contents of a HACCP

- Types of food that are TCS
- Flow diagram of each food – ingredients, recipes, methods and procedural controls of CCP's, equipment used, flow through establishment (if required)
- Training plan of employees
- SOPs that address each CCP, how and when CCPs are monitored, how and when the PIC verifies CCP, actions needed if CCP is not met
- Scientific data that validated food safety is maintained

Exceptions for a variance

ROP that has two barriers:

- Refrigerated acid foods (4.6 – 4.2 pH)
- Refrigerated “dry” foods (0.91-0.88 A_w)
- Refrigerated cured meats
- Raw meats and vegetables
- FROZEN Fish
- Cheeses
- Cook/Chill and Sous Vide

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.

To view the Michigan Food Law of 2000, as amended, and the 2009 Michigan Modified Food Code, go to:

http://www.michigan.gov/mda rd/0,4610,7-125-50772_45851_61711---,00.html

Do I need a variance?

The following are examples of processes that may require a variance. The regulatory authority may deem a variance is needed for any other process not listed

- Smoking for preservation – beef jerky
- Curing – nitrates/nitrites – DQ 10, prague powder, curing salt
- TCS to Non-TCS with additives – pickling, fermentation, acidification
- Reduced Oxygen packaging – Vacuum packing, canning, bottling
- Custom Processing animals
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- Anything deemed necessary by regulatory authority

Variance Granting Procedure Model

Agency Team:

Follow your agency’s variance policy. MDARD and persons certified in FDA 312 are resources for your agency to issue a variance. (Food Code § 8-103.10).

Proposal for specialized food processing:

A variance will be reviewed and given consideration for issuance. The person requesting the variance shall submit a proposal for specialized food processing to the regulatory agency that licenses the operation (local health department or MDARD). On site validation needs to be completed to ensure process prior to approval.

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.

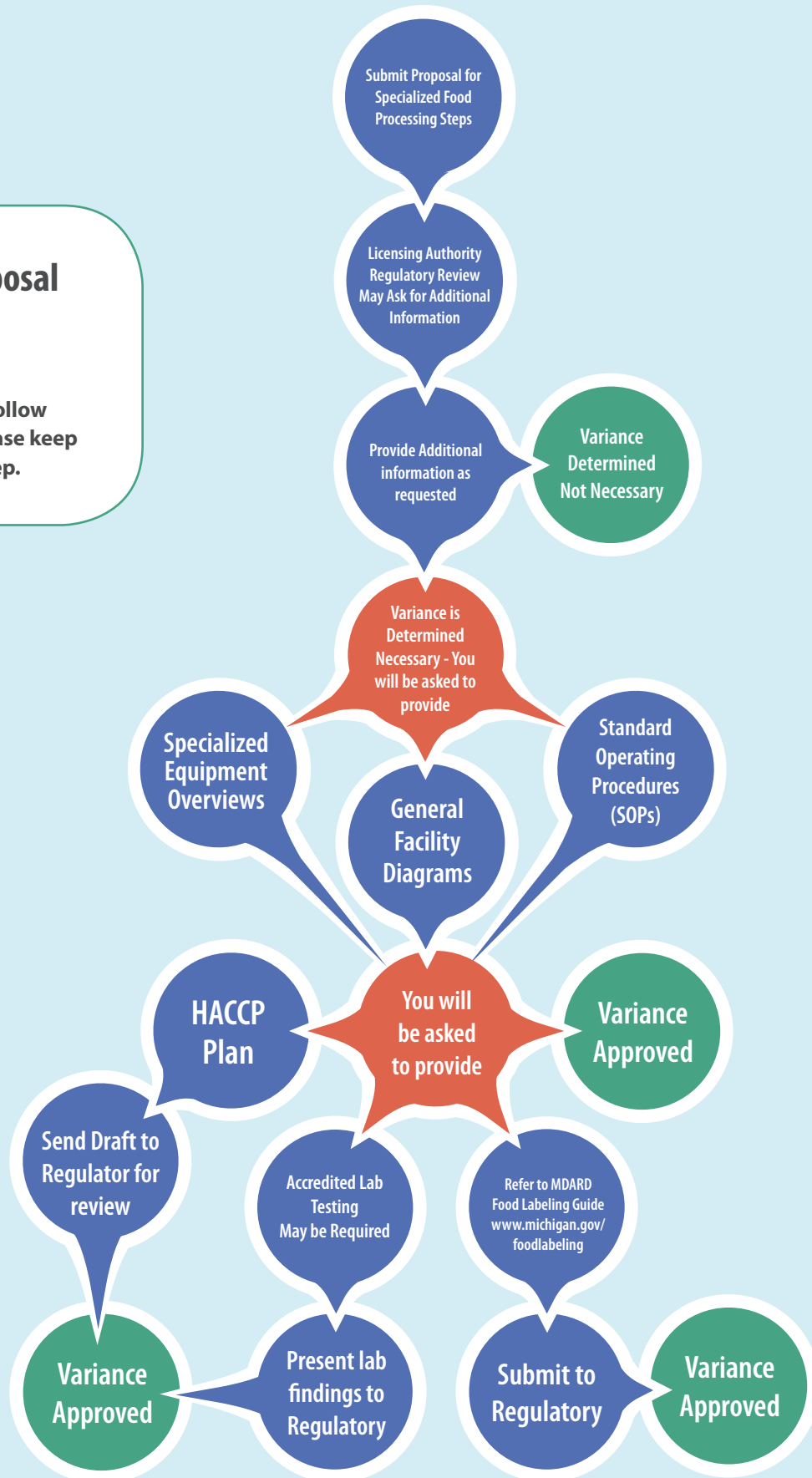
Withdrawing Approved Variances

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.

Variance Proposal Flow Chart

Please note not all applications may follow entire process, please keep copies for every step.





Proposal for Specialized Food Processing

General Information

Company

Name: _____

Address: _____ City: _____ Zip: _____

Contact Person (if different than above)

Name: _____

Title: _____ Email: _____

Mailing Address: _____

City: _____ Zip: _____

Food Establishment License Number: _____

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/ Recipe

Recipe Name: _____

Establishment: _____

Yield / Portion Size: _____

Ingredients

Item:	Amount:	Supplier / Source:
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____
_____	_____	_____

Procedures

Procedures must include cook temperatures and equipment used
This procedures document should be written so that the regulator could duplicate the recipe

Process Step	Who <i>(line cook, chef, prep cook)</i>	How	Temp	Time	Specialized Equipment <i>Examples: vacuum packer, immersion circulator, pressure cooker, smoker, blast cooler, crock</i>
Prep	_____	_____	_____	_____	_____
Process	_____	_____	_____	_____	_____
Cook	_____	_____	_____	_____	_____
Hold	_____	_____	_____	_____	_____
Served	_____	_____	_____	_____	_____
Storage / Package / Shelf-life	_____	_____	_____	_____	_____

Please review and select all that apply

- Method of Use/ Sale
 - In house use or service
 - Packaged for retail sale
 - E-commerce
 - Packaged for sale to other companies (wholesale/ distribution)

***Note: Processed meats, juice, and seafood products have additional regulatory requirements for wholesale – please discuss with your regulatory authority before proceeding.*

This information is commercial confidential trade secret and is not authorized for distribution

SUBMIT THE COMPLETED FORM TO YOUR HEALTH INSPECTOR. THEY WILL CONTACT YOU WITH FORMAL APPROVAL OR REQUEST ADDITIONAL INFORMATION.

DO NOT MAKE ANY MATERIAL PURCHASES OR CHANGES TO YOUR FACILITY WITHOUT RESPONSE FROM YOUR REGULATOR.

SAVE THIS DOCUMENT

THE COMPLETED PROPOSAL WILL BE RE-SUBMITTED AGAIN AS YOUR APPLICATION.

THIS COMPLETED DOCUMENT WILL BE REQUIRED THROUGHOUT THE PROCESS.

THE LOCAL HEALTH DEPARTMENT WILL SEND YOU THIS FORM WITH THE NECESSARY BOXES CHECKED.

Your recipe and process require a variance. Please provide documentation for ALL items that are checked and return to your regulator.

Variance Application – complete and submit enclosed variance application

Standard Operating Procedures SOP's

- 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 (not time and temperature) as a method to control bacterial growth
- thawing
- cooking
- potentially hazardous food
- cooling
- reheating
- hot holding
- cold holding
- supervisor and food employee training plan
- other _____, _____, _____

You should have SOP's as they are required in your plan review process.

General SOP's guidance

<http://www.michigan.gov/mdardplanreview>

You may download the state approved SOP builder for assistant <http://www.michigan.gov/mdard/>

General Facility and Specialized Equipment Overview

- provide a detailed floor plan of processing area and entire facility, including all equipment (must be drawn to scale)
- indicate what other food processes and activities that are happening at the same time in the same place
- attach a list of all equipment that will be used to prepare food item with manufacturer's specification sheet
- if any equipment requires calibration, include policy for calibration
- indicate details of water supply and wastewater supply facility

Provide a HACCP plan (additional instruction form) Accredited Commercial Lab Analytical Test

Results for Validation

- shelf life study and determination
- pH identification for non-TCS
- water activity for identification of non-TCS
- percent salt
- process authority documentation
- Microbial Challenge Study (NACMCF)

Please see the resource page of a list of process authorities and food testing labs

Labeling

- 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 and date codes

Refer to MDARD Food Labeling Guide at

https://www.michigan.gov/documents/mda/MDA_LBLGUIDE

******Note: Processed meats, juice and seafood products have additional regulatory requirements**

For wholesale – please discuss with your regulatory authority before proceeding

Terminology Guide

1-2

Acid food

- foods that have a natural pH of 4.6 or less

Acidified Foods

- means low-acid foods to which acid(s) or acid food(s) are added, they have higher water activity (A_w) than 0.85 and have a finished equilibrium pH of 4.6 or below

Low Acid Food

- any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (A_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods

Bottling

- see canning

Canning

- placing food in an air tight container to make food shelf stable (jars, bottles, cans, pouches)

Ceviche

- fish and shell fish marinated in lime juice and spices
- non-cooking method of preparing seafood by acidification; Journal of Food Protection, Vol. 71, No. 6, 2008, Pages 1287-1308

Charcuterie

- sausages, hams, pates, and other cooked or processed meat foods

Cook Chill (see ROP)

- cooked food is hot filled into impermeable bags which have the air expelled and are then sealed or crimped closed. The bagged food is rapidly chilled and refrigerated at temperatures that inhibit the growth of psychotropic pathogens

Curing

- meat and poultry are cured by the addition of salt alone or in combination with one or more ingredients such as sodium nitrate, sugar, curing accelerators, and spices.

These are used for partial preservation, flavoring, color enhancement, tenderizing and improving yield of meat. The process may include dry curing, immersion curing, direct addition or injection of the curing ingredients

Fermentation (Kombucha/ Sauerkraut / Kimchi / Yogurts)

- the use of yeast and or/bacteria, naturally occurring or added, to convert sugars into acid, gasses or alcohol

Hermetically Sealed-Container

- a container that is designed and intended to be secure against the entry of the microorganisms and in the case of low acid canned foods, to maintain the commercial sterility of its contents after processing

Highly Susceptible Population

- Persons who are more likely than other people in the general population to experience foodborne disease because they are
 - Immunocompromised; pre-school age children, or older adults
 - Obtaining food at a facility that provides services such as custodial care, health care, or assisted living, such as child or adult day care center, kidney dialysis

Infused beverages

- to allow something (i.e. fruits vegetables) to stay in liquid in order to flavor the liquid

Non-Continuous Cooking

- the cooking of the food in a food establishment using a process in which the initial heating of the food is intentionally halted so that it may be cooled and held for complete cooking at a later time prior to sale or service
- "non- continuous cooking" does not include cooking procedures that only involve temporarily interrupting or slowing an otherwise continuous process

Pasteurization

- a heat process that will kill or inactivate bacteria and other harmful microorganisms likely to be in time/temperature control for safety foods

Terminology Guide

2-2

Perishable

- foods that are likely to spoil, decay or become unsafe to consume if not kept refrigerated at 41°F (4.4°C) or below frozen at 0°F (-17.8°C) or below
- any food that the manufacturer, packer or retailer, in conjunction with the department, determines to have a significant risk of spoilage, loss of value or loss of palatability within 90 days of the date of packaging

Pickling

- the process of preserving or flavoring fish, meat or vegetable using liquid, usually prepared with salt or vinegar
- immediate use (up to 7 days)
- salt brine (beyond 7 days)

Preservations

- the process of treating and handling food to stop or slow down spoilage (loss of quality, edibility or nutritional value) and thus allow for longer storage

ROP: Reduced Oxygen Package

- the reduction of the amount of oxygen in a package by removing oxygen; displacing oxygen and replacing it with another gas or combination of gases; or otherwise controlling the oxygen content to a level below that normally found in the atmosphere (approximately 21%)
- includes: vacuum packaging; modified atmosphere packaging; controlled atmosphere packaging; cook chill packaging; sous vide packaging

Shelf stable

- products that do not spoil under ordinary unrefrigerated temperature and humidity conditions, if the package integrity is maintained. These products are free of microorganisms capable of growing in or on the product at unrefrigerated conditions (over 50°F) at which the product is intended to be held during distribution and storage.

Smoking

- hot smoke: slowing cooking food indirectly over a fire, can be done using a "smoker" which is a cooker specifically designed for the purpose
- cold smoke: application of cool smoke to a food for culinary effect

Sous Vide

- raw or partially cooked food is placed in a vacuum packaged or an impermeable bag, cooked in the bag, rapidly chilled and refrigerated at temperatures that inhibit the growth of pathogens

TCS (Time/Temperature Control for Food Safety)

- a food that requires time/temperature control for safety (TCS) to limit pathogenic microorganism growth or toxin formation
- includes: (a) an animal food that is raw or heat-treated; a plant food that is heat-treated or consists of raw seed sprouts, cut melons, cut leafy greens, cut tomatoes or mixtures of cut tomatoes that are not modified in a way that they are unable to support pathogenic microorganism growth or toxin formation, or garlic-in-oil mixtures that are not modified in a way so that they are unable to support pathogenic microorganism growth of toxin formation

Thermally processed

- CFR113 commercial technique used to sterilize food through the use of high temperatures

Variance

- a written document issued by the regulatory authority that authorizes a modification or waiver of one or more requirements of this Code, if the opinion of the regulatory authority, a health hazard or nuisance will not result from the modification or waiver
- salt brine (beyond 7 days)

Resources:

Food Processing Authorities/Services

- <http://www.afdo.org/foodprocessing>
- http://productcenter.msu.edu/venture_development_services/label_design_nutrition_labeling

Food testing labs

- <http://www.summitlaboratory.com/contact-us/>
- <http://www.bioreserchsol.com/>
- <http://www.michfpa.org/suppliers>

HACCP Assistance

- <http://glfoodprotect.com/haccp-training/>
- http://michiganfoodsafety.com/docs/HACCP_Plan_Basics.pdf

Standard Operating Procedures SOP's

General SOP's guidance

- <http://www.michigan.gov/mdardplanreview>

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