

FOOD PROCESSING: GUIDANCE FOR RHODE ISLAND STATE AND FEDERAL REGULATORY REQUIREMENTS

WHERE SHOULD YOU BEGIN?

If either of the following statements applies to your processing operation, see the corresponding links for regulatory guidance. If neither option describes your processing operation, proceed to “DEVELOP AN OPERATIONAL PLAN.”

- **If you are a farm home food manufacturer:**
 - See the *Farm Home Food Manufacture License* link for RI State requirements www.health.ri.gov/applications/FoodFarmHomeManufacturer.pdf
- **If you are processing food in a retail kitchen/commissary for sale at the retail market associated with the kitchen/commissary:**
 - See the *Food Code* [R23-1, 21-27-FOOD] for applicable RI State regulations <http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/6992.pdf>
 - You will need a Food Processor Retail License www.health.ri.gov/applications/FoodProcessorRetailWholesale.pdf

DEVELOP AN OPERATIONAL PLAN

Contact the Rhode Island Department of Health (RIDOH), Office of Food Protection to involve them, *from the beginning*, in your food processing venture. To get started, develop an operational plan that includes specific details about the product you plan to process, e.g. your contact information, what product you plan to make, where you plan to process the product, a flow diagram or list of steps outlining the production process, where you plan to sell your product, etc.). This detailed plan will promote the most efficient communication between your business and the RIDOH Office of Food Protection. Note: if you plan to sell your product out-of-state, Federal laws will have to be addressed. *Use the following questions as guidance to detail your process.*

1. What product are you making?
 - a. What is your recipe (i.e. list the ingredients and amounts)?
 - b. What are your processing steps?
 - i. Include where your raw ingredients are purchased from, and how and where will they be stored.
 - ii. Include where your packaging materials are purchased, and how and where they will be stored.
 - iii. Include an outline of the processing procedures (i.e. list the ingredients and equipment used at each processing step).
 1. Foods preserved by smoking, drying, acidifying, curing, fermenting, canning, and reduced oxygen packaging may have additional requirements for safety, per the RIDOH Office of Food Protection.

- iv. Include how the product will be packaged and labeled.
 - 1. You will need to fill out and submit a *Food Label Approval Form*
 - 2. You will need to include a copy of the product label.
 - 3. There are Federal labeling requirements that must be adhered to. For more information:
 - a. www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm
 - b. www.fsis.usda.gov/labels
 - v. Include how and where the product will be stored.
 - 1. Is your product shelf stable? Shelf stable foods do not need time/temperature control for food safety. Some examples could be food with $A_w < 0.85$ or acidified foods with a $pH < 4.6$ with proper thermal processing. Otherwise the interaction of A_w , pH and/or heat processing will have to be considered and evaluated by a Process Authority. All shelf stable foods should be assessed by a Process Authority to ensure food safety parameters are correct (see page 9 for information regarding Process Authority).
 - 2. Is your product a food that requires temperature control for safety (i.e. a potentially hazardous food)?
 - a. If yes, how will you maintain temperature control?
2. Where are you processing the product?
- a. Is your processing facility going to be newly constructed or will an existing facility undergo renovations? **DO NOT BEGIN CONSTRUCTION UNTIL PLANS ARE REVIEWED AND APPROVED BY RIDOH OFFICE OF FOOD PROTECTION AND THE CITY or TOWN!**
 - i. For newly constructed establishments, make sure to have the appropriate approvals and permits prior to seeking licensing, as outlined at: www.health.ri.gov/food/for/newfoodeestablishments
 - ii. For both new construction and renovated facilities, you must fill out and submit an *Application for Construction*: This is a facility plan review and is available at: www.health.ri.gov/applications/FoodEstablishmentNewConstruction.pdf
 - b. What facility are you using to process your product?
 - i. Are you using an incubator kitchen?
 - 1. If yes, you will need to provide the RIDOH, Office of Food Protection with:
 - a. A copy of the lease agreement.
 - b. The name and address of the facility.
 - ii. Are you using a shared-use/commissary licensed kitchen?
 - 1. If yes, you will need to provide the RIDOH, Office of Food Protection with:
 - a. A letter detailing the operational agreement.
 - b. The name and address of the facility.
 - iii. Are you using a co-packer?
 - 1. If yes and they are located in-state, you will need to provide the RIDOH, Office of Food Protection with the name and address of the facility.

- iv. Are you using an existing retail establishment to do your processing?
 1. If yes, you will need to provide the RIDOH, Office of Food Protection with:
 - a. The name and address of the facility.
 - b. If you do not own the facility, you need to provide a letter detailing the operational agreement, include the hours of operation.
 - v. Are you using an existing, licensed processing facility?
 1. If yes, you will need to provide the RIDOH, Office of Food Protection with:
 - a. The name and address of the facility.
 - b. If you do not own the facility, you need to provide a letter detailing the operational agreement, include the hours of operation.
3. Who are you selling the product to?
- a. Will the product be sold in-state?
 - b. Will the product be sold out-of-state?
 - c. Will your product be sold directly to consumer?
 - d. Will your product be sold to a wholesale distributor?

**RIDOH OFFICE OF FOOD PROTECTION:
FOOD BUSINESS LICENSES FOR PRODUCTION AND SALE**
www.health.ri.gov/licensing/food/

- **Food Processors and Distributors: Wholesale and Retail.** This license applies to food processors manufacturing baked goods, processors of seafood, meat/poultry, cheese, and miscellaneous food items, as well as processors repacking products.
www.health.ri.gov/applications/FoodProcessorRetailWholesale.pdf
 - Food Processor -Retail, In-State
 - Food Processor -Wholesale, In-State
 - Food Processor -Wholesale, Out of State
 - Food Distributor -In-State
 - Food Distributor - Out of State
- **Food Processor: Apple Cider**
www.health.ri.gov/applications/FoodProcessorBottlerAppleCider.pdf
- **Food Processor: Bottler, Canner**
www.health.ri.gov/applications/FoodBottlerCanner.pdf
- **Food Processor: Meat and Poultry**
www.health.ri.gov/applications/MeatPoultryProcessor.pdf
- **Farm Warehouse (Meat Products) License** allows farmers to take their animals to a USDA slaughter house and then to a licensed meat packing plant, where the meat must be packaged and frozen.
www.health.ri.gov/applications/FarmWarehouseMeatProducts.pdf

- **Shellfish Business** “Dealers License” for shipper, reshipper, repacker, shucker/packer
www.health.ri.gov/applications/ShellfishBusiness.pdf
- **Dairy Business Permit: Milk Producer** www.health.ri.gov/applications/DairyMilkProducer.pdf
- **Dairy Business Permit: Milk Processor**
www.health.ri.gov/applications/DairyMilkProcessorDistributor.pdf
- **Food Service Mobile License** allows for the sale of food by food truck operators.
www.health.ri.gov/applications/FoodMobileService.pdf
- **Retail Food Peddlers License** – Allows for the movement of product from an approved source (licensed retail or wholesale facility) for direct sale to the consumer at another site.
www.health.ri.gov/applications/FoodRetailPeddler.pdf

COMMODITY SPECIFIC REGULATIONS

- **Seafood and Shellfish**
 - Seafood HACCP Regulation - Procedures for the Safe and Sanitary Processing and Importing of Fish and Fishery Products
<https://federalregister.gov/a/95-30332>
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/6715.pdf>
 - *Required:* Training and HACCP Plans for Seafood and Shellfish
 - Seafood HACCP training
 - Seafood HACCP training
 - www.afdo.org/seafoodhaccp
 - www.seafood.nmfs.noaa.gov/training/HACCPtraining.html
 - University of Rhode Island
Food Safety Research and Education Program
Lori Pivarnik: 401-874-2972 or pivarnik@uri.edu
 - On-line training course with Segment 2 follow-up workshop:
<http://seafoodhaccp.cornell.edu/Intro/index.html>
 - Shellfish Dealers
 - 2013 Model Ordinance
www.fda.gov/downloads/Food/GuidanceRegulation/FederalStateFoodPrograms/UCM415522.pdf
- **Dairy**
 - Grade “A” Pasteurized Milk Ordinance (PMO)
[http://www.ncims.org/2013%20PMO-FINAL%20\(1\).pdf](http://www.ncims.org/2013%20PMO-FINAL%20(1).pdf)
- **Meat/Poultry**
 - Meat and Poultry HACCP Regulation - Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) Systems Final Rule
www.fsis.usda.gov/OPPDE/rdad/FRPubs/93-016F.pdf
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/6714.pdf>

- *Required:* Training and HACCP Plans
 - Meat and Poultry HACCP Training Programs
 - University of Connecticut
www.cag.uconn.edu/nutsci/nutsci/foodsafety/Food_Processing_landing_page/Processing_Meat_&_Poultry/HACCP.php
 - University of Maine
<http://umaine.edu/food-health/food-safety/>
 - Penn State
<http://extension.psu.edu/food/safety/courses/hazard-analysis-critical-control-point-haccp-for-meat-and-poultry-processors>
 - International HACCP Alliance
www.haccpalliance.org/sub/index.html
- Mobile Processing Units are licensed on a case by case basis. Requirements include:
 - An approved water source
 - A Food Processor License
www.health.ri.gov/applications/FoodProcessorRetailWholesale.pdf
 - Either a Retail Food Peddlers License or a Food Service Mobile License
 - www.health.ri.gov/applications/FoodMobileService.pdf
 - www.health.ri.gov/applications/FoodRetailPeddler.pdf
- **Juice**
 - Juice HACCP Regulation – Procedures for the Safe and Sanitary Processing and Importing of Juice
<https://federalregister.gov/a/01-1291>
 - If selling wholesale, juice must be processed under a HACCP program, which includes attending Juice HACCP training.
 - If selling directly to consumers, a Juice HACCP program and pasteurization per regulation is recommended for safety. If not, a consumer advisory regarding the pathogen risk is required.
 - *Required:* Training and HACCP Plans
 - Cornell Juice HACCP Training Program
<https://foodscience.cals.cornell.edu/extension/fruits-vegetables-cider-juice/juice-haccp-certification-course>
 - University of Florida Juice HACCP Training Program
www.crec.ifas.ufl.edu/extension/workshops/registration.shtml
- **Some food preservation processes may have state processing requirements.** *Examples include foods preserved by smoking, drying, acidifying, curing, fermenting, canning, and other reduced oxygen packaging.*
 - Talk to the Office of Food Protection. These products may require a Process Authority review and approve the process.

OTHER FOOD SAFETY CONSIDERATIONS:

- Do you have a “cleaning and sanitation” protocol?
See resource list below – GMPs and Sanitation; Food Code
- Do you know what food allergens are and how to prevent cross contact?
See resource list below – Food Allergens; GMPs and Sanitation; Food Code
- Do you have a recall plan (e.g. maintaining a list of customers and suppliers in case of a recall)?
See resource list below – Recalls and Traceback
- Do you have adequate insurance?
See resource list below - Insurance for Food Entrepreneurs

RESOURCES:

Good Manufacturing Practices (GMPs) and Sanitation

- Rules and Regulations Pertaining to Current Good Manufacturing Practices in Manufacturing Packing or Holding Human Food [R21.27; 21-31; 23-1- GMP]
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/6714.pdf>
- Basic Elements of a Sanitation Program for Food Processing and Food Handling
<https://edis.ifas.ufl.edu/fs076>
- Basic Elements of Equipment Cleaning and Sanitizing in Food Processing and Handling Operations
<https://edis.ifas.ufl.edu/fs077>

Food Code

- Food Code
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/4885.pdf>

Food Labeling

- 21 CFR 101- Food Labeling
www.gpo.gov/fdsys/pkg/CFR-2008-title21-vol2/xml/CFR-2008-title21-vol2-part101.xml
- FDA Food Labeling Guidance:
www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/LabelingNutrition/ucm2006828.htm
- USDA FSIS Labeling Guidance:
www.fsis.usda.gov/labels

Meat and Poultry

- USDA FSIS Compliance Guides Index for Meat and Poultry HACCP
www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/compliance-guides-index#HACCP

- Information Specifically for Small and Very Small Plant Owners/Operators
www.fsis.usda.gov/wps/portal/fsis/topics/regulatory-compliance/haccp/small-and-very-small-plant-outreach
- UCONN Meat and Poultry HACCP Resource List
www.cag.uconn.edu/nutsci/nutsci/foodsafety/Food_Processing_landing_page/Processing_Meat_&_Poultry/HACCP.php

Juice

- FDA Juice HACCP Resources
www.fda.gov/Food/GuidanceRegulation/HACCP/ucm2006803.htm

Seafood

- Fish and Fishery Products Hazards and Controls Guidance - 4th Edition, April 2011:
www.fda.gov/downloads/Food/GuidanceRegulation/UCM251970.pdf
- Rules and Regulations Prescribing Minimum Standards for Processing, Storage, and Transportation of Fish and Fishery Products [R21.27; 21-31; 23-1- FFP]
<http://sos.ri.gov/documents/archives/regdocs/released/pdf/DOH/6715.pdf>
- RIDOH Office of Food Protection Shellfish Program
www.health.ri.gov/programs/shellfish/

Food Allergens

- Food Allergy Research and Resource Program - Components of an Effective Allergen Control Plan: A Framework for Food Processors
<https://farrp.unl.edu/allergencontrolfi>
- Food Allergy Research and Education – Resources for Food Manufacturers
www.foodallergy.org/resources/food-manufacturers
- Rhode Island Food Allergy Awareness in Restaurants
<http://webserver.rilin.state.ri.us/publiclaws12/law12408.htm>

Recalls and Traceback

- FDA Guidance for Industry: Product Recalls, Including Removals and Corrections
www.fda.gov/Safety/Recalls/IndustryGuidance/ucm129259.htm
- Developing a Recall Plan (North Carolina State University)
http://fbns.ncsu.edu/extension_program/publications.html#acidifiedfoods

Product Monitoring

- Choosing and Using a pH Meter for Food Products
<http://pods.dasnr.okstate.edu/docushare/dsweb/Get/Document-988/FAPC-117web.pdf>

Food Processing

- **Acid and Acidified Foods**
 - Guidance for Commercial Processors of Acidified & Low-Acid Canned Foods
www.fda.gov/Food/GuidanceRegulation/GuidanceDocumentsRegulatoryInformation/AcidifiedLACF/default.htm
 - Fruit Jellies: Food Processing for Entrepreneur Series (University of Nebraska-Lincoln Extension)

- <http://ianrpubs.unl.edu/live/g1604/build/g1604.pdf>
 - Formulating Dressings, Sauces, and Marinades (North Carolina State University)
http://fbns.ncsu.edu/extension_program/documents/acidified_formulating_dressings.pdf
 - Processing Acid and Acidified Foods
http://aggie-horticulture.tamu.edu/food-technology/files/2012/03/ncsu-edu_foodscience_extension_program_documents_acid_acidified_foods.pdf
- **Food Safety**
 - Considerations for Developing a HACCP Plan for Acidified Foods
http://fbns.ncsu.edu/extension_program/documents/acidified_haccp_considerations.pdf
 - Scheduled Processes
http://fbns.ncsu.edu/extension_program/documents/entreprenerus_scheduled_processes.pdf
- **Refrigerated Foods**
 - Refrigerated Foods: Some Rules for Processing
http://fbns.ncsu.edu/extension_program/documents/entrepreneurs_refrigerated_food_rules.pdf
 - Extended Shelf-Life Refrigerated Foods
http://fbns.ncsu.edu/extension_program/documents/foodsafety_extended_shelflife.pdf
- **Insurance for Food Entrepreneurs**
<http://extension.psu.edu/food/entrepreneurs/starting-a-business/insurance>

PROCESS AUTHORITY

- **What is a Process Authority?**

The FDA requires that scheduled processes for preservation including smoking, curing, acidifying, fermenting, brining, and any other method used to eliminate the need for time/temperature control (make shelf stable) must be established by a qualified "Process Authority." A qualified Process Authority is a person(s) or organization(s) having expert knowledge, acquired through appropriate training and experience, of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions. The Process Authority must validate the process, safety of the product, and the adequacy of the HACCP plan.

- **When do you need a Process Authority?**

If you manufacture a food that is rendered shelf-stable after being subjected to a special process (see above), you need a Process Authority to conduct a process and product review and approve it.

- **Who is a Process Authority?**

Northeast Center for Food Entrepreneurship at the NY State Food Venture Center

Phone: 315-787-2273

Email: necfe@nysaes.cornell.edu

New York State Food Venture Center

Cornell University/NYSAES

Food Research Lab

630 W. North Street

Geneva, NY 14456

Rutgers Food Innovation Center

Phone: (856) 459-1900

Email: foodinnovation@aesop.rutgers.edu

450 East Broad Street (Rt 49)

Bridgeton, NJ 08302

University of Maine Pilot Plant

Phone: 207-581-3139

Email: pilotplant@maine.edu

www.foodsciencehumannutrition.umaine.edu/food-technology/process-and-product-reviews

**FOOD TESTING LABORATORIES:
RHODE ISLAND/MASSACHUSETTS/CONNECTICUT**

RHODE ISLAND

Food and Beverage Consultant (FABCO)

Dr. Dimitri Kazantzis

Tel: 401-463-5784 Product development and computer generated nutritional facts.

MASSACHUSETTS

Advanced Food Testing laboratories

31-B Foodmart Rd.

Boston, MA 02118

Tel: 617-269-6424

Fax: 617-268-1635

Analytical Testing Laboratories

345 Trapelo Rd.

Belmont, MA

Tel: 617-484-7400

Biomarine Laboratories

16 East Main Street

Gloucester, MA

Tel: 978-281-0222

Fax: 978-283-6296

Food Research Laboratories

130 Newmarket Square #3

Boston, MA

Tel: 617-442-3322

G and L Laboratories

246 Arlington Street

Quincey, MA 02170

Tel: 617-328-3663

Krueger Food Laboratories

21 Alpha Rd. #D

Chelmsford, MA 01824

Tel: 978-256-1220

Fax: 978-256-1222

Lapuck Laboratories

70 Shawmut Road #6
Canton, MA 02021
Tel: 781-401-9999

Microbac

100 Barber Ave.
Worcester, MA 01606
Tel: 508-595-0010

UL (formerly Shuster Food Laboratories)

85 John Road
Canton MA 02021
Tel: 781-821-2200
Fax: 781-821-9266

Vallid Labs Inc.

295 Silver St.
Agawam, MA 01001
Tel: 413.789.2206
Fax: 413.789.2208

CONNECTICUT

Alliant Food Safety Labs

1055 Farmington Ave.
Farmington CT 06032
Tel: 860-269-7248

Vallid Labs Inc.

608 Thompsonville Rd.
Suffield, CT 06078
Tel: 860-668-4330

Northeast Labs

129 Mill Street
Berlin CT 06037
Tel: 860-828-9787 or 800-826-0105
outside CT 800-654-1230
Fax: 860-829-1050

KB Analytical LLC

249 Boston Post Road
East Lyme CT 06333
Tel: 860-739-4080

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