# Introduction to Starting a Small Food Business for Food Entrepreneurs

# Food Business Guide

- Introduction
- Groundwork for Business Success
  - Vison
  - Planning
  - Business Plan
- Planning Product and Production
  - Food Safety Plan
  - Development
  - HACCP
  - FSMA
- Production
  - Package and Label
  - Quality Assurance
  - Paperwork
- Additonal Resources

# Table of Contents

## Introduction

Do you have an idea for a new food product and want to start a business to make and sell it?

This guide intends to outline important considerations a Massachusetts food business owner must consider as they take a food product idea to market.

This guide is food safety focused and intended for food products sold on store shelves (retail and wholesale products) not for food trucks, restaurants, food stands, and bakeries. *Food Service* businesses such as those listed above should consult the Massachusetts MDPH retail food page.

The University of Massachusetts Extension office serves the commonwealth by providing

- Short course trainings related to food science
- Food Science research support
- Access to the Pilot Plant for research and development

The Pilot Plant at the flagship campus in Amherst, Massachusetts holds a number of specialized industrial equipment pieces to conduct research that may assist businesses in their product or process development.

There are many elements to starting a food business. Among these elements are a number of regulations and governing agencies aiming to protect consumers and businesses alike.

Bite by bite, this website will help guide you and your enterprise to success. Before you start committing time, effort and money into this venture it is *highly recommended* that you take a moment to gage the road ahead. Think and thoroughly consider what you want to happen and how you will get there. Writing down your goals and define your expectations for your business.

This guide can be downloaded in the Additional Resources section below.

# Groundwork for Business Success

## Vision… and Revision

Before starting any in-depth analysis or research take half of an hour to inventory your idea and your current expectations for your product:

- Describe your product as it might entice a consumer.
  What sets it apart from other products of the same type?
- Where do you see this product being sold? What need is it satisfying for your audience?
- Describe your product as you would see it as a consumer on the shelf.
  What packaging is there? What does the label say?

Having a clear vision for your product will help you better seek and advocate for the resources you need to make it happen. Moving forward, it is likely that you will have to adapt your vision of your product to food safety regulation and business feasibility.

## Preparing for the Road Ahead

Owning your own business is a thrilling enterprise. You are your own boss and can join many others taking pride in the goods they market. Before taking the next step into entrepreneurship consider the following:

**Business Development:** Successfully growing a food product from an idea to a sellable item and then into a brand involves making informed choices about goals and parameters for the business itself. **Such choices require thought and planning.**

- *Business Plan* - Writing a business plan-a document detailing the human, financial, and ideological organization of the entity- can seem to be a large undertaking but clear goals guide you in the right direction, and will help define your business in the eyes of a regulatory agency.
- *What is the business goal*? – Is this a business you are hoping to build and sell once it gets big or something you plan to invest in until your retirement? Some of these decisions will influence how you will invest for your product development.
- *Understand the business*: There are several business considerations that should be accounted for before, during and after the product development. Often times, the product development will need to be adjusted based on business shifts. Examples include: formula costs, product claim deliverables, shelf life expectations, etc.

There are resources available to help new business through this process, such as
Small Business Association- Starting a Business.
Franklin County Community Development Corporation Tools and Resources for Business Planning

**Expenses**: There are a variety of expenses associated with a food product and it is important to be mindful of these finances from the beginning of your product development. Some examples include:

- *Labor* – There will be many hours invested in sorting out the technical and business logistics.
- *Product* – Ingredient costs, packaging costs (primary and secondary)
- *Operation* – Equipment investments or equipment rental fees, processing yield lost during production, processing parameters, storage fees for ingredients, distribution costs (i.e. frozen trucks are significantly more costly than ambient trucks), insurance.

**Product Development**: The primary goal of a new food product is to deliver a delicious product that satisfies a consumer need. In addition, it needs to be compliant to the regulatory policies and safe for consumers to eat.

- *Regulation* - Be sure to you research which federal governing agency your product will follow (i.e. USDA vs FDA). In addition, it is important to understand what regulatory requirements your product will need to follow. Note: Different processed foods have different regulatory requirements.
- *Safety* – Foods need to be prepared to ensure that they are free from microbial, chemical and physical health.

## Business Plan

With goals and expectations in hand, a Business plan is the written document detailing how those goals will be achieved.

The U.S. Small Business Association (SBA) aims to assist small businesses through access to capital and developmental resources. They define a business plan as “an essential roadmap for business success. This living document generally projects 3-5 years ahead and outlines the route a company intends to take to grow revenues.” (SBA.gov)

### Narrative

- An executive summary of your business
- Description of your company and product- including what state and federal licensure may be required on both the business and food safety ends
- Organization of the business- leadership division/structure
- Analysis of Market
- Plan of Production, Distribution
- Marketing Plan
- Financial Plan
- Sales estimates including all assumptions
- Additional Needs or Costs for your business- Loans, Insurance, Taxes,

Remember, your business plan is a living document; continually update it as your business grows.
More details about business planning, marketing resources and food production resources can be found at:

- Small Business Association: Writing a Business Plan
- MDAR Food Processors Resource Manual
- Massachusetts Small Business Development Center Network
- UMASS Libraries Business Research Guide

## Market Analysis

Before you plan details of how you will create your product, it is advisable that you first verify that your product concept is viable on today's market:

Is it worth the effort?

- Do people want to buy it
- Will they pay the price it will cost to make it?

To answer this question, conduct an **Analysis of Market Potential**.

Such analysis may start as a simple trip to several grocery stores and specialty markets. Find existing products that are similar to your concept and see how much they cost, review the ingredient statements, observe the product claims and flavors offered. Follow up by asking those around you how much they would pay for your product.

Determining the optimal price point that accounts for the competitive space, consumers' willingness to spend and will help cover your final costs will be a balancing act. Understanding the product price point will help with determining the budget parameters including margins, slotting fees, formula, overall quality of product, and packaging costs. A niche for your product will assist making some of these choices.

A more sophisticated analysis can be conducted using consumer insight databases. Databases can provide information that can guide how you market or develop your product. Including:

- Market Share
- Target Consumer Profiles
- Current Trends

There are many to choose from, all slightly different. Food Science Extension recommends thorough business planning and does not endorse any specific or particular database. The following is a non-exhaustive list:

- Product Launch Analytics
- Mintel Oxygen and Mintel Food and Drink
- MarketResearch.com
- IBIS World Industry Reports

Some require a fee for use, but note that often academic institutional libraries may have subscriptions for their cardholders. These reports are free from the UMass Business Library.

The UMass Amherst Library is open to the public and invites public use of its collection and services. All Massachusetts residents are granted full book-borrowing privileges at the UMass Library. Most of the Library's collections of over 400 subscription databases are available to the public on a walk-in basis. This includes many business research databases, such as those listed above.

For more information on Market Analysis

- Small Business Association's Market Analysis page
- UMASS Library Community Resources Guide
- UMASS Library Entrepreneur Research Page
- FCCDC- Business Counseling

## Financial Planning

As touched on in the previous section the financials set a business apart from a hobby. Ultimately you strive to break even and then make a profit, but to start requires an input of money- this is called capital.

Funding can be found in various ways with various degrees of success:

- Personal Savings
- Family Loans
- Bank Loans
- Investors
- SBA- Loans
- Business Loans or microloans from small business incubators, towns- FCCDC,
- Crowd Funding websites (kickstarter, indiegogo,)

No matter your vehicle or combination of vehicles, getting the money to start your business off right is challenging. This guide does not intend to exhaust and explain all options and avenues; a financial advisor or even a small business counselor will give you advice best tailored to your business and financial needs.

Information about obtaining loans, filing and understanding self-employed taxes, and choosing a Liability Insurance option is beyond the expertise of this guide. Learn more about them at the following:

- Small Business Association- Filing Taxes
- Small Business Association- Loans
- Franklin County Community Development Corporation- Risk Management
- Franklin County Community Development Corporation- Business planning

## Business Classification

The legal and administrative organization of your business is key to its success –how it is managed, what regulations apply? To support drafting this portion of your business plan, it will be advantageous to consult a lawyer early on. To familiarize yourself with the health department classifications continue reading.

The degree of connection your business has with the end consumer influences what local, state, or federal licensure you may have to apply for and which levels of Health Department (Local, State, and Federal) will inspect your production facility.

License names vary by town, check with your town to determine which town license may be required.

Figure 1 organizes the differences between the two classifications of business- Retail and Wholesale.

| Wholesale Food Business | Retail Food Business |
|---|---|
| •Sells product to other businesses<br>•Inspected & Liscenced by MDPH Food Procteion Program<br>•Observe 105 CMR 500.000<br>•Businesses include:<br>•Milk Pasteurization<br>•Dairy Products<br>•Seafood<br>•**Food Processing** (including Meat and Poultry)<br>•Food Warehouses<br>•Food Distribution Centers<br>•***Wholesale*** Residential Kitchens<br>•Bottled Water<br>•Carbonated Beverages | •Sells Directly to Consumer as primary funciton<br>•Inspected & Liscenced by Local (or County) Board of Health<br>• Observe 105 CMR 590.000<br>•Businesses Include:<br>•Farmer's Market Vendors that sell food products and processed foods (Market Vendors that sell Fresh Produce, Unprocessed Honey, Maple Syrup and Fresh eggs do not need a Retail Food Permit from Local Board of Health)<br>•***Retail*** Residential Kitchens<br>•Restaurants<br>•Mobile Food Units<br>•Food Stores<br>•Catering<br>•Temporary Food Operations |

**Figure 1- Wholesale vs. Retail Food Business Chart-**
Adapted from the MDPH FPP: Starting a Wholesale Food Business Brochure

## *Wholesale Food Business*

In the state of Massachusetts, a **wholesale food business** is one which sells food products, but not directly to the consumer. This applies to businesses that might sell to a specialty food store or boutique. As such, a wholesale food business must have a license to operate from the Department of Public Health's Food Protection Program.

Your business will be considered wholesale and will need to apply for a Wholesale Food Business license if any of the following apply:

- ❑ You operate out of a Residential Kitchen, but do not sell directly to consumer ( A Wholesale Residential Kitchen)
- ❑ You process food in any way
- ❑ You contract with a Co-Packer (your business is considered a distributor)
- ❑ Milk Pasteurization
- ❑ Dairy Products
- ❑ Seafood (including transport)
- ❑ Food Warehouses
- ❑ Food Distribution Centers
- ❑ Bottled Water
- ❑ Carbonated Beverages

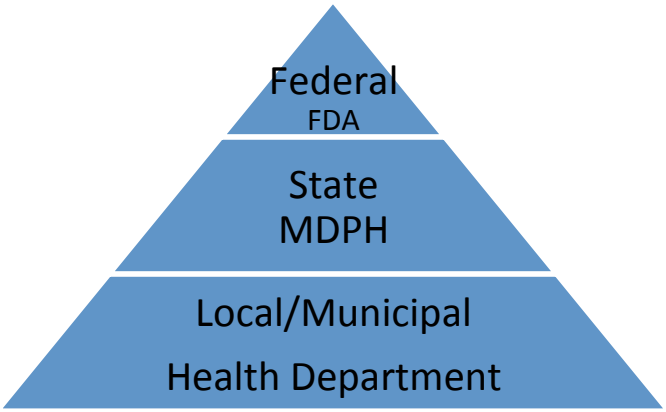
The application for a Wholesale food Business can be found on the Massachusetts Department of Health page. One license per business- per place of production. There is a $300 dollar licensing fee to register each facility.

Activities requiring a wholesale license include:

- Food Packing and Repacking
- Wholesale Residential Kitchen
- Distribution at Wholesale
- Cold Storage

### *Retail Food Business*

If you will be selling directly to the consumer, your business is classified as a **Retail Food Business**. This may be the case if you are selling at a Farmers market, or you rent a booth inside a specialty food store. You will be licensed as a Retail Food Establishment by a local or municipal Health Department. General regulations can be found on MDPH Retail Food Page.




Example:

Paula's Pasta makes dry pasta sold to Culinary Boutiques across the state. The business operates out of a Commercial Kitchen. Because this business does not sell directly to the Consumer, Paula's is considered Wholesale. As such, the business and facility ***must*** be registered and licensed by

1) *The State* as a Wholesale Food Business. With this designation it will be subject to inspection by the state Food Protection Program (FPP) before and during production. However, the business and facility ***must also be registered*** *with*
2) *The local* health department as a food establishment specifying that it is a wholesale food business.

The facility will be inspected by the Local Health department on a more frequent basis than by the FPP. If Paula's Pasta begins to sell over state lines or over the internet, the business must then register with the FDA as a food facility; at which point there will also be periodical FDA inspections.

Obtain both licenses so that you can diversify where you can sell your product. If your business sells to both directly and indirectly to the consumer- For example, the product is sold to specialty food stores but also at a farmer's market booth- you will need to apply for both classifications of license, but can sell to a wider audience. From there you can determine which market is more profitable.

## Other Certifications

### *Organic Certification*

Organic certification is recognition that the composition and production of your product meets standards set by the Federal Government. To ensure the integrity of products labeled as organic the term Organic is federally regulated. A product cannot be labeled as Organic or bear the "Certified Organic" seals without first passing through a third-party certifier. This certifier will review your product and process to ensure that it meets standards, namely that all prohibited materials were not used in production.

"Organic" can be a marketing tool by setting your product apart from others. Evaluate if it is worth the certification by visiting the links below.

USDA Guide for Organic Processors
7 CFR 205.000 National Organic Program
Northeast Organic Farming Association- offers one-on-one consultation and review of farm applications to certifier, can assist with state certification cost reimbursement program
Bay State Organic- Massachusetts Organic Certifiers

## Planning Product and Production

As you begin to develop your product for sale, remember customers trust that you are preparing a safe, quality food. Steps towards manufacturing a safe product must be taken at each part of the development stage all the way to the customer.

### Food Safety Plan

Throughout the production of food there are many points when the integrity and quality of the product can be jeopardized. There are several opportunities for food contamination, a smart operator anticipates these risks, identifies the food safety hazards and makes a Food Safety plan outlining the course of action to reduce and eliminate these risks.

Food Safety considerations should be assessed in 3 categories:

- ***Biological***- disease causing pathogens or organisms that promote spoilage
- ***Chemical***- excess ingredients or cleaning agents, allergens
- ***Physical***- broken glass, plastic particles, insects, metal filings

At every step in the development cycle, one can anticipate and work towards a safe product.

**Pre-Development:** Before you are even developing your product, try to orientate your food safety risks. A few considerations should include:

- Choose an appropriate production facility
- Choose an appropriate process for the intended product
- Anticipate Process and Formula Hurdles to use
- Observe set regulations and validation procedures

**Development:** On the development end there is an arsenal of techniques that a producer has to target biological contamination. This includes key formula hurdles such as:

- pH regulation- Many bacteria grow best in a relatively neutral pH environment. Adjusting the acidic character of the product through the addition of acid or by other means can prevent such bacteria from surviving in the food and potentially infecting consumers. University of Wisconsin- Using and Calibrating a pH meter
- Water Activity- Water Activity is a measure of the amount of “free” water in a product. The level of activity can impact product quality, shelf life and safety. Bacteria, like humans, require water to survive. Methods to reduce water activity include the physical removal of water through evaporation, dehydration, and freezing. Adding salt or sugar to a product chemically reduces water activity by binding up the “free” water, leaving little for the bacteria, preventing them from a suitable environment to grow in.
  UC Davis Quick Guide to Water Activity
- Processing Temperature and Time- Just as humans cannot stay out in the sun for too long without getting sunburned, bacteria cannot survive certain conditions without damage. Maintaining a certain temperature for a specific time incapacitates bacteria and other pathogenic cells. Unable to grow in the food, they eventually die and are no longer a risk for illness. This sensitivity allows food processors to create Critical Control Points (CCPs). These are thresholds for your product to ensure that bacteria will not survive. A processor will set these points in advance then monitor and continue to heat the product

until they are met.

Most processors combine the use of these three techniques to develop a safe product and process.

**Production-** Arrange procedures to ensure quality and safety before, during, and after production to ensure you and your staff are following the intended method of production, ensuring a safe and quality product.

- Pre-Requisites: Certificate of Analysis of incoming ingredients
- Good Manufacturing Practices
- Personnel Training: product quality thresholds, process checkpoints, cleaning and sanitizing protocol, recordkeeping
- Batch size optimization for equipment and production rate
- Process timing
- Operational Limits- Quality Control/Quality Assurance checks
- Formal Plans- HACCP, Preventative Controls

Be aware of the steps ahead: Figure 2- Chart of Regulations, gives a brief, non-exhaustive list of some common food product categories and key paperwork and registration required.

### Table 1: Quick Guide of Food Product Regulations Requirements

| Product | Residential Kitchen | GMPS | USDA | | FDA | | | |
|---|---|---|---|---|---|---|---|---|
| | Register with State FPP if Wholesale | | Registration | HACCP | Registration | HACCP | Form 2541 2541a | Process Authority |
| Acid Foods- Vinegar | | × | | | × | | | |
| Acidified Foods | | × | | | × | | × (Scheduled Process) | × |
| Baked Goods (non-PHF) | × | × | | | × | | | |
| Canned Foods | | × | × (If more than 3% meat) | | × | | × | × |
| Cheese | | × | | | × | | | |

| | | | | | | | | |
|---|---|---|---|---|---|---|---|---|
| Fermented Food | | × | | | × | | | |
| Frozen Entrees | | × | × (If more than 3% meat) | | × | | | |
| Jams and Jellies | × | × | | | × | | | |
| Juice | | × | | | × | × | | |
| Low Acid Canned Foods | | × | | | × | | × | × |
| Meat & Poultry | | × | × | × | | × | | |
| Seafood | | × | | × | × | × | | |

**Figure 2- Summary Chart of Regulations**

To Summarize:

- All food Processors must follow Good Manufacturing Practices as stated in the Code of Massachusetts Regulations and the Code of Federal Regulations.
- In general
  - FDA regulates the production of all food products
  - USDA regulates meat and poultry products
- HACCP plans are **required** by the government for juice, seafood meat, and poultry products. However, some consumers (buyers) may require a food safety certification in order to become an approved vendor.
- Additional forms and paperwork are required for shelf stable canned goods such as form 2541 and 2541a for canned goods, and process authority approval

NOTE: A product containing meat or meat products ***above 3%*** falls under jurisdiction of the USDA.
Additional regulations regarding the sale, slaughter, and grading of meat must be followed. For more clarification about which business will have to register with the USDA, observe this table from the Investigations Operations Manual.

## Facility

### *Residential Kitchen*

Are you considering making your product in your home?

The state of Massachusetts allows for the preparation of Non-Potentially Hazardous food (PHF) products in the home. In Massachusetts regulation this is referred to as a **Residential Kitchen**.

The state limits which products can be produced in the home and from which processes. *A PHF food is defined as one which is capable of supporting the rapid growth of infectious microorganisms without additional temperature control*. For instance, the cream filling of a cannoli without refrigeration can support the growth of bacteria such as salmonella. AS such it is considered and PHF and requires a temperature control: refrigeration.

In the state of Massachusetts, non-dairy baked goods, confections, jellies and jams can be processed in residential kitchens.

Products produced in a residential kitchen cannot be sold over state lines or over the Internet because they are not federally recognized as safe. Before any food produced in the facility can be sold, a Residential Kitchen **must be licensed by the Local Department of Public Health**.

Consult the following table, the Residential Kitchen Brochure, or the FAQ page on the MDAR Resource Guide for more about what can and cannot be made in a Residential Kitchen.

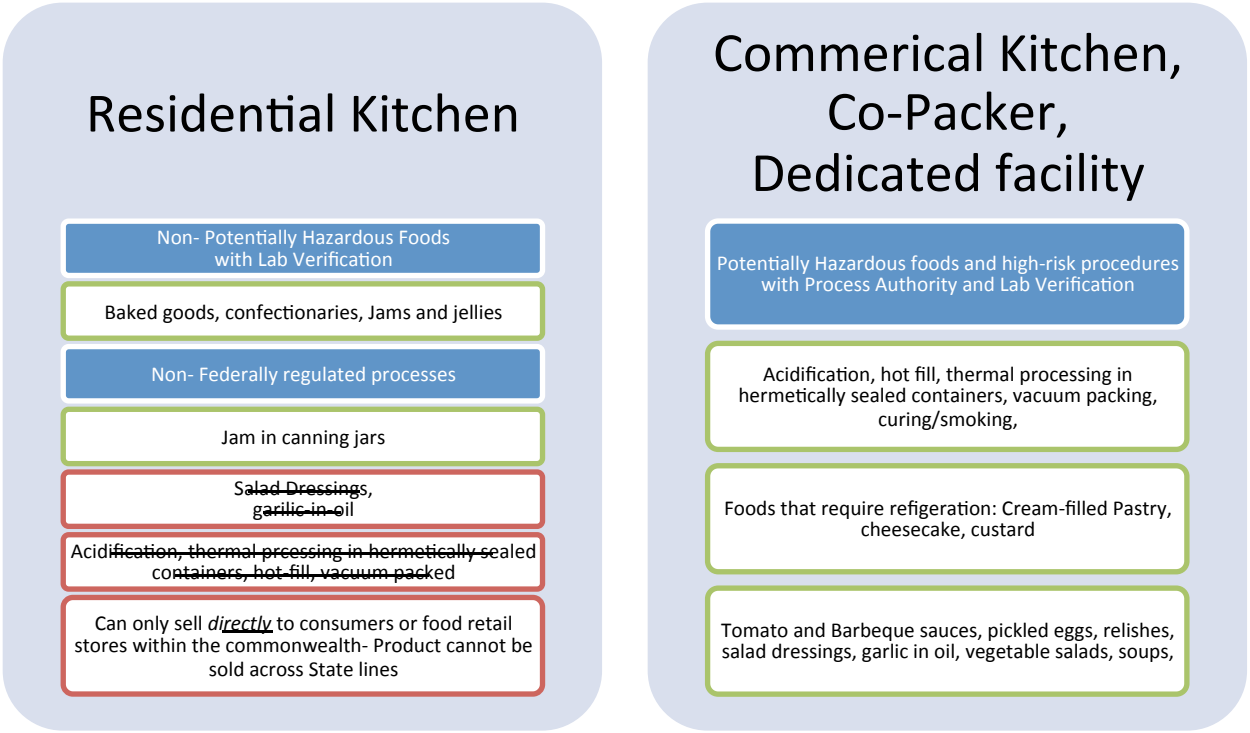



**Figure 3- Products for sale from Residential Kitchen**

In order to be licensed, the kitchen must follow Good Manufacturing Practices for food and food handling:

- Code of Massachusetts Regulations 105 CMR 500.000
- Code of Federal Regulations 21 CFR 110.000

These are the same rules for commercial kitchens, restaurants, and other food businesses.

Also note that a wholesale residential kitchen will have to follow the same regulations and licenses for a wholesale food business (see previous section).

### *Other Facility Options*

Owners of businesses with products that cannot be produced in the home have several facility options. Each of these options comes with its own costs and benefits.

Choosing which option is best for your business can be decided with the development of your business plan. Before you make a decision, you must simultaneously consider the cost to your business, as well as regulations for your product and desired process. Can this facility adequately fill your specific needs? Below is an outline of a variety of facility options you can consider to determine your options for manufacturing.

- Commercial Kitchen
  - Produces food as a business- a restaurant, school or church kitchen
  - Licensed by the state and municipality to adhere to all food facility regulations, but your business will have to apply for its own license for the space
  - Renting use of the equipment and completing all of the labor yourself.
  - Time of availability may be for off-peak hours

  - Start your search: “Rent Commercial Kitchen”
    - http://rentthiskitchen.com/
    - http://www.cookithere.com/
    - http://www.commercialkitchenforrent.com/
    - Ask local churches restaurants or community clubs (i.e. Elks lodges or VFW) if they are a licensed facility and if their kitchen is available for business development purposes.

  - Questions to ask:
    - Are there any minimum requirements for rental?
    - What is the rental rate? Pay by hour or day?
    - Are there any required Certifications? (Sanitation certificate)
    - Will I be sharing the space with any other groups during my rental?
    - Do you require insurance?
    - What materials are available for use during rental time?
    - What Storage options are there? How much space is allowed? How much will it cost?

- Shared Use Kitchen
  - A *Shared* commercial kitchen specifically for small businesses such as caters, food trucks, and producers
  - Businesses sign up for a time slot to use of the space, often competitive
  - Pay for time using equipment and storage
  - Complete all labor yourself

    - Start your search for a shared use kitchen at the New England Food Entrepreneurs page

- Food Business Incubator
    - Comprehensive Facility for *sprouting small* businesses
    - Consultation on the entire food business process from business management to product production
    - Commercial and industrial sized equipment for production and packing
    - Membership required, often for a fee
    - Additional fees for the type and scale of your product, the time and equipment you use in their kitchen
    - May contract as a co-packer
    - Listings:
        - culinaryincubator.com- Massachusetts Listings
        - Western Massachusetts Food Processing Center
        - CropCircle Kitchen inc/Pearl Food Production Center
        - Dartmouth Grange Shared-use kitchen
        - Cape Cod Culinary Incubator

- Co-Packer
    - A licensed facility that produces your product for you according to provided specifications
    - Good for products requiring specific equipment, small or infrequent runs
    - NEFE Co-Packers listing
    - Updated Massachusetts Listing
    - Co-packing Businesses

## Good Manufacturing Practices (GMPs)

***(21 CFR 110.000 and 105 CMR 500.000)***

Regardless of product type, all food manufacturers and service professionals are required to follow Good Manufacturing Practices (GMPs).

Such practices are the minimum standards for a legally safe operation. Health inspectors will be looking for implementation of these practices. Failure to follow these practices puts your product and business at risk.

GMPS cover details in the following categories:

- Personnel
- Building and facility
- Sanitary Operations
- Equipment
- Production and Process controls
- Default Action Levels.

It is highly recommended that you print a copy of sections 21 CFR110 and 105 CMR 500 to use as a checklist for your facility. As a resource for your operational team and for food safety record keeping it is helpful to have written standard operations procedures (SOPs) that detail the instruction protocols for your process. In addition, recording a log of your operational activities is a useful tool for verifying your operation is working correctly and helps to better identify trouble shooting if there is a shift in operational results. Furthermore, some food products require certain records to ensure proper food safety throughout your operation.

Similar rules, called Good Agriculture Practices (GAPs), are set for those early in the flow of food- growers and farm workers. Learn more about GAP with the University's GAP Page.

## Development

At Last: Your Product.

By now you probably have a small scale version of your product. Did you check the Code of Massachusetts Regulations to learn about any standards for your product?

Before production, standardize your formula:

- Convert all recipes into a weighted average percentage. This can be done by weighing your ingredients on a precise scale. When measured by weight quantities are much more accurate, making for a consistent product batch to batch.
- Record ingredient source and cost of all materials
- Test your formula to match your specifications- flavor, texture, dimensions, microbial limits, etc.
- For canned goods intended to be shelf stable, the appropriate process conditions will need to be reviewed and approved by a process authority. In order for a process authority to best support you, they will want to know what the pH and water activity is of your finished product. To learn more about how pH is measure and how it helps with food safety visit (UW Madison Directions). For food safety reasons, shelf stable canned foods with a pH above 4.6 will need to be processed aseptically or with retort (commercial scaled processing with high heat and pressure).

Conduct a Laboratory Review of the product to

- Verify final product is free from harmful biological organisms and safe for consumers; that the set controls and processes work as expected
- Establish expected Shelf-Life – the length of time and shelf conditions the product can withstand while still maintaining desired quality and functionality

For Canned, Low Acid, and acidified foods the development of a product extends beyond the product in the jar or can; an entire procedure must be tailored specifically to the formula and size of product. The extended shelf life from canning means that bacteria that survive the high heat of the process have ample time to turn your hard work into something inedible or potentially poisonous. Additionally, some nasty bacteria like C. Botulinum like the unique vacuum environment in a canned good- extra care and caution must be taken to make sure they are not feasting or living in your product:

- Consult 21 CFR 114.000 about the following regulations specific to Canned Goods:
  - Process Authority Approval
  - pH Limits
  - Method limitations
  - Record Keeping
  - Re-Certification of Process with each formula or process change
- Attend a Better Process Control School
  - In Compliance with CMR 500.006 and 21 CFR 108.113 and 108.114.
  - Learn the intricacies of the regulation and how to adapt you product, process and procedures to yield a safe product.
  - Upcoming UMASS BPCS
- Consult a Process Authority, a canned Food Safety Specialist, to confirm your formula and process are safe
  - Listing Here

## HACCP

**Hazard Analysis and Critical Control Points** is a planning system required by law for juice, seafood meat, and poultry manufacturers to systematically identify and control food safety hazards in the product. Use of this system in other food applications is voluntary, but highly encouraged.

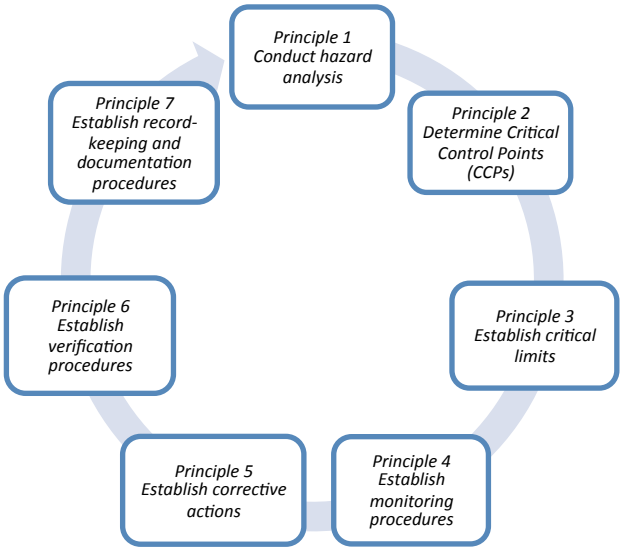



**Figure 4- HACCP Process**

HACCP has seven principles (Figure 4) that help identify the operational hazards associated with your process, establish scientifically validated process parameters to ensure foods safety and establish monitoring controls and records to manage food safety risks. For more details on how to start HACCP planning for your business, take a formal course.
The UMASS Food Science Extension currently offers an Introduction to HACCP certification course, visit the training page for upcoming courses!

For a HACCP plan to be recognized it must be documented as adequate by an impartial HACCP expert or auditor. Find a list of such resources on the Food Science Extension Webpage.

Learn more of the steps and actions of the HACCP

- FDA: HACCP Principles & Application Guidelines
- FDA: Manual for the Voluntary use of HACCP Principles
- International HACCP Alliance
- Massachusetts Department of Agriculture Food Processors Manual Section 3,

### FSMA and You

The **Food Safety Modernization Act** (FSMA) was signed into law in January of 2011. FSMA is an act intended to be more proactive rather than reactive to food safety issues.

Through FSMA Food Processors and producers who currently do not fall under categories additional regulations such as HACCP or Canned food guidelines would be required to formulate a system or plan called Preventative Controls for their food. The details of what is expected or required for such PC plan are not yet known as they are still being proposed and amended. One proposal for the regulation includes a Food Safety Plan.

Controls during the production process serve to eliminate or reduce widespread illness by reducing the possibility of pathogen survival in the product, eliminating allergen exposure, ensuring and recording proper sanitation practices, and preparing for the event of a recall.

The legislation is still being amended, however businesses are encouraged to stay astride or ahead of these proposed changes as to prevent shock when they are finally installed by starting to think about food safety planning.

Read more from the FDA about Preventative Controls.

## Production

### Package & Label

Choose your package carefully. The package will showcase your product well while keeping it safe during delivery.

A good package will fit the needs and requirements of the processing, delivery, display, marketing and storage of your product. When choosing a package, be sure to consider:

- Material: Strong and Food Safe
- Operational capability: Moisture and temperature impacts the stability of a label.
- Appealing
- Availability

- Cost

The label of your product is the portal between your business and your consumer. It sells your product. The package attracts and entices the consumer to pick up and buy your product. The label describes and pictures the product. It conveys information about the contained nutrition, ingredients, quantity, and quality of the product. Because of these numerous functions, it is important that you plan and draft your label carefully.

Be aware: there are some very specific label compliancy laws for food packaging. In order that businesses do not mislead the consumer, labels have become State and federally regulated.

Health claims cannot be made on the package unless the label and company are approved and inspected by the FDA.

All food for retail sale in the State of Massachusetts must be labeled, including food from residential kitchens. Failure to follow such regulation can be a costly oversight, potentially rendering your product unsalable.

Creating a visually appealing, yet complicit label for your product can prove to be a time consuming process. Failure to comply with these regulations can incur significant fees that could be quite costly. The following is a summary of State Labeling Regulation. Consult the FDA's Labeling guide for a more digestible version of the Federal regulation.

### *Minimum Information for Massachusetts*

(Adapted From Massachusetts Minimum Requirements for Packaged-Food Labeling Information Brochure)

To organize all of the required information for a complicit label, the label has been divided into two areas or locations:

- Principal Display Panel (PDP)- Is the front face of the product with the product name and similar information
- Information Panel (IP)- is located to the right of the PDP and contains nutrition and business information

**Principal Display Panel –** All PDPs require at least the following information:

- Common or usual name of Product – i.e. The term used that consumers will recognize what the food product is.
- Net Weight – in Metric (grams, liters) or US Units (Pounds, Ounces). Dual declaration stating unit equivalency if more than one pound: 1 Pound (16 oz)
- Storage conditions if perishable – i.e. "Keep Refrigerated" or "Keep Frozen," "Refrigerate after opening"
- Standard of Identity must be met if the product is to be sold under that product name Consult 105 CMR 510.000

**Information Panel**

- All ingredients in descending order by weight and a complete list of sub ingredients

- All FDA Certified Colors
- Open- Dating for perishable or semi-perishable foods
    - A calendar date stamped on products package to determine how long it is to be available for sale. After this date it may not be safe or of intended quality
    - "Sell By" "Best if used by" if Shelf life is less than 90 days
    - Exemptions; fresh fruit, meat, poultry, fish, pre-packaged for retail sale and net weight of less than 1.5 ounces.
- Name, address of Manufacturer/packer/distributor.
  Street address shall be included if company not listed in current edition of telephone book.
- Allergen Labeling (Dairy, Egg, Soy, Wheat, Tree nuts, Peanuts, Shellfish, Seafood)
  Either embedded in the ingredient statement or listed afterwards under the heading "Contains: XXX"
- Nutrition Labeling
    - Determining serving size 21 CFR 101.12 Table 2
    - Tabulate Nutritional content- Calculated or Analytically tested
      USDA's online Nutrient Data
      List of Nutrition Resources
    - Health and other claims-
      Consult the Food Product Labeling Guide about claims
      approved by the FDA and can only be used on federal lables

*Small Business Exemptions*

Businesses that sell their product over state lines are subject to FDA regulation and must follow additional labeling requirements. Small businesses, however, may be exempt or apply for such exemption. This would exempt them from some the expensive nutrition testing or qualification required for compliance with federal labeling laws.

A business can be considered exempt under the following two circumstances:

- Small Sales
  Annual Gross sale of food product amounts to less than $50,000. This Business does NOT need to file for a small business nutrition labeling exemption with the FDA.
- Low Volume
  The business employs fewer than 100 full time employees AND fewer than 100,000 units of product are sold in the US in a 12 month period.
  This Business **must** file for a Small Business Nutrition Labeling Exemption

If any nutrient, content, or health claim is made on the label, the *small business exemption no longer applies*; the label must adopt all Federal requirements and is subject to approval. More information about such exemptions and the application form can be found on the FDA website.

## Quality Assurance

Now that your product is ready to roll out, ensure it reaches the consumer exactly the way you want it to. To do this take a few steps to assure the quality and integrity of your product.

Put your planning into action:

- Train all personnel on specific responsibilities, standard operating procedures (SOPs) and protocols
- Identify and monitor your product as it is produced to make sure targets in taste and integrity are met. i.e. time and temperature recordings, water activity, pH testing, etc.
- Complete set safety checkpoints for product
- **Take** and **Keep** records of each batch and corrective actions taken (if necessary)

## Paperwork

- Register your business with the appropriate federal agency
    - Seafood and non-meat: FDA
    - Meat and Poultry: USDA
- Apply for all required licenses for both your facility and business (refer to section X)
- Receive necessary Food Safety Training
    - Take a Food Sanitation Training Course (Serve Safe) if required by your local Board Of Health
    - HACCP certification
- Obtain General and Product Liability Insurance
- Be mindful of Small Business and Self-Employed tax guidelines
- Determine a price for your product using your formula and operational costs
- Confirm where your production facility will be, establish the minimum production capacity necessary to be operational and cost effective, and determine schedule lead times.

And with that, you are open for business and your product ready for sale!

## Additional Resources

- MDAR- Massachusetts Department of Agriculture Resources
- NECFE- New England Center for Food Entrepreneurship
- New England Extension Food Safety Consortium
- .pdf of this Guide