

Shaping the future of Pittsburgh's artisan food community.

La Dorita Cooks

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# **Business Planning and Development**

Your friends tell you your salad dressing is the best they have ever tasted. Your grandmother has been serving her "world's best" homemade dulce de leche milk caramel spread for years. Your aunt's pasta sauce is the hit of every family dinner. You think about selling your food product, but you don't know where to begin. This resource guide aims to change that and get you cooking.

Pittsburgh is currently experiencing the emergence of its next generation of craft food pioneers. And yet, while the food scene has blown up in the last five years, there is still a surprising lack of accessible startup resources available to aspiring food entrepreneurs. This guide aims to answer the basic questions that will help you turn your idea into a scalable startup that you can launch to market—whether it is a food product, a mobile food service, or a restaurant.

As tastes shift towards specialty, local, natural and clean foods, more food startups are entering the market. And for good reason: today's consumers are walking away from America's most iconic big-box food brands. Millennials are a large driving force behind this emerging trend. They have different food values and are less loyal to traditional consumer brands. They gravitate more toward the perimeter of the grocery store, where fresher foods like produce, meat and dairy predominate. Millennials are looking for real, authentic, simple food, and it shows up in the things they are avoiding—artificial sweeteners, GMO's, preservatives, flavors. They are making it easier for small startups to break into the food business.

In addition consumers' growing concern about sustainability and health, consumers also have an increased interest in small-batch production—knowing where food is made and who made it. Consumers are attracted to specialty foods because they have the image of being "homemade" from natural ingredients and lacking preservatives. Shifting population demographics, such as an increase in Asian-American and Hispanic-American communities, are also driving the development and sale of ethnic specialty food products. This trend has created a ripe opportunity for food entrepreneurs who want to share their unique ideas and bring them to market.

There's no denying that the specialty food business is booming and helping to bring flavor to Pittsburgh's burgeoning food landscape. Establishing a specialty food business, however, is a

daunting task to say the least. Extensive research must be done to develop a consistently reliable recipe for commercial production. This is followed by tests to consider shelf life as well as the cost of the product. Quality has to be balanced against profits. To be a success, it is vital that the food product be of high quality and fill an open marketing niche. Eighty percent of new products fail in the first 2 years. Positioning your product correctly can help you be in the 20% that succeed.

This resource guide is intended to help all local food artisans navigate the complex food industry in Allegheny County, Pennsylvania, including its technical and regulatory complexities, as you try to bring products from concept to commercialization. We will use examples and scenarios from our own food startup, La Dorita dulce de leche, as well as those of our kitchen share members. We will discuss the basics of commercializing a food concept, from understanding the FDA categories that your product falls within, as well as the rules and regulations that will apply to your product. With this guide we aim to act as a road map by compiling the most relevant information on licensing and regulations in an easy-to-understand format. Ultimately, it is vital that specialty food manufacturers be successful—not only do they utilize a number of Pennsylvania commodities, bringing additional revenue to farmers, but they also strengthen local economies.

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# Filling a Need

You have an idea for a great new product or plan to bottle your grandmother's recipe for spaghetti sauce because, quite frankly, none of us know what we have been missing all of these years. Or perhaps you plan to bottle fresh-pressed, live enzyme juices or hot sauce. It might be a seasoning blend or your own energy bar. No matter the product, you're sure it will be the next big hit. We don't doubt that, but making that happen takes steadfast research, perseverance, a significant investment and a lot of heart.

So how do you make something that people actually want? You must start with a real problem or need. Obviously it should be a problem for you, but be sure it's also a problem or need for others. For instance, the model for La Dorita Cooks food-specific, co-working space organically developed over the course of three years after we were unable to secure licensed kitchen space to launch our own for-profit specialty food start-up business, La Dorita dulce de leche, to

market. The incubator resulted from a personal need that threatened to deter our own personal success, and we were determined to fill this void. Now, with its central location, La Dorita Cooks is well situated to serve our area's following core groups: bakers, caterers, specialty food producers, personal chefs, cart vendors & food trucks.

Second, you have to ask yourself the following question: Is my idea original? It's possible the product is out there, but you haven't seen it. If it's not on the market, you have to consider whether that's because it cannot be manufactured, cannot be commercialized due to regulatory licensing restrictions, or has no market potential. While the majority of entrepreneurs have unique ideas that are conceptually good in theory, many hit several road blocks while developing a prototype and have to either continue to reinvent and adjust their product, or call it quits. We can provide a few scenarios from our own La Dorita dulce de leche arsenal of startup stories as well as draw from the experiences of our kitchen share members.

We first launched our dulce de leche spreads in our local Whole Foods Market in 2009. We had worked extensively with a food scientist to make sure that our all natural, preservative-free spread would meet Whole Food's requirement that the dulce de leche be <a href="https://shelf.com/sh

This is just one example of questions many entrepreneurs face when developing their prototype—do I sacrifice the integrity and quality of my product to meet licensing and regulatory requirements or grocers' and distributors' commercial demands? You can only figure out the best option for your product by learning more about these processes, consulting with food scientists and experts in the field, and continuing to adapt your product accordingly.

One of our first members at our kitchen share incubator made what just might be the best vegan food I have ever tasted—their vegan "chicken" wraps were so good they could fool even a diehard, Argentine carnivore like my husband, Gastón. This family-run company prided itself on growing most of its food, and only using the highest quality ingredients. After operating for six months, this company landed a spot in the freezer section of our local Whole Foods Market. Unfortunately, it was clear just after three months of sales that there pricing margins did not render any profit. They made the difficult choice to pull their product from the market and have since returned to the drawing board to fine tune their product. Some of the questions they have to ask themselves is whether they are willing to lower the cost, and quality, of some of their ingredients, and make an equally delicious product—even if it varies from their original home recipe. They also have to look at where they were sourcing their ingredients, and consider whether they should continue to grow their own vegetables or partner with a farm that might be able to do so at a fraction of the cost. Scaling up your original home recipes is no easy task more often than not they will need significant adjustments to become market-ready. In the end, one thing is for sure, no matter how good your product is, consumers are only willing to pay so much for it.

Another scenario deals with local, raw, organic juices that alkalize your body with living enzymes. Our kitchen member makes batches of her juice in a commercial kitchen that is approved by both the PA Department of Agriculture and Allegheny County Health Department (ACHD). In addition, she has secured her own regulatory licenses and even has an approved Hazard Analysis Critical Control Point Plan (HACCP), which is required of all raw-juice manufacturers and bottlers. The member currently sells the refrigerated, fresh juices at local gyms and local farmers' markets and certain Kiosks in one specialty grocery stores. The fact that the juices are cold-pressed and unpasteurized sets them apart from its competitors. The member's original business plan outlined a plan to wholesale the juices to natural supermarket chains. The question is, "Can the member produce a shelf stable juice product line with live active enzymes?" Will the local supermarket accept an unpasteurized product, and if they do, will the ACHD, PA Department of Agriculture and/or U.S. Food and Drug Association (FDA) allow an unpasteurized product on a refrigerated supermarket shelf? If regulatory demands require the member to pasteurize the juices, that will also kill off the live enzymes—which is exactly what makes her juices unique in the market. What steps does the member need to take to protect the integrity of the juices while preparing them for commercialization? Should the member alter the original business plan and

forego supermarket sales and open a juice bar instead and consider pursuing a national franchising model as she looks to grow in the future?

Often times, food startups come across road blocks that don't have to do with food, but branding and intellectual property. Businesses work very hard to build their brand through marketing and providing superior goods and services. Branding is a top priority for entrepreneurs. One of our members was well on his way to growing his brand of specialty and boozy popsicles. He had successfully grown from selling out of a bike cart to a frozen treats food truck. Low and behold, as he is in the process of branding his newly purchased food truck, he receives a cease and desist letter from another food company warning him that he was infringing upon the use of their name. So, after successfully branding his product for more than two years, this member was forced to go back to the drawing board and rebrand his company—from the name, to the logo to the packaging. While he successfully persevered, these are the type of hiccups you hope to avoid as they can set you back in time and capital. Once you have worked hard to establish your brand and have invested in logos and marketing, it is so important to begin to look into trademark registration and aggressive defense of your brand. We always like to advise startups to invest in a trademark search prior to committing to your brand—this way you know if you might be infringing upon another brand before investing in establishing your brand.

This is yet another of dozens of scenarios we have come across at or kitchen incubator and gives you only a taste of how much there is to learn about food-industry and general startup requirements. Your situation may not match up exactly with these stories, but they will most likely strike a chord in the future. The amount of information out there is enormous, especially when you consider the wide variety of food ideas and products that exist. For this reason it is so important to research your product, and the category to which local and national regulatory agencies relegate it, in a disciplined and thorough fashion. This way you can attempt to avoid the pitfalls that often stump food entrepreneurs before you have invested in labeling, marketing, or packaging options, and increase your chances of transforming your idea into a viable microenterprise.

# Am I the Entrepreneur Type?

An entrepreneur is an innovator—a risk-taker who identifies a need or envisions an opportunity in the marketplace, sizes up its value, and takes the leap to make it a reality. Not everyone is cut out

for business ownership in the food industry. Throughout our efforts to advance the urban food-making community, we are constantly reminding our members that while a heartwarming back story about their food tradition helps, in the end it isn't going to make the sale. We often have to provide a reality check and explain why adjustments are necessary.

If you are thinking about starting your own food business, ask yourself these questions to see if you have what it takes to be a food entrepreneur who is both autonomous and self-employed:

- Do I have self-initiative and perseverance?
- Can I successfully wade through a sea of "no's" without becoming discouraged?
- Am I good at making decisions?
- Do I have a network of trusted advisors, such as lawyers, accountants, and industryspecific contacts?
- Do I have unnerving determination?
- Am I willing to face failure and reinvent my product to adjust with the market?
- Am I willing to work two jobs until my startup's income can sufficiently support me and my family?
- Am I willing to put in fourteen hour workdays, up to seven days a week?
- Am I willing to put my own skin in the game and self-fund my dream—or part of it at least?
- Do I have an exceptional food product or recipe that sets me apart from my competitors and fills a need in the marketplace?

Bringing your product to market can be exciting and rewarding, but may also be time consuming and back breaking. You need to consider some of the advantages and disadvantages to bringing your homemade product into the specialty foods marketplace.

### Advantages:

- · Creating your own work schedule
- Doing something you love/are passionate about
- · Benefiting directly from your hard work
- Unlimited earning and growth potential
- Satisfaction of being your own boss
- Sharing favorite recipes with others

#### Disadvantages:

- Long hours
- Personal strain/change of lifestyle
- Financial risk linked to startup costs
- Filling many roles within the business
- · Risk of regulatory violations
- Product failure

It is very important to understand the proper steps needed to turn a recipe into a profitable product. You can't simply make a food item in your home kitchen, place it in a bottle, and start selling it. You need to follow the many production and labeling requirements that exist to keep consumers safe. You need to understand the markets you want to enter. You need to get your product to those markets. You need to know your competition. You need to determine the correct selling price for your product and much more.

First, you must be honest with yourself. What is your vision for your business? Will it be a fun hobby? Do you expect it to remain small, providing only part-time income? Do you envision something larger with an expanding product line and future employees? Describing your vision of the business is best done through a business plan. This guide includes a summary of the main elements of a business plan.

Now that you've contemplated these questions, it is important take the first steps towards launching a food product—research, research, research!

# Market Research

Eliminating all the unknowns associated with starting a small food business is simply impossible, but good planning, preparation, and insight greatly improve your chances of success. Don't do it alone—reach out to experts in business and technology who are there to help. Keep in mind, though, that if your business does not succeed, you may be putting ownership of your personal property at risk.

There will indefinitely come a time that you will have to take a risk and jump into the market with your food product, but it's best to do your homework first. First, research your product's chosen food category on the <u>U.S. Food and Drug Administration (FDA)</u> website and research the

regulatory requirements that are attached to that category. Then visit the local grocery stores in your metropolitan area—including the local large-chain, ethnic and specialty stores—and browse the organic, specialty, international and local foods aisles. Spend some time in this aisle and observe shoppers' tendencies and food product choices within your food category. Why do they select the specific pricing? Which is the most popular? You will likely notice that the 80/20 rule applies to consumers shopping preferences. If you intend to sell barbeque sauce, it is likely that 80% of all consumers will consistently select the same brand. Why are they choosing this brand? What would your brand do differently to break this brand-loyalty and sway the consumer to give your sauce a taste? As you are asking yourself these questions, also consider consumer behavior and purchasing patterns for your product category. For example, how many times a year does a consumer typically purchase a product in your category. Research shows that on average Americans will purchase barbeque sauce twice a year, with demand peaking in the weeks leading up to the 4<sup>th</sup> of July.

Shopping your local farmers markets is also a must as other local food startups often try out their products here. Joining the <a href="Specialty Food Association">Specialty Food Association</a> is also a fairly inexpensive way to access state-of-the-industry reports that discuss market trends and new food-product launches.

Attending industry trade shows is also a first-hand way to discover what's new or trending in the market and to see what products directly compete with your product. Many start-up companies exhibit at these shows. You can also find shows that focus on ingredient sourcing and packaging. Attending a trade show can save you hours of research.

The websites listed below frequently offer annual shows as well as free online and print magazines that discuss trends and new food-product launches.

- Good Taste! Pittsburgh
- <u>Fabulous Food Show Cleveland</u>
- Specialty Food Association Fancy Food Show
- Natural Products Expo East
- Chicago Gourmet
- Boston Seafood Show
- Sweets and Snacks Expo
- National Restaurant Association (NRA)
- Institute of Food Technology Annual Show

- Pack Expo Trade Shows
- Private Label Show
- Research Chefs Association Annual Conference

If you decide to attend a trade show, below are some tips to help prepare for the show:

- Research the types of shows available that include products similar to yours.
- Be sure to apply for admission well in advance; registration fees will be lower early on.
- You will receive a listing of vendors in advance; take the time to review the list before attending.
- Comfortable clothing and shoes are a must. You will be on your feet for 6-8 hours a day.
- Bring a good supply of business cards.
- Arrive at least 1-2 hours before the show begins. There will be a show book with detailed descriptions of vendors and their products as well as a layout of the building to help you plan your day efficiently.
- Many shows include industry related workshops. These typically require advance registration and may possibly involve fees. Review the list to see if any are appropriate for you and plan accordingly.
- Be sure to take an empty tote bag as you will be gathering a lot of information.
- Take advantage of the sampling as much as possible. Take notes on all items you taste and packaging materials.

Finally, research local food startup workshops and attend as many as you can...for both guidance and networking purposes. Some local companies and universities providing entrepreneurial workshops or further resources include:

- La Dorita Cooks
- <u>Urban Innovation21</u>
- Idea Foundry
- Launch Millvale: Food Incubator
- Penn State Extension Food Entrepreneur Workshops
- Penn State Extension Food Safety Courses
- Chatham College Food Studies Program
- Chatham University Center for Women's Entrepreneurship
- Pennsylvania Association for Sustainable Agriculture
- Pittsburgh Food Trucks

As you are researching and begin to envision the company you intend to form and successfully lead, begin to work on developing a homogeneous prototype of your product that consistently comes out the same from batch to batch.

# **Basics of Food Product Development**

Developing a successful specialty food product is not easy. Entrepreneurs should follow these basic steps or stages in developing new products:

- Idea Stage
- Development and Shelf Life
- Taste Paneling
- Consumer Sampling
- Packaging
- Production
- Test Marketing
- Commercialization

The **idea stage** involves that infamous light bulb moment—when all of the sudden you come up with a novel concept you suddenly know will fill a need in the market. At this point you have to make every effort to determine whether consumers would find value in your idea, purchase it, and continue to purchase it in the long term. The following questions need to be answered:

- Does the product satisfy a consumer need?
- Is it unique?
- Does it provide a new service or superior taste to customers?
- Will it return a profit?
- Will it be acceptable to consumers, wholesalers and retailers alike?
- Do you have the production technology to develop the product?
- Do you have the marketing skills to sell the product?
- What products will it replace or compete against?

The <u>development</u> and <u>shelf life stage</u> involves the creation of a prototype of the new product—and making sure it is safe to sell to consumers. Simply being a good cook will not ensure good

products for commercial marketing. The success of any new specialty product depends on the quality of its flavor, color and texture, its stability under various storage conditions and its safety. These factors are intimately related to the ingredients in the food product and to the physical processes and handling procedures to which it has been subjected. Often, additives may be needed to maintain or enhance product quality throughout and after processing. Consequently, you cannot rely alone on an old family recipe once you enter the commercial market. At this stage, you have to consider how you will safely preserve your product without compromising its quality and the integrity of its ingredients.

If your product contains ingredients that spoil quickly at room temperature, how do you intend to maintain quality and prevent growth of disease-causing microorganisms and spoilage? The amount of time your product can be expected to stay wholesome under a given set of storage conditions is called the "shelf life." Shelf life is extremely important because you must know how long a new product will keep under a variety of temperatures and other environmental conditions. Shelf life loss may be due to chemical or microbial (bacteria, mold and yeasts) spoilage.

It is your responsibility to determine the shelf life of the product(s) you intend to sell. Reliable "use by" or "best before" times cannot be determined by guesswork or by copying the shelf life of a competitor's product. Shelf life testing plays a large part in developing a prototype and is something you can begin to test on your own once you are in the early development stages and able to reliably produce a homogeneous product with consistency from batch to batch (and have determined the best packaging for your product). At this stage, you can take the first step towards determining a safe expiration date for your product by making a two-dozen batch of the product, packaging and sealing it and storing the product under realistic temperature conditions to perform expiry testing. Each month, on the same date, open one jar and document any changes in quality, including rancidity, texture changes, moisture loss, moisture gain, staling, flavor loss, light induced changes, crystallization, enzymatic browning, chemical browning, and spoilage. As you are performing your own testing, keep in mind that most distributors and/or supermarkets are going to require your product have a shelf life of at least one year.

Food producers normally contract with independent or consulting laboratories to have accelerated shelf life studies performed on new products. These studies are done by raising the temperature of the packaged product above normal storage conditions (110 to 120 degrees F). Although this is not as good as a prolonged shelf life study at normal temperatures (75 to 80 degrees F), it does

give some indication of product shelf life. Lot codes for recall and product liability are based on these studies. Here are some of most common ways to extend the shelf life of commercial food products:

- <u>Canning</u>, or thermal processing, is perhaps the most common method for preserving fruits and vegetables, pickles, salsas, and sauces.
- <u>Refrigeration</u> and <u>freezing</u> extends shelf life by slowing or stopping microbial and chemical changes in food. The question you have to ask yourself is how you intend to keep your product cold or frozen until it gets to the consumer?
- Preservatives are typically used in combination with other techniques to extend shelf life.
  But the type and amount of preservatives are strictly controlled by government regulations
  and must meet market standards. For instance, if you intend to sell your product in
  specialty and natural food markets, most of these specialty retailers do not sell products
  that include chemical preservatives.

Many other technologies are available for extending product shelf life, including pasteurizing, controlling <u>pH</u> and <u>moisture</u>, smoking, and curing. You'll need to do some research on which methods are most appropriate for your product and your budget.

The **taste panel** stage should run concurrently with formula or recipe development. It's here that you rigorously check quality parameters such as color, texture, appearance and flavor at various stages of product formulation to distinguish tasty from undesirable traits.

The **consumer sampling stage** provides valuable information about the product's potential success. You should sign up for local vendor samplings and demonstrations at various farmers markets and grocery stores. You should even consider attending a specialty food show as a vendor. You can show your product at a <u>specialty food trade show</u> before it is officially on the market. Although it's expensive to exhibit at these shows, you can receive great feedback from both consumers and industry buyers.

During vendor demonstrations, consider giving shoppers a sample to taste and a questionnaire about the new product to fill out on-site. This sampling can sometimes be done with the product available for sale during the sampling period if the store will cooperate. Actual sales after tasting

reinforce the questionnaire. For instance, if 100 people say they "will purchase" but only five purchase the product, there may be some question about the truthfulness of the answers. Commercial demand for the product should be evaluated to determine if sufficient volume can be produced and sold to make the venture economically feasible.

The <u>packaging stage</u> is especially important because the package often <u>brands</u> and sells a new product. Consumers want colorful, attractive, conveniently packaged forms. You should even consider the texture when it comes to wrapping. Packaging should not impart flavor to the product or react chemically with the food. It should be resistant to tearing, lightweight and, most important, economical. It should also aim to help preserve and prolong the shelf life and quality of your product.

The <u>production stage</u> includes making plans for a production line to manufacture the product. This is when you have to consider who will manufacture your product, and where. Do not arrange a full-scale production line until after successfully test marketing a new product. Many startups will have their products <u>co-packed</u> by an existing plant for test marketing. The production line should be set up according to a blueprint of its layout. Processing controls must be established to ensure consistent quality during production. Likewise, quality control procedures must be developed to determine if the standards are being met during production and to know when to take corrective action to prevent economic losses due to deviations and to ensure product safety.

The <u>test marketing stage</u> involves introducing your new market-ready product into a limited area, such as a local grocery store as a direct vendor. It is important to select a site with a population made up of many ethnic groups and income levels. Farmers markets are also a good place to test your product's consumer appeal, but keep in mind that people who go to farmers' markets are usually willing to pay higher prices for healthy and local ingredients than the average consumer. If the product fails, another product can be tried. If the product succeeds, you have to consider <u>distribution options</u> to distribute in stages to progressively larger areas (regional, national).

You may even want to take the extra step to hire a marketing firm to get market feedback on your concept. While you may incur extra up-front costs, their research may save you time and money

down the road. One local firm that focuses on this very thing is <u>Olson Zaltman</u>. Other market research resources include:

- The Center for Culinary Development
- The National Food Lab
- Tragon Sensory Evaluation

The **commercialization stage** is the final step in determining the success or failure of a new product. Most small food companies sell mainly to privately owned stores or small chains in the beginning year(s). Larger chains will not take on a new food product unless it is heavily advertised by the company. The buyer for a large chain must be convinced that the product is good and that advertising exists.

# How to Commercialize a "Home" Recipe

Once you have done your research, it's time to start turning your home recipe into a shelf stable, marketable product. Scaling up food recipes is no easy task. Often times when your goal is to produce your product on a mass scale, it's hard to know where to begin to make it ready for market.

The first step is converting dashes, pinches, tablespoons, cups and other standardized units used at home to pounds, grams or gallons—the units typically used when measuring large amounts of ingredients. If you are considering using a <u>co-packer</u> to manufacture your product, you will need to present your recipe in percentages. A "recipe" and a "formula" are not really the same thing (although the terms are often used interchangeably). A recipe is what you make at home, using common measuring cups and spoons. A formula is how a professional specialty-food manufacturer documents your information in pounds, kilograms, grams and other weight measurements. These weights are converted to relative percentages and then used to make any amount or batch size of your product.

For example, if your recipe calls for 2 cups of milk, you have to weigh it out. And 2 cups of honey will not weigh the same as milk as it has a different density. Even different types of honey have different densities. As a rule of thumb, it is always advisable to document your formula by weight. That's how to ensure the formula remains consistent no matter the size of the batch.

Scaling up a recipe is not only about the units, but it also is about the business side of production and cost effectiveness of the ingredients. For instance, many people do not realize their production costs. Initially, they will often purchase home-style ingredients for their product at retail cost, then switch their ingredients for a cheaper alternative to lower production costs. In some cases, there are ingredients available with specific functionality that may be used to replace home-style ingredients in scaled-up batches. An example of a cheaper alternative is replacing a thickening agent purchased at the store for a commercial gum. The important thing is to source the best ingredients at the lowest cost possible without compromising the quality of your product.

The next step in the scale-up process is observing the batch and noting any changes that may have occurred in comparison to the original recipe. Sometimes it is possible to predict what changes may occur in a scaled-up recipe, but often that is not the case. For instance, when scaling-up a recipe, the ingredients sometimes react differently when produced on a larger scale, resulting in differences in taste, texture, aroma or appearance. Further, commercially sold products often receive a higher degree of scrutiny compared to home-style products. The scaled-up batch makes observing "flaws" easier, which may have already existed in the small batch.

Some ingredients are more difficult to scale up than others. An example is mixing spices with lighter-colored ingredients in large quantities. The colors may run or bleed together. Fruits and vegetables may be difficult, as well. It is important to consider whether the fruit and vegetables need to be peeled, cored or seeded when scaling-up the recipe. You may have to sometimes change the ingredients so your product will work well on a larger scale. It is a trial and error experience. In some cases, it might not be possible to make the scaled-up batch identical to the original small batch. The key is to make it equally or more delicious.

When developing your commercial formula always remember the "BASICS":

- Balance: Balanced flavor based on consumer taste preferences
- Acidity: Acids can enhance other flavors and increase product stability
- Sweetness: Sweeteners may enhance other flavors or mask bitterness
- Intended flavor and texture: Visual appeal and consistency are important
- Color: Processing may degrade color
- Saltiness: Salt enhances flavor. It aids the cooking process and is a preservative

Getting a <u>shelf stable</u> product to taste like what you make at home may take some time. It is possible that it will never taste exactly the same. In some cases getting the recipe and process just right happens in a single session. In other cases it can be a lengthy process. It depends on the complexity of your recipe, how well you can homogenously recreate each batch, and your personal standards for perfection.

If necessary, you can find a qualified food-scientist consultant who has experience making your specific type of product. Whatever your chosen <u>food category</u>, there are experts who have experience in that area. One such expert we often turn to at La Dorita Cooks is <u>Parker Development</u>, <u>Inc</u>. Penn State Extension's <u>Food & Health Division</u> may also be able to provide you connections to local ingredient suppliers and access to packaging materials that make it possible to mock up your prototype so that it simulates a real manufactured product. <u>The Pennsylvania Association for Sustainable Agriculture</u> and <u>The Pittsburgh Food Policy Council</u> are also an invaluable resource for connecting artisan food producers to local farmers. <u>Idea Foundry</u> also has a local food project that aims to connect food producers to local agriculture and food systems. <u>Nutrifections</u> is a local food consultant in Belle Vernon, PA that specializes in product development of confections and bars.

Once you have your prototype, you have to decide where you can best efficiently manufacture your product. In Allegheny County all food-manufacturers must prepare their food in a <u>licensed</u> and inspected facility before you can legally make and sell your food product. There are several manufacturing options to bring your product to market, each with its own costs, pros and cons, and requirements.

# **Business Planning**

Before starting your new food business, you need a clear vision of how you want your business to operate; how it will be managed, marketed, and financed; and how you expect it to perform in the future. To achieve this goal, you need to write a business plan.

Writing a business plan forces you to take a realistic look at exactly what your business will involve and helps you estimate start-up costs. A business plan helps you define your reasons for entering the food business, the type of enterprise you want to run, and allows you to set realistic goals. It enables you to organize and prioritize all of the great ideas you have for your business and communicates your business ideas to others including lenders. It shows why your business

venture is feasible and if it is profitable. Your plan will lay out detailed, research supported plans for how you will reach these goals and succeed in the marketplace. A successful business plan must be focused, clearly define target markets, and prove to lenders that you will have sufficient cash flow to repay debt and cover all business expenses.

Writing your plan down on paper allows you to:

- Identify who you are, what your product is, and why you are qualified to succeed
- Lay out your goals and action plans for making your business profitable
- Identify and resolve potential problems before they occur
- Target areas where financing is needed and locate funding sources

As you draft your initial plan, you create a visible version of your dream; get your idea out of your head and begin to make it a reality. You will need a network of advisers and supporters, and your plan will be essential for communicating your ideas to them. In fact, most lending and consulting agencies insist that you write your plan before they provide their services.

#### Components of a Successful Business Plan

There is no single correct format for a business plan. However, successful plans contain the following basic elements:

- 1) **Executive summary:** A concise one-page overview of the plan. This is a condensed outline of your plan designed to spark the reader's interest so they will want to read the rest of your plan. It should highlight the crucial information you present in the plan. The information in this section must match elements included in the rest of the plan. It should include company information describing the product, your objectives, your background, and your management team. It should include a complete project description, describe market opportunities, and summarize the financial data detailed in your financial statements.
- 2) General description of the business: The reader should be able to have a true understanding of what your business is all about. It should be clear and focused. This section should describe the following: why you are starting the business, the legal structure, the location of the business, and the hours of operation (if applicable). It should describe your staff, how you will handle day to day operations, the manufacturing of the product, and your plans for the future (immediate and long term). This should also answer the following

questions: Where are you now? Where are you going? What stage of development is your business in and what is your general plan for growth? How are you going to produce and package your product?

- 3) **Personal and business mission statement:** What are your qualifications for success? Why are you in business?
- 4) **Business goals and objectives:** What is your timeline for what you want to accomplish?
- 5) **Background information:** What is the current state of the industry? What are current and future industry trends? How does your business fit in the industry?
- 6) Ownership, government regulations, and contracts: How will your business be structured? What government regulations apply? What contracts and leases do you intend to enter? What kind of coverage is needed?
- 7) Management issues: Who will do what? How will you manage employees? How will you manage risk? How will you face the unexpected? This section describes key players in the business. Provide an outline of your management structure that includes titles and job descriptions for key positions, and information on your lawyer, banker, business advisor, accountant, and insurance agent. The reader should be able to see that you and your staff have the expertise to run this business successfully. This is a great time to take a good look at your skills and determine where you need improvement or assistance. This section includes a description for you, the owner, and each person listed as management. For each person you should include education, employment history, technical training, depth of industry experience, practical business/management experience, and other notable skills. Also include organizations you and your staff are associated with or plan to join. This section should identify who will be responsible for various functions in the business. Formal resumes should be included in the Exhibit section for the owner and key managers.
- 8) Succession and estate plans: Who will take over the business if you are no longer there to handle it? Under what circumstances would you hand over the business to someone else? This section may come at a later stage of your business, once you have fully launched to market.

- 9) Marketing plan: What features and benefits does your product offer? How will you promote and sell your product? Who do you want your customers to be and what is your competition? What is the expected life cycle of products and what plans do you have for future products and business expansion? This section should demonstrate your complete understanding of the competition, referral sources, and potential customer base. You must set realistic objectives and revenue targets. Your marketing strategy should include a product description and detail how it differs from the competition. Describe your distribution channels and whether you will focus on retail, wholesale, or both. Describe your target markets, how you'll create and maintain customer loyalty, and your competitive position. The competitive position includes price comparisons with existing products, the number and types of competitors, and what makes your product different. Describe your promotional strategies; website, brochures, in-store demonstrations, specialty food trade shows, flyers, advertising, referral network, and other outreach activities.
- 10) Financial plan: What are your expected expenses and how will you pay them? What is the expected profitability of your venture? How will you create a budget based on financial needs and expected income? What is your current personal financial situation? You must show detailed projections (pro forma statements) of earnings and expenses for three years, including Cash Flow Statements, Income Statements, and Balance Sheets. Projections for the first year should be broken down month by month. Projections for years two and three should be shown on an annual basis. You must show your ability to repay any debt. You must include the assumptions you used to create your pro forma statements. It is best to underestimate revenues and overestimate expenses; be conservative.

A brief, non-inclusive list of food startup expenses includes (startup restaurateurs would have a much more extensive list of expenses):

- Regulatory Food Licenses (@ \$100-\$500) ← don't skip these!
- State Business Registration Fees (@\$100)
- Opening a Bank Account (@\$50)
- Product Liability Insurance (@ \$500-\$1,000/year)
- Nutritional Labeling Analysis (@ \$300-\$600/recipe)
- Shelf Life Studies (@ \$100-\$500/recipe)

- pH and Water Activity Studies (@\$150/recipe)
- Ingredients
- Labels and Packaging
- Kitchen Tools & Equipment (misc.)
- Licensed kitchen rental
- Website (\$1,000)
- Business cards (\$50)
- Sales sheets (\$20)
- Trademarking fees (@\$1000 per registration)
- 11) **Supporting Documents**: The business plan narrative should flow without interruption. Supplemental materials can be added in the Appendix section. The SBDC recommends the following documents be included in the Appendix:
  - a) Business Certificate / Corporation documentation
  - b) Purchase Offer Agreement/Lease Agreement—include any agreements made regarding the lease or purchase or equipment or property.
  - c) Collateral—a list of assets that will be security for the loan, including estimates of the present market value for each item.
  - d) Resumes for owners and key staff
  - e) Labor Schedule—list job positions—current and to be created, the number of employees in each position, and approximate wages.
  - f) Examples of marketing collateral if available—brochures, flyers, examples of labels and logos, screen shots of your website homepage or Facebook page, and articles about your business.

# **Guiding Questions for Business Vision Planning**

As a first step to writing your business plan, ask yourself the following questions.

- 1. Morning Routine: What time do you wake up and what does your morning routine look like?
- 2. **Workday Routine:** What does your workday look like? Do you see yourself designing new products/taking sales calls/working on marketing material/meeting with your employees/or a combination of all of those and more? What tasks are you good at? What weaknesses have

you strengthened through courses, books, or life experiences? What responsibilities have you outsourced to experts or have you hired on your own experts to be on your staff? If you're working on this business part-time, describe what your workday looks like after you're done with your 'normal' job.

- 3. **Workspace**: Do you work from a home-based commercial or in a commercial kitchen outside of your home? Do you do 'office work' out of your home, an office you rent, or a coffee shop? Describe what this space looks like. Do you own it or rent it? Do you feel frenzied and worried when you're there or excited about the opportunities before you? Is your email in-box crammed with messages and orders? Do you have employees who will be helping you (if so, what time do you see them coming into the workspace)? Do you have capital to pay for employees or extra help?
- 4. Business Outlook: What does your business look like at this point? Are you selling your products wholesale and, if so, how many stores are your products in? Do you have a loyal group of online customers who make up the bulk of your revenue? Do you see yourself sending off samples of your product to magazines and bloggers to review? Or perhaps your company was recently featured in your favorite media outlet? Are you planning to introduce a new product soon? What do customers think of your <u>branding</u> and <u>marketing</u>?
- 5. **Length of Day:** How long is your workday? Do you see yourself working 9 to 5? More? Less? Maybe you're product requires that you sell fresh to markets each morning person and you'll need your day to start at 4 a.m. Or maybe you have kids who need to be picked up from school so you see yourself being done by 3 p.m. every day. Perhaps your workday hours will be more sporadic because of your current life situation. There's no wrong answer, just highlight how this business fits into the life you want for yourself.
- 6. **Financial Goals:** What financial goals do you want your business to hit? This can be highlighted via a specific number, a monthly salary, or even an item that you'd buy or status that you'd achieve that, to you, symbolizes that you've hit your financial goals.
- 7. **Post Work Week:** When you leave work for the day what do you do? Are you headed out for a run with your dogs or out for drinks with friends? Do you check email throughout the night or after the kids are in bed or do you shut down your computer entirely at the end of the day and not check back until the next morning? Remember, don't say that you're willing to work 24x7

if it's only going to make you miserable. Be truthful with yourself about what you want so that you can craft a business plan that will help you achieve that.

### Writing a Business Plan

If you have a hard time getting started, you are not alone! Almost everyone has to overcome writers' block before their business plans can take shape. Many people claim to have so many ideas in their head, but become overwhelmed when it comes to putting them down on paper. Find solace in knowing that almost all of what you need to learn can come through researching and talking to knowledgeable people. Here's how you'll know if you are on the right track:

- New issues and problems become evident as you write. If you find some surprises to address, it means that you are taking time to make basic decisions that will impact the future of your business, as opposed to just filling in the blanks.
- You constantly reevaluate and revise your objectives and goals. Business planning is a never-ending process; your plan will grow and change along with your business.
- You will realize that there are questions to be answered about marketing, technology and regulations, and capital needs and resources.

# **Business Plan Tips**

- You must write your own plan! Definitely seek assistance during the writing process, but you must take final ownership. Afterall, if you can't write your own business plan, how are you going to commandeer your company in the future?
- You must have a clear understanding of everything that is in your plan. You will find the research and preparation phase to be a great learning experience.
- Your narrative should be clear and focused. It is very easy to go off on side topics. Supplemental materials should be added to the Appendix section so the narrative flows without interruption.
- Know your audience. Is this for your banker? Will employees be part of the development process or have access to the finished copy? You may only want your employees to see specific sections of the plan.
- Keep your language formal. Speak in a third person voice; don't use "I" or "we".
- Don't show a draft version of your plan to anyone but trusted advisors.

- Speak confidently but be realistic about your future plans. Don't be overly optimistic. Don't
  make unsubstantiated financial assumptions. If you project strong revenue growth, you
  must explain why it is feasible. If you project expense savings while your revenues are
  growing, you must explain how you will make it happen.
- Don't ignore obvious issues in your external environment. Address them and how you will cope with and/or overcome these obstacles.
- Your business plan is never finished. You should review, and revise it if necessary, every six months or if you are undergoing major changes or issues.

### Getting Help

Anyone can write a business plan. However, most people do not have the knowledge or discipline to sit down and write a good plan without some one-on-one assistance. Plenty of books are available on how to write a business plan, and templates are available on the Internet for you to use. But these alone are not adequate to create a plan since a one-size-fits all approach is seldom useful. The best way to write a plan is to find a course or consultant that can help you through the process. Penn State Extension has resources available to help you write or review your business plan. In addition, a number of agencies, such as Small Business Development Centers and SCORE, offer seminars, one-on-one sessions and templates to assist you in creating a business plan.

Some online resources and local companies that provide Business Plan Development Services include:

- La Dorita Cooks
- The Institute for Entrepreneurial Excellence at the University of Pittsburgh
- Small Business Development Center at Duquesne University
- Bridgeway Capital
- LivePlan
- Score

# Ownership and Structure

The right structure—corporation, LLC, partnership, or sole proprietorship—depends on who will own your business and what its activities will be. Which of these forms is right for your business

depends on the type of business you run, how many owners it has, and its financial situation. No one choice suits every business. You have to pick the structure that best meets your needs.

In large part, the best ownership structure for your business depends on the type of services or products it will provide. As the manufacturing and selling of edible goods carries a considerable amount of risk, you'll almost definitely want to form a business entity that provides personal liability protection ("limited liability"), which shields your personal assets from business debts and claims, such as, for instance, food borne illnesses. When considering the best ownership and structure for your business, it may be worth consulting with your local small business development center and/or a lawyer. If you are a woman or of a racial or ethnic minority, you should also consider the advantages of registering your small businesses as a minority-owned business. Below we examine the advantages and disadvantages of each type of business structure.

#### **Types of Business Operations**

1. Sole Proprietorship: A sole proprietorship is a business that is owned by one person. As such, you own and control the business. Setting up a sole proprietorship is the simplest, quickest and least expensive way to go into business. Legally, all that is required for set up is to obtain a license as required by the federal, state or local government. If the business has a name other than your own, you must also register your fictitious name. You do this through a Certificate of Doing Business under an Assumed Name for sole proprietor, commonly referred to as a "DBA" (doing business as) form.

The sole proprietor is held personally liable for any business related obligation. What this means is that if your business fails to pay a vendor, defaults on a debt, or loses a lawsuit, you are personally liable for the debt. In the eyes of the law, the sole proprietorship is not legally separate from the person who owns it. The sole proprietor simply reports all business income or losses on his/her individual tax return—IRS form 1040 Schedule C.

# Advantages:

- Easiest, quickest and least expensive type to organize
- Easy to discontinue if desired
- Minimum of legal restrictions
- Owner receives all profits

Owner has complete control

#### Disadvantages:

- Owner has unlimited liability. Owner is legally responsible for business debts.
- Personal assets are at risk.
- Business dissolves upon death of owner
- More restrictions on deductibility of employee benefits
- 2. Partnership: This is a business owned by two or more persons who get together to run the operation. Partners can contribute capital, specialized knowledge, marketing or management skills, and other valuable tools. They also share the risk. Partners share in the right and responsibility of managing the business, and by law each partner is responsible for all debt and obligations of the firm. This means you are personally liable for the full amount of the partnership's debts, even if they exceed your investment and you did not personally consent to the debt. A formal written agreement should be prepared to properly define each partner's role in the business. A partnership's profits and losses are included on each partner's personal tax return. The partnership files an information return with the IRS.

### Advantages:

- Easy, quick and inexpensive to organize. However, time should be spent on a legal agreement: decisions, time spent, capital invested, profits, disputes, buyout agreement or new partner coming in, and steps to dissolve
- Easy to discontinue if desired
- More than one source of funds
- Share skills
- Profits or loss flow to personal tax return

### Disadvantages:

- Partners are jointly and individually liable for the actions of the other partners
- Personal financial hardships of one partner can affect the business assets
- Profits must be shared
- Disagreements can occur
- More restrictions on deductibility of employee benefits

- The partnership may have a limited life; it may end upon the withdrawal or death of a partner
- 3. "S" Corporations and "C" Corporations: A corporation in the Commonwealth of Pennsylvania is an entity mutually exclusive of the individual(s) that own and manage the business. A corporation is authorized to sell, buy and inherit property in its own name and has legal rights, powers and duties. Corporations are operated for profit and may raise capital by selling shares of interest in the corporation. A corporation's debts and obligations are distinctly its own. To create a corporation you must meet specific statutory requirements, which include filing a Certificate of Incorporation with the Pa Department of State, creating corporate bylaws, and issuing stock certificates.

Income and expenses of the "S" corporation flow through to investors in proportion to their shareholdings, and profits or losses are taxed to shareholders at their individual tax rates. Not all corporations qualify for this status. Certain restrictions apply: no more than 75 shareholders, no non-resident alien shareholders, and the corporation may not own stock in other corporations.

"C" Corporations are separate, taxable entities that report income and expenses on a corporate income tax return and are taxed at corporate tax rates. Profits are taxed before dividends are paid. Shareholders pay taxes on dividends by reporting them as income. It may result in a double taxation.

### Advantages:

- Shareholders have limited liability for corporate debts
- Officers can be held personally liable if fraud or negligence exist
- Lenders normally require officers to personally guarantee debt
- Corporations can raise funds through the sale of stock
- A corporation may deduct the cost of benefits it provides officers and employees
- Can elect "S" corporation status if certain requirements are met. Profits and losses pass through to owner's personal returns. Eliminates double taxation of corporate profits. IRS monitors for "reasonable compensation."

#### Disadvantages:

- The process of incorporation requires time and money (filing fees and legal fees)
- Corporations are monitored by federal, state and some local agencies, and as a legal entity there is more paperwork to comply with regulations.
- 4. Benefit Corporations or "B" Corporations: A Pennsylvania Benefit Corporation or "B" Corp is a Pennsylvania business corporation that is organized for profit, with a corporate purpose of creating general public benefit, in addition to any other purposes they have as a business corporation. A "B" Corp differs from a typical for-profit corporation by allowing the entity to consider how it can provide a greater good for the public, otherwise known as a public benefit. A "B" corporation may have as a purpose one or more specific public benefits. Such public benefits can include bettering the environment, bringing healthy food to a food-insecure area, or reducing poverty. A "B" corporation offers entrepreneurs and investors the option to build, and invest in, businesses that operate in a socially and environmentally responsible manner. Being a benefit corporation is purely voluntary. An existing business corporation may elect to become a benefit corporation by a two-thirds vote of its shareholders. In Pennsylvania, a benefit corporation may be formed at the time of filing of articles of incorporation or by amendment of existing articles to elect benefit corporation status.

To clarify, benefit corporations are not not-for-profit organizations, and any investments made in benefit corporations are not tax deductible. The benefit corporation is a new type of entity that allows companies to be socially responsible while still generating profits. Corporations that have adopted this model include <a href="Ben & Jerry's Ice Cream">Ben & Jerry's Ice Cream</a>, whose overall mission is to advance new models of economic justice that are both sustainable and replicable, <a href="King Arthur Flour Company">King Arthur Flour Company</a>, whose corporate mission is environmental sustainability, and <a href="Patagonia">Patagonia</a>, a company working to promote safe, fair, legal and humane working conditions.

### Advantages:

• "B" corporation legislation allows the entity more freedom to provide a benefit to society by not being required to have a single goal of maximizing the profit of its shareholders. Although "B" corps still strive to make profits to continue their business, this legislation allows them to consider society's needs as well as the

needs of their employees in conjunction with the desire to make a profit. The benefit is that this change in corporate purpose allows entrepreneurs and investors to promote social interests while still generating an investment return.

• "B" Corp status provides an avenue for corporations that want to pursue investment dollars to forward their societal interests.

#### Disadvantages:

- Expanded reporting requirements are a significant drawback to operating a benefit corporation. Transparency is an important aspect for a benefit corporation. In Pennsylvania, the benefit corporation must prepare and distribute to its shareholders an Annual Benefit Report describing its efforts to create public benefit during the preceding year. The report must be filed with the Department of State, making it a matter of public record. The report must also be posted on any public website maintained by the corporation. The fee for this filing is \$70. The report must:
  - 1. Describe the general public benefit and any specific public benefit pursued and created during the year and any circumstances that may have hindered the creation of these benefits;
  - 2. Assess the overall social and environmental performance of the benefit corporation against a third-party standard and state the process and rationale for selecting the third-party standard;
  - 3. Give the name and contact information of the benefit director and the benefit officer, if any;
  - 4. Provide the compensation paid to each director;
  - 5. Give the name of each person that owns 5% or more of the outstanding shares of the benefit corporation; and
  - 6. Contain the annual compliance statement of the benefit director, contain a statement of any connection between the organization that established the third-party standard and the benefit corporation, or their directors, officers or any holder of 5% or more of the governance interests/outstanding shares in either organization, including any financial or governance relationship which might materially affect the credibility of the use of the third-party standard; and

- 7. If the benefit corporation has restricted the powers of the board of directors, a description of the persons who exercise those powers and of the benefit director.
- Another potential drawback is that as "B" corporations are fairly new legal entities, uncertainty lies in how courts will interpret mandates that seek to increase profit and the greater societal good.
- 5. Limited Liability Company (LLC) and Limited Liability Partnership (LLP): An LLC combines attributes from corporations and partnerships (or sole proprietorships), protections from personal liability from business debts, and the simpler tax structure of a partnership. For tax purposes, one owner LLCs are treated the same as sole proprietorships. Profits are reported on Schedule C as part of his or her individual 1040 tax return. Multiple owner LLCs are treated as partnerships. The LLC files IRS Form 1065, Partnership Information Return. Profits are reported to each owner on a Schedule K-1. Each owner then pays taxes on this income on his or her annual 1040 income tax return. An LLP is a form of partnership with financial liability limited to the amount of each partner's investment. There must be at least one general partner who controls the firm and is responsible for its debt and obligations. The limited partner gives up the right to participate in the day-to-day management of the business. While the partnership does not pay taxes, it must file Form 1065 with the IRS. This form defines each partner's share of the partnership profits.

### Advantages:

- Owners have limited personal liability
- Can elect to file as a corporation (certain requirements must be met)
- Business structure designed to provide the limited liability features of a corporation and the tax efficiencies of a partnership

# Disadvantages:

- Relatively new business structure-limited case study
- Certain businesses cannot be LLC (banks, insurance companies, non-profit organizations)
- Requires filing fees and possibly legal fees

Once you have consulted with a qualified accountant, advisor and/or lawyer and determined the best ownership structure for you, you can apply for your SS-4 Federal Employer Identification Number (EIN) from the <u>Internal Revenue Service</u>. An EIN can be obtained via telephone, mail or online. If you obtain one by phone, the IRS representative may request that you mail or fax the signed SS-4 Form to them. Once you have a valid tax identification number, you may register your business at <u>PA Biz Online</u>.

Questions related to business structure, fictitious name registration, etc. can be directed to the PA Department of State Customer Service at: 717-787-1057. Tax-related questions can be directed to the PA Department of Revenue Taxpayer Service and Information Center at: 717-787-1064. If you need additional help regarding starting or expanding your business, go to the PA Department of Community & Economic Development's website.

Some of our most trusted legal and accounting advisors we work with and rely on at La Dorita Cooks include:

- <u>Trellis Legal LLC</u>—Provides legal services to non-profits, businesses (with a focus on startups), and citizens devoted to local agriculture, ecological development, and social entrepreneurship.
- <u>Cohen & Grigsby</u>—Provides general business and tax planning, as well as intellectual property services for <u>trademarking</u> your brand.
- Wilke and Associates—Provides general startup planning and accounting services, from ownership and structure, to deciding on a business entity, to providing projections for financing or establishing budgets, to helping you set up a Quickbooks account for invoicing and payables. Managing partner, David Wilke, is a wonderful advisor to all local area entrepreneurs—no matter the stage of your business.
- The Institute for Entrepreneurial Excellence at The University of Pittsburgh—Provides
  startup education and consulting resources, as well as workshops and IT services.

Once you have consulted with a qualified advisor as to the structure of your business, you may also want to consider registering your corporation and the required documents on a legitimate legal website (such as <u>Legal Zoom</u> or <u>Rocket Lawyer</u> as they are typically more economical than using traditional legal services.

### **Insurance for Food Processors**

Once you have registered your food business, you should begin to research and shop for business insurance to provide adequate general liability protection. Due to the specialized nature of food manufacturing, retailers, wholesale distributors, and commercial kitchens all require food vendors and manufacturers to carry a minimum insurance policy of \$1 million per occurrence in both product and general liability and a \$2 million annual aggregate limit. Product liability insurance helps protect you—and the retailer—should a food you produce for sale harm consumers. For the victims of a foodborne illness, one of the main worries is the medical expenses, which can be staggeringly high—sometimes up to \$1 million or more. Some examples of foodborne illnesses are salmonella, E. coli, listeria, and campylobacter. The young, the elderly and those with weakened immune systems are the most likely to fall victim to foodborne illnesses and the most likely to suffer the most harm from them. In these cases product liability insurance is vital, as it will cover the medical expenses should a customer come down with a foodborne illness.

General liability insurance, on the other hand, is designed to cover risks that may include bodily injury or property damage caused by direct or indirect actions of the insured; for example, it would cover a market canopy falling over during a windstorm and injuring a customer. A comprehensive insurance plan should include vendor liability coverage for goods in process, food inventory and spoilage in transit. In addition, insurance can provide product recall coverage based on recalls mandated by the FDA, as well as non-FDA potential bodily injury determinations that require a recall.

Don't wait until you have your first product on the grocery store shelf to purchase an insurance policy. You will need insurance coverage before you start developing products and handing out samples to prospective clients.

### How Expensive Is It?

Rates for product and general liability can vary. Because the premiums are based upon annual income, you can expect to pay anywhere from \$525 to \$850 per year if your annual income is equal to or less than \$25,000/year, and \$1000 to \$1500 for vendors who generate between \$25,000 and \$100,000 in total annual sales. For vendors who generate more than that in annual sales, the cost of the policy will generally increase at a rate of approximately \$5 per thousand in sales. It is important to get at least three independent insurance bids to make sure you secure maximum coverage at the best price.

Choosing an insurance agent is as important as choosing an insurance policy. Your agent should be someone who can guide you and with whom you are comfortable discussing your concerns and needs. Many people start with the agent who handles their personal insurance, such as personal property, vehicle, or life insurance. This may or may not be the right choice for you. Make sure your business insurance agent has a thorough knowledge of the insurance industry, as well as realistic experience with food businesses, so that the plan you select provides adequate and appropriate coverage at a reasonable price. Have your agent explain all aspects of the policy to you in detail so you know exactly what is or is not covered. This will help eliminate any future surprises. If your current agent does not handle business insurance, he or she should be able to refer you to another reputable agent or agency that will meet your needs.

In all cases, it is best to shop around, and contact several insurance brokers to quote you the best coverage and price. At La Dorita we often recommend our new members quote out their insurance with <a href="Spodek Insurance Agency">Spodek Insurance Agency</a>, as they will often provide special consideration to food startups working out of our space. Your banker or accountant, trade organizations, and other businesses may also be helpful resources for finding the right insurance agent.

# **Funding**

Fundraising is a major challenge for food entrepreneurs. Going after the right type of funding can make or break your business. With a new business comes new financial responsibilities added on to the old responsibilities of a mortgage, monthly bills and food. The biggest surprise in starting a business is how fast you can easily burn through money. Navigating the options for funding your company and finding investors who support your goals is easier said than done.

First and foremost, you need to determine how much money you really need. Start by asking yourself how much you can actually produce. Coming up with a concrete business idea, being

able to show that there is profitability after everything else is paid, and keeping the overhead low are all things you must carefully consider.

Second, keep business overhead low. Everything from rent, computers, ingredients, office supplies, utilities, and, your time will be an expense even before you start making profits. Every business owner we talk to echoes the same advice: keep your overhead at the lowest level possible. For example, if you must rent kitchen space, look into shared or <a href="underutilized">underutilized</a> <a href="commercial kitchen">commercial kitchen</a> spaces that allow you to only pay for the time you are actually using the kitchen. Or, even consider working for a restaurant or bakery and negotiate use of the kitchen on off hours into your compensation package. Finally, before seeking funding, you need to sit down and ask yourself how you will pay expenses before your venture turns a profit. Some options to consider are:

- Personal resources. Use savings, credit cards, or a credit line on your house. You maintain complete financial and operational control over your business and there are no co-owners to pay off if the company hits it big. But if the business fails, you will still have the personal debt, and credit card debt carries high interest rates. Tapping into your IRA is also an option to consider. You may want to check with your accountant, but you can borrow a certain amount of money from your IRA as long as you pay it back the next year. You get penalized if you don't. That's not the worst thing in the world if you have at least \$100,000. But tapping into your 401(k) is a last resort because that's money that goes to you tax free. Either of these options carries the highest risk, but allows you the most autonomy over your company.
- Friends and family. You could raise money from people you know well, either in exchange for a share of your business or as a loan to be repaid. But remember, you must first sell those closest to you on your idea, and speaking from experience, those closest to you may not necessarily support your endeavor or condone the risk you are about to take on—for you and/or your spouse and/or children. To ask is to make yourself vulnerable to scrutiny by those you most care about. On the flip side, if they do agree, this option allots money that is readily available, but it's usually a one-time source.

Mixing friends, family and money can be a dangerous combination, so make sure it's spelled out in a contract that will protect friends' or family members' investments. People

should keep in mind that even with friends, if the company goes belly up for some reason, people you owe money to are not going to be happy. You want to put up a fairly decent contract that also protects yourself. Be honest with yourself. *Are you ready to deal with the consequences and criticism if your business does not succeed?* 

• Crowdfunding. Crowdfunding, also known as "crowdsourcing" is an ever increasing trend when it comes to food startup fundraising. If you have not heard of crowdfunding, this is a web enabled way for smaller companies to get funding vs. traditional angel or venture funding. Everyone from jam makers and picklers to want-to-be food truck vendors and bakery owners are taking a chance on crowdfunding. It not only allows food startups to continue to grow their business organically, but they it also provides a platform to market your product or service in a grass-roots, community-like fashion. Not only are crowdfunding giants like Indiegogo and Kickstarter helping food startups launch and grow, but crowdfunding platforms (both equity and non-equity) are popping up, too, all aimed at helping food entrepreneurs grow their businesses faster and smarter.

Using sites like <u>Kickstarter</u>, <u>IndieGoGo</u>, <u>Food Start</u>, <u>Barnraiser</u>, <u>CircleUp</u>, <u>CrowdFooding</u>, <u>EquityEats</u>, and <u>Pie Shell</u> (to name a few), individuals typically create a video describing their product and stating their funding goal. Donors make online pledges, in amounts as small as \$5, to \$5,000 and up. Instead of a stake in the company, their "return" is usually a simple reward in the form of a thank-you, T-shirt or token gift. Some small businesses also choose to use "equity crowdfunding" that lets them raise money from investors who receive a stake in their company. Individuals can donate up to \$1 million.

At La Dorita, we are no strangers to crowdfunding. In 2012 we successfully raised \$50,000 on <a href="Kickstarter">Kickstarter</a> to open our community shared kitchen and introduce our dulce de leche liqueur to market. While it was no easy task raising the funds—which required 30 days of rigorous networking and an unyielding perseverance of asking those you know and don't know to support your cause—it allowed us to take a huge step forward in our food endeavors. It should also be noted that of the \$50,000, we netted \$42,000 after taking into consideration Kickstarter and Amazon's percentage, the fee to make our video, and the cost of the rewards attributed to each donation. Finally, one thing to consider prior to launching a Kickstarter.com is that while it seems to cater to larger donation amounts, it also carries a higher risk as the campaigns are all of nothing—if you don't meet your goal in

the allotted time of your campaign, the campaign does not fund...even if you miss this by just a smidgeon.

Another previous member of our community shared-kitchen, <u>Sticklers Pops</u> (formerly known as the Pop Stop) successfully raised more than \$2000 to help purchase a new frozen dessert truck on <u>Foodstart.com</u>. Unlike Kickstarter, Food Start allows the campaigners to walk away with the funds collected—even if they don't reach their initial goal. This is something you definitely want to consider when choosing the best crowdfunding platform for your product and situation.

In recent years, a staggering number of new food and agriculture funding sources have launched across the country. Prior to launching your campaign, it's important to research each funding platform as each carries its own risks and rewards. Some tips to successfully raise money through crowdfunding, include:

- Network, Network: Reach out to your network of friends, family, patrons, existing clients and customers PRIOR to launching your campaign. You will always have the most traction and donation more towards the launch of your campaign. Enthusiasm often wains as the campaign persists. Use social networking, as well as word of mouth.
- Make it personal: It's about an emotional connection to you and your project. Tell
  why it's important or how it will benefit others. Backers want to be part of something
  that matters. Use short-but-sweet videos, personal testimonials, examples of your
  project, etc.
- **3. Show progress**: It's helpful for supporters to see you've made progress on an idea. If you've got a prototype, show it. Ideally, limit your funding campaign to 30 days.
- Bank Financing. Borrowing money from a bank or credit union keeps home and business finances separate. It is probably the hardest thing to do because of the strict regulations banks impose on companies—such as showing a profit and having a perfect credit score. Startup businesses with no track record often find getting a loan difficult. Prior to seeking bank financing, make sure to have a solid business plan that includes 3 years of financial projections. If you should succeed, the relationship you create with your bank will be useful

as you expand and need additional capital. Keep in mind you will most likely have to provide personal collateral, such as your home, to secure the loan.

In addition to seeking funding from traditional banking institutions, there are housing and social service lenders such as Bridgeway Capital, whose mission is to bridge the way from entrepreneurial ideas to actual business growth and economic impact. These financial institutions tend to better understand the challenges that startups face, and offer less rigorous regulations to secure a loan. Bridgeway Capital offers small business loans that are categorized into two primary stages, Entrepreneur and Growth. Entrepreneur Loans are typically best suited for startup businesses looking for the resources need to make the first moves. Growth Loans are mostly utilized by business with larger operations, and can help them reach a higher level of success. They also offer non-profit loans and a Flexible Food Financing Fund that includes a mix of grant monies and loans that was made possible by the <u>Hillman Foundation</u> in partnership with <u>The Heinz Endowments</u>. In addition to offering loans, Bridgeway Capital offers its clients an enormous amount of educational and small business resources to help you fine tune your business plan, brand your product, and even create a website. Bridgeway Capital's loans can be as small as \$2000 to help you buy a food cart, to hundreds of thousands of dollars. No matter the size of the loan, the same resources are available to all of their clients.

Idea Foundry, a Pittsburgh-based economic development organization founded in 2002, has created a pilot revolving loan fund designed to support local entrepreneurs innovating around connecting consumers with local foods, reducing regional food insecurity, increasing on-farm sustainability, and increasing jobs in local farming. Idea Foundry's focus on strengthening local food systems is a sub-focus of their work supporting local social enterprise companies ("B" Corps"): for-profit ventures that are driven by a social or environmental mission, and that deliver sustainable social, environmental, and economic benefits to stakeholders all across the value chain. Funds will be dispersed to as many as six businesses in year one, with the goals of creating jobs and addressing the specific capital needs of both agricultural businesses and the innovative food, agriculture, and horticulture startups that serve them. With repayment, it is expected that participating businesses will generate monies that will then be recycled back into the fund. The revolving loan fund pilot program is being supported with a grant from the Richard King Mellon Foundation.

<u>Kiva Zip</u> is another pilot program, launched by Kiva.org, to drive innovations in person-to-person lending. Kiva Zip provides 0% interest loans up to \$5,000 for small businesses and entrepreneurs who are financially excluded and underserved. The program uses an entrepreneur's network as a measure of creditworthiness. Borrowers invite family and friends to start their fundraising. After reaching a designated threshold, the Kiva Zip community takes care of the rest. This is a simple, transparent way to help small businesses.

If you do choose to seek funding, keep in mind that lenders often refer to the five "C's" when evaluating a financing deal:

- Capital—is the ownership team investing any of its own funds into the venture?
- Collateral—what is the business using to secure the financing (equipment, inventory, accounts receivable)?
- Conditions—is this the right environment for this business? Industry trends, economic vitality of a community, and amount of competition often figure into this analysis.
- Capacity—Does the ownership team have other sources of repayment should the business venture not work? For example, if the business were to fail, could the business ownership team gain other employment to continue servicing the debt?
- Character—has the business and ownership team shown the ability to manage finances? This is often most evident in their credit history
- Angel Investors/Venture Capitalists. Angel investors are private individuals that invest
  into small businesses. Each angel investor will have different expectations on how he or
  she wants to structure a deal, so it is advisable to consult with legal and accounting
  professionals for advice before making a commitment to a deal. Venture Capitalists are
  more organized investors or investment groups that tend to look for a very large return on
  investment and usually seek a large equity portion and some form of management
  oversight.
- **Grants.** There may be special programs designed to support determining the feasibility of an enterprise or demonstrating an innovative process. Not all grants require payback and

you don't pay interest to the funding source, so grants are essentially "free money." Most grants have "deliverables"— things you promise to do in exchange for the funds—and report schedules you must follow. Also, grants usually are available during a specific window each year, rather than responding to your schedule. Most foundations also require that you have a non-profit company to be considered for grant monies. Keep in mind that competition for grants is stiff, so you may need help writing the application.

<u>Bridgeway Capital</u> offers a Flexible Food Financing Fund that includes a mix of grant monies and loans that was made possible by the <u>Hillman Foundation</u> in partnership with <u>The Heinz Endowments</u> that is worth looking into—especially if you intend to establish your company in an area deemed a food desert (an urban area in which it is difficult to buy affordable or good-quality fresh food). The Pittsburgh Post Gazette's online resource guide, "<u>Mapping Hunger: Where are Pittsburgh's Food Deserts</u>," provides an in-depth look at our area's neighborhoods that are deemed to be food-insecure.



# **Manufacturing Options**

Aspiring food makers, caterers and chefs can easily whip up a passion for their craft. However, finding the up-front funding to establish a brick and mortar, licensed commercial kitchen presents a whole different challenge. This alone often deters food entrepreneurs from pursuing their dream of launching their product to market.

According to a recent U.S. Small Business Administration (SBA) report, one statistic remains constant: "About half of all new establishments survive five years or more and about one-third survive 10 years or more." The SBA cites three fundamental reasons for this rate of failure—a lack of planning; a lack of access to sophisticated resources; and an inability to execute in increasingly complex and competitive economic environments.

Many successful food businesses begin in a home kitchen with nothing but a family recipe and devotion to their craft. However, Allegheny County Health Department's <u>Food Safety Division</u> requires that a food business use a certified commercial kitchen if selling food to the public—no matter the type of food maker or the markets where you sell. A certified commercial kitchen must include a separate and dedicated entrance from the outside, a commercial kitchen hood for heat and fumes, a grease trap, and separate hand, food-prep and three-basin sanitation sinks, to name a few of the common regulations. These features are difficult and expensive to achieve in a home kitchen.

Like all small businesses, specialty food entrepreneurs start up with an investment in development, production, marketing and sales. One of the differences, however, is that for a lot of new businesses, products can be made in the basement until sales show enough of a market to invest in a separate location. For food artisans, the basement isn't an option. Nothing can be publicly tested, marketed, much less sold, unless it's been prepared in a health department-approved kitchen from the start.

You must first be honest with yourself, and figure out whether you will outsource your manufacturing or whether you want to be an integral part of the process. Some options to consider:

• Start out small and keep your "day job." You can feel your way while there is still money coming in, but you may be working long hours for six or seven days a week for an extended period of time—even years.

- **Get your family or friends to help out for a while.** This may be the right solution for those on a small budget, but the arrangement might put a strain on your family life and your relationship with friends.
- Hire people or a <u>co-packer</u> to do the work. You are free to manage the business, or to work at another job. But employees mean higher upfront costs for wages, training, insurance, etc.

Keeping this in mind, ask yourself the following questions as you are developing and perfecting your product prototype:

- Where will I manufacture my product?
- Where can I source my ingredients at the best wholesale price?
- Can I realistically make my product at an affordable price?
- What are the quality and safety parameters of my product?
- Are there state and federal regulations for my type of product?
- Do I want my product to be organic/gluten-free/kosher/halal certified?

At this point, you should have a professional-looking version of your product in hand. Now you must produce a large enough quantity to sell. You have several production options:

- Home-Based Commercial Kitchen
- Underutilized, Shared-Use Commercial Kitchen
- Commercial Incubator Kitchen
- Utilizing a Co-Packer
- Building Your Own Processing Facility (out of the home)

There are advantages and disadvantages to each, and you should research each option to determine which one will work best for you.

# Home-Based Commercial Kitchen

Home processing may be a legitimate way to start your business depending on your food item. However, unless you plan to build a commercial kitchen in your home, it is likely just a temporary solution. Cottage food laws are basically laws that allow small-time producers to use appliances

in their homes to bake, cook, can, pickle, dry or candy certain low-risk foods for sale. By contrast, state laws require all other food producers to process foods in licensed kitchens. Pennsylvania is a bit different than other states in that it doesn't have laws specific to cottage food operations, but the Pennsylvania Department of Agriculture's Food Safety simply allows "limited food establishments" that meet specific guidelines. The Pennsylvania Department of Agriculture allows certain foods to be prepared in a licensed home kitchen, while others cannot due to food safety concerns. Some of the most common foods allowed include:

- Honey and Maple Syrup
- Home canned products that reach a <u>pH</u> of 4.6 or less such as salsa, pickled beets, pickled vegetables, hot sauces, and barbeque sauce. Some traditional fruit jams, jellies, and marmalades (even dulce de leche milk caramel spreads), will also be considered
- Bakery products, i.e., bread, rolls, cookies, cakes, brownies, fudge, and double-crust fruit
  pies for wholesale marketing or retail agricultural venues such as farms, farm stands,
  farmers' markets, craft fairs and flea markets
- Spices or herbs
- Snack items such as popcorn, caramel corn and peanut brittle
- Candy (excluding chocolate)—tempering chocolate for molding/dipping is typically not allowed.

If you plan to open a home-based commercial kitchen, make sure to inquire whether you will need a zoning variance with your local municipality to operate a commercial food business from your home. A zoning variance is an authorization to allow an exception to certain standards as outlined in a zoning code.

La Dorita dulce de leche was founded in a licensed home-based commercial kitchen, and operated from the same the first three years we were in business. At the time we were unable to find any shared-kitchen options that met our needs. With no other options available to us, we decided to convert our home's dining room into a separate commercial kitchen that we maintained under lock and key so that our small children could not access the kitchen. While this was an expensive endeavor that forced us to take out a third mortgage on our home, it did enable us to launch our company while maintaining our full time day jobs, as we cooked and prepared our product after our children were sound asleep. I do have to warn you that building a separate commercial kitchen in your home is no easy endeavor. You are required to submit a plan review prior to construction to your local Allegheny County Health Department Food Inspector officer, in

addition to seeking licensing with the <u>PA Department of Agriculture</u>—not to mention seeking licensing approval from your local municipality. All-in-all, the licensing process took us just over seven months to complete.

The first thing you need do, if you plan on home production, is contact the Pennsylvania Department of Agriculture. This agency will certify your home kitchen if your food item and production process fall under their jurisdiction. Generally, the types of production that can occur in 'limited food establishments' (whether an actual home-use kitchen or a kitchen designed in a residential fashion) are limited to foods that are not 'time and temperature controlled for safety' (TCS) foods (i.e., potentially hazardous foods, 'PHF'). TCS foods are foods that will support the growth of pathogenic microorganisms and require temperature controls (kept hot or cold). TCS foods can only be produced in a licensed/registered 'commercial' food establishment kitchen that meets the full regulatory code requirements, including separation from residential-use areas, and adequate plumbing fixtures. This does not specifically prohibit processing of TCS foods from a residential property, but the foods could only be produced in a second 'commercial' processing kitchen separate from the private home kitchen or any residential personal use areas, and that meets the full regulatory standards for a food establishment. While the application process is lengthy, limited food establishments have a lot of flexibility once they're setup.

Don't be intimidated by the licensing process. You need to follow some common sense rules and ask your inspector in advance what is expected of you. In Pennsylvania, there are many similarities between the registration process for home-based food establishments and other food processors. You will need to discuss the options for your particular product and your particular household situation with your Pennsylvania Department of Agriculture sanitarian. If you are allowed to make your product in your home, then you will have to get your kitchen up to state standards before beginning production. You may have to purchase new equipment appropriate for commercial food production and learn about handling, preservation, and packaging methods that keep your products safe.

The fee to <u>apply</u> is only \$35, but the startup costs could be much greater since certain types of products require you to build a separate kitchen that meets <u>Allegheny County Health Department Food Safety</u> requirements from your family's daily kitchen. Ingredients for the business must also be kept separate from those for personal use. Most products also require laboratory testing. If you are considering in operating out of your home, one notable restriction is that pets are ONLY allowed in your home if you can completely prevent them from accessing the parts of it where you

operate your business. You cannot carry any ingredients or products through an area that pets can access, and your kitchen, storage, and prep areas must be completely shut off from them. If you can't guarantee that your pets will be precluded from those parts of your home, then you can't run a limited food establishment. Caged pets (birds, snakes, etc.) that are kept away from the kitchen are allowed.

The Department of Agriculture also requires home food producers to create a business plan and get your home inspected before getting approved. The approval process could take up to 60 days to complete. Once licensed, home-based food producers have a lot of freedom in running their business. Pennsylvania allows more types of food than most states, and it is the only state to allow meat jerky to be produced from the home. Home-based food producers can sell anywhere they want (including interstate), and there is no limit on the amount they can sell.

Here are some of the common sense rules of home processing:

- Keep your work area clean.
- As mentioned above, there should be no pets in the kitchen if you are producing food commercially. If you have a cat or dog, you should have a door to your kitchen.
- Use dedicated equipment and ingredients that are just for your commercial production (spoons, bowls, cutting boards, etc.).
- Put dates on every perishable ingredient you use, as well as every batch of food you produce.

With home production, the amount you are able to produce will be limited by the size of your space and equipment, but you'll be able to work whenever you want, control the quality of your product, and the rent is great. On the flip side, many wholesalers will not deliver orders to residential areas, limiting your access to lower-priced, bulk ingredients. Maintaining a consistent taste and consistency for different batches can also sometimes be an issue in this type of small scale production.

To determine whether establishing a home-based kitchen is right for you, visit the <u>Limited Food</u> <u>Establishment</u> page on the PA Department of Agriculture Food Safety Division website.

# Underutilized, Shared-Use Commercial Kitchen

If your home kitchen is not suitable, consider renting an underutilized commercial kitchen. You can prepare you food product in an already established underutilized commercial kitchen in a local neighborhood restaurant, church, or fire hall. In this scenario, someone else is responsible for meeting kitchen standards. But you will have to pay rent for the space, you will need to register with the Allegheny County Health Department (ACHD) Food Safety Division to make your product at that location, and most importantly, you have to work around someone else's schedule. Often time's entrepreneurs will work in a restaurant or bakery and negotiate access and use of the kitchen in off-hours as part of their compensation. This certainly helps to control up-front processing costs. You must still apply for your own permits when using another company's commercial kitchen.

If you need specialized equipment, you'll likely need a more sophisticated set-up than most underutilized church or restaurant kitchens provide. It is best to use a facility that allows you to lock up your ingredients (including separate refrigerated items) and equipment. Ask other small food producers you meet for kitchen recommendations. You can also look for not-for-profit community kitchens in your area. <a href="Launch Millvale Food Incubator">Launch Millvale Food Incubator</a> helps connect local food startups to underutilized kitchens in the Pittsburgh metropolitan area.

# **Commercial Incubator Kitchen**

Allegheny County Health Department and PA Department of Agriculture-approved commercial shared-use kitchens such as La Dorita Cooks aim to absorb the upfront financial risk of opening and operating a commercial kitchen. They provide food producers with a production space, and most often offer a place to conduct business with Wi-Fi access. Members are able to rent by the hour and are afforded a great opportunity to start at their own pace and grow. You must still apply for your own permits when using a shared commercial kitchen. The kitchen's management team will often walk you through the licensing process—which can be achieved in as little as one week.

The model for La Dorita Cooks food-specific, co-working space organically developed over the course of three years after we were unable to secure licensed kitchen space to launch our own for-profit specialty food start-up business, La Dorita dulce de leche, to market. The incubator resulted from a personal need that threatened to deter our own personal success, and we were determined to fill this void. Now, with its central location, La Dorita Cooks is well situated to serve

our area's following core groups: bakers, caterers, specialty food producers, personal chefs, cart vendors & food trucks.

If you make your product locally in a fully licensed commercial kitchen, your product will be fairly easy to create as you can use ingredients sourced from wholesale distributors or local restaurant supply stores and can work with equipment already in the kitchen. Most incubators also offer access to shared buying, which affords you more competitive pricing when sourcing ingredients. Shared-use kitchens typically have larger equipment, which can enable you to operate more efficiently and produce larger batches. Many shared-use kitchens provide other coaching services, such as help commercializing your recipe or help getting it into the marketplace. They may also help you identify vendors for ingredients and packaging.

Most shared kitchens allow you to lock up your ingredients (including separate refrigerated items) and equipment. Due to limited space, storage fees are often assessed in addition to hourly rental fees. They also provide a business address to receive large, wholesale deliveries and ship large orders using palettes. While shared-use kitchens typically offer accessible rates to commercial kitchen space, you will have to work around the schedule of other members, and plan accordingly to secure enough kitchen time to meet your production needs.

All shared kitchens will require you to have your own liability insurance, a city food-service sanitation certificate and a shared-kitchen license. Visit the <u>Penn State Extension Food</u> <u>Entrepreneurs</u> website for a list of shared kitchens in Pennsylvania.

# Co-Packer

Unless you plan to build your own production facility, at some point you may need to consider using a co-packer as your sales volume increases. A co-packer refers to a facility that either manufactures your product according to your recipe and specifications or receives your finished good in bulk and packages it for you. They have commercial equipment, professional staff, and the ability to buy ingredients and packaging at a lower cost than a small individual producer. This is an efficient, cost-effective way to bring your product to market rather than building your own manufacturing facility. Co-packers can provide a range of services important or essential to the development and production of food products:

• Canning and jarring (fruits, sauces, salad dressings, blends)

- Liquid products and bottling (beverages, sauces, supplements, cooking aids)
- Dry products (foods, cereals, seasonings, baked goods)
- Ingredient pre-blends (produce, fruits, spice or flavor mixes/additives)
- Labeling & packaging service only (meats, fruits, produce, baked goods)
- Product development/recipe conversion or scaling

Using a qualified contract packer enables a small business to devote time to management, marketing and sales, while avoiding the enormous expense and responsibility of operating a food production facility. You can also benefit from the co-packer's expertise. Some co-packers will provide only packaging. Others may help with formulation, recipe scaling, production, packaging, and labeling process. Many will offer a low or no cost initial consultation as part of their service. Some co-packers also offer marketing and distribution support. A con is that you are not personally overseeing the manufacturing process and the quality of your product could suffer as a result. Costs are also higher and there are a limited number of <u>co-packers in Pennsylvania</u>.

Keep in mind when making your co-packing choices that the food industry is, in general, a narrow margin industry and that each added layer of service has financial implications. Balance the margin pressures with the value received and the access to services that may dramatically improve your market presence, access, and reach. For example, a good co-packer may have more ready access to certain types of packaging. They may be able to obtain ingredients at better pricing as they combine your purchases with other products on their production schedule. Other reasons to work with a co-packer include compliance with regulation and market expectations.

Typically, food production requires permitting, registration, batch control, and a host of other compliance issues. Carefully select a co-packer that is familiar with the segment of the food industry you are seeking to enter or expand into. Particular markets may also have shipping, labeling or packing 'norms'. Is there a standard case size or count? Do customers prefer banding or shrink wrapping on pallets? What is the bar coding sequence being used beyond the individual UPC for cases, bulk pack, etc.? What is the dating/ labeling format that is preferred? Good co-packers will share their experience in the industry with you. This can be instrumental in planning, saving you from mistakes and revisions.

Your work with a co-packer will be defined by the co-pack agreement. It is vital to have all contracts reviewed by reliable legal counsel representing you and your interests. The co-pack agreement in simplest terms defines the business arrangement between you and the business entity that will be sourcing, producing, packing, labeling or in some other way playing a role in the preparation or delivery of your food product. There are some key elements common to many co-pack agreements.

- Protection of intellectual property: This will include the recipe or formulation, confidentiality of process, ingredients, sources, brand materials, and the description of process (what exactly is being done; preparation, packaging, labeling, shipment, etc.) If you want exclusive ownership and a proprietary formula, you may be charged for the copacker's R&D time. You can also hire your own food science consultant to act as a liaison between you and the co-packer.
- **Customization of Existing Product**: A less expensive option is to customize an existing product that the co-packer already makes.
- **Roles:** Who is providing what? Key ingredients, flavor or spice mixtures that may be sourced from other than the co-packer, packaging materials, etc.
- **Compliance:** Your access to certificates of insurance, registration, inspections, batch records, type and data included in batch records.
- **Time frames:** Set realistic time frames for each segment of the processes you are having performed from sourcing to prep to storage to packing and shipping.
- Quantities: How much product, what is the storage life at the co-packer, what is the required transit time, what is the shelf life, and what is the lead time from order to finished product?
- Nutritional statements and compliance: Will the co-packer prepare these to assure label compliance? Will they calculate or test the ingredients? Who is responsible for the ingredients panel and interaction with labeling graphics services?
- **Boilerplate:** No agreement is complete without the structures and terms your legal counsel will provide for your protection. From payment terms to communication to duration of agreement to penalties, this area requires skill and forethought to integrate it with your plans and needs as well as the co-packer's needs and requirements.

If you plan on using a co-packer from the beginning, we recommend finding one before creating your prototype as they will have specific rules about what ingredients are allowed in its facility and

may be limited in its processing capabilities. The co-packer will typically take your original product or recipe and modify it by adjusting the size, shape, ingredients and packaging to match what they have in house. You must discuss these details with the co-packer, who could ultimately own the final recipe formula depending on your agreement.

Developing a good relationship with your co-packer is vital. Get to know them in advance. Don't be afraid to ask for references. Make sure you are comfortable that they will be able to provide you with the service you need. The last thing you want is to buy 100 cases of product that doesn't meet your standards, or to sell out of your product and not be able to get another batch for several months.

Shopping for a co-packer is a challenging task; there are always trade-offs. While one co-packer may be willing to do a test-run for free, another that may charge for a test-run may be cheaper over the long term. Be prepared to answer the co-manufacturer's questions. They will want to know your expected volumes and distribution plans. Some of the concerns that may arise when working with a co-packer can be: loss of quality control, confidentiality risks, scheduling concerns, and high costs.

Visit the <u>Penn State Extension Food Entrepreneurs</u> website for a list of co-packers in Pennsylvania.

# **Building Your Own Food-Processing Facility**

If you plan to build your own manufacturing commercial kitchen, you will need to first contact the local Allegheny County Health Department food inspector for your jurisdiction to ensure compliance with all applicable requirements. You will also want to check with your local PA Department of Agriculture Food Safety Inspection officer. Both require pre-build out plan reviews be submitted and approved *prior to construction* to assist food manufacturers to incorporate food safety into their facility through the installation of appropriate equipment and proper structural design. This preventative approach is designed to reduce or eliminate problems once your business is in operation.

When renovating and or designing a facility, consider how the equipment and workspace will be kept clean. Facilities should be arranged so contact with contaminated sources such as garbage

or dirty utensils and equipment is not likely to occur. Consider hiring a professional commercial kitchen designer to help you set up your production facility. This could save you time and money in the long run. When leasing property, have the layout approved before signing the lease. Don't take the landlord's word that it is in compliance

Allegheny County's plan review submission requirements consist of:

- 1. A complete facility floor plan drawn to scale;
- 2. A signed and completed Plan Review Checklist;
- 3. A complete equipment list that includes manufacturer's names and model numbers;
- 4. A proposed menu or description of your product(s); and
- 5. Payment of the applicable <u>fee</u> for review of the construction plan. (Contact the ACHD Food Safety Program at 412-578-8044 for assistance on fees or procedures.)

Upon receipt, your plan will be logged, and then forwarded to an <a href="Environmental Health Supervisor">Environmental Health Supervisor</a> assigned to the municipality in which your facility is located. You will be notified by letter whether your plan is in compliance, or whether additional information is needed, once it is reviewed. Construction can then commence once the plan is in compliance. All plumbing work must be conducted by a Registered Master Plumber who will file separate plans with the appropriate plumbing office prior to beginning work. The plumber that you hire will be responsible for filing these plans. A pre-operational inspection is then conducted prior to opening and permit issuance.

# **Key Practices for Ensuring Food Safety**

You should learn more about storing and organizing your ingredients whether you decide to become a home processor, use a shared kitchen, or set-up a production facility. To keep food safe in your operation, you should focus on the following things:

- Proper food storage: Control the temperature of products, including ingredients and the finished product. Proper temperatures must be maintained at all times.
- Prevent cross contamination of food: Cross contamination occurs when microorganisms are transferred from one surface to another. This often occurs when a work or cutting surface is used to cut or prepare raw meat/seafood/poultry and then not properly cleaned and sanitized before it is used for other food preparation. Contamination also occurs when

- raw foods touch or drip fluids onto other food ingredients or ready-to-eat foods or hands are not washed properly.
- **Practice good personal hygiene:** Learn the rules for hand washing, hair coverings, and glove requirements as they pertain to your set-up and production steps.
- Clean and sanitize floors, surfaces, and equipment following guidelines provided by the governing agency for your food product. Clean surfaces with a basic grease cutting dish detergent and then wipe them with a water and bleach solution. Purchase test strips to check the level of bleach/ sanitizing solution you are using. These can be purchased through your cleaning supply vendor and are inexpensive.
- Understand proper procedures for cleaning equipment, utensils, and other cooking
  equipment: A three compartment sink set-up allows you to have one clean and one dirty
  drain board, a soap and water wash compartment, a rinse compartment, and sanitary
  compartment.
- Attend a <u>food protection 2-day certification course</u> offered through the Allegheny
  County Health Department Food Safety division. Current food safety regulations require
  that a Certified Food Protection Manager be on-site during ALL HOURS of operation in
  facilities where food preparation occurs. It appears there is no age requirement to take this
  course, however, the exam is written on an 8<sup>th</sup>-grade reading level. The fee for this course
  is \$100 per person.
- **Be very selective** when choosing suppliers.

# Food Safety Regulatory Agencies and Regulations

As you consider starting your own specialty food business, you will need an understanding of the various regulatory requirements. Two key regulatory agencies within Allegheny County with whom you will have to interact on an ongoing basis include the <u>Pennsylvania Department of Agriculture Bureau of Food Safety and Laboratory Services</u> and the <u>Allegheny County Health Department Food Safety Program</u>. In addition, you will have to <u>register</u> your business with the <u>Food and Drug Administration (FDA)</u> and depending on the type of food you manufacture, the FDA may have additional reporting requirements that apply to your business.

The <u>FDA</u> and the <u>United States Department of Agriculture (USDA)</u> are the two national agencies that oversee the production of all foods and food ingredients introduced into or offered for sale in interstate commerce. The USDA Food Safety Inspection Service (FSIS) is the public health agency responsible for ensuring that the nation's commercial supply of meat (excluding game meats such as venison), poultry and egg products are safe, wholesome, and correctly labeled and packaged. The USDA is also in charge of ensuring the legitimacy of <u>organic</u> products. The FDA is the federal agency responsible for overseeing the rest of the U.S. food supply, including fruits, vegetables, nuts, seafood, and dairy products. If a product contains less than 2% cooked meat or poultry or less than 3% raw meat, it falls under FDA jurisdiction.

All FDA and USDA regulations are based on the Code of Federal Regulations (CFR). The FDA and USDA interpretations of the CFR can change as new scientific information comes to light. Sometimes the new interpretations are not communicated clearly to the food-manufacturing industry, so it is important to monitor industry news and trade journals to keep up with changes as they occur. Title 21—Food and Drugs—of the CFR is reserved for rules of the FDA while Title 9 of the CFR is reserved for rules of the USDA (animals and animal products).

Rules and regulations are always subject to change. Accordingly, when it comes to these regulations your first step should always be to contact the agencies to confirm your understanding of the required licensing/permits. A rule of thumb is that if you're dealing with food, you will need at least one food license—chances are you will need several.

Make sure you understand the rules and regulations that apply to your type of business. In addition, make sure that you contact your local municipality Zoning Board to ask whether you need to obtain a license to operate from your place of business. If you plan to open a <a href="https://example.com/home-need-to-obtain-alicenses-need-to-obtain-a

<u>based commercial kitchen</u>, make sure to inquire whether you will need a zoning variance to operate a commercial food business from your home. A zoning variance is an authorization to allow an exception to certain standards as outlined in a zoning code.

About 80% of food sold in the U.S. falls under FDA jurisdiction. To avoid confusion, the FDA has published an <u>instructional guide</u> that shows which foods fall under FDA or USDA jurisdiction.

# PA Department of Agriculture

The <u>PA Department of Agriculture's Bureau of Food Safety and Laboratory Services</u> oversees all of our state's farm-to-fork commerce, from eating and drinking establishments, retail food stores, and food manufacturers to ensure compliance with food safety laws. This includes services such as good agricultural practices audits on farms, licensing and inspections of commercial food facilities, and milk inspection services across the state. The Bureau's electronic reporting program provides consumers with real-time access to <u>inspection reports</u> for eating and drinking and retail food facilities from across the state.

The Food Safety Act of 2010 (3 C.S. §§5721 – 5737) requires that "all food establishments that include, a building, or place or portion thereof, or vehicle maintained, used or operated for the purpose of commercially storing, packaging, making, cooking, mixing, processing, bottling, baking, canning, freezing, packing or otherwise preparing or transporting or handling food" obtain a PA Department of Agriculture license.

If you are considering starting a food business, we suggest you contact the appropriate <u>Food Sanitarian within your locality</u> so that you can meet face-to-face and discuss all of the requirements you will have to meet in order to successfully begin to sell your product. All food processors must submit a completed <u>Application Packet for a Food Establishment Registration</u>, prior to work begun in construction, remodeling, alteration of a facility, change in type of food operation, new ownership or the preparation/sale of foods from a food establishment and at least 60 days prior to opening. There are no fees associated with this Application.

The regional <u>Food Sanitarian</u> and/or Supervisor assigned to your locality will review the application and notify you of its approval. If your application is disapproved, you will receive a written letter stating the reasons for the application disapproval. Applications take approximately 4-6 weeks for processing and can be resubmitted at any time. Once you receive your approval,

you will have to notify your Food Sanitarian or regional office at least ten (10) days prior to operation to arrange a licensing inspection. Registration fees are then collected upon a compliant inspection. Initial registrations and annual renewals are \$35.00.

The <u>Pennsylvania Meat and Poultry Hygiene Law of 1968</u> requires all producers who prepare animals or poultry for food purposes, including but not limited to meat and poultry canneries, sausage making, smoking or curing operations, complete a separate and additional <u>Application for State Meat Establishment License</u>. Further, any retailer in Pennsylvania that is producing food(s) using a specialized process must also have a <u>HACCP plan</u> (Hazard Analysis Critical Control Point). <u>HACCP plans</u> must be reviewed by your Sanitarian before the food can be made using the specialized process.

#### Specialized Processing would include:

- 1. Reduced Oxygen Packaging (ROP to include vacuum packaging sous vide or cook-chill
- 2. Packaging Juice—If preforming a 5-log reduction for Juice HACCP
- 3. Curing, smoking, and drying of fish for preservation
- 4. Curing, smoking of meat and poultry for preservation
- 5. Drying of meat and poultry for preservation
- 6. Fermentation of sausage
- 7. Acidification, fermentation or adding components or additives to render a product shelf stable
- 8. Sprouting

For those of you hoping to operate pout of your home, the PA Department of Agriculture will allow some <u>'limited' types of food processing</u> to occur in a 'residential style kitchen' that may not meet the full regulatory code requirements, with the intent of the producer to offer these products for sale to the public. This this exemption is restricted to non-potentially hazardous home processed foods. Some of the most common include:

- Honey and Maple Syrup
- Home canned products that reach a <u>pH</u> of 4.6 or less such as salsa, pickled beets, pickled vegetables, hot sauces, and barbeque sauce. Some traditional fruit jams, jellies, and marmalades (even dulce de leche milk caramel spreads), will also be considered

- Bakery products, i.e., bread, rolls, cookies, cakes, brownies, fudge, and double-crust fruit
  pies for wholesale marketing or retail agricultural venues such as farms, farm stands,
  farmers' markets, craft fairs and flea markets
- Spices or herbs
- Snack items such as popcorn, caramel corn and peanut brittle
- Candy (excluding chocolate)—tempering chocolate for molding/dipping is typically not allowed.

Obtaining approval from the PA Department of Agriculture is one of several hurdles you will have to overcome if you intend to operate a licensed limited-establishment kitchen out of your home. You will still be required to complete a PA Department of Agriculture application packet. Producers of Acidified Foods must have written recipes/formulas and procedures. You will need to provide a Process Flow for your products and have it approved by your Sanitarian prior to registration and sale of your product. The PA Department of Agriculture will also require you to submit a letter of approval from your local zoning official stating that you are approved to operate a commercial food business from your home. Your municipal zoning officer will primarily be concerned with the safety of your production, the waste produced by your food product and whether this will be dumped into public sanitary waste lines, and your methods of sale. Most municipalities will not allow home-based food processors to sell directly out of their home. You will also have to obtain a license for your home-based commercial kitchen from the Allegheny County Health Department. Your local PA Department of Agriculture Food Sanitarian can walk you through the first steps of this process.

# Pennsylvania Department of Agriculture—Bureau of Food Safety and Laboratory Services, Region 4-S

226 Donohoe Road, Suite #101 Greensburg, PA 15601 (724) 832-1073

# **Allegheny County Health Department**

<u>Allegheny County Health Department's Food Safety Program (ACHD)</u> licenses and regulates all of the restaurants, retail markets, food processing facilities, caterers, warehouses, mobile vendors and temporary/seasonal food facilities doing business in Allegheny County. The ACHD

provides comprehensive surveillance, monitoring and complaint investigation for approximately 9,000 food facilities and establishments. Once you have met with your local <u>Department of Agriculture Food Sanitarian</u>, we recommend immediately acquainting yourself with the <u>ACHD Food Safety Supervisor</u> assigned to your locality. You should also review the ACHD's <u>Food Safety Rules and Regulations</u> to familiarize yourself with the regulations that apply to your specific product(s).

If you have any uncertainties as to whether your line of business falls under the ACHD's jurisdiction, it is always advisable to give them a call to speak to an inspector directly. County health inspectors can easily find people operating without a permit by reviewing advertised events and performing follow up on any food vendors at these events. In addition, the ACHD may identify people operating without a permit through complaints or anonymous calls. So it is always best to be 100% transparent before getting your product out to market, especially considering that the ACHD publicized consumer alerts of all <u>food safety enforcement safety actions</u>. You definitely don't want to find yourself on that list!

There is also a common misconception among home-food producers that once they are approved by the PA Department of Agriculture to operate as a <u>limited food establishment</u> (as described in the previous section), that their business is not subject to further regulation. However, a home processor that has an exemption under the PA Department of Agriculture licensing process then becomes subject to meeting the standards of their local county health department. As such, home processors in Allegheny County are required to obtain a permit from the ACHD' health inspection process. One outcome of the permitting process is that you most likely will find that extensive modifications are required to bring your home kitchen into compliance with the ACHD sanitary code. It is very difficult to get permission to make food products in your home. You cannot use the same preparation areas, storage areas, and cooking equipment that you use for your family's food preparation. While it is possible, if may sometimes be more expensive to bring your home-based kitchen up to compliance—or to even build a separate kitchen as was required of our dulce de leche startup—than to move your operations to a facility that already has an ACHD permit. This alternative is a great way to test out your business before investing in major renovations. If you're renting space through a facility with an approved permit, you'll still need to obtain a separate permit. (i.e. If a baker produces goods at a fire house or church kitchen that has an established permit, a separate permit is still required.) Be sure to ask your local health department before you begin any work from your home.

Contrary to popular belief, temporary food stands and seasonal food facilities must also have a current Allegheny County Health Permit. Temporary Food Stands are food facilities that operate at a fixed location for a period of time of not more than 14 consecutive days in conjunction with a single event or celebration. Seasonal Food Stands are food facilities that routinely operate for no more than six (6) consecutive months each year at a flea market or farmers market. The Department requires a separate permit for each event and location; however, Seasonal Farmers Market stands require one permit for each stand that may be used for multiple recognized farmer's market locations in Allegheny County. A temporary permit costs \$41, while a seasonal permit will run you \$68.00. To obtain a health permit you will need to complete the Temporary and Seasonal Food Facilities Checklist and submit it at least two weeks prior to the event to allow sufficient time for processing. The Health Permit will either be mailed in advance or delivered the day of the event. Something to note in the ACHD guidelines for temporary and seasonal food facilities is that all potentially hazardous foods (meats, cheeses, dairy products, fish, pasta, rice, cooked vegetables, etc.) must be prepared on the site of the event or at another ACHD-permitted facility. Foods prepared in a private home may not be used or sold at the event. According to ACHD recommendations, the number of different menu items should be minimized and food preparation steps should be simplified to reduce risk.

#### Plan Review for New Food Establishments

If you are planning to open a new food business, or already have a licensed food business but plan to build a new production facility, the ACHD requires you to submit a Food Safety Program Plan Review is to assure that all equipment and construction in a new or remodeled food facility is in compliance with the <u>Food Safety Regulations</u>. You must submit the completed application prior to opening your business or breaking ground on construction to assist operators to incorporate food safety into their facility through the installation of appropriate equipment and proper structural design. This preventative approach is designed to reduce or eliminate problems once your business is in operation.

The following five items must be included in your plan submission:

- 1. A complete facility floor plan drawn to scale
- 2. A signed and completed Plan Review Checklist (mobile food vendors should use this checklist ,while transient caterers should use this checklist)
- 3. A complete equipment list that includes manufacturer's names and model numbers;
- 4. A proposed menu; and

5. Payment of the corresponding <u>fee</u> for review of the construction plan. (You can contact the Food Safety Program at 412/578-8044 for assistance on fees or procedures.)

The <u>Food Safety Supervisor</u> assigned to the municipality in which your facility is located will then review your application. You will be notified by letter whether your plan is in compliance, or whether additional information is needed. Construction can then commence once the plan is in compliance. The ACHD requires that all plumbing work be conducted by a Registered Master Plumber who will file separate plans with the appropriate plumbing office prior to beginning work. The plumber that you hire will be responsible for filing these plans.

You should plan to schedule a <u>pre-operational inspection</u> at least 10 days prior to your projected opening date. Make sure your plumber has arranged a final plumbing inspection prior to your *pre-operational* inspection. A health permit will not be issued unless the plumbing work has been approved.

## **Food Safety Inspection Report**

Facilities subject to permitting by the ACHD also will be inspected at a minimum of once per year. Routine inspections are unannounced and may occur up to twice annually depending upon the type of facility and past inspection history. As a result, facilities that serve a wide variety of foods and utilize potentially complex means of preparing and cooking foods are inspected more frequently than facilities that have limited menus, do little preparation, or serve only commercially pre-packaged foods.

The purpose of a routine inspection is to identify and, if necessary, correct issues within the facility that may pose a health risk to the consumer. Violations are written up on inspection reports. The type and quantity of violations found in a facility are dynamic, changing from day to day. Observations made at the time of inspection, while a good approximation of a facility's overall sanitary condition, are unique to that day. Violations are coded as either critical or non-critical. Critical violations pose an immediate risk to the consumer's health and well-being and embody the primary focus of inspection. Examples of critical violations include but are not limited to: poor personal hygiene; inadequate hand washing facilities; and improper cooking, cold and hot holding temperatures. Other issues, known as non-critical violations do not pose an immediate risk to public health but still are undesirable and should be corrected. Non-critical violations are typically structural and aesthetic in nature. Examples of non-critical violations include broken and cracked floors, walls and ceilings; insufficient ventilation; and inadequate

lighting. In order to favorably pass an inspection, a facility should be able to demonstrate effective managerial control over food borne illness risk factors and these aforementioned violations.

Should a facility be deemed out of compliance and fail inspection, a re-inspection is scheduled whereupon all uncorrected violations are re-examined. Failure to abate previous violations may result in administrative intervention, civil penalty assessment, or facility closure, depending on the nature and frequency of the violations. Posting a Consumer Alert placard on the facility's front door also constitutes a possible consequence of non-compliance. A Consumer Alert is a warning to the public that conditions noted at the time of inspection pose a health risk to the consumer.

#### **Food Protection Certification**

In Allegheny County, a <u>certified food protection safety</u> manager is required to be on-site during all hours of operation in facilities where food preparation and handling take place. This will be one of the items your ACHD Supervisor will look for during a routine inspection. If you own or operate a food facility, it is your responsibility to ensure that a sufficient number of your staff is certified.

The ACHD offers a <u>Food Protection 2-Day Certification Course</u> that also counts towards your certification with the PA Dept. of Agriculture. This two-day course is offered throughout Allegheny County and provides education of ways to eliminate common problems discovered in inspections. Take advantage of this resource! The class time for the 1st session is 8:30 am to 4:00 pm and the 2nd session is 8:30 am to 5:00 pm, including exam time. The ACHD requires you attend both days. The fee is \$100 per person.

## Allegheny County Health Department Food Safety Program

3901 Penn Avenue, Building 1, 3<sup>rd</sup> Floor Pittsburgh, PA 15224 (412) 578-8044

# U.S. Food and Drug Administration (FDA)

Prior to opening a food business, you must <u>register</u> your business with the FDA, unless you are exempt under <u>21 CFR 1.226</u> from the registration requirements. Farms, retail food establishments such as deli's, restaurants, fishing vessels and non-profit food establishments in which food is prepared for, or served directly to, the consumer (i.e. food banks, soup kitchens,

and nonprofit food delivery services) are among those exempt. Once you have acquainted yourself with regulations mandated by the PA Department of Agriculture and the ACHD, we suggest discussing your specific product and facility with the FDA's <u>Pittsburgh District Office</u> to identify the regulatory requirements that you will need to meet. Some FDA requirements apply to all food businesses, and some are specific to the particular food product, such as low-acid canned food, seafood, or juice.

Facilities that manufacture, process, pack, or hold food that is intended for human or animal consumption in the United States must <u>register with FDA</u> before beginning these activities. The registration requirement applies to any facility that conducts these activities and it must be renewed every other year. The FDA publishes an online guide on <u>How to Start a Food Business</u> that helps business owners identify what you need to do before starting a food business and after it is in operation.

## **Food and Drug Administration**

7 Parkway Center, Space #250 Pittsburgh, PA 15220 (412) 644-3394

# Food Safety vs. Food Quality

As you are researching regulatory requirements, it's important to understand the difference between food safety and food quality. Many harmless microorganisms such as yeast and mold can affect food quality and cause spoilage (see chart below). To ensure quality, food manufacturers are required to follow "current good manufacturing practices (cGMPs)," as described in detail in <u>21 CFR 110</u>. <u>21 CFR 110-Sub G</u>. Even if foods are prepared using current cGMPs, they can sometimes contain natural or unavoidable quality defects that, at low levels, are not hazardous to your health. The FDA has established maximum defect levels and lists them in the <u>Defects Level Handbook</u>.

Outline of good manufacturing practice (GMP) regulations				
Personnel	<ul><li>A. Disease control</li><li>B. Cleanliness</li><li>C. Education and training</li><li>D. Supervision</li></ul>			
Plants & Grounds	A. Grounds     B. Plant construction and design			
Sanitary Facilities & Controls	<ul> <li>A. Water supply</li> <li>B. Sewage disposal</li> <li>C. Plumbing</li> <li>D. Toilet facilities</li> <li>E. Hand-washing facilities</li> <li>F. Rubbish and offal disposal</li> </ul>			
Sanitary Operations	<ul> <li>A. General maintenance</li> <li>B. Animal and vermin control</li> <li>C. Sanitation of equipment and utensils</li> <li>D. Storage and handling of cleaned, portable equipment and utensils</li> </ul>			
<b>Equipment &amp; Procedures</b>	<ul><li>A. General</li><li>B. Use of polychlorinated biphenyls in food plants</li></ul>			
Process & Controls	<ul> <li>A. Raw materials and ingredients</li> <li>B. Raw ingredient containers and carriers</li> <li>C. Ice</li> <li>D. Food processing areas</li> <li>E. Food processing equipment</li> <li>F. Good processing conditions and controls</li> <li>G. Testing procedures</li> <li>H. Packaging processes and materials</li> <li>I. Product codes</li> <li>J. Storage and transportation of finished products</li> </ul>			

While the food manufacturer is responsible for ensuring food quality, the <u>Pa Department of Agriculture</u>, <u>Allegheny County Health Department</u>, <u>FDA</u> and <u>USDA</u> are responsible for policing food safety. They must enforce the rules and regulations that prevent the growth of microorganisms, primarily bacteria and viruses that cause illness, as listed in the chart below.

<b>Common Food Pathogens</b>	Common Spoilage
(Food Safety)	<b>Microorganisms (Food Quality)</b>
Bacillus cereus	<ul> <li>Lactobacillus</li> </ul>
<ul> <li>Campylobacter jejuni</li> </ul>	<ul> <li>Aeromonas</li> </ul>
<ul> <li>Clostridium botulinum</li> </ul>	<ul> <li>Pseudomonas</li> </ul>
<ul> <li>Clostridium perfringens</li> </ul>	• Enterococcus
• Escherichia coli 0157: H7	<ul> <li>Vagococcus</li> </ul>
<ul> <li>Listeria monocytogenes</li> </ul>	<ul> <li>Corynebacterium</li> </ul>
<ul> <li>Hepatitis A (virus)</li> </ul>	• Vibrios
<ul> <li>Norovirus (virus)</li> </ul>	<ul> <li>Candida yeast</li> </ul>
• Shigella	<ul> <li>Saccharomyces</li> </ul>
• Salmonella	Aspergillus
<ul> <li>Staphylococcus</li> </ul>	Penicillium
Yersinia enterocolitica	

# Controlling Microorganisms in Food

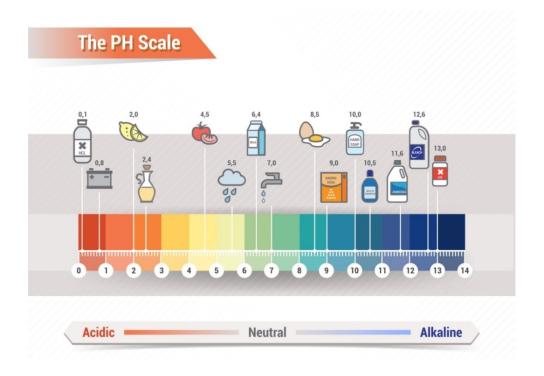
Food quality and safety depend on destroying and/or inhibiting the growth of spoilage and pathogenic microorganisms. Four factors that play a big role in microorganism growth are acidity (pH), water activity (a<sub>w</sub>), oxygen, and temperature. Allegheny County Health Department's <u>Article III Food Safety</u> requires that all food producers produce a shelf stable food product that has a pH level of 4.6 or below or water activity of 0.85 or less in standard conditions in order to inhibit pathogens, yeast, mold, and lactobacillus, all of which can cause spoilage. A shelf stable product is one that can be stored at room temperature for long periods of time without becoming spoiled or unsafe for human consumption.

If your product does not meet these standards, you have to be able to show that it is handled in such a manner as to preclude contamination with and the growth of pathogenic microorganisms after heat processing; or provide other scientific evidence demonstrating that your specific product will not support the growth of pathogenic microorganisms. When developing your product, it is important to research the type of processing and regulations that are required to achieve safe <a href="shelf-stability">shelf-stability</a> for your specific product. Not only is it important to meet all regulatory safety standards, but you also want to make sure that your product does not succumb to mold or physical changes in nature, as these issues can eat away at the reputation of the producer.

## Acidity/pH

The acidity of foods has been used for centuries to preserve foods. The tartness or sour taste of grapefruit, sauerkraut, yogurt, and pickles is the result of the intensity of acidity in these products. The acidity of a food may occur naturally as in citrus fruits, apples, tomatoes and strawberries or it may be produced in foods through microbial fermentation. Selected acid producing bacterial cultures added directly to foods can produce flavorful products like yogurt, buttermilk and fermented meat products. Acid may also be added directly to a food; an example is the addition of acetic acid to fish and vegetables, lactic acid to Spanish-type olives and citric acid to beverages. Acidity plays a primary role in the preservation of fermented foods and combined with other factors such as heat, water activity, and chemical preservatives acts to prevent food deterioration and spoilage.

The intensity of acidity of a food is expressed by its pH value. A pH measurement is based on a scale of 0 to 14. A product that has a low pH (between 0 and 4.6) is considered acidic. If the pH is above 7, the product is alkaline or "basic." If it falls right in the middle, around 7, it is neutral. The pH of a food is one of several important factors that determine the survival and growth of microorganisms during processing, storage and distribution. Consequently, food processors are interested in determining the pH of foods and in maintaining pH at certain levels to control microbial growth and prevent product deterioration and spoilage.



#### **Shelf Stable Processing**

The FDA classifies certain foods by their acidity, which informs how they should be processed for shelf stability. Here are the three categories:

## • Acid Foods (pH <4.6)

Foods that have a natural pH of 4.6 or below include apples, oranges, lemons and blueberries.

## • Low-Acid Food (pH ≥4.6)

Foods with a natural pH  $\geq$  4.6 include meats, milk and vegetables. Low-acid foods are potentially hazardous because they provide an ideal environment for pathogenic bacteria.

## • Acidified Foods (original natural pH >4.6, final "adjusted" pH ≤ 4.6)

Foods that are naturally "high" pH (>4.6) but have had acid or acid food, like lemon juice or vinegar, added to reduce the pH to at or below 4.6. These include vegetables pickled with vinegar and banana salsas.

The specific processing conditions and regulations for acid, acidified and low-acid foods are described in the following chapter. The <u>PA Department of Agriculture</u>, for instance, will only allow businesses that operate from a <u>home-based limited-establishment kitchen</u> to can products that reach a pH of 4.6 or less such as salsa, pickled vegetables, hot sauces, and barbeque sauce. Some traditional fruit jams and preserves (including dulce de leche milk caramel spreads) that have a pH ≤ 4.6 are also allowed. Microbac Laboratories, Inc. is a local laboratory that provides extensive <u>food shelf life studies</u>, including measuring pH. They can answer any questions about your specific product. In "<u>Bad Bug Book: Foodborne Pathogenic Microorganisms and Natural Toxins Handbook pH Values of Various Foods</u>", the FDA includes a listing of the approximate pH of foods and food products. We have also provided a sample listing below.

#### Average pH Value of Various Foods

Low Acid Foods	pH>4.5	High Acid Foods	pH<4.5
Artichoke	5.6-6.0	Apples	3.4-3.9
Beef	5.1-6.2	Cherries	3.2-4.1
Beets	4.9-5.6	Dill Pickles	3.2-3.5
Cabbage	5.2-6.0	Grapefruit	3.0-3.3
Carrots	4.9-5.2	Green Olives	3.6-3.8
Chicken	6.5-6.7	Lemon	2.2-2.4
Dulce de Leche	6.4-6.5	Lime	1.8-2.0
Eggs	7.1-7.9	Mayonnaise	4.2-4.5
Fish	6.6-6.8	Tomato Juice	4.1-4.2
Milk	6.3-8.5	Raspberries	3.2-3.7
Sweet potatoes	5.3-6.1	Vinegar	2.0-3.4

Every microorganism has a minimum, an optimum and a maximum pH for growth. Most microorganisms grow best at pH values around 7.0 while only a few grow below pH 4.0. Yeasts and molds are generally more acid tolerant than bacteria and can grow at lower pH values. Foods with pH values below 4.5 are usually not easily spoiled by bacteria but are more susceptible to spoilage by yeasts and molds. Microorganisms can grow in wide pH ranges and these ranges are probably the difference between different bacterial strains, types of food or growth medium and the type of acid or base used to adjust pH.

# Moisture and Water Activity

Water in food that is not bound to food molecules can support the growth of bacteria, yeast, and mold. In food science, the term "water activity" (a<sub>w</sub>) refers to this unbound water that microorganisms thrive on. The water activity of a food is not the same thing as its moisture content. Although moist foods are likely to have greater water activity than are dry foods, this is not always so. In fact, a variety of foods may have exactly the same moisture content and yet have quite different water activities. Water activity (a<sub>w</sub>) is especially useful in predicting the growth of bacteria, yeast, and mold. For a food to have a useful shelf life without relying on refrigerated storage, it is necessary to control either its acidity level (pH) or the level of water activity (a<sub>w</sub>) or a suitable combination of the two. This can effectively increase the product's stability and make it possible to predict its shelf life under known ambient storage conditions.

Allegheny County Health Department's Article III Food Safety requires that all food producers produce a shelf stable food product that has a water activity of 0.85 or less in standard conditions in order to inhibit pathogens, yeast, mold, and lactobacillus, all of which can cause spoilage. Most foods have a water activity above 0.95 and that will provide sufficient moisture to support the growth of bacteria, yeasts, and mold. *Clostridium botulinum* will grow and produce deadly botulism toxin if the pH is above 4.6 and the water activity is above 0.85. Food can be made safe to store by lowering the water activity to a point that will not allow pathogens such as *Clostridium botulinum* and *Staphylococcus aureus* to grow in it. Different methods to lower the a<sub>w</sub> in food include adding solutes such as salt or sugar, physically removing water through drying or baking, or binding water to various components in the food like fiber, sugar or starch. Always conduct shelf life studies to find the ideal balance of solutes and a<sub>w</sub> that will maintain your product's quality and prevent spoilage for the duration of its shelf life.

Penn State Extension provides a <u>Water Activity of Foods Table</u> that illustrates the effect of water activity (a<sub>w</sub>) on the spoilage of certain foods. Microbac Laboratories, Inc. is a local laboratory that provides extensive <u>food shelf life studies</u>, including measuring water activity. They can answer your questions about your specific product.

#### Oxygen

Most microorganisms are aerobic and require oxygen for growth, but some pathogenic organisms—including the notorious *Clostridium botulinum* mentioned above—are known as "anaerobes" and do not need oxygen to grow. Not only can C. botulinum bacteria thrive without oxygen; they can also produce deadly spores inside an improperly heated can of food that has no access to oxygen. Not surprisingly, this is one of the reasons they're so dangerous, and of such concern to the food industry.

## **Temperature**

Most microorganisms grow well at temperatures of 60 to 100°F and are killed during a thermal process that reaches 180 to 200°F. However, bacterial spores, like those of the deadly *Clostridium botulinum* ("botulism") can be destroyed only if heated to 250°F for at least 3 minutes (the time varies depending on the food). The low-acid (pH >4.6) food canning industry relies on the canning, or "retort," process to deactivate the anaerobic spore–forming *C. botulinum* as well as other more-resistant spoilage organisms to yield a spoilage-free, shelf stable product.

# Potentially Hazardous vs. Non-Hazardous Foods

## **Potentially Hazardous Foods**

Disease causing bacteria grow particularly well in foods high in protein such as meats, poultry, seafood, eggs, dairy products, cooked vegetables such as beans, and cooked cereal grains such as rice. Because of the high potential for rapid bacterial growth in these foods, they are known as "potentially hazardous foods." A potentially hazardous food is one that needs to be held at 41°F or colder or 135°F or hotter to prevent the rapid and progressive growth of pathogenic bacteria, the toxic production of *Clostridium botulinum* or the growth of *Salmonella Enteritidis*. Potentially hazardous foods include foods of animal origin that are raw or heat-treated, a food of plant origin that is heat-treated or consists of raw seed sprouts, cut melons, and garlic-in-oil mixtures that have not been properly acidified to prevent the growth of pathogenic bacteria. To determine whether a food is potentially hazardous, the <u>FDA</u> considers its intrinsic and extrinsic factors.

Intrinsic factors are traits of the food itself; extrinsic factors relate to the environment surrounding the food. Most food-safety experts are likely to classify foods into three categories based on an evaluation of all of their intrinsic and extrinsic factors:

- No time/temperature control needed to ensure safety (non-hazardous foods)
- Time/temperature control required to ensure safety (hazardous foods)
- Questionable time/temperature requirement

In this case, safety experts may look to further scientific evidence, such as microbiological challenge studies, to make their decision. <u>Microbac Laboratories</u> is a local food analytics lab that provides microbial food challenge studies and pathogen detection studies.

Some examples of potentially hazardous foods include:

# **Bakery Foods**

- Cream pastries
- Cream/custard pies and tarts
- Pudding prepared from a mix or scratch

## **Dairy Foods**

• Whipped butter/whipped margarine

- Cheese—mozzarella, cottage, cream cheese, Ricotta
- Cream, real
- Cream sauce, white sauce
- Dairy whipped topping
- Ice cream
- Milk

## **Eggs**

- Egg casseroles, Egg dishes
- Deviled eggs
- Fried eggs
- Hard-cooked eggs
- Omelets
- Scrambled eggs

## Fruits and Vegetables

- Dry beans—cooked (examples—navy, refried, baked beans, etc.)
- Potatoes—baked, boiled, mashed (fresh, instant), scalloped/au gratin
- Cut/prepared fresh fruits and vegetables, including melons,
- tomatoes and salad greens

#### Meats

- Bacon—in raw form
- Beef—round, roasts, steak
- Gravy
- Ground meats—all
- Hot Dogs
- Lunch meat
- Meat casseroles

- Pork—ground, ham, roasts
- Processed meats—all
- Sausage
- Soups
- Stews

#### Miscellaneous

- Gravy
- Salad dressings prepared from a mix

#### Pasta

- Noodles—all kinds, cooked
- Rice—cooked

## Poultry

- Chicken—ground, roasted, barbequed, fried
- Chicken—nuggets, patties, strips
- Casseroles with chicken/turkey Dressing
- Precooked, processed products
- Turkey—ground, roast
- Soups
- Stews

#### Seafood

Fish, Salmon, Tuna

An example of a "questionable" potentially hazardous food would be a fermented meat or a processed cheese spread.

Foods that are not potentially hazardous include:

- An air-cooled hard-boiled egg with shell intact, or a shell egg that is not hard-boiled, but has been treated to destroy all viable Salmonella, such as pasteurized in the shell eggs;
- A food with a water activity value of 0.85 or less, such as jams or jellies;
- A food with a pH level of 4.6 or below when measured at 75°F, such as properly prepared sushi rice or pickles;

- A food, in an unopened hermetically sealed container, that is commercially
  processed to achieve and maintain commercial sterility under conditions of nonrefrigerated storage and distribution;
- A food for which laboratory evidence demonstrates that the rapid and progressive growth of pathogens cannot occur.
- A food that does not support the growth of pathogenic microorganisms even though the food may contain an infectious or toxigenic microorganism or chemical or physical contaminant at a level sufficient to cause illness.

The Allegheny County Health Department's <u>Food Safety Article</u> spells out the preparation and storage requirements for all potentially hazardous foods. The ACHD also lists the <u>minimum</u> <u>construction and equipment requirements</u> for manufacturers that produce potentially hazardous foods.

It should be noted that the <u>PA Department of Agriculture</u> requires that all potentially hazardous foods be produced in a licensed/registered commercial food establishment kitchen that meets the full regulatory code requirements, including separation from residential-use areas, and adequate plumbing fixtures—even if your sales are limited to seasonal <u>farmers markets</u>. This does not specifically prohibit processing of these foods from a residential property, but the foods can only be produced in a second 'commercial' processing kitchen separate from the private home kitchen or any residential personal use areas, and that meets the full regulatory standards for a food establishment. We learned this firsthand in 2009, when pursuing licensing for a home-based commercial kitchen. The results of our pH and water activity testing showed our dulce de leche to have a pH of 6.44 and an a<sub>w</sub> of 0.837. While we just met the water activity threshold of 0.85, our pH levels come in well above the <4.5 level. In the end, we were able to produce our dulce de leche spreads from home, but in a separate commercial kitchen space (that had previously been our dining room) that was used exclusively for our specialty food business.

#### **Non-Hazardous Foods**

Non-hazardous foods do not require time and/or temperature controls to ensure food safety. They are usually naturally high in acid, sugar or salt (all of which lower a<sub>w</sub> and inhibit microorganism growth), or they are baked or dehydrated to achieve a very low water activity level. Non-hazardous foods include standardized jams and jellies (as described in <u>21 CFR 150(b))</u>, cakes, chocolates, confections, vinegars, coated nuts, cotton candy and popcorn. If your food is in this

category, it is considered to be low-risk, and fewer regulations will govern how it is brought to market.

# Hazard Analysis Critical Control Points (HACCP)

Hazard Analysis Critical Control Points (HACCP) is a common method used in the food industry to reduce the risk of foodborne illness. It aims to prevent problems in your manufacturing and packaging process before they occur, and to correct deviations as soon as they are detected.

#### A complete HACCP includes:

- A. Identifying hazards of high risk foods;
- B. Assessing the hazards posed by each preparation step;
- C. Determining the critical points for controlling hazards;
- D. Monitoring a critical control point or points; and
- E. Implementing immediate and appropriate corrective action when control criteria are not met;
- F. Verifying that the system is working;
- G. Keeping records.

At present, most foodservice operations are not required to have a HACCP plan unless the following are being prepared:

- <u>Custom Processed Meat and Poultry Products</u> (USDA)
- <u>Unpasteurized Juice Products</u> (FDA)
- <u>Seafood Products and/or Shellfish Displayed in Tanks</u> (FDA)
- <u>Dairy Products</u> (FDA)
- Reduced Oxygen Vacuum Packaged Foods (FDA)

Individual health jurisdictions might also determine that other types of menu items that are served in a foodservice establishment need to be prepared using a HACCP plan. Examples would include: sushi rice or hollandaise sauce prepared with raw shell eggs.

The <u>PA Department of Agriculture</u> requires that all seafood and juice food establishments must have training related to HACCP and have developed HACCP plans to be compliant with the regulations. In addition to juice and seafood manufacturers, the <u>Allegheny County Health</u> <u>Department</u> requires that all food facilities using specialized processing methods (i.e. vacuum sealing foods) develop a HACCP Program and maintain a copy of this program at the processing site for review by the appropriate regulatory authority. This HACCP Program must include:

- A complete description of the processing, packaging, and storage procedures. The program must also identify the critical control points in the procedure with a description of how these will be monitored and controlled
- A list of the equipment and food-contact packaging supplies used including compliance standards required by the regulatory agency (i.e., NSF, U.S.D.A., etc.) 29 ARTICLE III FOOD SAFETY Effective 01/01/2000, Amended 02/07/2015 Table of Contents
- 3. A description of the lot identification system
- 4. A description of the employee training program
- 6. If gases are used, they must be identified as being of food grade quality and must be listed by proportion of gas(es) used in the packaging
- 7. A description of the procedure along with the frequency for cleaning and sanitizing the involved food contact surfaces in the processing area
- 8. A description of action to be taken if there is a deviation from the process approved by the regulatory agency

While a HACCP plan will not be required for most foodservice establishments, it is still important for food producers to understand the basic principles of HACCP. As your company grows and you work with larger chain stores, they may require you to have one in place. Penn State Extension offers several specialized <a href="HACCP Workshops">HACCP Workshops</a> to further familiarize you with this effective approach for producing safe food.

# Regulated Food Categories

Substances which the FDA regulates as food are subdivided into various categories, including foods, food additives, added substances (man-made substances which are not intentionally introduced into food, but nevertheless end up in it), and dietary supplements. The specific standards which the FDA exercises differ from one category to the next depending upon each food products' potential hazards. As mentioned in <a href="mailto:chapter3">chapter 3</a>, all products sold in the U.S. must be manufactured under FDA's mandatory current good manufacturing procedures (cGMPs), as described in <a href="mailto:21 CFR 110">21 CFR 110</a>. In addition to the cGMPs, some products must be further regulated because they are potentially hazardous—and even deadly—if made incorrectly. For this reason, the FDA requires that most food companies that manufacture/process, pack, or hold food <a href="mailto:register">register</a> their business with the regulatory agency prior to operating in business. At the time of registration, you will have to select from the applicable <a href="mailto:food-product categories">food-product categories</a> that are listed on the food facility registration form.

Examples of food types that require FDA facility registration include:

- Dietary supplements and dietary ingredients
- Infant formula
- Beverages (including alcoholic beverages and bottled water)
- Fruits and vegetables
- · Fish and seafood
- Dairy products and eggs
- Raw agricultural commodities for use as food or components of food
- Canned and frozen foods
- Bakery goods, snack food, and candy (including chewing gum)
- Live food animals
- Food for animals (e.g., pet food, pet treats and chews, animal feed)

Among the food facilities that are exempt from having to register with the FDA are:

- Farms
- Retail food establishments such as deli's, restaurants, fishing vessels
- Food banks, soup kitchens, and nonprofit food delivery services

If you are required to register your business with the FDA, you will have to select from the following FDA general food categories (defined under <u>21CFR 170.3</u>). Once you have determined your product's chosen food category, you can easily <u>research</u> the regulatory requirements that are attached to that category.

### **FDA General Food Categories:**

- 1. Baked goods and baking mixes, including all ready-to-eat and ready-to-bake products, flours, and mixes requiring preparation before serving.
- 2. Beverages, alcoholic, including malt beverages, wines, distilled liquors, and cocktail mix.
- 3. Beverages and beverage bases, nonalcoholic, including only special or spiced teas, soft drinks, coffee substitutes, and fruit and vegetable flavored gelatin drinks.
- 4. Breakfast cereals, including ready-to-eat and instant and regular hot cereals.
- 5. Cheeses, including curd and whey cheeses, cream, natural, grating, processed, spread, dip, and miscellaneous cheeses.
- 6. Chewing gum, including all forms.
- 7. Coffee and tea, including regular, decaffeinated, and instant types.
- 8. Condiments and relishes, including plain seasoning sauces and spreads, olives, pickles, and relishes, but not spices or herbs.
- 9. Confections and frostings, including candy and flavored frostings, marshmallows, baking chocolate, and brown, lump, rock, maple, powdered, and raw sugars.
- 10. Dairy product analogs, including nondairy milk, frozen or liquid creamers, coffee whiteners, toppings, and other nondairy products.
- 11. Egg products, including liquid, frozen, or dried eggs, and egg dishes made therefrom, i.e., egg roll, egg foo young, egg salad, and frozen multicourse egg meals, but not fresh eggs.
- 12. Fats and oils, including margarine, dressings for salads, butter, salad oils, shortenings and cooking oils.
- 13. Fish products, including all prepared main dishes, salads, appetizers, frozen multicourse meals, and spreads containing fish, shellfish, and other aquatic animals, but not fresh fish.
- 14. Fresh eggs, including cooked eggs and egg dishes made only from fresh shell eggs.
- 15. Fresh fish, including only fresh and frozen fish, shellfish, and other aquatic animals.

- 16. Fresh fruits and fruit juices, including only raw fruits, citrus, melons, and berries, and home-prepared "ades" and punches made therefrom.
- 17. Fresh meats, including only fresh or home-frozen beef or veal, pork, lamb or mutton and home-prepared fresh meat-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
- 18. Fresh poultry, including only fresh or home-frozen poultry and game birds and home-prepared fresh poultry-containing dishes, salads, appetizers, or sandwich spreads made therefrom.
- 19. Fresh vegetables, tomatoes, and potatoes, including only fresh and home-prepared vegetables.
- 20. Frozen dairy desserts and mixes, including ice cream, ice milks, sherbets, and other frozen dairy desserts and specialties.
- 21. Fruit and water ices, including all frozen fruit and water ices.
- 22. Gelatins, puddings, and fillings, including flavored gelatin desserts, puddings, custards, parfaits, pie fillings, and gelatin base salads.
- 23. Grain products and pastas, including macaroni and noodle products, rice dishes, and frozen multicourse meals, without meat or vegetables.
- 24. Gravies and sauces, including all meat sauces and gravies, and tomato, milk, buttery, and specialty sauces.
- 25. Hard candy and cough drops, including all hard type candies.
- 26. Herbs, seeds, spices, seasonings, blends, extracts, and flavorings, including all natural and artificial spices, blends, and flavors.
- 27. Jams and jellies, home-prepared, including only home-prepared jams, jellies, fruit butters, preserves, and sweet spreads.
- 28. Jams and jellies, commercial, including only commercially processed jams, jellies, fruit butters, preserves, and sweet spreads.
- 29. Meat products, including all meats and meat containing dishes, salads, appetizers, frozen multicourse meat meals, and sandwich ingredients prepared by commercial processing or using commercially processed meats with home preparation.
- 30. Milk, whole and skim, including only whole, low-fat, and skim fluid milks.

- 31. Milk products, including flavored milks and milk drinks, dry milks, toppings, snack dips, spreads, weight control milk beverages, and other milk origin products.
- 32. Nuts and nut products, including whole or shelled tree nuts, peanuts, coconut, and nut and peanut spreads.
- 33. Plant protein products, including the National Academy of Sciences/National Research Council "reconstituted vegetable protein" category, and meat, poultry, and fish substitutes, analogs, and extender products made from plant proteins.
- 34. Poultry products, including all poultry and poultry-containing dishes, salads, appetizers, frozen multicourse poultry meals, and sandwich ingredients prepared by commercial processing or using commercially processed poultry with home preparation.
- 35. Processed fruits and fruit juices, including all commercially processed fruits, citrus, berries, and mixtures; salads, juices and juice punches, concentrates, dilutions, "ades", and drink substitutes made therefrom.
- 36. Processed vegetables and vegetable juices, including all commercially processed vegetables, vegetable dishes, frozen multicourse vegetable meals, and vegetable juices and blends.
- 37. Snack foods, including chips, pretzels, and other novelty snacks.
- 38. Soft candy, including candy bars, chocolates, fudge, mints, and other chewy or nougat candies.
- 39. Soups, home-prepared, including meat, fish, poultry, vegetable, and combination home-prepared soups.
- 40. Soups and soup mixes, including commercially prepared meat, fish, poultry, vegetable, and combination soups and soup mixes.
- 41. Sugar, white, granulated, including only white granulated sugar.
- 42. Sugar substitutes, including granulated, liquid, and tablet sugar substitutes.
- 43. Sweet sauces, toppings, and syrups, including chocolate, berry, fruit, corn syrup, and maple sweet sauces and toppings.

In addition to the FDA federal regulations, you must become familiar with <u>PA Department of Agriculture</u> and <u>Allegheny County Health Department</u> regulations as discussed in Chapter 3.

In addition to these food categories, you should familiarize yourself with the main categories that have regulations and potential safety risks. You should review the complete details for each category on the <u>FDA</u> and USDA websites.

### Low-Acid Canned (LAC) Foods/Acidified Foods (AF)

Low-acid canned foods (LACF) refers to canned foods and flexible pouches of products such as tuna, low-acid baby food pouches and glass jars of creamy, dairy-based sauces such as Alfredo sauce. The LACF category includes any food (other than alcoholic beverages) with a pH greater than 4.6 and a water activity (aw) greater than 0.85, excluding tomatoes and tomato products having a pH less than 4.7. This is a very important category because, as discussed earlier, pathogenic bacteria grow well at pH ranges above 4.6, especially *Clostridium botulinum*, an anaerobe that produces a deadly toxic spore inside the can and causes botulism. LACD foods must be thermally processed in a retort (a very large oven that cooks product to about 250°F) to inactivate both the bacteria and the spores.

LACF foods are packaged in sealed containers that create an anaerobic environment. Examples include fruit- and vegetable-blended baby food products, shelf stable fruit and vegetable



smoothies, tomato salsas with chunks of corn and vegetables, sauces that have more than 10% ground nut meal, pickles that have been acidified with vinegar (not bacterially fermented), banana purees that have been preacidified with citric acid and are being repackaged, very ripe mangos with a pH above 4.6, oil and garlic condiments.

An acidified food (AF), on the other hand, is a low-acid food to which acid(s) or acid food(s) are added and which has a pH of 4.6 or below and  $a_w$  greater than 0.85. As you may recall from the previous chapter, a product with an  $a_w$  below 0.85 does not support the growth of pathogens. If the  $a_w$  is at or above 0.85, the product can support the growth of *Clostridium botulinum*. So if your product has an  $a_w$  below 0.85, it does not fall under the AF category.

Some examples of low-acid foods include bananas, meat, and beans. Acids or acid ingredients include citric acid, vinegar, lemon juice and other acidic fruits. If enough acid or acid ingredients are added to the low-acid food, the blend may yield a final equilibrium pH below 4.6—the pH you want to fall below to help make your product shelf stable. The process of forcefully "acidifying" the product to get to this low pH level is what makes it an acidified food. If only a small amount of a low-acid food (say <10% of the final product) is combined with a large amount of acid food, the product may be considered an acid food rather than an acidified food.

#### How to tell if a product is LACF/AF:

- Is the product stored at room temperature?
- Is the product packaged in a hermetically sealed (airtight) container—metal cans, glass bottles/jars, plastic bottles/jars, laminated pouches, plastic bags?
- Does the finished product have a water activity of greater than .85?
- Is the raw pH of the product greater than 4.6?

If you answered yes to all above questions, your product appears to be LACF or AF.

#### What Products are excluded from LACF/AF Regulations?

- Alcoholic Beverages
- Carbonated Beverages
- Jams, jellies, and Preserves IF they meet the definition of <u>21 CFR 150</u>
- Fermented Foods (low-acid foods subjected to the action of certain microorganisms, which produce acid during their growth and reduce the pH of the food to 4.6 or below (i.e. some green olives, pickles, and sauerkraut)

If your product is an LACF or AF, you should seek the development assistance of an LACF/AF facility R&D center or process authority to determine the critical processing parameters that ensure your product's safety. A "processing authority"—described in 21 CFR 113.83 as a qualified person having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations—must validate LACF thermal process times and temperature schedules. The process authority can help you understand how your product will be processed and how to formulate it optimally for those processing conditions. If you have an LACF, it will have to go undergo an in-container, high temperature sterilization process (retort process). The process authority will work with your

product and formulate it with industrially available ingredients and test it on the actual retort system that will produce the finished product, allowing you to see and taste it after it has been mixed and cooked. The effects of the retort can be drastic, so you may want to compensate for loss of flavor and texture by adding additional ingredients before the product is cooked. AF products do not have to be retorted like LACF products. Once the pH is below 4.6, *Clostridium botulinum* cannot grow, so a 250°F cook temperature is not necessary. If you plan to make an acidified food product, you must still develop safety process and production schedules with an authorized process authority. Penn State Extension offers a <u>list of process authorities</u> who can assist you with your LACF/AF product.

In addition, <u>Allegheny County Health Department (ACHD)</u> requires anyone developing an LACF or AF to attend <u>Better Process Control School (BPCS)</u>. The FDA and USDA also require this course for supervisors, who work with LACF or AF products, but it can also help you, the developer, understand how your product will be processed and how to formulate it optimally for those processing conditions. BPCS is offered both online and on-site at many <u>universities</u>.

Finally, anyone developing an LACF/AF product must obtain a <u>Food Canning Establishment</u> (FCE) registration with the FDA.

### **Fermented Foods**

Fermented things can be the kinds of food that people refer to as "acquired tastes." But what we don't realize is that some of the most common things we eat and drink are fermented. The words aged and cured should be your first clue. Fermentation is a process in which food is exposed to bacteria and yeasts, either via inoculation or naturally through the air. Beneficial microorganisms beat out the kind that cause food-borne illnesses, and eat up the carbohydrates in the food. The result is a low-acid food with a pH below 4.6 that has interesting flavors, textures, and smells. Before refrigeration, curing meats, pickling vegetables, and clabbering milk was the only way to extend the life of perishables. And if fermented foods haven't been cooked, they are really good for you (cooking kills off the beneficial bacteria).

Many people are unsure about what makes fermentation different from home canning and pickled foods. In general, preserving food is all about the <u>pH</u>, or <u>acid level</u>, in the food because the acid content prevents the growth of botulism, a deadly bacterium. The process of fermentation produces acid-loving bacteria, which in turn lowers the overall acid content to a pH below 4.6.

Fermentation is all about the relationship of food nutrients and live bacteria as a means of food preservation. In contrast, other food preservation methods like hot water bath canning, pressure canning, and pickling are only means to preserving food by removing the ability for bad bacteria to grow.

Here are 24 fermented foods, some more common than others:

- 1. Coffee
- 2. Cheese
- Yogurt, Sour Cream,
   Cultured Buttermilk, Crème
   Fraîche
- 4. Chocolate
- 5. Wine
- 6. Beer
- 7. Charcuterie (Country Ham, Salumi, Sausage, etc.)
- 8. Vanilla
- 9. Vinegar
- 10. Bread
- 11. Pickles, Sauerkraut, and Kimchee

- 12. Fish Sauce
- 13. Fermented Fish or Rakfisk
- 14. Ginger Beer
- 15. Miso
- 16. Tempeh
- 17. Natto
- 18. Marmite
- 19. Rumptoff
- 20. Century Egg
- 21. Kumiss
- 22. Kombucha
- 23. Kvas
- 24. Rejuvelac



Fermented products are very similar to acidified foods because the production of acid (through microbial fermentation) has lowered their pH. Although a fermented product is essentially "acidified" in the same way as an acidified food, FDA has never seen any cases of botulism caused by fermented foods, so it is not subject to the <u>acidified food regulations</u>. Fermented meat products fall under USDA jurisdiction and must be made in a USDA-approved facility with an HACCP plan. The USDA website provides a generic <u>model HACCP plan for non-heated, shelf stable meat products</u>. Fermented meats fall under this category.

Some not-so-obvious exceptions to the regulations applying to fermented foods include any fermented product that is combined with a low-acid ingredient. For example, olives stuffed with a low-acid nut are in the low-acid food category. Tempeh is another exception. This food must be made with care because, unlike other foods, the pH of tempeh rises during fermentation from 5.0 to 7.5, allowing it to support pathogen growth. Therefore, tempeh should be treated like a meat product, as it carries the same microbiological risks and, in contrast with other fermented soybean products, is not protected by low pH levels or salt. It should be kept refrigerated at all times.

When making fermented products, always start with high-quality base ingredients. You will be adding your fermenting bacteria, so you don't want to have to compete with bacteria that the food already contains. Work with starter cultures from a manufacturer that can provide you with a supply of carbohydrate fermenting bacteria (like lactobacillus or acidophilus) that will perform consistently across all production runs. Monitor your fermentation process to ensure it reaches the desired pH in the right amount of time, and make sure drying happens quickly to prevent the growth of surface yeast and mold.

## Naturally Acidic (High-Acid) Foods



High-acid foods have a pH that is naturally below 4.6. This category includes most fruits, fruit juices and vinegar and are typically processed in bottles, flexible pouches or jars. High-acid fruit juices used to be considered safe because their pH fell below 4.6, naturally inhibiting the growth of the pathogen *Clostridium botulinum*. However, in the 1990s, some pathogenic bacterial outbreaks were associated with fruit juices. So, in 2001, the FDA issued juice HACCP rules. The rules require that juice manufacturers and importers establish a juice HACCP plan whose specified process produces a minimum 5-log reduction (that is, lowering the number of microbes 100,000-fold) of "pertinent" organisms (the bugs that are the most resistant and are of public health significance) for the normal shelf life of the product. A juice HACCP plan does not have to be submitted to the FDA for pre-approval, but the FDA will request this information if and when it inspects your operation. The

Allegheny County Health Department Food Safety Program and PA Department of Agriculture also require that high-acid juices be made in a licensed facility with a pre-approved HACCP plan.

## Beef Jerky and Other Dried Meats

Beef jerky and other dried meat products are nutrient-dense meats that have been made lightweight by drying. The word "jerky" is derived from the Quechua word "ch'arki", which means "dried, salted meat". Jerky is a food known at least since ancient Egypt. Humans made jerky from animal meat that was too big to eat all at once, such as bear, buffalo, or whales. North American Indians mixed ground dried meat with dried fruit or suet to make "pemmican" and "Biltong" is dried meat or game used in many African countries.

Dried meat products are a fast growing segment in the meat industry. Drying is the world's oldest and most common method of food preservation. Canning technology is less than 200 years old and freezing became practical only during this century when electricity became more and more available to people. Drying technology is both simple and readily available to most of the world's culture.



The scientific principal of preserving food by drying is that by removing moisture, enzymes cannot efficiently contact or react with the food. Whether these enzymes are bacterial, fungal, or naturally occurring autolytic enzymes from the raw food, preventing this enzymatic action preserves the food from biological action.

Jerky is the oldest style of simply dried meat, made from muscle strips and dried with salt, sugar or marinades to inhibit the growth of bacteria. All that is needed to produce basic "jerky" is a low-temperature drying method, and salt to inhibit bacterial growth. Formed jerky is made from preshredded meats, and meat snacks (like a Slim Jim) are made of shredded meat stuffed into a casing. A pound of meat or poultry weighs about four ounces after being made into jerky.

Because most of the moisture is removed, the products are shelf stable and can be stored without refrigeration, making them handy for backpackers and others who don't have access to refrigerators. In the past few years, jerky with clean labels and no preservatives has become popular in the artisan food community.

Dried meat products are regulated by both <u>USDA</u> and <u>PA Department of Agriculture</u>. If the dried meat is only being sold locally in the shop where it was made, it may be regulated only by our state and <u>county food safety</u> regulatory agencies. However, if the product is being sold out of state, or even at a local farmers' market away from where it was manufactured, it must be made in a <u>USDA-approved facility</u> and have a USDA stamp on the packaging.

Illnesses due to *Salmonella* and *E. coli* from homemade jerky raise questions about the safety of traditional drying methods for making beef and venison jerky. The USDA Meat and Poultry Hotline's current recommendation for making jerky safely is to heat meat to 160 °F and poultry to 165 °F before the dehydrating process. This step assures that any bacteria present will be destroyed by wet heat. But most dehydrator instructions do not include this step, and a dehydrator may not reach temperatures high enough to heat meat to 160 °F or 165 °F.

After heating to 160 °F or 165 °F, maintaining a constant dehydrator temperature of 130 to 140 °F during the drying process is important because the process must be fast enough to dry food before it spoils; and it must remove enough water that microorganisms are unable to grow. The danger in dehydrating meat and poultry without cooking it to a safe temperature first is that the appliance will not heat the meat to 160 °F and poultry to 165 °F—temperatures at which bacteria are destroyed—before the dehydrating process. After drying, bacteria become much more heat resistant.

The USDA also requires beef jerky and other dried meets to have a final  $\frac{\text{water activity }(a_{\underline{w}})}{\text{between 0.60}}$  level between 0.60 and 0.70 to prevent pathogen growth and inhibit spoilage bacteria, yeast and mold and to extend shelf life

It is advisable to do all the R&D work in the same type of dehydrating ovens that you'll use to make your final product. A home dehydrator produces a very different product than the commercial ones in a manufacturing plant. You may want to consider purchasing your own water activity unit if you plan to spend a long time formulating and experimenting with the product. Water activity can also be tested at any food testing laboratory such as Microbac, as previously

mentioned. Beef jerky is one of the most frequently recalled items because improper drying and lack of salt, sugar and preservatives leads to mold and product spoilage. Mold growth on beef jerky can potentially alter the overall stability of the product and lead to a total product breakdown, an increase in aw, and possible subsequent pathogenic growth.

## Salad Dressings



Many entrepreneurs enter the food industry by manufacturing sauces and dressings. The FDA's strict "standard of identity" definition of a salad dressing (21 CFR 169) is an emulsified semi-solid food prepared from vegetable oils, an acidifying ingredient (lemon or lime juice, vinegars), a starchy paste prepared from food starch, food starch-modified, tapioca flour, wheat flour, rye flour, or any two or more of these and an optional egg yolk-containing ingredient. Other versions or styles of dressing may not meet the definition of a salad dressing as described in 21 CFR 169, which may affect what you are allowed to call it.

Salad dressing may be shelf stable or refrigerated. Shelf stable dressings are more preserved (with salt, sugar and mold inhibitors) to prevent spoilage; refrigerated ones are less preserved, as refrigeration inhibits spoilage organisms.

Commercial salad dressings usually belong in the <u>acid food category</u> because they are naturally acidic, with large amounts of acidifying agents such as vinegar and lemon juice, and are considered to be microbiologically safe. Some non-standardized salad dressings with large amounts of low-acid ingredients (like egg or tofu) may be in the acidified foods category (<u>21 CFR 114</u>). FDA allows acidified dressings to be cold-filled only if the producer conducts a <u>microbiology safety study</u> that documents the conditions under which vegetative (non-spore forming) pathogens are appropriately reduced. Commercial dressings must be made in an FDA-approved facility, and manufacturers must follow strict quality controls and diligently comply with FDA-mandated <u>cGMPs</u> (<u>21 CFR 110</u>). Commercial salad dressing and sauce products should also be made with industrial pasteurized eggs that are free of salmonella and other pathogenic bacteria.

When developing your salad dressing formula, you must first determine whether you wish to sell it as a refrigerated or shelf stable product. You must also make sure the product meets the requirements of the salad dressing definition (21 CFR 169) if you wish to call it "salad dressing." If not, you will need to use an alternative name like "dipping sauce" or "spread." A refrigerated salad dressing has an easy to read label advantage, as fewer preservatives are needed to keep it safe, but it also has a shorter shelf life.

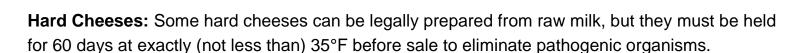
### **Cheese and Cheese Products**

The FDA defines cheese in general in 21 CFR 133.3 (A) and further identifies, in detail, 94 standardized types of cheese in 21 CFR 133 (B) (section 102-196). While the FDA specifically defines only 94 cheese types, more than 800 varieties of cheese exist, including hard and soft styles, ripened and un-ripened and aged for different amounts of time to produce unique flavors. Hard, ripened cheeses include Cheddar and Manchego, and un-ripened cheeses include cream cheese, Jalisco Mexican cheeses, Neufchâtel, and cottage cheese.

Cheese Regulations are unique to the type and makeup of the cheese.

Unripe Soft Cheese: Unripe soft cheese must be made with pasteurized milk that complies with the <a href="Grade A">Grade A</a>
<a href="Pasteurized Milk Ordinance">Pasteurized Milk Ordinance</a>. Soft cheeses made with raw

milk are illegal in the U.S. because raw milk may be contaminated with pathogens like *Listeria monocytogenes*, which can cause illness and death especially in pregnant women, young children, the elderly and immunocompromised patients.



The <u>FDA Food Code</u> specifies that most cheese products be date-marked to indicate the date by which the food shall be consumed or discarded. Not all cheeses need to be date-marked, however. Some hard and semisoft aged cheeses, as well as pasteurized process cheese, each



manufactured according to <u>21 CFR 133</u> and maintained under refrigeration, are exempt from the Food Code's date-marking provision. They include:

- Hard cheeses containing no more than 30% moisture, as defined in 21 CFR 133
- Cheeses and related cheese products such as Cheddar, Gruyère, Parmigiano-Reggiano and Romano
- Semi-soft cheese containing 39% to 50% moisture, as defined in <u>21 CFR 133</u> and related cheese products, such as blue, Edam, Gorgonzola, Gouda, and Monterey Jack.

All cheeses should be made in a FDA-approved facility that follows <u>21 CFR 110</u> (<u>cGMPs</u>). Milk should be free of antibiotics and tested in a state- or FDA-approved milk-testing facility. Properly sanitize all equipment used to make cheese to prevent post-process contamination. Closely monitor all temperatures and pH levels to ensure both the safety and quality of the finished product.

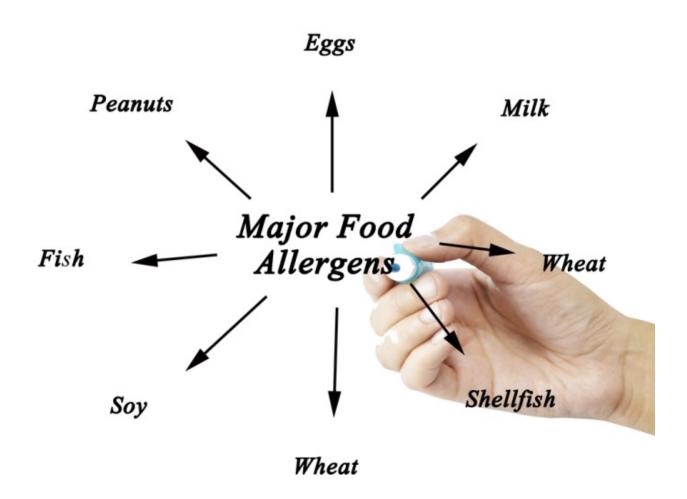
### Non-Hazardous Foods



Non-hazardous foods are products that do not require time and/or temperature controls to ensure food safety. They're usually naturally high in <u>acid</u> or sugar, or they are baked or dehydrated to a very low <u>water activity</u> level. Examples include baked goods and energy bars with an a<sub>w</sub> <0.85, jams, popcorn, marshmallows, candied nuts, trail mix, spices, herbs, jellies and fudge. If your food is in this category, it is considered to be low-risk, and fewer regulations will govern how it is brought to market. The industry is trending with trail mixes, jams, and energy bars because they do not present a food-safety risk, so many commercial kitchens and co-manufacturers are able to manufacture and package these items easily and possibly with less liability.

Even if a food does not pose a microbiological health or safety risk, the manufacturer must follow FDA <u>21 CFR 110</u> (cGMPs) to ensure that the product is made in a sanitary

way, <u>21 CFR 101</u> to ensure that the label is truthful, and the <u>Food Allergen Labeling and Consumer Protection Act</u> to ensure that all <u>allergens</u> are declared. If you wish to mass-produce a non-hazardous food, you will want to thoroughly research all packaging materials options that will protect your product from light and air, and extend your shelf life quality. You will also want to ensure that your product is manufactured to reflect its unique, FDA-defined standard of identity as described in <u>21 CFR 130</u>.



# Food Processing and Preservation

Food preservation through processing is an extremely broad area in food science. Entire textbooks are written on each method of processing, including refrigeration, freezing, pasteurization, canning, fermentation, concentration, irradiation and dehydration. Only the essentials needed to acquaint one with each method of product development are mentioned below.

## Refrigeration

Mechanical refrigeration is the most common and a less expensive method of preserving perishable foods. Ice is still used in addition to mechanical refrigeration to extend the shelf life of fish, seafood, poultry and some vegetables. A mechanical refrigeration system includes a closed piping system that contains refrigerant (ammonia or freon), a compressor and a condenser. Air circulation and humidity control must be regulated to achieve good product shelf life.

The use of modified or controlled atmospheres is a relatively new concept in food processing, where the atmospheric condition around the product is different from normal air. Most systems involve elevation of the  $CO_2$  levels and reduction in the  $O_2$  content in a room or package. Low storage temperature and package design as it relates to gas transmission rates are critical to the success of these systems.

### Freezing

If done properly, freezing preserves foods without causing major changes in shape, size, color, texture and flavor. There are three broad methods of freezing foods commercially—in air, by indirect contact with a refrigerant and by immersion in a refrigerating medium. There are variants of each of these methods.

Air freezing, such as is used in home freezers, is the oldest and least costly method, using still air at temperatures in the range of -10 to -22 degrees F. Air blast freezers, used commercially, are operated at temperatures ranging from -22 to -50 degrees F and use rapid air flow. Consequently, air blast freezing is much quicker than air freezing.

Indirect contact freezing involves placing food on plates, trays or belts that are chilled by a circulating refrigerant and that put the product in direct contact with the cold wall but not the refrigerant itself.

Immersion freezing places the food or package directly in a refrigerating medium that can be sprayed onto the food or package. If the refrigerant comes into contact with unpackaged foods, it must be non-toxic, pure, clean, free of foreign taste, odor and color, and non-bleaching. Two broad classes of refrigerants are used for immersion freezing: liquids with a low freezing point (such as freon), and cryogenic liquids (such as compressed liquefied nitrogen or carbon dioxide).

Commercial freezing operations require a high capital investment because of high equipment and energy costs.

# Heating

Heating food destroys a large proportion of the microorganisms and natural enzymes that reduce shelf life. Heating will not completely sterilize a food product, so even if the food is protected from recontamination, spoilage may eventually occur.

- **Blanching** is a type of preservation used to inactivate most natural enzymes in fruits and vegetables by par-boiling or steaming. It is normally used before freezing and, depending on its severity, will reduce the load of microorganisms.
- Pasteurization is a moderate heat treatment at temperatures below the boiling point of water. The main objectives in pasteurizing food are to destroy pathogens and to extend shelf life. Batch pasteurization is used for liquid foods (such as milk) with mild agitation. The temperature is kept low (145 degrees F), for a treatment time of 30 minutes for milk. High temperature/short time pasteurization has largely replaced batch pasteurization for most liquid foods. As the name implies, temperatures are higher (161 degrees F) and times shorter (15 seconds) for milk.
- Canning is a severe heat process using temperatures of 240 degrees F and above and is
  designed to render the packaged product shelf stable. Canned foods are often considered
  to be sterile, but this is not true because not all bacterial spores are destroyed even at
  these temperatures. The shelf life of canned foods may vary from several months to

several years. The exact temperature and time used for heating food depends on many factors, including the food's <u>pH</u>, viscosity, load of microorganisms and possibility of bacterial spores. The processing time and temperature chosen for any product must be certified by the FDA before the product can be manufactured. The canning of low acid foods (those with a pH greater than 4.6) requires a large capital investment. <u>Penn State Extension</u> offers extensive articles on home food preservation and canning.



- Aseptic Canning is the process of heating a liquid or semi-liquid food at a high temperature for a short time, cooling it in a sterile chamber and then packaging it in a sterile container under microbial free conditions. The equipment and operation are expensive.
- Acid/Acidified foods have a pH of 4.6 or less. Because of their natural acidity, these products can be processed at atmospheric temperatures (212 degrees F) or less, usually around 190 degrees F, and packaged while hot. Many fruits and their juices are processed in this manner. Sometimes, acids or acid foods are added to low-acid foods to yield products that have a final equilibrium pH of 4.6 or less. These foods are "acidified" and strict processing regulations have been established to ensure their safety. Relishes, most sauces and many pickled products are "acidified" and are popular items among specialty food processors.

Penn State Extension offers extensive articles on acidified foods.

- Dehydration preserves foods by removing moisture. In dehydration, enough water is removed so that the final moisture content is one to five percent, making the food products shelf stable. Hot air and freeze-drying are two common methods of dehydration. Freeze-drying is a form of vacuum dehydration in which the product is frozen and water is removed as vapor.
- Concentration is the method of preservation used to make jams, jellies, preserves and related products that are popular among specialty food producers. But achieving a quality product that jells properly is not always easy. The four



essential ingredients for successful jelly manufacturing are fruit, pectin, acid and sugar. These ingredients must be present in the correct ratios to yield an acceptable jelled product. Some fruits, such as apples, have enough natural pectin to make a high-quality product. Others require added pectin for firming. Most processors add pectin to their

formulations so they can use fully ripe fruit, reduce cooking time and increase yields. A sugar concentration of 67.5 percent solids and a pH of 3.1 are considered optimum for jelly manufacturing.

#### **Fermentation**

<u>Fermentation</u> is a very old method of preserving food in which more flavorful foods are produced from original products. Fermentation depends on proper microbiological activity. It is used to produce beer, wine, vinegar, cheese, sauerkraut and many spicy luncheon meats.

# High-Pressure Food Processing (HPP)

HPP is a non-thermal preservation technique that causes minimal change in the quality and nutritional attributes of the product. It involves applying 100 to 1000 mega Pascals (MPAs) of hydrostatic pressure to food products via a water bath. The water bath distributes the pressure equally, allowing the products to withstand the pressure without being crushed. The applied pressure essentially disables pathogens, yeast and molds to a safe level that can be maintained at refrigerated temperatures for up to 30 days. Raw and unpasteurized juice beverages on the market that claim a 30-day shelf life are produced using high-pressure processing, or HPP. They are raw tasting, last for 30 days (refrigerated) and taste like fresh-squeezed fruits and vegetables.



Some popular brands include Blueprint, Evolution (sold at Starbucks) and Harmless Harvest Coconut Water. HPP is not just restricted to juices. It has been successfully applied to dairy products, meat, poultry, seafood and nut purees. They all carry a hefty price tag, but some people think that fresh uncooked flavor is worth the cost. It turns out this process is not that new. It is also known as "pascalization" in honor of the

17th century French scientist Blaise Pascal, famous for research on how pressure affects liquids.

The <u>FDA</u> and <u>USDA</u> recognize HPP as an effective "lethal" process that significantly reduces microorganisms in food in the same way that pasteurization reduces the microbial load. The inhibition delays spoilage and increases shelf life, too.

HPP processing has its pros and cons. As discussed above, HPP products are fresh-tasting and do not have that "cooked fruit" flavor characteristic of most thermally processed equivalents. They can also be refrigerated for up to a month, which eliminates waste and saves time when preparing for culinary functions that would normally require rushing to the store for fresh produce at the last minute. For food scientists and product developers, HPP processing means using fewer preservatives and thus generating cleaner labels.

On the flip side, HPP products are expensive to manufacture. A 12-oz bottle of HPP juice can cost as much as \$10 dollars retail. As more companies use HPP, the price is likely to become more affordable. Some experts debate whether HPP has an effect on the "live enzymes" that are part of the "raw juice" appeal, arguing that the high pressure that inactivates the bacteria may also inactivate some of the enzymes. Questions about HPP can be put to experts and scientists in the LinkedIn High Pressure Processing.



**Branding Your Product** 

Crucial to your success is determining the branding of your product(s)—the correct positioning, packaging, and pricing combination of your product so you will reach your target customer. To properly brand and position your product, marketers often refer to the *Five Ps* of success:

- The right **Product**
- Packaged right
- **Priced** right
- At the right **Place**
- Maximizing *Promotional* opportunities at the right time and located in all possible areas for maximum consumer availability

Your brand's positioning is part of a strategic plan and frames how your brand is compared to your competition and what you are trying to say to the customer. When you launch a new product, 80% of new products fail in the first 2 years. Branding your product correctly can help you be in the 20% that succeed. Below we offer examples from our own startup to help you articulate and write your own story that will help you to craft your brand.

### Your Back Story

If you want your product to end up in your customer's shopping cart, they have to first select it from a sea of large-brand competitors. What you say on your label and packaging has to resonate with the customer and provide a value proposition that motivates people to try it. The first way to do this is provide them with your back story.

Everybody loves a good story: stories are a critical component in content marketing. Stories communicate shared traditions—they endure and contain essential elements that each person can relate to; they teach us about ourselves and make us realize our own needs and desires.

As a food startup, you can build on this and position your product's brand on a personal story that allows you to convey your brands' features, benefits and attributes. Every brand has a story. With the farm-to-table movement we see more and more brands carefully articulating their back story and building it into their brand. First you have to think back to the earliest inkling of where and when you began to think of the idea behind your product.

When Gastón and I realized that dulce de leche was not readily available in the US market, we reached into our family tree and picked the face of our company straight from its branches. La

Dorita dulce de leche is based on my Argentine grandmother Dorita's recipe. As a child, she made batches and batches of homemade dulce de leche for our entire family. It was a part of our everyday culinary traditions and is representative who showed us love and care through the food she prepared for us.

Once you identify that certain "aha" moment behind the inspiration of your product, you can use that experience to help select your company's name and company logo. For instance, my grandmother Dorita's portrait adorns our products' labels and her recipes are the foundation of the products. We chose a portrait that was painted by my sister to keep costs down and also to make sure we had full rights to use the image. Whenever we would serve dulce de leche to our friends during barbecues or birthday parties, people would always fall in love with it. Our friends often asked us if we could make some for them to take home. This is when we realized we really had something special and decided to test it at local farmers markets.

Choosing a business name is the second critical step in the business planning process. Not only should you pick a name that reflects your brand identity, but you also need to ensure it is properly registered and protected for the long term. You should also give a thought to whether it's webready. Is the domain name even available? Some factors to consider when naming your business include:

- How will your name look?—on the web, as part of a logo, on social media.
- What connotations does it evoke?—is your name too corporate or not corporate enough? Does it reflect your business philosophy and culture? Does it appeal to your market?
- Is it unique?—pick a name that hasn't been claimed by others, online or offline. A quick web search and domain name search will alert you to any existing use.
- Check for trademarks—trademark infringement can carry a high cost for your business.
  Before you commit to a name, use the U.S. Patent and Trademark Office's Trademark
  Electronic Search System (TESS) to see if any mark has already been registered or applied for that is similar to your mark and used on related products or for related services.
  If your search yields a mark that you think might conflict with your mark, you should then check its status to see if the application or registration is still "live," since any "dead" mark cannot be used to block a new application.

• If you intend to incorporate, check to see if the name is available—if you intend to incorporate your business, you'll need to check with <a href="PENN File">PENN File</a>—Pennsylvania's online business document filing system—to check whether your intended business name has already been claimed and is in use. If you find a business operating under your proposed name, you may still be able to use it, provided your business and the existing business offer different goods/services or are located in different regions.

Once you've identified your back story and committed to a name for your company, you have to determine your brand identity and communicate it effectively to your target customer. To begin brainstorming about your brand's identity, ask yourself some of the following playful questions:

- If my brand could speak, what would its voice sound like? Is it male? Is it female? Young? Old? Robotic? La Dorita's voice has the loving and gentle feel of a devoted grandmother calling her grandchildren to gather at her kitchen table.
- What drink would my brand order in a bar? Is it old enough to get served? Or does it prefer not to drink alcoholic beverages all together? At La Dorita, our brand would order a vodka and tonic with lemon, but wouldn't dare order a second drink.
- Is my brand serious or tongue-in-cheek? Is it funny? Bombastic? La Dorita's character connotes wisdom and caring.
- What kind of clothing does my brand wear? An Audrey-Hepburn-like simple, black dress or a carefree sundress made from upcycled fabrics? La Dorita's wears nonnesense comfortable clothes that are simple yet elegant.
- What kind of car does my brand drive? A Toyota Prius or a sleek Jaguar
  Convertible? Maybe my brand isn't old enough to operate a motor vehicle or all
  together prefers to arrive by bike to its destinations. La Dorita never learned to drive.
  Always relied on others or took taxis.
- Does my brand smile in photos? Is it showy? Does it like to be the center of attention or blend in to the background? Is it authentic? La Dorita is always smiling and always looking to make you feel like the most important person in the world to her when you are in her presence.

Once you have determined and imagined your brands persona and character, you can begin to effectively communicate it. You can begin to imagine the color palate, selected fonts and textures

included in your packaging. You can begin to develop taglines and mottos that effectively position your brand.

Communication is about emotion. Emotion is the cornerstone of your brand's story. We used my grandmother Dorita's 90<sup>th</sup> birthday to launch our dulce de leche spread. She turned 90 on September 25, 2009, the same month our first jars of dulce de leche were accepted into our local Whole Foods Market. It was our "gift" to her. We had recreated her dulce de leche to leave her legacy. My son, Nacho, barely two at the time, was our first dulce de leche model. He enjoyed several semi-homemade baby food breakfasts and earned his spot as the little boy on the side of our original dulce de leche jar. Most everyone responds to a grandmother who shows love through cooking and baking. By having Dorita's picture adorn our logo, and our son's baby picture on the side panel we let people into our lives and let them know we are not only selling them a great product but a part of the love we were raised on and continue to raise our own children on.

Now that you have identified the essence of your back story, you can use this to carve out the core of your message, and use this as the building blocks for your product name and brand. By including your back story as a message on your label, you will effectively communicate the roots of your brand to the consumer. This message should also convey your products features, benefits and attributes.

Our dulce de leche spread conveys the following messages on each jar:

- 1. "Just say duel-say!"—this message is intended to make the consumer feel comfortable pronouncing the term "dulce de leche". It seems so easy to say in Spanish, but in English dulce de leche doesn't exactly roll off the tongue. With this simple phrase we are saying: Go ahead, try it 10 times fast. It sounds like this: duel-say day lay-chay. Laugh at yourself as you pronounce the words and it will become as natural to say as the product itself. Or, you can defer to the Italian pronunciation, "dolce". This is also okay since, in many ways, Argentinian Spanish sounds more like Italian than the Spanish spoken in Spain and throughout Latin America. If all else fails, just call it DDL. In the end, it doesn't matter how you say it, as long as you taste the sweet goodness that dulce de leche can bring into your life.
- 2. Second we share the different ways the consumer can use dulce de leche. Since it is not exactly a part of our everyday diet here in the United States, it's important to convey dulce

de leche's versatility as an ingredient to the consumer, and establish its rightful place on their breakfast table and weekly shopping list—"Spread on toast, croissants...Spoon over pancakes, waffles...For sweet bitefuls, tuck into crêpes, cakes, cookies...Drizzle warm over your favorite ice cream...Mix into mashed banana for a healthy baby treat...OR simply grab an apple and dip away!"

3. Finally, we let our customer know about the matriarchal inspirations that embody the values of La Dorita dulce de leche—good, simple, real food made with the love and care that only a grandmother can offer—with our sign off: "On behalf of my Grandma Dorita and my mom, Poupée, I hope you enjoy our dulce de leche as much as we do. Thanks from all of us at La Dorita, Josephine Oría, Granddaughter and Founder."

Now that you have written your back story, you can work on developing your brand's positioning statement. Positioning statements are a way to concisely communicate to web designers, people designing your packaging and your advertising what they need to do. Consider the Positioning Statement as a short blueprint for them to follow.

An effective positioning statement includes the following 5 steps.

Step 1—Define your target audience. Are you selling only to retail? Are you an ecommerce business? Are you doing both? Is your customer someone with expensive taste, or someone who prefers to only eat local, seasonal products? Is it someone who is seeks out gourmet offerings or who is driven by impulse buying? Be honest with yourself here. Your target customer should have other needs and desires that are not fulfilled by the major brands. Describe your customer in enough detail so the world can see a "picture" of your customer. Think about why your customer is different, how they might use your product in their lives. This should be compelling enough that a retail supermarket buyer can see that your customer is also their customer.

Step 2—Communicate what you are making or offering. Are you creating your own brand, private label or both? What differentiates your product from your competitors? Make sure you are very clear as to what you sell. If you make ice cream, be sure you articulate if you are premium, gluten free, vegan, etc. since ice cream is such a large category with many sub-categories.

Step 3—Explain the benefits of buying your product. The benefit must focus on an intangible aspect that the consumer cannot make an easy comparison to your competition. This is your

unique selling proposition and should be more than taste. For instance, is your ingredient panel "clean" as compared to your competitor's or is your product certified organic? Make sure you are very clear as to what you sell. If you make ice cream, be sure you articulate if you are premium, gluten free, vegan, etc. since ice cream is such a large category with many sub-categories.

**Step 4—State your product's features.** These are the tangible parts of your product. Some features might be an enticing aroma, bold/aromatic flavor, packaged in sustainable packaging, smooth flavor, made in small artisanal batches. This should not be a laundry list so keep it to the most important.

#### Step 5—Give the consumer a real reason to buy your brand repeatedly, not just once.

When all is said and done, everyone needs a reason to buy. This is the incentive for the customer to put your product in their cart. This could be an introductory offer for first time buyers, free shipping, the flavor is a seasonal offering and goes away after a few months, etc. *How, when, where will the consumer buy and then consume my product?* 

As you are formulating your positioning statement, ask yourself why the retail buyer should give you shelf space. Retail shelves are full, so if you want to get on the shelf, the retailer has to either discontinue another brand or reduce the number of facings in the category to make room for your brand. If you fail to articulate a compelling positioning statement, you have little chance to get on the shelf.

Now that you have defined your positioning statement, it's time to think about developing you logo and packaging. Packaging is among the most important sales tools available to food marketers. When deciding on your packaging, many questions must be answered. The following list of design criteria must be considered:

- How can I make my product packaging drive the consumer's purchase impulse?
- Is my consumer also the primary end-purchaser of my product?
- How much will they buy at one time? How often?
- How much are they willing to pay? (How are competitive products priced?)
- What is the right size for my product? (What are my competitors' sizes?)
- How will consumers, merchandisers, retailers, distributors, and freight carriers expect my products to be packaged? (Don't forget regulatory and industry standards).

- How can I create my packaging to take advantage of shipping master pack and pallet configurations that will maximize freight efficiencies and sales?
- What materials and methods should I use to efficiently achieve the highest protection of the product during shipping and handling and to extend shelf life and ultimate sale-ability, while being environmentally conscious?
- How can I add value? How can I get my first time customer to buy my product again?
   Adding value at the time of purchase helps to drive repeat customers. Box Tops for Education is one way that participating food company's encourage moms and dads to purchase their product over a non-participating competing brand.

There are other issues that must be considered when designing your products' packaging. Find products on the shelf that are doing well and ask yourself: Why and what drew your eye to that specific product? Keep in mind where your product is going to be stocked and who's going to read it. If your product is on a supermarket shelf, you've got to consider that you'll be among other brands. One of the best things you can do is to know your competitors, so you can see how your brand needs to differ from existing ones.

When it comes to designing your own identity and packaging materials, consider doing it yourself. For instance, at La Dorita we used a portrait painted by my sister, Verónica Caminos Ranieri, as the face of our company. This allowed us to easily design a logo without much overhead cost. However, I realize not everyone should be so lucky to have a sister who is also an artist. There is both art and science involved in creating a successful logo and image...for this reason you have to ask yourself whether you will benefit by working with a marketing agency. A relatively small investment up front can save tens of thousands of dollars in the long run, not only in lost sales, but in costly redesigns and new packaging printing and inventories. We recommend that you locate a good graphic designer or package design firm by asking around. Public Relations firms can help too as can some universities. Study portfolios. Ask about their successes and failures.

Branding isn't just about a logo; it's the experience as a whole. It's about everything that surrounds whatever you're selling, the entire brand aesthetic and textures. Along these lines, investing in a good photographer can also help to build your brand's identity. Photography is, particularly important for food related products. Invest in somebody who can distil the essence of your business through the lens and make your brand warm, welcoming and engaging. People want to get involved with these brands because they feel like it's a lifestyle to buy into... that must

come through in your imagery! Many food startups successfully convey this in an Instagram account.

Setting yourself apart from the big brands is something that is integral if you want to make waves in the food industry. Make sure to thoroughly research your market. Having a unique perspective with an authentic story is key in the specialty food business. Being authentic makes it so much more personal—that's the key way to differentiate yourself from the big box brands. The successful food brand provides experiences that are novel, engaging and honest.

### **Trademarking**

Establishing your brand identity will be among the larger investments you will need to make as a startup. That includes coming up with a name to communicate the value of your product or service to customers, as well as a logo and tagline to visually connect with your customers. After perfecting these concepts, you will want to make it a priority to protect your name and logo.

As discussed in the previous section, you should always perform a thorough trademark search prior to committing to a company name. Trademark infringement can carry a high cost for your business. We have seen this firsthand. One of the original members of our kitchen share program received a cease and desist letter, also known as infringement letter or demand letter sent to an individual or business to halt purportedly unlawful activity ("cease") and not take it up again later ("desist"), in its second year in business. The letter was signed by a company who had a common law trademark on the same company name that our member had built his brand around. He had, unfortunately, not performed a thorough trademark search prior to committing to his company name, and slapping it all over his website, packaging, and food truck. So, after successfully branding his product for more than two years, this member was forced to go back to the drawing board and rebrand his company—from the name, to the logo to the packaging. While he successfully persevered, these are the type of hiccups you hope to avoid as they will set you back in time and capital.

Once you have worked hard to establish your brand and have invested in logos and marketing, it is so important to begin to look into trademark registration and aggressive defense of your brand. We always like to advise startups to invest in a trademark search prior to committing to your brand—this way you know if you might be infringing upon another brand before investing in establishing your brand. You can hire an Intellectual Property lawyer, or perform your own

search using the U.S. Patent and Trademark Office's (USPTO) <u>Trademark Electronic Search System (TESS)</u> to see if any mark has already been registered or applied for that is similar to your mark and used on related products or for related services. If your search yields a mark that you think might conflict with your mark, you should then check its status to see if the application or registration is still "live," since any "dead" mark cannot be used to block a new application.

A complete search is one that will uncover all similar marks, not just those that are identical. In this regard, searching for trademark availability is not the same as searching to register a domain name. A domain name search may focus on exact or "dead on" hits, with no consideration given to similar names or use with related products and services. Basically, a domain address is either available or it is not. The trademark process, on the other hand, is more complex. As part of the overall examination process, the USPTO will search its database to determine whether registration must be refused because a similar mark is already registered for related products or services (i.e., even identical marks may co-exist if used on goods or services not considered to be related in any way).

On the flip side, a thorough trademark search may confirm that you can indeed use a name that you previously considered to be off limits. For instance, when we first consulted with a trademark lawyer about using my grandmother Dorita's name for our company name, our legal counsel immediately advised us to look for another name as they considered it might infringe upon Frito-Lay's "Doritos" brand. In this case, we obviously went with our gut feeling and continued to pursue trademarking the use of my grandmother's name for our product. We have a very strong back story that was integrally tied to our name choice. We decided to file a declaration for use of the name, La Dorita, along with a declaration of use of our logo and tagline, "Its dulce delicious." Our legal counsel understood our unwavering determination to use my grandmother's name and together we decided to publish the three marks in the USPTO Official Gazette and see if Frito-Lay or any other party contested the use of the name. After the mark is officially published, any party who believes it may be damaged by registration of the mark has thirty (30) days from the publication date to file either an opposition to registration or a request to extend the time to oppose. An opposition is similar to a proceeding in a federal court, but is held before the Trademark Trial and Appeal Board (TTAB). If no opposition is filed or if the opposition is unsuccessful, the application enters the next stage of the registration process. In this case we

took a risk that could have cost a couple thousand dollars had Frito-Lay's contested, but in the end it worked to our favor.

There is one more point you will have to consider. There may be names and trademarks that are being used by other food companies that have not secured federal trademark registrations. These food service competitors may have acquired <a href="common law rights">common law rights</a> through their use of the name, which is defined by limited geographic regions of use. With this result, you may not have the priority to enter a region with your proposed name as you may risk infringing such common law trademark rights. One way to further research common law rights is to perform a <a href="fictitious name search with the Pennsylvania Department of State">fictitious name search with the Pennsylvania Department of State</a> as well as perform name searches on Google and other search engines for companies that have not registered their trademarks through the USPTO but may still have common law rights in a similar name.

As you can see, making an educated decision for the name of a new food business is not an easy task. It can be filled with complicated details and analysis. We suggest that unless you are an attorney yourself, the best way to fully understand the implications of trademarking your brand and choosing an appropriate name is to consult with an attorney who has a firm grasp of US trademark law.

Before performing your own Trademark search, consider watching the video tutorial, <u>Basic Facts About Trademarks</u>: <u>What Every Small Business Should Know Now, Not Later</u>. It highlights the important role of trademarks in that process, including a discussion of how trademarks, patents, copyrights, domain names, and business name registrations all differ. It gives guidelines on how to select the right mark—one that is both federally registrable and legally protectable. It also explains the benefits of federal registration and suggests resources if you need help with your application. By the end of the video, you'll understand why having a trademark component of your business plan is critical to your success.

Owning a federal trademark registration on the Principal Register provides the following several advantages:

Constructive notice to the public of the registrant's claim of ownership of the mark;

- A legal presumption of the registrant's ownership of the mark and the registrant's exclusive
  right to use the mark nationwide on or in connection with the goods and/or services listed in
  the registration;
- The ability to bring an action concerning the mark in federal court;
- The use of the U.S registration as a basis to obtain registration in foreign countries; and
- The ability to file the U.S. registration with the U.S. Customs Service to prevent importation of infringing foreign goods.

#### When can I use the trademark symbols TM, SM and ®?

Any time you claim rights in a mark, you may use the "TM" (trademark) or "SM" (service mark) designation to alert the public to your claim, regardless of whether you have filed an application with the USPTO. However, you may use the federal registration symbol "®" only after the USPTO actually registers a mark, and not while an application is pending. Also, you may use the registration symbol with the mark only on or in connection with the goods and/or services listed in the federal trademark registration.

Lynch Law Group's <u>Kathleen Kuznicki</u>, <u>Esquire</u> works with startup businesses and individuals to maximize protection of their own brand identity, and to minimize risk with regards to others' intellectual property. Kathleen works with several startup companies, who often ask her if they can copyright their logo as a first level method to protect their brand. "Well, *technically* yes you can," Kathleen explains, "but copyright is <u>not</u> the ideal protection for your brand/source identifiers. Copyright only protects your logo as an artistic expression; it does not protect your logo as a brand/source identifier."

Protection of brand/source identifiers falls under trademark law, and if you are doing business across state lines, federal protection occurs through trademark registration. Federal registration of a trademark gives an owner exclusive nationwide use of their mark for the goods and services listed in their registration. A copyright, on the other hand, would only give the owner the exclusive legal right to reproduce, publish, sell, or distribute the logo as an original creative work. A work is considered original if it is <u>not copied</u> from some other preexisting work; it does not need to be novel or unique. This exclusionary protection provided by a copyright is too narrow for a logo. Someone can independently create an original artistic work similar to your logo and you could not prevent them from using it.

The legal definition of a trademark is a word, phrase, symbol, and/or design that identifies and distinguishes the source of goods and services. A registered trademark protects your brand by providing you certain legal rights. Registration gives you a legal presumption of ownership of the trademark in connection with the goods and services listed on your registration. Anyone using a "confusingly similar" mark could be considered infringers, (unless they have established rights in their local area as a common law trademark <u>before</u> your federal registration) and you can pursue them to stop using the mark and potentially seek damages, especially if the infringement is willful. Federal registration provides a public record; there is constructive notice nationwide of your claim, which means others have a duty to inquire to ensure they are not infringing others' marks. So, even if someone unknowingly creates a logo similar to yours (that covers goods and services related to yours) you may legally be able to stop them from using their logo, and they should be refused federal registration, if they were to apply.

If you are not doing business across state lines, you can still protect your branding through state trademark law, but first, you need to build up your common law rights to your trademark in your local area. How do you do that? Essentially, the longer you use the mark, the more effort you put into your marketing, the more name and logo recognition you have with the your customer base, the stronger your common law rights to your mark. Unfortunately, under state trademark law, whether or not you can prevent someone from using a confusingly similar mark is very dependent upon the specific facts and circumstances surrounding the use of the marks and how these circumstances are interpreted under your particular state's laws.

It is vital that startup owners understand that their intellectual property has an immense value. Intellectual properties are assets that can generate revenue. Unprotected intellectual property can be stolen (infringed) by a competitor. Without the proper protections in place, you have no recourse to protect your brand and identity from infringers. And if your intellectual property is not reviewed beforehand, you may unsuspectingly find yourself to be an infringer, and the recipient of a threatening cease and desist letter signaling the beginning of a legal battle, or sending you back to the drawing board to rebrand your product.

Generally Intellectual Property (IP) can be broken down into 4 categories:

- 1. Literary and artistic works that includes books, newsletters, blogs, website layout, music, images-hand drawn or digital, photographs, sculptures, movies, broadcasts, software code, and much more that can be protected by **COPYRIGHT REGISTRATION**.
- 2. Product names and logos can be protected by TRADEMARK REGISTRATION.
- 3. Inventions, whether simple or complicated, any new unique way to solve a problem or a new ornamental design can be protected by **ISSUED PATENTS**.
- 4. Trade secrets are concepts or designs that are only known to you, that give you an advantage over your competitors, and that are of economic value. Trade secrets are protected by having a **PROTOCOL** in place to maintain secrecy and confidentiality.

### Does it Make Sense to Patent My Food Recipe?

A <u>patent</u> is a federal grant of exclusive rights given in exchange for the public disclosure of a new and non-obvious invention. In other words, obtaining a patent requires the inventor to fully disclose what might otherwise be treated as a trade secret, and, if it meets the statutory requirements, the government grants the patentee the exclusive rights to make, use, sell, offer to sell, or import the invention for almost twenty years. One of the most common questions the <u>Office of Innovation Development</u> receives is whether or not food recipes can be patented.

According to Title 35 of the United States Code, Section 101 (35 U.S.C. 101), patents may be granted for any "new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof". A food product or recipe typically has three components: a list of ingredients, instructions on how to combine and cook them, and the final product resulting from the first two components. In terms of patentable subject matter, a list of ingredients can fall under the headings of a composition of matter and/or manufacture, and the way the food product is produced can fall under a process. So, the short answer is yes, food recipes and formulas are eligible for patent protection.

According to the U.S. Patent and Trademark Office, food recipe patents fall under Patent Class 426: Food or Edible Material "intended to be consumed by human beings or lower animals in

whole or part via the oral cavity." So as long as your recipe is intended for making a nutritional (as opposed to a medicinal) composition to be eaten by people or pets, then it passes the first hurdle of being a "food or edible material." When making the decision about whether or not to patent a product, carefully consider whether your product passes the "novel" and "non-obvious" test. To be patentable, an invention must also be "novel" and "nonobvious," as determined by 35 U.S.C. 102 and 35 U.S.C. 103, respectively. That means a patentable invention can neither have existed before, nor be an obvious improvement or alteration of a previously known invention, which could be determined by someone with reasonable skill in the art encompassed by the invention. This is where patenting a recipe gets a lot more complicated.

Consider that some of the earliest known examples of written language are food recipes. And often they are modified into a "new" recipe with the simple tweak of one humble ingredient. Even if a previous version of a recipe cannot be found, a "new" recipe could still be considered obvious. Similarly, adding tarragon to a dish that doesn't usually include tarragon may result in an unexpected taste for that particular dish. This means that trivial changes like amounts of ingredients are simply not enough, especially not from the perspective of another chef or home cook of ordinarily skill.

There are exceptions in which the combination of ingredients used, or the way they are processed, results in a food product totally unexpected. That's something that may be patentable. Numerous patents on food products are issued each year. However, if you take a look at most of these patents, you'll find that the recipe was more likely to have been created in a laboratory than on a kitchen counter. Experts advise performing a USPTO <u>patent search</u> to determine whether your recipe or formula can surpass the "novel" and "non-obvious" hurdles. Before performing your own patent search, consider reviewing the web-based tutorial, <u>How to Conduct a Preliminary U.S. Patent Search: A Step-by-Step Strategy</u>. In most cases, it makes sense to consult with a patent attorney about whether or not getting a patent makes sense for your small business.

However, before you spend the money on the patent process (which can get expensive), carefully consider your situation, and your product. While obtaining a patent on your particular recipe, formula or process can exclude others from making, using, or selling your delectable creation, some recipes are better left secret and thus fall under trade secret protection. Trade secrets include such things as a company's manufacturing processes and precise product formulations.

They include any formula, method, or information that takes time, money, or effort to develop and gives you a competitive advantage. The FDA has adopted the following <u>definition of trade secret</u>: "A trade secret may consist of any commercially valuable plan, formula, process, or device that is used for the making, preparing, compounding, or processing of trade commodities and that can be said to be the end product of either innovation or substantial effort. There must be a direct relationship between the trade secret and the productive process."

A patent isn't the only way to acquire intellectual property protection for food products. It goes without saying then that a recipe patented cannot also remain a secret. If you don't patent it, you don't have to make public the ingredients, components, and/or manufacturing methods. Labeling something a trade secret is a common safety measure taken by businesses. Many food companies and restaurants choose to use trade secrets to protect their recipes and methods because it allows them to use the secretive nature as a marketing tool. If your product is that vital and important, filing a patent only opens it to the public, whereas protecting it as a trade secret can make it harder for the competition to copy your work. That doesn't stop imitators from trying. In food and beverages, secrets can be reverse-engineered by amateurs and food scientists. You have to consider whether your recipe could be copied by a home cook or chef who is skilled in the art of cooking.

Contrary to patents, trade secrets are protected without registration or any procedural formalities. Instead, they are often locked away in corporate vaults and fiercely protected by fail-proof non-disclosure agreements. Consequently, a trade secret can be protected for an unlimited period of time. For these reasons, the protection of trade secrets may appear to be particularly attractive for food companies such as Coca Cola, Thomas' English Muffins, KFC's fried chicken batter, Dr. Pepper, and Bush's Baked Beans. There are, however, some conditions for the information to be considered a trade secret. Compliance with such conditions may turn out to be more difficult and costly than it would appear at first glance. While these conditions vary from country to country, some general standards exist which are referred to in <a href="Art. 39 of the Agreement on Trade-Related Aspects of Intellectual Property Rights">Aspects of Intellectual Property Rights (TRIPS Agreement)</a>:

• The information must be secret (i.e. it is not generally known among, or readily accessible to, circles that normally deal with the kind of information in question).

- It must have commercial value because it is a secret. For instance, Thomas' English Muffin claims that the secret to their signature nooks and crannies is a well-protected secret with approximately \$500 million in yearly sales at stake.
- It must have been subject to reasonable steps by the rightful holder of the information to keep it secret (i.e., through confidentiality agreements).

There are, however, some concrete disadvantages of protecting confidential business information as a trade secret, especially when the information meets the criteria for patentability:

- If the secret is embodied in an innovative product, others may be able to inspect it, dissect
  it and analyze it (i.e. "reverse engineer" it) and discover the secret and be thereafter entitled
  to use it. Trade secret protection of an invention in fact does not provide the exclusive right
  to exclude third parties from making commercial use of it. Only patents and utility models
  can provide this type of protection.
- Once the secret is made public, anyone may have access to it and use it at will.
- A trade secret is more difficult to enforce than a patent. The level of protection granted to trade secrets varies significantly from country to country, but is generally considered weak, particularly when compared with the protection granted by a patent.
- A trade secret may be patented by someone else who developed the relevant information by legitimate means.

In is article, "Can I Patent a Food Recipe?" Mark Levy Esq. offers some considerations to keep in mind when determining whether or not to seek a patent.

#### What Can Be Patented?

As mentioned above, food patents have two primary categories—food recipes and food processes. Patents can be obtained in either category, but almost all food patents touch on both.

### 1) Composition of matter

Like chemical compounds, food recipes are technically compositions—that is, combinations of certain ingredients to make something different. Many U.S. patents on food recipes are new, useful, and non-obvious compositions of matter. Let's say you have a new recipe for a sugar-free barbeque rub and you use ingredients that have never been combined before—and it's not

obvious to do so—then it's possible to seek a composition-of-matter patent on the recipe. In preparing your patent application, you might list the ingredients and their proportional ranges.

#### 2) Process for making the product

If part of making a food product from your recipe is heating it up or cooking it, that step is considered a process. The process is essential to the patent if the method for cooking your recipe ingredients, or the precise order in which you add foods together, is new, novel, and not obvious. Unless your recipe has something really inspired about it, like mixing the ingredients in zero gravity for unexpected results, it isn't patentable.

Other processes that might make your recipe patentable include (but are not limited to) the non-obvious steps of heating, frying, sautéing, poaching, baking, bottling, canning, aging, separating, blanching, stirring, grinding, whipping, mixing, chilling, freezing, melting, dehydrating, soaking, cutting, layering, stamping, molding, smoking, and grilling.

#### Types of Recipe Patents: What Has Worked

As you might expect, many food patents cover large-scale food production, such as mass-producing cereal or cheese, or extending a food's shelf life with additives. But other patented recipes, such as chewable tablets for astronauts (Patent #6,149,939) and dried food for arthritic pets (Patent #6,596,303), have a narrow audience. Levy has comprised the following list, though not complete, that will give you a sense of the wide range of types of recipes that have earned U.S. patent protection:

- Reduced calorie: A surge of these appeared in the 1980s and continue with many hundreds of recipes for things like fat replacements (Patent #5,466,479) and sugarless bakery goods (Patent #5,804,242)
- Microwavable: Sponge cake that can rise when microwaved (Patent #6,410,074)
- Texture: Ingredient-replacing egg whites to reduce toughness of batter coatings (Patent #6,288,179)
- Moisture protection: Preventing a cream filling from making its outer bread layer soggy (Patent #5,145,699)
- Shelf life: Single-dough cookies that store well (Patent #4,344,969)
- **Smoothness**: Cooking process that improves mayonnaise (Patent #6,579,558)
- Flavoring: Additive that improves chocolate flavor in baked goods (Patent #3,733,209)

- Shaping: Controlling cookie geometry (Patent #5,374,440)
- **Convenience**: Toaster cookies (Patent #6,093,437); ready-to-bake dough (Patent #5,560,946)
- **Appearance**: Confections that swim in a carbonated beverage (Patent #6,319,535)
- **Special diets**: Diabetic nutritionals (Patent #6,248,375)
- **Combinations**: Storing peanut butter and jelly in the same container (Patent #3,117,871)

Levy advises startups to <u>look up</u> and read the details of some of the patents listed above to help you learn what makes a recipe patentable and how to keep a patent claim broad.

#### **Creating a Strong Recipe Patent**

According to Levy, the more novel and non-obvious the idea, the stronger your patent application will be. That goes for all inventions, including recipes. If you come up with a totally new sugarless confection or dry-rub marinade that never existed before, or a substitute ingredient that generates unexpected results, those are likely to have strong patent potential.

You should also make the patent's parameters—ingredients, temperatures, cooking times—as broad as possible. That helps prevent your competition from designing around your claims by making small variations.

So if you're cooking a solution, for example, you'll want to say in your detailed specification and in your claims, "Heated between a temperature of X and Y." If you're listing quantities, also make those a range. For example, use wording like "between 1 and 1.5 parts water," and "approximately 2 parts sugar." You don't want to claim an exact amount that someone could modify only slightly to avoid infringing on the patent for your recipe.

#### **Common Mistakes**

According to Levy, the most common error in preparing a food-recipe patent application is missing the non-obviousness requirement. The test is this: Would your recipe be obvious to someone skilled in the art of cooking? The answer must be no. For example, if you merely take conventional and predictable food items off the shelf and mix them without doing anything special to the process, your invention probably does not reach the level of non-obviousness required for patentability.

Also, people fail to think of substitute ingredients that may be equivalent to those they're disclosing, so they specify their ingredients too narrowly. Sure, sugar works great, but so might honey, corn syrup, or molasses. If that's the case, just say "a sweetener" when describing that ingredient. Does your recipe require pecans? If walnuts or almonds might work, just say "nuts." By keeping the patent application broad, you will prevent other people from stealing your idea by swapping out one nut for another—and then legally selling their products using your idea.

#### **Remember the Basics**

Above all, in your excitement to patent your recipe, don't forget the basics of patent law. For example, people will often try to patent recipes that have been passed down from past generations. You can't do that for a couple of reasons. First, a patent goes only to the inventor, meaning I can't patent my Grandmother Dorita's dulce de leche recipe—because I am not the inventor and she's not the one applying for the patent. Second, if the recipe has been in my grandma's family for generations, the recipe has likely been long disclosed. Upon any public-disclosure, inventors get only 365 days to submit a patent application on the idea. After that, the idea is not patentable.

## **Packaging**

Now that you've committed to a name and have begun investing in and protecting your brand, it's time to determine how to package it. You've already started to survey your competition to see what does and doesn't work. Remember, big box brands invest thousands of dollars to research their packaging, so you can learn a lot from them. You know what kind of packaging they are using and you don't want to stray too far from what works for them, especially the size. This may seem counterintuitive. It's natural to want to make a product that stands out on the shelf. Thinner, fatter or taller than all the rest. Bigger than your largest competitor. You may want people to see your jar as soon as they come around the corner, and pick it out from all the rest. This is when you need to fight your instincts and consider going with the flow—as it's already been market-tested.

Unique packaging is expensive and when you're producing goods at a small scale you need to watch costs. You have to not only consider the cost of your packaging, but the freight involved in getting it to you, as well as any technology and time required to properly seal it.

Customers will compare your product to neighboring products. If your product is 20 ounces and the competition is 16 ounces, it will make your product seem more expensive, even if the cost per ounce is the same, or less. Perception goes a long way in a consumer's mind, and they won't pore over every detail on your label the way you will when you are designing it. You want a level playing field in the consumer's mind.

Retailers will also want a product that fits in with the others so they don't have to rearrange their shelves. If barbecue sauce usually comes in 6-inch bottles and yours is 8 inches tall, the retailer will need to take the entire section apart and reset the shelves so your product will fit. Your bottle could make the grouping look off balance and cause a gap above the product, something retailers try to avoid. It's also in your best interest to use a package that stacks well. Products that are easy to stack (without crushing) make better displays, and displays get people's attention. There's a saying in grocery stores: "stack 'em high and watch 'em fly."

You'll notice that in some areas of the store there are similar color schemes on products. Food manufacturers know that certain colors will convey automatic associations to most shoppers—and they are cleverly influencing your buying decisions with the use of color. Salsa is a great example. Almost every salsa on the shelf contains red, yellow and/or green in its label. You

rarely, if ever, see blue or purple. This is not an accident. Red and yellow are considered "hungry colors." Research has shown these colors increase appetite. The newest example: the color green, which traditionally has been associated with the outdoors, is now being used to get food shoppers to assume that certain foods are natural and



healthful. If all of your competition uses a similar color scheme, you should consider whether it has value for you as well. Don't copy your competition's design, learn from it. They've spent a lot of money to determine what works with consumers. With some careful examination, you can put that research to work for you.

#### Packaging has several objectives:

- **Physical protection**—The food enclosed in the package may require protection from, among other things, shock, vibration, compression, temperature, bacteria, etc.
- Barrier protection—A barrier from oxygen, water vapor, dust, etc., is required.
   Permeation is a critical factor in design. Some packages contain desiccants or oxygen absorbers to help extend shelf life. Modified atmospheres or controlled atmospheres are also maintained in some food packages. Keeping the contents clean, fresh, and safe for the intended shelf life is a primary function.
- Containment or agglomeration—Small items are typically grouped together in one package to allow efficient handling. Liquids, powders, and granular materials need containment.
- **Information transmission**—Packages and labels communicate how to best use your product—for instance, fresh, recycle, or dispose of the package or product. Some types of information are required by regulatory licensing agencies.
- Marketing—The packaging and labels can be used by marketers to encourage potential
  buyers to purchase the product. Package design has been an important and constantly
  evolving phenomenon for several decades. Marketing communications, graphic design,
  even textures are applied to the surface of the package and (in many cases) the point of
  sale display.
- Security—Packaging can play an important role in reducing the security risks of shipment. Packages can be made with improved tamper resistance to deter tampering and also can have tamper-evident features to help indicate tampering. Packages can be engineered to help reduce the risks of package pilferage; some package constructions are more resistant to pilferage and some have pilfer-indicating seals. Packages may include authentication seals to help indicate that the package and contents are not counterfeit. Packages also can include anti-theft devices, such as dye packs, <a href="RFID tags">RFID tags</a>, or electronic article surveillance tags, that can be activated or detected by devices at exit points and require specialized tools to deactivate. Using packaging in this way is a means of retail loss prevention.
- **Convenience**—Packages can have features which add convenience in distribution, handling, stacking, display, sale, opening, reclosing, use, and reuse.
- Portion control—Single-serving packaging has a precise amount of contents to control
  usage. Bulk commodities (such as nuts and grains) can be divided into packages that are a
  more suitable size for individual households. It also aids the control of inventory: selling

sealed one-liter bottles of milk, rather than having people bring their own bottles to fill themselves.

The Internet is a gold mine for information about package sourcing. You can ask your food scientist, co-packer, shared-use kitchen, or other food producers who they use for packaging. Your co-packer may have specific sizes of containers that fit in their production, so if you decide to work with them, ask them in advance about the size limitations. Shop around. Ask for samples and price out several different quantities, as the larger your purchase, the lower your cost.

When considering packaging, carefully weigh the benefits and drawbacks of what is available. Darker colored glass can help protect food from sun damage, but clear glass gives a better view of your product. Plastic may keep products fresher than paper, but isn't biodegradable, which many consumers prefer. Note that you have to determine the jar, bottle, box, or bag the product comes in, and also the case it ships in. A typical case of grocery store product holds 12 pieces. That is something else to consider when choosing a package.

Finally, you may want to consider looking into sustainable packaging options—although this is often a more costly option for food startups. Reduced packaging and sustainable packaging are trending in the food industry. The motivations can be government regulations, consumer pressure, retailer pressure, and cost control. While reduced packaging often saves packaging costs, the process of engineering more environmentally acceptable packaging can include a considerable amount of costs and research. Sustainable packaging is the development and use of packaging which reduces the product's environmental impact and ecological footprint. Sustainable packaging must meet the functional and economic needs of the present without compromising the shelf stability of the product itself. Sustainable packaging is a relatively new addition to the environmental considerations for packaging. It requires more analysis and documentation to look at the package design, choice of materials, processing, and life-cycle. This is not just the vague "green movement" that many businesses and companies have been trying to include over the past years. Companies implementing these eco-friendly actions are reducing their carbon footprint, using more recycled materials and reusing more package components. They often encourage suppliers, contract packagers, and distributors to do likewise.

Penn State Extension provides several packaging resources:

Packaging Materials and Suppliers Equipment

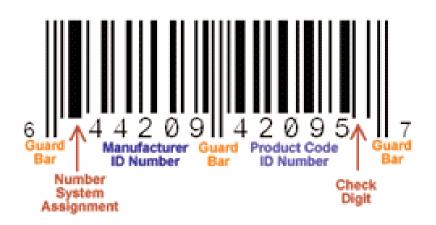
- Plastic Packaging Codes
- An Overview of Oxygen Scavenging Packaging and Applications

We have also used the following printing and packaging companies for die-cut packaging labels and supplies:

- Print Tech of Western PA
- <u>Lightning Labels</u>
- BRP Box Shop (for bakery businesses)

#### **UPC Barcodes**

One portion of your packaging and label not mandated by federal law, but required by many retailers, is a Universal Product Code (UPC) or bar code. Barcodes are symbols that can be scanned electronically using laser or camera-based systems. They are used to encode information such as product numbers, serial numbers and batch



numbers. Barcodes play a key role in supply chains, enabling parties like retailers, manufacturers, transport providers and hospitals to automatically identify and track products as they move through the supply chain.

While UPCs are now found on all sorts of products, they were initially developed for grocery stores to speed up the check-out process and to help stores keep better track of their inventory. They are now standard on almost all food products. Getting one is easy and affordable and makes your product look more professional.

You can launch your product without a UPC, but if you are looking to grow into regional or national distribution, you will need a UPC. If you are manufacturing products for retail sale, especially at major retail outlets, you will almost certainly need to have identifying barcodes on the packaging. Contact your intended retailers for information.

If you plan to have few products and buy individual codes, you are not required to obtain the manufacturer identification number through the <u>GS1</u>, a non-profit organization that sets the standards for global commerce using barcodes. GS1 operates in over 100 nations, so you can likely contact an office in your country or region. Purchasing barcodes directly from GS1 requires a membership and payment of a renewable annual fee, which is why some people prefer to buy their barcodes from resellers for a one-time charge. GS1 membership, however, is the best way to ensure the legitimacy of your barcodes, but it can cost you several hundreds of dollars. An individual bar code, on the other hand, will cost you less than \$10. Prior to purchasing, make sure your barcode comes with a certificate of authenticity verifying that your barcode is indeed a unique number that will be accepted by all major retailers and distributors worldwide. There are a number of reputable online resources for buying UPCs, including the following four websites:

- www.upccode.net
- www.buyabarcode.com
- www.simplybarcodes.net
- www.speedybardcodes.com
- www.nationwidebarcode.com
- www.EZUPC.com
- www.gs1.org/barcodes

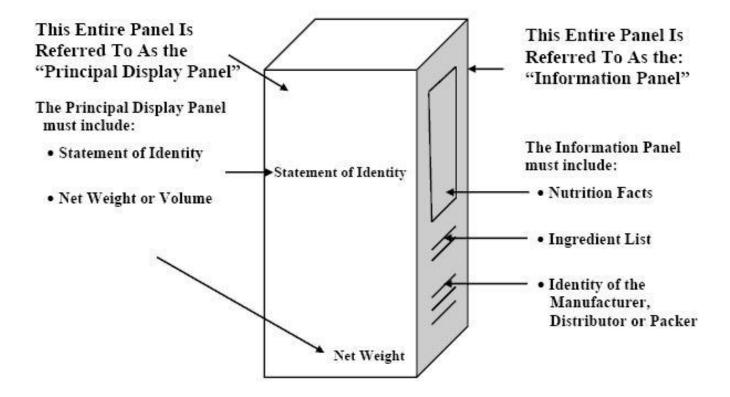
If you will be launching a product line with several different products and intend to continue to expand your product line, it is likely you will need a <u>GS1 barcode</u>. You will first have to estimate your barcode needs. The first step in joining GS1 U.S. is acquiring a GS1 Company Prefix, and the length of the prefix (6-12 digits) determines how many barcodes you can create. A six-digit prefix lets you create 100,000 barcodes, while a ten-digit prefix gives you only ten. Based on your barcode need, you then select your membership level. Not surprisingly, the more blocks of barcodes you buy, the lower price per barcode you pay. Currently, for example, you will pay a \$250 initial fee and \$50 annual renewal fee for up to 10 unique barcodes, and \$10,500 / \$2,100 for 100,000 of them. Instead of buying already-created barcodes as you do when purchasing secondhand, with GS1 membership you will actually create the barcodes for your product(s). GS1 US offers a "Data Driver" interface that enables you to create the barcodes yourself, or you can utilize (for a fee) an authorized GS1 US Solution Provider to do the work for you.

Once you have your barcode images in hand, make sure the copies you render for your product packaging are of the same quality. Barcodes don't necessarily have to be black and white, but a high contrast between the alternating bars is essential for easy reading. When designing your label, make sure to place the UPC barcode image in a place that can be easily scanned. Prior to printing your labels, it is best to provide your retailers with an art-ready sample of the label to make sure your barcode is properly placed and has a high enough resolution that can be easily scanned.

# Food Product Labeling Requirements

Your food label is your product's calling card. It allows consumers to compare one product to another and provides instructions for safe handling and storage, as well as identifies the manufacturer responsible for making the product. Labels list ingredients to help consumers choose foods with ingredients they want or need to avoid. If you have a simple product you may have fewer regulations to follow. Keep in mind that the regulations governing a food product are more complicated if you want to make any sort of health claim, for example low fat, high fiber, etc. If you keep it simple, you can learn much of what you need to know from your competition's labels. This section will cover the fundamentals.

# Components of a U.S. Food Label



The <u>FDA</u> and <u>USDA</u> are responsible for ensuring that foods sold in the United States are safe, wholesome, and properly labeled. Both agencies dictate the type of information that must be on

the label and where the label can be placed on the package. This applies to foods produced domestically, as well as to those imported from foreign countries. Locally, the <u>PA Department of Agriculture</u> enforces the federal guidelines for all foods sold within the state of Pennsylvania. Food labeling is required for most prepared foods, such as breads, cereals, canned and frozen foods, snacks, desserts, drinks, etc. Nutritional labeling for raw produce (fruits and vegetables) and fish is voluntary. Before you have labels printed, share a draft version with a <u>Pennsylvania Department of Agriculture sanitarian</u> to make sure you have met all labeling requirements.

As we mentioned earlier, you should look for common color themes in the labels of similar products. Trends in the food industry change quickly. Take these trends into account and make decisions accordingly. You don't want to change your label every year, but you also don't want your product to look antiquated or stale. First you'll want to establish the creative part of your label: the logo, the font, all the fun stuff. Then you'll need to deal with the compliance issues. Be sure to add lead time for the review when you are timing the printing of your labels. During the design process, you will find that your product's label is a work in process.

There is some basic information you should have on the front of your product label. The FDA refers to this part of the label as the "PDP" or "Principal Display Panel." The first is the common or usual name of the food. So if it's deep-fried, seasoned grated potatoes, the label should clearly state this, even if you simply call them "Tater Tots." The common name of the food needs to be prominent and stated in English. For instance, the FDA requires dulce de leche manufacturers like us to write "milk caramel" on the label, merely for the fact that there is no other English translation for the spread other than "milk jam." And, quite frankly, how enticing does that sound anyone? (It's all much more romantic when said in the Spanish tongue.) The PDP should also include the amount of product in the package. It must show the net contents in both metric (grams, kilograms, milliliters, liters) and U.S. Customary System (ounces, pounds, fluid ounces) terms, in no particular order. The font must be large enough and clear enough to read.

The next section of the label is the information panel labeling. There are three pieces to this section:

- Nutrition Facts
- Ingredients
- Manufactured By

Federal law requires that the information panel be located to the right of the PDP. These three items need to be placed together, without any other information interrupting them. Below we will continue to further dissect labeling requirements on both a state and federal level.

### PA Department of Agriculture Requirements

While the federal government is responsible for establishing food labeling regulations, the <u>PA</u>

<u>Department of Agriculture Bureau of Food Safety and Laboratory Services</u> reviews food labels to ensure compliance by food entrepreneurs in Pennsylvania.

The PA Department of Agriculture provides several different guides with a brief summary of the labeling regulations governing foods offered for sale in Pennsylvania:

- Retail Food Facility Guideline by Food Type
- Labeling of Packaged Foods at Retail
- Labeling Requirements of Food Products at Retail Food Facilities Flow Chart
- Labeling Requirements of Retail Self-Service Unpackaged Foods (i.e. take out cartons)
- <u>Labeling Requirements of Retail Service by Employee Packaged Food Flow Chart (any</u> unpackaged food portioned to consumer specs)

The basic label requirements outlined in these guides include:

- Identity of food in package form—the common name of the food, or absent a common name, an adequately descriptive identity statement;
- Name and place of business of the manufacturer, packer, or distributor;
- Name of the food source for each major food <u>allergen</u> contained in the food unless the food source is already part of the common or usual name of the respective ingredient;
- Ingredient declaration—if made from two or more ingredients, a list of ingredients and subingredients in descending order of predominance by weight, including a declaration of artificial colors, artificial flavors and chemical preservatives, if contained in the food
- · An accurate declaration of the net quantity of contents;
- Nutrition labeling as specified in <u>21 CFR 101 Food Labeling</u> and <u>9 CFR 317 Subpart B</u>
   Nutrition Labeling;
- For any salmonid fish containing canthaxanthin or astaxanthin as a color additive, the labeling of the bulk fish container, including a list of ingredients, displayed on the retail

container or by other written means, such as a counter card, that discloses the use of canthaxanthin or astaxanthin.

The only exemption to this section of the code, with ingredients still available upon request, is:

- 1. **Packaged Food:** Bakery products that are made or prepared on the premise of the food facility or another food facility/processing plant owned by the same owner. This exemption includes 'bake-off' items.
- 2. Unpackaged Food, such as deli salad, which is portioned to a consumer request and is made on the premise of the food facility or another food facility/processing plant owned by the same owner and makes no health claims.
- 3. **Self-service bulk foods**, such as bulk candy bins, have alternative labeling requirements.

If food is considered packaged, it must be appropriately labeled with ingredients (including subingredients), and all other required labeling information, as listed above. The term "Packaged" is defined in the Food Code:

- "Packaged" means bottled, canned, cartoned, bagged, or wrapped, whether packaged in a Food Facility or a Food Processing Plant.
- "Packaged" does not include wrapped or placed in a carry-out container to protect the food during service or delivery to the consumer, by a food employee, upon consumer request.

The PA Department of Agriculture will exempt the following Grab-n-Go food products from being fully labeled on the packaged product if all of the following apply:

- 1. Item is made or assembled in the Retail Food Facility
- 2. The item is a single serving and packaged
- 3. The item is marked with the date of preparation
- 4. The item is sold within 24 hours or discarded
- 5. The service case has a placard, poster, card, book or similar, displayed with or near the food item, and which included the common name, all ingredients and subingredients, and major <u>allergens</u>.

6. The packaging itself contains a label with the common name, general ingredients (not sub ingredients), name and address of the store, net quantity and major <u>allergens</u>.

Considering the FDA does not pre-approve labels for food products, it's a good idea to contact your local food sanitarian at the <u>PA Department of Agriculture Bureau of Food Safety and Laboratory Services</u> for a general review of your label before finalizing it sending it to a printer. This review is not a requirement but is strongly recommended because your label may be reviewed during unannounced inspections. There should be no fee for a general review of your label.

### **FDA Requirements**

The U.S. Food Drug and Administration (FDA) is responsible for establishing food labeling regulations. The FDA's <u>Food Labeling Guide</u> is a lengthy read and one that you should become familiar with. As the FDA does not pre-approve food labels for food products, it is especially important to carefully review this guide and check label compliance prior to putting your product on a supermarket shelf. Further, the FDA does not prescribe how any company determines nutrient content for labeling purposes. It is the responsibility of each food manufacturer to keep abreast of—and comply with—the legal requirements for food labeling.

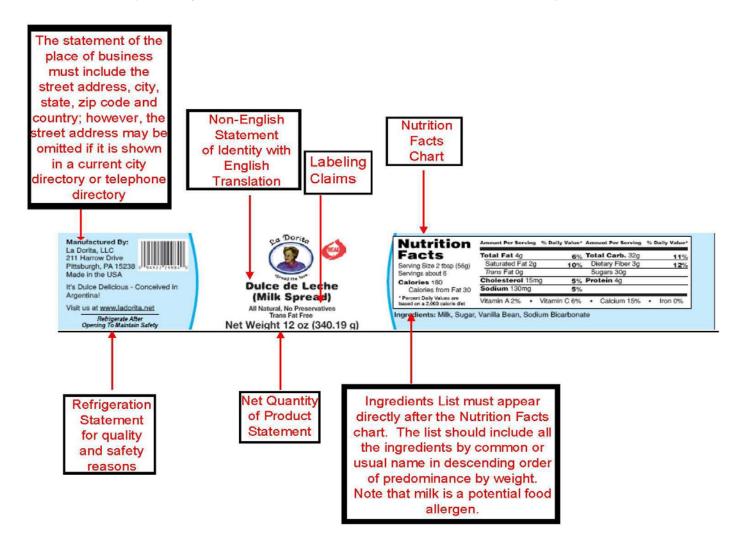
The FDA regulates every statement on your label, with the exception of your logo and name. While the FDA does not regulate the use of your logo(s) or name on a food product label, the FDA does expect that your label contain truthful, not misleading information. Generally the following information is required on food labeling:

- Statement of Identity (name of product)
- Net Quantity of Contents statement (amount of product)
- Nutrition Facts chart (nutritional information for the product)
- Ingredients List (the contents of the product)
- Allergen Warning (alerting consumers to the presence of an allergen in the product) and
- Manufacturer, Distributor or Packer Identity statement (with company name and address)

There are two places on packages and containers where required labeling statements may be displayed:

- 1. You may place all required statements on the **Principal Display Panel (PDP)**, which is the primary side of the product that the consumer will view, or
- 2. You may place the Statement of Identity and the Net Quantity of Contents statement on the PDP and all other required statements on the **Information Panel** (the first usable panel immediately to the right of the PDP as displayed to the consumer).

Below is a draft of the first label we created for our dulce de leche spreads. This is a draft only and has since undergone several changes to adhere to FDA regulations. The general information required by the FDA is identified with an arrow that corresponds to each section.



#### **The Principal Display Panel**

As mentioned above, **The Principal Display Panel (PDP)** is the part of a label that is most likely to be displayed, presented, shown, or examined under customary conditions during display for retail sale. The PDP must be large enough to accommodate mandatory information with clarity and conspicuousness. Mandatory information cannot be obscured by designs, vignettes, or crowding (21 CFR 101.1).

Many containers are designed with two or more different surfaces that are suitable for display as the PDP. These are alternate Principal Display Panels. Where packages bear alternate PDPs, information required to be placed on the Principal Display Panel shall be duplicated on each PDP (21 CFR 101.1). All required declarations must appear in English or provide an English translation. In our specific case, we were required to add the word "caramel" into our English translation of dulce de leche, as "milk spread" is not recognized as a food category by the FDA.

As you design your label, refer to <u>21 CFR 101: FDA Regulations for Food Labeling</u>. The FDA's labeling requirements found in 21 CFR 101 subparts A to G describe where to place a label, font sizes, rules for making health and nutrient claims, and how to label specific ingredients such as colors, additives and spices.

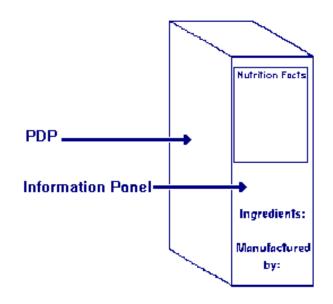
#### The PDP generally consists of:

- 1. The Statement of Identity is the product name of the food contained in your container or containers. The FDA requires that the Statement of Identity be sized so that it is "reasonably related" to the largest text on the label (21 CFR 101.3(d)). Chapter 4 of the FDA Food Labeling Guide recommends that a "reasonably related" Statement of Identity is generally one-half (1/2) the size of the largest text on the label. It must also be oriented in lines generally parallel to the base on which the package rests as it is designed to be displayed. The FDA requires your statement to fall in one of three categories (21 CFR 101.3(b)):
  - a. The name specified by federal law or regulation or a common or usual name of the food and, if none exists, then;
  - b. An appropriately descriptive term or;
  - c. When the nature of the food is obvious, a fanciful name commonly used by the public for such food.

- 2. **The Net Quantity of Contents Statement** sets forth the weight or volume of the product in your container. The FDA requires that the Net Quantity of a food that is a solid, semisolid, or viscous, or a mixture of solid and liquid must be expressed in the terms of weight (21 CFR 101.105(a)). Weights and volumes must be displayed in both U.S. and metric units--for instance, 1 lb 8 oz (680 g) or 1 gal (3.79 L).
  - a. The FDA states that the term "net weight" is to be used when stating the Net Quantity of Contents statement in terms of weight (21 CFR 101.105(j)(3)). FDA also states that a decimal fraction shall not be carried out to more than two places (21 CFR 101.105(d)).
  - b. The FDA states that the statement of Net Quantity of Contents statement appear on the Principal Display Panel within the bottom 30 percent of the panel (21 CFR 101.105(a), 21 CFR 101.105(f)).

#### **The Information Panel**

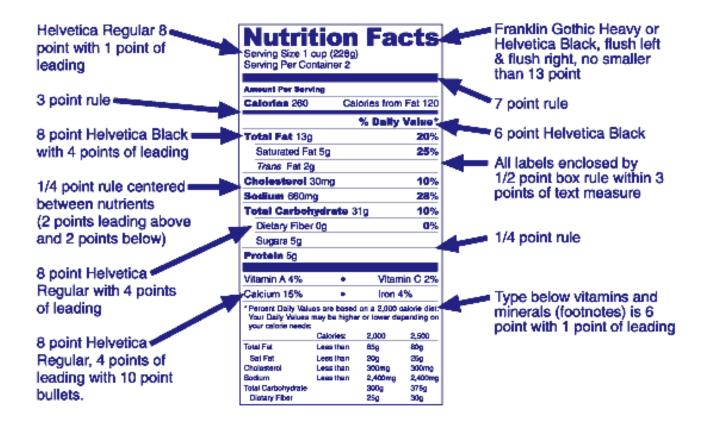
The Information Panel is the part of the label immediately contiguous and to the right of the PDP. If that area is too small to accommodate the necessary information or is otherwise unusable label space, (i.e., folded flaps or can ends), the panel immediately contiguous and to the right of this part of the label may be used. The FDA requires that the following information be placed on the Information Panel if not otherwise stated on the PDP in type no less than 1/16th inch unless otherwise allowed (21 CFR 101.2(b), (21 CFR 101.2(c)):



#### 1. Nutrition Facts Chart

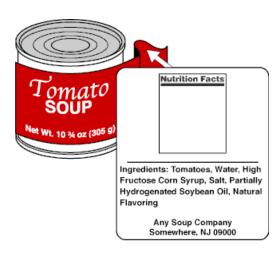
a. Large food manufacturers are required by federal regulations to display nutritional information on the label. However, small businesses with fewer than 100 full-time equivalent employees and that produce fewer than 100,000 units of product per recipe per year are exempt from nutrition labeling, unless a health or nutrient claim is made. (Exempt

- companies may still be required by retailers to include nutritional information on the label.)
- b. Nutrient information must be presented on a per-serving basis (the typical weight or number of pieces eaten) and must include calories, total fat, cholesterol, sodium, carbohydrates, protein, vitamins A and C, calcium, and iron. To determine the amount of nutrients in your product, have your product tested in a commercial laboratory, purchase nutrition-labeling software to calculate nutrient values based on <u>USDA reference values</u>, or hire a consultant to do the whole job. (See section on Calculating Nutritional Information in this chapter.)
- c. This label must be displayed in a box format, even if your label is round, and located near the ingredient list and the name and address of the producer/packer/distributor. It must be presented together on the label. It is also mandatory that this information be found to the right of the Principal Display Panel. Check the products in your pantry and you'll find that every single nutritional fact labels is to the right.
- d. The FDA provides specific rules regarding the layout of a Nutrition Facts chart (21 CFR 101.9(d)). Chapter 7 of the FDA Food Labeling Guide also provides the below illustration of what it considers a compliant Nutrition Facts chart and recommends (but does not require) that you use Helvetica font in the label, 13 point text for the Nutrition Facts heading and specific thickness for the three main bars within the label. The following is an example of a properly formatted Standard Nutrition Facts chart.



#### 2. Ingredients List

a. Packaged foods that consist of two or more ingredients must list the product's ingredients directly after the Nutrition Facts chart. <u>Chapter 6 of the FDA Food Labeling Guide</u> provides a general graphic regarding how to set forth your ingredients:



b. The FDA requires that you list all ingredients in your product by common or usual name in descending order of predominance by weight (21 CFR 101.4(a)(1)). When there is less than 2 percent (2%) of an ingredient by weight, that ingredient is placed at the end of the list followed by a quantifying statement such as "Contains \_ percent or less of \_\_\_\_" or "Less than \_ percent of \_\_\_\_" (21 CFR 101.4(a)(2)).

#### 3. Allergy Warning

- a. The <u>Food Allergen Labeling and Consumer Protection Act of 2004</u>
  (<u>FALCPA</u>) requires manufacturers to declare all the major food allergens that are present in a packaged food product or are processed in the same plant as a packaged food product and can result in in severe or life-threatening allergic reactions. This includes allergens present in any of the ingredients (or processing aids) used in the food as well as allergens present in the processing environment where crosscontamination between the allergen and the food could occur. Under FALCPA, the major allergens that must be declared include:
  - i. Milk
  - ii. Eggs
  - iii. Fish
  - iv. Crustacean shellfish
  - v. Tree nuts
  - vi. Peanuts
  - vii. Wheat
  - viii. Soybeans
  - ix. Any ingredient that contains a protein derived from milk, eggs, fish, crustacean shellfish, tree nuts, peanuts, wheat or soybeans x. If you work in a facility that may contain allergens, you should list potential allergens. You can write:
    - "Processed in a facility that may contain..."
    - "Processed in a facility that contains..."
    - "Manufactured on equipment that is also used to manufacture products containing..."

#### 4. Food Safety Label

a. Another required safety label is the expiration date and the product's storage needs, such as: "Keep Refrigerated," "Refrigerate after opening," or "Keep Frozen."

#### 5. Manufacturer, Distributor or Packer Identity statement

a. The FDA requires the name, address, city, state, and zip code of the business appear so that consumers are able to contact the manufacturer for any reason. If you make your product in your home kitchen, this is your address. If you make your product in a shared incubator kitchen, that is your address. If the business is not the actual manufacturer, a qualifying phrase must be present that states the firm's relation to the product, such as "manufactured for" or "distributed by." If you use a co-packer, then it should read: "Manufactured at" and the name and address of your packer. If it is produced in another country, it should say: "Distributed by" and the name of the distributor. A street address is not required if it is in a current city or telephone directory.

#### 6. Country of Origin statement

a. The Country of Origin statement is required by the United States Customs and Border Patrol pursuant to the United States Tariff Act of 1930 (19 CFR 134.11). This statement must be in English and must set forth in a conspicuous location the actual name of the Country of Origin or a recognized abbreviation (19 CFR 134.45).

#### 7. Nutrient and Health Claims

a. Federal regulations limit the kind of claims you can make about the nutritional content of your product or any health benefits for consumers. If you make a nutrient claim, such as "high in vitamin C" or "low-fat," you must declare the actual amount of that nutrient on the Nutrition Facts panel and your product must meet minimum and/or maximum nutrient content levels in order to qualify for the claims. Claims that your product may have a beneficial effect on a disease or health-related condition are limited to those approved by government scientific experts. For

example, you may claim that because your product is low fat, high fiber, or high in fruit and vegetable content, it can reduce risks from cancer or heart disease. You should weigh the benefits of making a health or nutrient claim against the cost of creating a Nutrient Facts panel before you proceed with this option.

#### 8. Product Dates

a. Many packaged foods are labeled to indicate the last date that the food should be sold for optimum quality or safety. "Sell by" or "best before" dating is not required by regulations for most packaged foods. In Pennsylvania, only fluid dairy products, raw eggs, infant formula, and reduced-oxygen packaged meats require dating. However, wholesale distributors and grocery stores will require you to date your product so they can better manage their inventory. Check with your potential customers to determine if they require product dating.

#### 9. UPC Bar Coding (UPC)

a. Although not a regulatory requirement, most large grocery store chains require UPC labels. If you plan to sell your product at these outlets, you must purchase your codes and arrange to have UPC labels made. if your sales will be strictly limited to small specialty food stores, farmers' markets, your own retail store, or over the Internet, the extra expense may not be worth the cost. If you add a barcode to your label, you must ensure that it does not interfere or intermingle with any of the FDA mandatory requirements as you construct your label. See the previous section on UPC barcodes.

Except for the Country of Origin statement, the nutrient and health claims, and product claims, the above information must appear together in one place and without material intervening between statements (21 CFR 101.2(e)).

# **USDA Requirements**

If your product is made with more than 3% meat you must follow the US Department of Agriculture's <u>Labeling and Program Delivery Division (LPDD) Procedures</u>, which outlines the regulations to ensure the labels are truthful and not misleading. The USDA's regulations for meat products, found in <u>9 CFR Part 381.400</u>, are available in an easier-to-read format on the <u>USDA's Nutritional Labeling Information</u> webpage. You can also review the USDA's <u>Food Standards and Labeling Policy Book</u>.

# **Small Business Exemption**

Cottage food operations and small businesses are not required to have a nutritional panel unless they are making nutrient content or health claims or if they fail to meet certain FDA <u>exemption</u> <u>requirements</u>. These exemptions are only for nutrition labeling information and have no effect on all other mandatory information, including statement of identity, net quantity of contents, ingredient statements, allergen listings, name and address of manufacturers and the packer/distributors.

The FDA has a <u>web-based submission</u> process for small businesses to file an <u>annual notice of exemption from the nutrition labeling requirements</u>. The federal Food, Drug, and Cosmetic Act requires packaged foods and dietary supplements to have nutrition labeling unless they qualify for an exemption. One exemption, for low-volume products, applies if the person claiming the exemption employs fewer than an average of 100 full-time-equivalent employees, and if fewer than 100,000 units of that product are sold in the United States during a 12-month period. To qualify for this exemption, the person must file a notice annually with FDA. (Note: Low-volume products that bear nutrition claims do not qualify for an exemption of this type.)

Another type of exemption applies to retailers with annual gross sales of \$500,000 or less, or with annual gross sales of foods or dietary supplements to consumers of \$50,000 or less. For those exemptions, a notice does not need to be filed with the FDA.

If you believe you qualify for an exemption, it is best to contact your local FDA office and <u>PA</u> <u>Department of Agriculture Food Sanitarian</u> to verify your exemption with both agencies. If you plan to sell your product wholesale, or in a grocery store, while you may meet regulatory exemptions, the vendor may still require you to meet all labeling standards.

#### **Food and Drug Administration**

7 Parkway Center, Space #250 Pittsburgh, PA 15220 (412) 644-3394

# **Labeling Claims**

Food producers and manufacturers use their product labels to explain to the customer the superior nutritional benefits of their product versus that of their competitors. More than ever, there is growing interest in updating processed food recipes to remove artificial ingredients, such as synthetic colors, flavors and preservatives and other food substances that some consumers want to avoid, such as gluten and GMO (genetically modified organism) ingredients. Claims such as "gluten-free," "preservative-free," "low glycemic index," "high fiber," "low fat," and "all-natural" help to promote the advantages of the product and persuade the customer to choose one brand over the other. The FDA closely regulates these claims and holds food producers responsible for ensuring that the claims are accurate, truthful and not misleading. Prior to printing your labels, you should carefully review the <u>labeling regulations</u> for any voluntary claims you strategically place on your labels. Always be careful how you word your marketing materials on your product packaging and your website. Lawsuits in which consumers or groups of consumers sue a food company or a restaurant chain for "misleading statements" have become more common.

The FDA has three categories for food labeling claims:

1. Health Claims (21 CFR 101.14): A health claim is any claim made on the label or in the labeling of a food that characterizes the relationship of any substance to a disease or health-related condition. Implied health claims include those statements that suggest that a relationship exists between the presence or level of a substance in the food and a disease or health-related condition. Examples include "healthy," "nutritious," and "low glycemic index." Before you make any health claim about your product, check the FDA standards.

You may use the term "healthy" or related terms (e.g., "health," "healthful," "healthfully," "healthfulness," "healthier," "healthiest," "healthily," and "healthiness") as an implied nutrient content claim on the label or in labeling of a food that is useful in creating a diet that is consistent with dietary recommendations if:

If the food is	The fat level must be	The saturated fat level must be	The cholesterol level must be	The food must contain
A food not specifically listed in this table	3 g or less of fat per reference amount customarily consumed (21 CFR 101.62(b)(2))	1 g or less of saturated fatty acids per reference amount customarily consumed and not more than 15 percent of calories from saturated fatty acids (21 CFR 101. 62(c)(2))	If a food contains more than 60 milligrams (mg) of cholesterol, per reference amount customarily consumed, then that food must bear a statement disclosing that the nutrient exceeding the specified level is present in the food as follows: "See nutrition information for content" with the blank filled in with the identity of the nutrient exceeding the specified level, e.g., "See nutrition information for fat content." (21 CFR 101.13(h))	At least 10 percent of the RDI or the DRV per RA of one or more of vitamin A, vitamin C, calcium, iron, protein or fiber

Unless you have laboratory and nutritional analysis testing that substantiates the FDA's "healthy foods" criteria listed above, you should think twice before you proceed with a healthy food claim. Nutella maker, Ferrero, is a recent example of a food company succumbing to the regulatory pitfall of using the health claim, "healthy" on its labeling and advertising campaigns. A couple of years back, Nutella settled a

multi-million dollar class-action suit filed by a California mom over misleading advertising that made the chocolate-hazelnut spread seem healthy. The mom says she fed her 4-year old daughter Nutella each morning after she was taken in by ads and product labels that claimed Nutella was "healthy" and "part of a balanced breakfast." When friends eventually pointed out Nutella's high sugar and fat content, she sued Ferrero for deceptive advertising and health claims. The company was forced to change its nutrition labels and its advertising, in addition to a \$3 million payout.

We ran into a similar regulatory issue when creating La Dorita dulce de leche's first labels. Because we source our milk from creameries that only sell "hormone-free milk", we chose to advertise this on our label. After asking the PA Department of Agriculture to perform a pre-printing label review, we were informed that the term "hormone-free milk," is misleading and false because naturally occurring hormones are present in all milk and milk products. Due to the presence of naturally occurring hormones, milk cannot be produced in a way that renders it free of hormones. We were strongly advised to omit this claim before printing our labels.

2. **Nutrient Content Claims (NCC) (21 CFR 101.13):** These are claims on a food product that, directly or by implication, characterize the level of a nutrient in the food (e.g., "low fat," "high in oat bran," "contains 100 calories").

"Trans Fat free" is a common nutrient claim found on food labels. The FDA states the term "Fat free" may be used on the label or in labeling of foods, provided that:

- The food contains less than 0.5 gram (g) of fat per reference amount customarily consumed and per labeled serving or, in the case of a meal product or main dish product, less than 0.5 g of fat per labeled serving; and
- The food contains no added ingredient that is a fat or is generally understood by consumers to contain fat (21 CFR 101.62(b)).

If the food meets these conditions without the benefit of special processing, alteration, formulation, or reformulation to lower fat content, it is labeled to disclose

that fat is not usually present in the food (i.e., "broccoli, a fat free food"). If you do make a "Fat Free," claim then you must make sure to list the "Trans Fat" nutrient in the Nutrition Facts chart (21 CFR 101.9(c)(2)(ii)).

3. Claims That Are Neither Nutrient- nor Health-Related (21 CFR 101.95 (f)): The term "fresh," when used on the label or in labeling of a food in a manner that suggests or implies that the food is unprocessed, means that the food is in its raw state and has not been frozen or subjected to any thermal processing or other form of preservation. The terms "fresh frozen" and "frozen fresh" mean that the food was quickly frozen while still fresh (i.e., the food had been recently harvested when frozen). "Quickly frozen" means frozen by a blast freezer or at a subzero Fahrenheit temperature.

# "Natural" Product Labeling

While the FDA considers the term "Natural" as a claim, it has not developed a precise definition for the term "natural" or its derivatives. However, the agency does not object use of the term if the food contains no added color, artificial flavors or synthetic substances.

The USDA, on the other hand says that a "Natural" product is one that contains no artificial ingredients or added color and is only "minimally processed." The USDA's Food Safety and Inspection Service (FSIS) clarifies that foods labeled with "Natural" claims must meet the following requirements:



- a. The product does not contain any artificial flavor or flavoring, coloring ingredient, or chemical preservative, or any other artificial or synthetic ingredient; and
- b. The product and its ingredients are not more than minimally processed, including:

- Those traditional processes used to make food edible or to preserve it or to make it safe for human consumption, e.g., smoking, roasting, freezing, drying, and fermenting, or
- Those physical processes which do not fundamentally alter the raw product and/or which only separate a whole, intact food into component parts, i.e., grinding meat, separating eggs into albumen and yolk, and pressing fruits to produce juices.
- Relatively severe processes, i.e., solvent extraction, acid hydrolysis, and chemical bleaching would clearly be considered more than minimal processing. Accordingly, the use of a natural flavor or flavoring that has undergone more than minimal processing would place a product in which it is used outside the scope of these guidelines.

The USDA requires all products claiming to be natural or a natural food be accompanied by a brief statement, which explains what is meant by the term natural, i.e., that the product is a natural food because it contains no artificial ingredients and is only minimally processed. This statement should appear directly beneath or beside all natural claims or, if elsewhere on the principal display panel; an asterisk should be used to tie the explanation to the claim (FSIS Labeling Policy Book). As the regulations behind the terms "natural" and "all natural" are a bit vague, you should err on the side of caution before making a claim on your label. If you are making a product that is being regulated by both FDA and USDA (for example, a certified organic vegetarian energy bar) and wish to call the bar "all natural," you must comply with both agencies' regulations. If you are unsure—as many people are—confirm with a food scientist or regulatory expert.

#### Is Your Product Truly "Natural"? Ask yourself the following questions:

- What is the nature of your claim? Is the product really all natural or just made with natural ingredients?
- Were any synthetic processing aids used, even at insignificant levels, in the finished product?
- Were any colors added, even natural derived colors like beet juice or purple carrot concentrate? If you add a color to a product—even if the color itself is natural—the product cannot be called "all natural." Descriptions like "made with all natural ingredients" and other similar alternatives may be used.
- Were any vitamins or minerals added? The way in which a vitamin is prepared for production does not always meet FDA definitions of "natural."

If your product meets all of the "natural" claims listed above, make sure your ingredient supplier provides complete documentation on every ingredient it sells to you. Most ingredient companies will not offer any regulatory advice, but you can request information on how the ingredient should be labeled.

# **USDA Certified Organic Product Labeling**



The FDA does not regulate organic claims or labels. Rather, the jurisdiction falls under the USDA's National Organic Program (NOP). NOP develops national standards that assure consumers that products with the USDA organic seal meet consistent, uniform rules. The USDA organic regulations describe organic agriculture as the application of a set of cultural, biological, and mechanical practices that support the cycling of on-farm

resources, promote ecological balance, and conserve biodiversity. These include maintaining or enhancing soil and water quality; conserving wetlands, woodlands, and wildlife; and avoiding use of synthetic fertilizers, sewage sludge, irradiation, and genetic engineering. Organic producers use natural processes and materials when developing farming systems—these contribute to soil, crop and livestock nutrition, pest and weed management, attainment of production goals, and conservation of biological diversity. The NOP's <a href="Introduction to Organic Practices">Introduction to Organic Practices</a> provides an overview of some common practices that organic producers and handlers use to ensure organic integrity and operation sustainability.

The NOP publishes a <u>National List of Allowed and Prohibited Substances</u> that identifies substances that may—and may not—be used in organic crop and livestock production. It also lists substances that may be used in or on processed organic products. In general, synthetic substances are prohibited unless specifically allowed, and non-synthetic substances are allowed unless specifically prohibited. Products that are USDA-certified organic do not contain GMOs because that is one of the excluded methods not allowed in organic production. All USDA-

certified organic ingredients are considered to be GMO-free. Products that are not USDA-certified organic are not required to be GMO-free, but they may be. Regularly check the NOP's website or the CFR 205.605 and 205.606 for updates and changes to this list.

If you wish to develop a product that can be labeled Certified Organic for sale in the U.S., you must follow USDA regulations, found in <u>21 CFR 205.301</u>, for your product formulations, manufacturing and documentation control. <u>CFR 205.302</u> explains how to mathematically calculate the percent of organic ingredients in your formula. Some certifying agents will provide you with easy-to-use spreadsheet templates to ensure you calculate properly.

**Organic Product Labeling** 

Organic Product Labeling					
Certified 100% Organic (100% organic)	Certified Organic (95% organic)	Certified "Made with Organic" (70% organic)	Specific Organic Ingredients (less than 70% organic)		
Products must contain 100% certified organic ingredients and state the name of the certifying agent on the label.	Products must contain at least 95% certified organic ingredients (excluding salt and water). The last 5% can only be non-organic if it's a non-agricultural ingredient, there is no organic equivalent on the market and it's in the "allowed" section of the National List of Allowed and Prohibited Substances.  Products must list the name of the certifying agent on the label.	Products must contain at least 70% certified organic ingredients (excluding salt and water). The remaining 30% do not have to be produced organically, but they must not be produced using certain excluded methods (genetic engineering, ionizing radiation, or sewage sludge). The product must list the name of the certifying agent on the label.	Products cannot be USDA Organic Certified and cannot carry the USDA Organic Certified seal or a certifying agent on the label. They are permitted only to list certified organic ingredients as organic in the ingredient list and the percentage of organic ingredients. Remaining ingredients are not required to follow the USDA organic regulations.		

# Gluten Free Product Labeling

In 2013 the FDA issued a <u>final rule defining "gluten-free"</u> for food labeling meant to help consumers, especially those living with celiac disease, be confident that items labeled "gluten-free" meet a defined standard for gluten content. It requires requirements of the definition, including that the food must contain less than 20 parts per million of gluten. The rule also requires foods with the claims "no gluten," "free of gluten," and "without gluten" to meet the definition for "gluten-free."

Whether a food is *manufactured* to be free of gluten or *by nature* is free of gluten, it may bear a "gluten-free" labeling claim if it meets all FDA requirements for a gluten-free food. Some foods and beverages, such as bottled spring water, fruits, vegetables, and eggs, are naturally gluten-free. However, because a "gluten-free" claim isn't required to be on a food package, it may not appear even if the food is, in fact, gluten-free.

Currently, no federal laws govern the production and labeling of gluten-free foods. For this reason, several large-chain grocery stores and wholesale distributors require food producers who claim to have a gluten free product to provide certification substantiating the claim. The QAI (a USDA Organic certifying agency) and the National Foundation of Celiac Awareness (NFCA) have started their own gluten-free certification program. This program, which is not federally funded or regulated, offers the tools that companies need to "prove" they have taken extra steps—including sensitive testing procedures, stringent auditing and an independent application-review process—to make their products gluten-free. Using feedback from consumers, manufacturers and retailers, the program includes product review, on-site inspection, testing to ensure compliance to 10 ppm or less of gluten and ongoing-compliance features such as random product testing.

# **Calculating Nutritional Information**

The Nutrition Facts Chart is a vital part of the Information Panel. If you plan to sell your product in a retail setting, your label will need to include a complete nutrition panel, even if your company meets the small business exception rule. The first step in developing your product's nutritional panel is to determine the FDA suggested Serving Size for your product. 21 CFR 101.12(b), Table 2 lists the single serving reference amounts that the FDA deems are customarily consumed per eating occasion. Once you have determined the FDA-approved single-serving size for your product, you can determine the amount of servings available in your packaging and calculate the nutrition information based on the single serving size.

The nutrition analysis will include the following information per serving size:		
Calories	Total Carbohydrate	
Calories from Fat	Dietary Fiber	
Total Fat	Sugars	
Saturated Fat	Protein	
Trans Fat	Vitamin A & Vitamin C	
Cholesterol	Calcium	
Sodium	Iron	

Now that you know your product's FDA-approved serving size, you can calculate the nutritional analysis in two ways. You may submit food samples to a third-party laboratory that uses chemical



testing methods to identify macro- and micronutrients. A less expensive but equally acceptable approach is to calculate the nutritional information using your product formula and pre-existing database information on the ingredients in your finished product.

## **Chemistry Testing and Nutritional**

Analysis: If you plan to make a product claim or are not quite sure what the nutritional profile will be after thermal processing or shelf life, you should submit your product to a laboratory for chemistry testing. In addition to providing nutritional analysis, these laboratories will often calculate the percentages per serving size to assure your food product receives the

proper nutritional labeling according to the FDA's strict requirements. Below are some labs that provide nutritional analysis and nutritional labeling services:

- Microbac Laboratories (Warrendale, PA)
- Food Fast Works (Bensalem, Pennsylvania)

Penn State Extension also provides a list of <u>food testing laboratories</u> that can perform this testing. The lab will ask you for several samples of product so that it can run enough tests to ensure repeatability of the results. Typical costs range from \$300 to \$600 per product sample, depending on which nutrients you wish to validate.

**Database Nutritional Analysis:** The naturally occurring nutrients in commodity ingredients can vary, but it's still acceptable to, and many food companies still do, conduct their nutritional analyses using estimates of the ingredients' nutritional values found in reliable databases.

<u>Genesis</u> is an industry-standard program that many laboratories use to calculate their products' nutritional content. The program uses information from the <u>USDA database</u> and from ingredient manufacturers. Other programs exist, but many manufacturing companies feel comfortable with Genesis because of its reputation, reliability, and regulation updates.

If you choose to have your product analyzed via a database, expect to pay about \$150 to \$300 per food product. The company doing the analysis will ask that you provide the following information:

- Product formula
- Nutritional information per 100 grams for each ingredient (can be based on <u>USDA</u> <u>Database Values</u>)
- Ingredient statements for each individual ingredient
- Manufacturer allergen statements
- Cooking process (water lost through dehydration can be considered, for example)
- Claims you wish to make (although we do advise having a full nutrition analysis to back any claims you make on your label)

Here are some companies that can perform a database nutritional analysis for you:

- Food Fast Works (Bensalem, Pennsylvania)
- RQA Product Dynamics (Orlando Park, Illinois)

Recipal, a nutrition fact panel website is a less expensive alternative to Genesis. Recipal provides easy nutritional analysis, nutrition fact labels, ingredient lists, recipe costing, and recipe management to up-and-coming food businesses, established food businesses, commercial kitchens, food business consultants, and co-packers. It also offers business one-time label-

making fees and monthly business plans. Recipal is a great resource, but you still need to become familiar with FDA labeling rules in order to create a compliant nutrition facts panel. If you plan to perform your own nutritional analysis online or via a spreadsheet, you must familiarize yourself with 21 CFR 101: FDA Regulations for Food Labeling.

Database nutritional analysis is only as accurate as the information that is plugged into the program. If you do not submit the correct official documentation directly from the manufacturer, you will jeopardize the accuracy of your label.

For more information on nutritional reporting requirements, Penn State Extension publishes the online guide, <u>The Due Diligence Challenge: A Guide to Accurate Database Nutrition Analysis</u>.

## Food Technology and Laboratory Testing

Food testing is integral to the efficient production of safe, quality products—and the secret to protecting your brand's reputation as a successful specialty food producer. Nothing drives people away from a restaurant, food or beverage faster than a barrage of headlines about people being sickened by *E. coli* or *listeria*, or opening a jar of jelly only to find the inside cap laden with mold. For example, Chipotle Mexican Grill is still scrambling to recover from a multistate *E. coli* outbreak that drove the company's stock down more than 40% and has resulted in a class-action lawsuit. Or Blue Bell Creameries, which faced several recalls and factory shutdowns and now faces a Department of Justice investigation in connection with *listeria* contamination of its ice cream. With the food industry increasingly subject to scrutiny, testing to ensure compliance with food safety regulations and to protect public health is a must.

Once your product has been developed in your commercial kitchen or with your <u>co-packer</u>, you should make it a priority to submit it to laboratory testing to confirm that it meets all quality and safety parameters and will remain bacteria-free for the duration of its shelf life. Many startups new to the industry are not familiar with all the tests out there, so they often spend money on testing that is inappropriate for their products.

Prior to subjecting your product to third-party specialized laboratory testing, you can begin to test certain quality attributes of your product in your own facility—during and after the manufacturing process.

## **Shelf Life Testing**

After a product has been developed and manufactured, but before it goes on the market, you should run tests to determine its shelf life and, for quality purposes, and identify its "best by" date. It is the manufacturer's responsibility to assign a shelf life for each product that is produced. The shelf life of a food product begins from the time the food is finished processing and packaged. The time depends on factors like ingredients, manufacturing process, packaging, and storage conditions (temperature, light, etc.).

Aside from infant formula, the <u>FDA does not require expiration dates</u> on food products. It's at your (the food manufacturer's) discretion, but sometimes it won't be entirely up to you because the

stores you'll be selling to will require it as well. Keep in mind that a core principle of U.S. food law is that foods must be fit for consumption. So, just because you're not required to have an expiration date, doesn't mean you can sell food that has gone bad. The FDA's food safety regulations maintain that foods in U.S. commerce must be wholesome and fit for consumption. A "best by", "use by" or expiration date does not relieve a food manufacturer from this obligation. A product that is dangerous to consumers would be subject to potential action by FDA to remove it from commerce regardless of any date printed on a label.

Shelf Life Testing is comprised of three study components:

- **Time:** Shelf life time should reflect how long the product will be on the market. If the shelf life is 6 months, for example, the study should last a minimum of 6 months. Accelerated testing can be done using an incubator, which simulates an expedited timeframe. However, this is just an indicator test (a shortcut), so it is best to use real-time and real-temperature scenarios when possible. To beat the clock, you can begin to informally test this in your own facility. Keep in mind that most wholesale distributors and retailers require that your product have a shelf life of at least 12 months to be considered a part of their product portfolio or secure shelf space in their stores.
- **Temperature:** Shelf life temperature should reflect how the product will be handled from the manufacturing plant to the consumer pantry. Typical temperatures include ambient (72°F), refrigerated (40°F), and incubator (85–90°F).
- Product Attributes: Measure attributes that you think will go downhill in your product over time. For example, if products in the same category are known to go rancid, you may want to perform peroxide testing, which is a chemical marker of rancidity. If your product is known to crystallize after time, you will want to check the texture over time. Alternatively, if you expect your product to become stale, you may want to measure the moisture content, which reflects whether or not it's stale. Quality measurements should be repeated multiple times during shelf life testing to identify precisely when your product crosses the threshold into the unacceptable category.

Before you begin any shelf life study, however informal, you should have a finalized recipe and production process. Changing ingredients, packaging, and processing can alter the shelf life, so

formula and packaging has to be established and be able to be reproduced identically. There is also a difference between when the food starts to spoil and when it starts losing quality. Most customers care more, or just as much, about the quality of the food they are feeding their families, so even if a product hasn't spoiled you might not be happy selling it to customers after a certain point. Lastly, certain products have specific regulations on shelf life regarding "sell-by" dates and "best-by" dates. Do your research and figure out where your product falls before doing any formal testing.

Before you commit to a formal shelf life study with a lab, which can cost from \$100 to \$500 per product, you should first do informal testing in your own facility. This will cost you nothing, and help you to immediately remediate any problems that arise and adjust your product or packaging accordingly.

First things first, check your competitors' labels. Do they all have similar "best-by" or "sell-by" dates? That might be a good starting point. Just be careful when comparing your product, since your competitors may use different ingredients, processing techniques, preservatives and packaging. In fact, you should take note of their <u>packaging</u> choice. Remember, packaging isn't just an aesthetic choice. It is chosen to best maximize the shelf life of each product.

Second, conduct your own (informal) study. Take your product and store it under recommended storage conditions. Does it say to refrigerate on the packaging? Leave it in the fridge. Every few weeks, open a bag and take detailed notes. How does it look, smell, taste, and feel? Is it cloudy? How does the texture feel on your tongue? Is the viscosity the same? How has it changed from a "fresh" bag? Keep checking until you notice changes. You may also want to run basic tests. Does your product require certain pH levels? Test the pH if you have the tools.

Finally, make sure you have enough samples. Decide what shelf life would make you really happy. How many weeks is that? Talk to retailers you plan to sell through and inquire about their shelf life requirements. Then decide how often do you want to check your samples? Divide the total weeks of testing by how frequently you'll be checking it and have at least that many samples. For instance, for a 24 week study with tests every 2 weeks, you'd need at least 12 or 13 samples. For a 40 day study of a refrigerated item with tests every 3 days, you'd need at least 13 or 14 samples.

Once you have conducted your own informal shelf life testing, you will want to seek out a lab that does formal shelf life studies to test for microbial spoilage. It's best to find a reliable third-party laboratory, preferably one near your manufacturing facility so that you can have samples regularly and inexpensively transported for analysis. You should also share your notes and observations from your own informal shelf life tests. This will alert the lab technologies of certain attributes they should keep a special eye on. At La Dorita, we use Microbac Laboratories, a local foodtesting facility in Warrendale, PA. Penn State Extension also publishes an online list of commercial food testing laboratories that can perform the testing you need.

Many startup food companies skip this initial laboratory testing period because they are eager to get their products to market quickly. But that can only land you in deep water later on, as shelf life testing allows the manufacturer to confirm the minimum acceptable quality and what degree of degradation is allowed before the product is no longer sellable—in other words, how long can this product sit on the shelf before it becomes a liability to your reputation? Most quality parameters are quantitative and can be measured analytically, but sometimes a trained sensory panel is useful for assessing more-qualitative, subjective changes such as flavor and mouthfeel.

As shelf life testing is exhaustively time consuming, many food laboratories also offer accelerated shelf life studies. In these studies the food product is conditioned and stored at elevated temperature and/or humidity and the quality changes of the product are evaluated at a specific sampling rate. The accelerated shelf life study could significantly shorten the duration of shelf life study to ½ or ¼ of the standard shelf life study. During these studies, the laboratory will perform sampling, quality analysis, microbial analysis, sensory evaluation, data analysis and study report for each product.

## **Quality and Safety Testing**

Many food companies submit their product(s) to quality testing parameters to ensure that their product(s) meets both company requirements and their consumers' expectations. Texture, color and viscosity are examples of measurable quality attributes that you should monitor during and after production. For instance, you may want to measure the brix, or percentage of soluble solids, of your soup during production, to ensure it was formulated with the right amount of salt, sugar and other solids. Catching an error during production may save the next batch.

Depending on the product, it may need to be tested for <u>water activity</u> (a<sub>w</sub>), microorganisms and <u>pH</u>. The finished-product testing protocol should be discussed with a food microbiologist who is familiar with the potential microbiological hazards. For example, <u>beef jerky</u> should have a water activity level below 0.85 to inhibit growth of *Clostridium botulinum*, and an acidified food's equilibrium pH level must be under 4.6 The reasons and frequency for testing are specific to your product.

#### Food quality analysis and texture testing

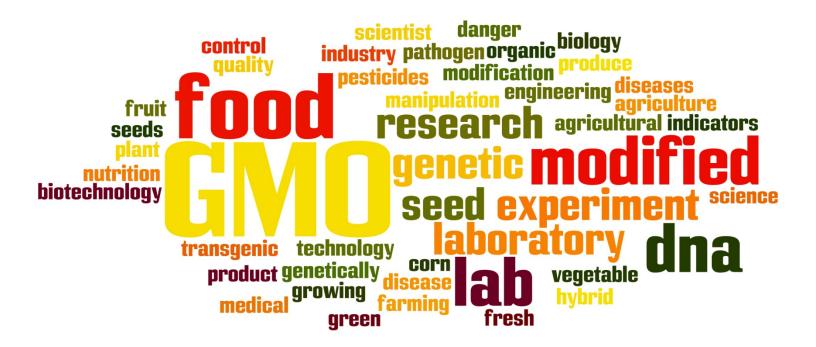
Food Quality analysis	Food Texture Testing
pH (acidity)	Firmness Tenderness
Brix (sugar level)	Shearing strength
Water Activity (a <sub>w</sub> )	Elasticity
Color analysis	Chewiness
Cloudiness	Gumminess
Viscosity	Brittleness
Microbiological	Viscoelasticity & Customized texture testing

The reasons and frequency for food laboratory testing is specific to each product. Some food manufacturers invest in their own testing equipment to ensure that repeated batches are meeting the quality and safety standards for their <u>regulated food category</u>. Below is a list of some of the more common food testing equipment you can use to test your individual batches on-demand.

Test	Equipment
pH	pH Meter
Acidity	Titration
Moisture	Moisture Analyzer
Water Activity (aw)	Hygrometer
Brix (% soluble solids)	Refractometer

## **Nutritional Analysis**

If you intend to wholesale your food product, then you will be required to provide nutritional analysis information on your labels to ensure your product is both safe for consumption, and to inform your customers' details on the ingredients you use. Food chemistry testing provides the levels of additives and contaminants in your product that the customer otherwise would not know about. Many local laboratories such as <a href="Microbac Laboratories">Microbac Laboratories</a> provide a full range of food chemistry testing, from nutrition labeling analysis and calculations, to food safety testing, and food microbiology testing for a variety of applications. More specialized testing includes food allergen detection and GMO analysis.



# Marketing

Specialty foods and beverages exemplify quality, innovation, and style in their category. They are often known for their authenticity, ethnic or cultural origin, commitment to specific processing rules or traditions, clean labels and superior ingredients, limited supply, or extraordinary packaging. Before you can begin making your product you must understand the more than \$120 billion dollar market here in the US.

Below is a snapshot of the top-five largest, fastest-growing, and slowest growing specialty food categories by dollar sales provided by the Specialty Food Association's annual <u>State of the Specialty Food Industry 2016</u>. Unit sales change is also included for a fuller picture of each category's growth.

LARGEST CATEGORIES		
	Dollar Sales %	Unit Sales %
	Change 2013 - 2015	Change 2013 - 2015
Cheese and Cheese Alternatives	14.7	9.7
Frozen and Refrigerated Meat, Poultry, and Seafood	23.1	12.5
Chips, Pretzels, and Snacks	22.3	20.2
Coffee, Coffee Substitutes, and Cocoa	17.3	19.8
Bread and Baked Goods	14.7	9.0
FASTEST-GROWING CATEGORIES		
	Dollar Sales % Change 2013 - 2015	Unit Sales % Change 2013 - 2015
Refrigerated RTD Tea and Coffee	262.2	301.6
Eggs	218.12	162.3
Jerky and Other Meat Snacks	68.4	60.1
Refrigerated Pasta	58.3	49.7
Water	51.4	43.9
SLOWEST-GROWING CATEGORIES		
	Dollar Sales % Change 2013 - 2015	Unit Sales % Change 2013 - 2015
Frozen Juices and Beverages	-45.0	-43.3
Shelf Stable Non-Dairy Beverages	-5.4	-8.2
Cold Cereals	-5.2	-7.3
Shelf Stable Pasta	3.0	1.8
Pickles, Peppers, Olives, Other Vegetables	5.6	3.4

More takeaways from the Specialty Food Association's annual <u>State of the Specialty Food</u> <u>Industry 2016</u> show:

- Fresh, protein, and convenience are three trends holding steady as evidenced in the specialty food categories showing the most sales growth: refrigerated RTD tea and coffee; eggs; jerky and other meat snacks; refrigerated pasta; and water.
- Specialty food sales through foodservice are growing faster than retail sales: 27% versus 19.7%. More U.S. consumers are dining out and seeking high-quality, flavorful foods when doing so.
- The supply chain has embraced the importance of e-commerce as a way to sell directly
  to consumers. Eighty-five% of manufacturers sell via their own website and 49% use a
  third-party platform like Amazon. Importers cite online sales as one of their fastestgrowing channels.
- Manufacturers, importers, and brokers all say non-GMO will be a product claim of growing importance to consumers. Forty-nine percent of manufacturers plan to introduce products that are non-GMO in 2016.
- The top 3 up-and-coming cuisines for 2016 are Mediterranean, Middle Eastern and Thai.
- Specialty grocery accounts for 32% of sales in specialty food stores.

The Specialty Food Association publishes an annual <u>State of the Food Industry Guide</u> which reports on emerging trends and cuisines and can help you begin to properly understand the

Specialty Food Market. The <u>guide</u> is free to members, and \$40 to non-members. It is money well spent and can help you begin to develop a comprehensive SWOT analysis (strengths, weaknesses, opportunities, and threats). Established companies typically perform a SWOT analysis on their company as a whole, their competition, and their product. For the startup entrepreneur with a single product, this can be combined into one analysis.



A proper SWOT analysis will help you answer the following questions: Where will your customers find value? Hopefully they find it in your product, their dealings with your company, in the ease of purchasing the product, all balanced with the price they pay. Where does your company find value? Hopefully in being able to charge a price that will enable you to make a profit, while building a relationship with the customer that will ensure repeat business. The SWOT analysis will help you create a marketing plan that will offer the right product at the right price to the right target market, offering it in a place where the market can access it, and being able to promote it in such a way that the target market can discover it.

Strengths and Weaknesses are those things that are internal to your business, or things over which you have control. Perhaps you have a strong background in sales and customer service. This could be considered a strength for marketing your product. Perhaps you know that you don't have a salesforce to cover several stores in one region at a time. This might be considered a weakness. Make a list of strengths and weaknesses for both yourself and your product.

Opportunities and Threats are those things that impact your business but over which you have no control. To make it easier to identify opportunities and threats, you can focus on several general areas: the economy, technology, socio-cultural trends, laws and regulations, and your competition. Take the economy for example. What effect does a declining economy have on the sale of your product? You may feel that it would adversely affect sales. However, when you take a look at socio-cultural trends you might find that, depending on your product, a declining economy might actually help sales. For example, you want to market party dips to be served with crackers. When people are eating out less, they may be entertaining more at home. Consumers may actually be looking for products they can use in home.

Perhaps the greatest threat to the small entrepreneur in the specialty food market is a larger competitor entering the market with a similar product at a lower cost, utilizing economies of scale. Knowing this can help you focus on what is special about your product and where the consumer truly finds value. Having a list of strengths and weaknesses, coupled with a list of opportunities and threats updated on a regular basis, will help provide direction to you now and in the future.

## **Your Competitive Advantage**

One of the threats just mentioned above is a larger competitor offering a lower priced item that is comparable to yours. In today's food markets there are many similar products. What is important

is whether the consumer feels they are similar or sees a distinct difference between "like" products. If they see a difference, will they pay extra for that difference? Why would a consumer want to purchase your product rather than the less expensive, brand-name one? It is essential to



in your product. If you don't understand why consumers want to purchase your product, it is doubtful that consumers will understand this either. What comprises a competitive advantage? It might be particular attributes of your product, for example, the ingredients or where the ingredients come from. It might be the story behind how your product was conceived or the history of the recipe (see previous chapter on

#### Branding).

In order to be successful, it is essential that you communicate the advantages to the consumer. Attributes you can differentiate on may include:

- Higher product quality
- Cleaner ingredients panel
- Locally sourced ingredients
- Sustainable packaging that reduces the product's environmental impact and ecological footprint.
- Higher level of service
- Market innovation
- Non-GMO
- Gluten-free
- Kosher-certified
- Halal-certified
- All Natural
- Organic
- Fair Trade

#### Your Target Market

Before launching your product, you must first understand who you are making it for. A market can be defined as a group of consumers with similar characteristics that have the desire and the ability to purchase your product. What comes first, the product or the market? That is, do you find a market you are interested in and then think of a product that would interest them, or do you conceive of a product and then think about who you will market it to? The truth is that it happens both ways.

According to Specialty Food Association, consumers most likely to purchase specialty food products are those with the following characteristics:

- Income of \$65,000 or higher
- Two people living together
- Ages 35-44
- No children in the household
- Homeowners
- College graduates

These are the most basic shared characteristics of a specialty food market. Depending on where you are located, this may or may not be representative of your local demographic. It challenges you to think beyond your local community. With the advent of Internet sales and proper promotion you may be able to reach larger target markets.

Can you put your target market into words? Can you associate adjectives with this market? It is essential to do this as it will help you as you think about the "<u>5 Ps</u>" of marketing your product. As discussed in the chapter on branding, to properly brand and position your product, marketers often refer to the *Five Ps* of success:

• The right *Product*, in the right *Packaging*In an elevator pitch you have about 30 seconds to communicate your message with words and non-verbal communication. You won't have thirty seconds once your product is sitting on a store shelf; It will have to speak for itself. *Where do you begin?* Start with the name of the product. *What does it say about the product?* Tell your back story as you develop the

rest of the label. Ask yourself whether the design of the label captures the essence and feeling of your product? When you think of a few adjectives to describe your company, your product, and your target market, are they the same, or comparable, adjectives someone might use to describe the label?

Your name, your logo, and any symbols you use in packaging become a part of your brand. Your brand helps the consumer identify you and differentiates you from your competitors. Your choice of name, logo, and packaging communicate a message about your product. Make sure that you are consistent with that message by using the same styles in your flyers, business cards, signage, clothing, website, social media, and any other supplementary item you use to help market your product.

#### At the right *Place*

How will you get the product to the marketplace? This is also referred to as the distribution network or channel. Chances are you don't have access to a fleet of trucks and can't afford to secure end-cap shelf displays with a major retailer. Where will you place your product so that the target market can see it and purchase it?

Many new entrepreneurs begin by selling products at events, like farmers markets or merchant fairs. Consumers attend events because of the number and variety of vendors participating. It gives you a chance to do some personal selling. You can tell the consumer more about the product and explain its features, advantages, and benefits. You can offer samples and gauge the market's response.

The advantages to selling at events include low costs for table or booth space and promotion by the event planners. The larger and more popular events expose you to larger audiences but usually have higher entry fees and may include products that compete with yours. You have to find the right events for your product. Booth accessories such as signage, props, and company clothing make you look established and convey a brand image. Invest in a vendor tent if you plan to do a number of outdoor events. Consider selling beyond your local community.

Internet sales through established online "Stores", on your own website, or as a part of a group can give you much greater exposure. Just be prepared to service these new

customers in a timely manner and with a level of service that enables you to develop strong customer relationships. Many new food product entrepreneurs have been overwhelmed by the high volume of internet requests for their product.

#### Maximizing *Promotional* opportunities

Advertising is just one component of promotional marketing. It is important to understand the many segments involved with promotion because advertising alone can be expensive and sometimes ineffective.

As with marketing, promotion encompasses a number of different components. These components are referred to as the promotion mix. The promotion mix includes public relations, advertising, sales promotion, and personal selling. Public relations is usually considered a free form of advertising. It is communication about your business or product that you do not purchase. Will the local newspaper run a story about your product? Are there local newsletters, both in print and online, in your community that might run a story about you? Are you donating some of your product to a charitable event to gain positive exposure in your community?

Advertising, on the other hand, can quickly consume your budget, and there are no guarantees that you will get a profitable return on your investment (ROI). Advertising is paid communication and it can come in many different forms. There are newsletters, newspapers, television and radio ads, mailers, Internet ads, etc. Before you pay for advertising carefully compare the rates and think about where your target market looks for information or entertainment and what you want to communicate about your product.

One of the least expensive and trendiest ways to advertise and communicate with your target market is through social networks like Facebook, Twitter and Instagram. Social networks allow you to combine your "address book" with the "address books" of everyone you know for a multiplier effect. This concept is very appealing when you think about the number of people you can reach. You can also choose to sponsor your postings for a price to gain even more exposure. But, just as you throw out junk mail and delete e-mails, others may ignore your message. If your audience isn't entertained and informed by your communication, you'll soon find yourself without an audience.

Social networks also enable you to take advantage of a phenomenon known as viral marketing. Viral marketing describes any strategy that encourages individuals to pass on a marketing message to others, creating the potential for exponential growth in the message's exposure and influence. Like viruses, such strategies take advantage of rapid multiplication to explode the message to thousands, to millions.

Personal, in-store demos will probably be a large component of your activities, especially in the beginning. This is when you can answer the "What's in it for me?" question. Customers are always looking for the benefit and value of a product. This is your opportunity to help them understand your product's benefit by explaining its features and advantages in a clear and knowing voice. Sincerity and passion for your product sells itself.

The very best form of advertising is good word of mouth. People trust the good reviews of other consumers that have used your product. Keep in mind that negative word of mouth can be destructive to all of your efforts. Treat each transaction with the level of service that you would expect if you were the consumer. Referrals and momentum will slowly build.

Sales promotion is a catch-all category for anything that isn't advertising or public relations. It includes coupons, "buy one, get one free" ("BOGO") offers, bundle or case pricing, and loyalty cards. These additional efforts may help capture a new customer and build product loyalty. One aspect to be considered in all promotional efforts is building in the ability to capture information about your customers.

One of the core components of marketing is building relationships with customers. In your promotion efforts, you should capture information from your customers such as: customer name, e-mail address, first time buyer or repeat, and any suggestions or comments they may have about your product.

## • **Priced** right

What does the price convey about the product? Consumers expect to pay more for a specialty food item, but how much more are they willing to pay? Is your price what the target market expects? What are your closest competitors charging for their product? All of these are questions you need to ask as you begin to think about pricing your product. The most basic question however is: Can you make a profit over time?

#### The marketing equation to gage future success is: "Cost versus Benefit = Value"

If the consumer feels the benefits of a product outweigh the cost, he or she finds value in the product. If the opposite is true, if the consumer can't find the benefit to justify the cost, he or she won't find value in the product. Typically if the consumer doesn't find value, the product won't be purchased again.

Many specialty foods are of a superior quality and worth the extra expense to the consumer. Keep in mind the price bracket your product fits into when determining your own price. Price will often convey a perceived value to the consumer that may have little to do with fact. Pricing is discussed in detail in the following section.

To briefly summarize, you must know your target market. You must know your own product. You must know your competitors. When you understand your market, your product, and its competitors, you begin to understand where the consumer will find the value in your product and the reasons he or she will purchase it.

## Pricing

Now that you have created a quality product, decided where to make it, gotten licensed, and packaged it with a catchy, professional label that includes its ingredients and a nutritional panel analysis, there is one last strategic decision you must make before making a sell: its price. For most stores and consumers, the only thing that matters is the price. If you plan to turn a profit, you need to price your product appropriately. This is easier said than done; by the time the consumer is finally provided the opportunity to buy your product, many parties—distributors, brokers, and retailers—will have significantly increased its price. In fact, some products are sold to your customer for more than 100% of what you originally charged.

Keep your long-term pricing strategy in mind while determining your branding and packaging decisions. Distributors must mark-up for their service; retailers, too. The freight carriers and distribution centers have to charge. Sales, marketing, and promotions contribute to the price. Then there may be other "hidden charges" that consumers pay for when they buy your product. Brokers, merchandisers, additional sales costs, shrinkage, advertising, various retail fees, taxes, and more must be taken into account when determining your price. If you are planning to sell your

product in other countries, don't forget costs associated with special packaging, customs and duties, and currency fluctuations outside the US. There are as many levels of margin, mark-up, fees, and commissions, as there are entities associated with bringing your product to the consumer. Study the market to determine the ins and outs, what works and what doesn't, and how to price your product for profits while giving your consumers a good value, without losing it all in the process.

You should plan to set a price that you can live with for an extended period of time. The price of competitive products is the major variable that consumers will consider when contemplating your product. If your competitors are pricing in the \$2.00 range, your product priced at \$1.53 would probably be very well received. You may rationalize that your product is superior due to quality and taste, but to most consumers, the price is the factor that makes the initial sale.

A common mistake is setting a short-term price that only reflects the current cost of production, without taking into consideration the increased costs as the business grows. Many people begin selling to individual grocery stores as a direct vendor. They set a "direct vendor" price without taking into account the wholesale distribution costs that they will incur as their product grows and they are forced to sign with a distributor—which always results in drastically lower profit margins. Other food startups begin by making their product in their home. As they grow and move to a copacking facility or set up a permanent production site and hire employees, their costs increase. To stay profitable, they have to reflect these costs in their pricing strategy. Cost increases can alienate retailers and consumers that started buying a product while it was new.

Another common mistake is setting the price unsustainably low in order to seem more attractive when entering the market. This strategy leads to the same scenario of cost increases down the road that could have been avoided. Undercutting the competition may seem like a smart way to grow your business, but your early gains will be washed away if your product suddenly jumps in price. The retail partners who took a chance on you may feel that you don't know what you're doing or, even worse, they may feel that you're taking advantage of their initial loyalty to your product.

When it comes to pricing, short term thinking is fatal. You should set your price where you think it will need to be in future years, right from day one. This will allow you some flexibility to offer introductory pricing and periodic "sales". This strategy also provides a little more income as you launch your product, enabling you to invest in your company's growth, and it sets the fair value for your product.

#### **Understanding Your Food Costs**

You can't know how much to charge for your products until you know how much it costs you to make them—otherwise known as your "cost of goods sold." Once you know your cost per unit you can determine your profit margin.

#### DETERMINING YOUR PROFIT MARGIN

STEP 1. CALCULATE YOUR TOTAL COST PER UNIT

=TOTAL COST FOR EACH INGREDIENT (INCLUDING SALES TAX IF APPLICABLE)) + (CONTAINER & PACKAGING) + (LIDS OR CLOSURE) + (LABOR) + (INSURANCE) + (FREIGHT IF USING A DISTRIBUTOR)

STEP 2. SET YOUR WHOLESALE PRICE PER UNIT (TYPICALLY ABOUT TWICE THE TOTAL COST PER UNIT)

STEP 3. CALCULATE YOUR PROFIT MARGIN:

= 100 x (WHOLESALE PRICE – TOTAL COST PER UNIT) (WHOLESALE)

So, if your Total Cost per Unit is \$1.79 and your Wholesale Price is \$4.00, then your Profit Margin is 55.25%. If your Wholesale Price is \$3.58, then your Profit Margin is 50.00%.

Now that you have determined your profit margin, there are three prices you should set for your product: the wholesale price, the manufacturer's suggested retail price (MSRP), and the distributor's price.

## Manufacturer's Suggested Retail Price vs. Wholesale Price

The wholesale price is a good starting point as it often helps determine the other two prices. As mentioned above, the wholesale price is typically about twice what it costs you to make your product. If it costs \$1.79 per piece to produce, many businesses will wholesale that product between \$3.50 and \$4.00. There are no set rules here. Ultimately you need to set an amount that is sustainable for your business and will leave enough gross profit to cover your fixed costs. You

can have a strategy in which the price increases or decreases from there, but you need to be competitive. If you are making three pallets of your product at a time, it's hard to envision a way to undercut the huge corporate food producers and it is best not to try. You don't need to have the cheapest product in your category, but you don't want to have the most expensive one either.

#### VALUE = COST VERSUS BENEFIT

Generally, you should aim to set a price that is within a dollar of the price set by the rest of the competition—especially if you are selling a product that retails for \$10 or less. You should also make sure that you're comparing apples to apples. For instance, if your competitor sells a 16 oz. jar for \$7.99 and you sell your product in a 14 oz. jar, you should attempt to adjust your price accordingly and sell at a more competitive price. From there, you can calculate a suggested retail price by knowing that a retailer is generally going to apply a 35-50% margin, depending on the product and the store's pricing strategy. The margin is the difference between the sales price of the product and its cost.

## **DETERMING YOUR MSRP AS A DIRECT SALE VENDOR**

## MSRP = WHOLESALE PRICE (1 - STORE'S MARGIN)

To apply a grocery store's margin of 40% to your wholesale price of \$4.00 would look like this: \$4.00 / (1-.40) = \$6.67 as a suggested retail price. If the store uses a 35% margin, your item will cost \$6.15. If the store uses a 50% margin, your item will cost \$8.00. That means stores will sell your \$4.00 product for anywhere between \$6.15 and \$8.00.

Do the math and determine your suggested retail price. This is the price you should use when selling your product as a direct vendor—directly to consumers at farmers markets, online, or in your own retail space. You should use this number as your suggested retail price. This is the price you give to retailers if they ask for it. Keep in mind that a manufacturer's suggested retail price is just that, a suggestion. Retailers choose their retail price based on their own costs for owning and maintaining a store, as well as their particular pricing strategy. Some producers want to control the price that consumers pay in retail stores, but it's not up to you to determine price at

the store level. If you want your product to be sold at a lower price, then you need to charge less for it.

#### **Distribution Price**

Prior to committing to a MSRP as a direct vendor, you should plan ahead and take into consideration the distribution price. As you grow, the time will come when you have to use third party distribution. Many startups are blindsided by the reality that they will likely have to lower their wholesale price in order to keep it low enough for retailers. Distributors that buy your product wholesale and sell it to the retailers have their own set of costs and in turn will need to mark the price up. They typically apply a margin of 35-50%.

#### DETERMING YOUR DISTRIBUTION SALES PRICE

# DISTRIBUTOR SALES PRICE = WHOLESALE PRICE (1 – DISTRIBUTOR'S MARGIN)

Applying a distributor's margin is the exact same formula a determining a store's margin as a direct vendor. So, if the distributor uses a 35% margin, the distributor will wholesale your \$4.00 product to retailers at approximately \$6.15. If the distributor uses a 50% margin, your distributor will wholesale your \$4.00 product at approximately \$8.00. That means distributors will wholesale your \$4.00 product for anywhere between \$6.15 and \$8.00.

# Once you have determined your Distributor Price, calculate your new MSRP MSRP = <u>DISTRIBUTOR SALES PRICE</u> (1 – DISTRIBUTOR'S MARGIN)

So, if both the distributor and vendor use a 35% margin, your new MSRP for your \$4.00 product will be approximately \$9.47/unit.

Let's examine this \$9.47 suggested retail price as your product leaves the processing plant. If you sell directly to consumers with a cost of \$1.79/unit, then you would receive \$7.68 per unit. If your product is going into a wholesaler's distribution warehouse, you would not receive \$7.68 per unit. To maintain the \$9.47 retail price, the wholesaler would sell the product to retailers at \$6.15. The wholesaler expects to make approximately 35 percent, so they would pay you approximately \$4.00 per unit. You are now receiving \$2.21/unit. If a broker is used to help place your product, their normal fee is five percent, so the net you would receive per until would be approximately \$1.42.

These "down the road" costs underline the importance of setting a beginning price that you can live with for an extended period of time. Take into account future expenses that come when you expand production. Stores and consumers don't like to see price increases. Having to raise the price as your product gains popularity can be risky. If you must increase your price, you must negotiate this increase in advance with each retail partner.

Deciding on the right price for your product is among the most challenging of undertakings for a startup. One would expect that pricing would be based on your total cost plus a margin of profit, but as discussed above, the price received by the manufacturer starts with setting a competitive retail price and working backward through the distribution chain. In reality, most small startups become a price taker rather than a price setter, so it becomes essential that food processors develop a very accurate cost accounting system.

Penn State Extension publishes a <u>Price and Pricing Fact Sheet</u> that can help you put your theory into practice, and walks you through determining your annual break-even threshold. In the end, pricing is an art combining facts and figures with your best estimate. And, as with any art, it takes practice to do it well. Successful retailers carry products that sell, and an overpriced sticker tag could land you on the "discontinued item" vendor list. Invest time into researching and calculating the best price you can determine to start, and retain, a profitable business venture.

## **Sales Tax**

If you sell product(s) in Pennsylvania that are subject to sales tax, you are required to collect the tax from the person to whom you make the sale. Taxable sales are sales of tangible personal property and services generally referred to as specifically enumerated services. Some food items are taxable.

<u>061 Pa. Code § 60.7, Sale and preparation of food and beverages</u> includes a list of taxable food and beverage items. Under the provisions of the sales and use tax law, the sale of food or beverages may be taxable or exempt depending upon the type of food or beverage or upon the basis of the location from which the food or beverage is sold. Generally, the wholesale of selected food items to a distributor are exempt from tax.

The Pennsylvania Department of Revenue publishes an online Retailer's Guide to State and Local Sales, Use and Hotel Occupancy Tax that further defines taxable sales and services.

## **Distributing & Selling Your Product**

#### **Distribution**

When it comes to distribution, you've got two options: delivering your product as a direct vendor to each store individually, or having a distributor centralize your deliveries to stores regionally and nationally. Many retailers won't buy directly from small producers, so you may not have a choice as you grow but to use a distributor. In the meantime, distributing your own products as a direct vendor is a viable first step towards developing relationships with local grocery stores in your area.

If you are working with stores local to you, you can make deliveries yourself. It is common for vendors to charge a fee for delivering, so delivering your product enables you to offer a discount. You can offer free delivery if the store buys a minimum amount—for instance, buy three cases, get free delivery. Or you can offer free delivery on the first order, which is a good initial incentive. The other option is to use one of the many shipping agents out there: the U.S. Post Office, UPS, FedEx, or DHL. Their rates will differ depending on what you're shipping and where you're shipping it. Check with all of them to find the best pricing. You can ship orders to yourself or to friends to see how long it takes, how the product survives the process, and what it costs. The downfall of selling as a direct vendor is that stores cannot automatically restock your product on a weekly basis as they do with products they order through their main distribution channels. For this reason, your product will run the risk of being out of stock for several days or even weeks before the store buyer gets around to placing an order. This requires diligent policing of your products and the inventory available in each store.

Working with a third party distributor offers many benefits, but it comes at a cost. They take orders from many different stores and make sure the delivery is the same time every week. Retailers prefer to work with distributors because they can place one order for thousands of items and have everything show up at once and on one invoice. It enables them to more efficiently schedule staff and get products onto the shelves. The downside of working with a distributor is that they need to get paid too. If you charge \$50 per case to sell your soup directly to a store, then ideally you want your distributor to sell it for \$50 as well. That means you have to sell your product to the distributor for less.

Finding the right distributor for your product(s) presents a chicken-and-egg proposition. In the food industry, a wholesale distributor typically won't give a small startup the time of day if they do

not have shelf space secured in several large retail grocery stores. They usually want to see that you have at least a regional footprint with a large grocery chain. On the other hand, a grocery chain often won't even consider placing a product on its shelves if it is not available through a wholesale distributor's catalogue. Distributors will also require that your product(s) have a shelf life of at least 6-18 months in order to include it in their catalogue. If you choose to sign with a distributor, you should carefully review the contractual clauses regarding expired product. Many distributors will require you to purchase back any expired product, or they will deduct payment on your next order. Even if the distributor is mishandling your product—in other words, sending out new product prior to sending out product with previous dates—you, as the manufacturer, are typically responsible for assuming the financial risk of having to purchase back any product that is considered out-of-date.

As mentioned above, distributors typically add 35-50% on top of the cost they pay. Shop around to see which distributor is a good fit for you. If you develop a strong relationship with some of your local stores and have a steady sell record, they may introduce you to a distributor to set you up regionally or even nationally within their stores. This is a win-win situation as it gives you an entry to the distributor, and opens doors with you to sell to the distributor's other clients. Many distributors have sales reps working for them. Sales reps go from store to store giving out samples and offering sale pricing. They can very effectively increase your business, but just know they typically push the higher volume products as they typically work on commission. Ask the distributor if it uses reps, and if it does, ask what it can do to promote your product. This might come at an additional cost.

#### **Retailer Expectations**

Introducing a new food into the market is an uphill battle. Selling your product to retailers offers challenges that are very different than the ones you encounter when producing your goods. After you've spent months and maybe years perfecting, developing, and learning how to produce your particular item on a large scale, it can be discouraging if you don't have immediate success selling it. The food industry is diverse and competitive. Some of your competition is entrenched on store shelves. Those producers are more sophisticated at producing, marketing, and distributing their products. They are better funded and have established relationships with retailers and distributors. But if you know what you're getting into, have a quality product, and have a well thought out plan, you can be successful.

Some retailers simply don't buy directly from small-scale producers. It takes more work and if the products don't fly off the shelves the way the brands they're replacing do, the retailers lose money. Some food producers have unrealistic expectations of retailers or of the marketplace. The big companies offer free cases of new products to retailers to try out. They have sales teams available to help sell the product and answer questions. Their products are easy to order, come in on time, have frequent sale prices, have marketing campaigns under way so the customers often already know them. There is not much you can do to change that reality, so you need to find an advantage. For instance, you can offer a great product and superior, personalized service. Be consistent and focus on what you can do well.

Retailers expect you to offer payment terms. Few stores pay on delivery, so expect to send an invoice with the shipment and receive payment later. The standard is called 10/2/30 terms. This means the retailer has 30 days to pay you, but if they pay within 10 days, they get 2% off the total of the invoice. Some companies also offer 14 or 21 day terms. Determine what you can afford and what is typical in your area. Be willing to offer something to the retailers. You need to trust the retailer is going to pay, but have a regular policy on how to proceed in case the retailer doesn't pay. Friendly reminders when payments are late are appropriate, and so are late fees if the policy is clearly stated on your invoice. Give the payment reminder to an employee in charge of payments and not to a clerk stocking the shelves. As a start-up business, you will be expected to pay immediately for your ingredients, packaging, and typically the co-packing charges. You need to anticipate the timing of operational cash coming into your business to keep up with your bills.

Set a standard for ordering and delivering. Make sure whatever method you choose is clear to the people that buy your product. Let them know how to order, the order lead time, and when and how delivery will occur. Orders are typically placed over the phone or through email. If you get an email order, send a confirmation email that shows you received the order and the expected delivery date. When shipping the product, be sure the invoice is included with the shipment. You must respond to inquiries quickly. This can be difficult if you are still maintaining other employment, but it is vital to maintaining quality customer service.

Retailers expect you to be consistent in all you do: pricing, delivery and ordering systems, product quality, packaging, and customer service. If you need to work on any of these components, practice before you aggressively hit the market. Spend time working with just a handful of stores. Try one close to home and a second that you'll need to ship to, maybe 60 to 100 miles away.

Begin by targeting retailers that sell local food products. Don't worry if it doesn't all go smoothly at first. Selling food takes practice. Learn from mistakes and do not repeat them.

Consider getting a farmers' market booth for a season. Getting up at 5 am to drag a display and stacks of product that you sell one at a time may not seem like the short path to success, but the experience you gain will be invaluable. You'll learn first-hand what people look for in your product. You'll get to see their reactions to your food. You'll also learn to give your sales pitch a couple hundred times every week, and it will build a little buzz in the community as you launch your product. Many local grocery stores, such as Whole Foods Market, Giant Eagle Market District, and McGinnis Sisters also have their own local farmers markets in the summer, or feature local foods during certain months of the year. This is a great way to get your foot in the door with these stores. If you spend a summer working the farmer's market while selling wholesale to a couple of accounts, you can be ready to start making your pitch to a larger market in late summer or early fall. This is when many trade shows are scheduled and many new products are released. It's also the start of the busiest sales quarter of the year for grocery stores. Stores are looking for new products, especially items their competition does not have.

#### **New Product Presentation**

One of the most common questions we hear from startups is, "How do I get in front of a buyer?" The only answer is: try, try, and try again. If your product is directed toward retail food stores, the key is acceptance from either a buyer of the food chain or an independent wholesaler. The decision to stock an item is made by the buyer, and part of the decision process is based on the "new product presentation." Paco Underhill's, "Why We Buy: The Science of Shopping," is a well-rounded resource guide that offers advice on how to keep your changing customers and entice new and eager ones in the retail environment. The guide will help you to understand your product placement from a buyer's perspective.

Participating in your local stores' farmers markets and local month promotions is a good way to get your foot in the door and meet the buyers who can choose to put you on their shelves. You can also personally go and ask who the buyer for your specific food product is, and then set up a meeting with him or her. You don't want to try to sell a pitch without a meeting, as the buyers are generally very busy going about their daily obligations. If you do get a meeting, you will want to make sure to come prepared.

Keep in mind that there are several basic items that buyers might ask you about the product before making their decision. These are listed in the table below.

Factors to consider in new	product presentation
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Size of container	Amount of product liability insurance
Containers per case	Delivery time in working days
Case weight and cube	UPC Code
Palletizing arrangement (cases per layer and # of layers)	Current product advertising-media and dates
Case cost (delivered and picked up at your plant)	Coupon program
Payment terms (for example, 2% cash discount if paid in 20 days; net due in 30 days	Method of shipping
Promotional allowance	Introductory allowances
Quantity discounts	Swell allowance (damaged goods)
Advertising allowance	Price protection
Minimum order quantity	Product taxability
Maximum order quantity	Vendor spoils policy
Slotting allowance	Pull date information (if applicable)
Present distribution in the trade area	Manufacturer's suggested retail price (MSRP)

Major factors to be considered before setting up a meeting are whether you are prepared to offer introductory and promotional allowance, advertising allowance, slotting allowance and product liability. Be prepared for buyers to ask for all these allowances on a new, untested product. Introductory and promotional allowances are expected of new products and may be formulated in different ways. The two most popular means are "free" goods or a "cents off" program. "Free goods" means that for every "x" number of cases ordered, one case is given free. "Cents off" is a discount off the processor's unit price on all products bought during the period.

Advertising allowances are fees stores charge per item to stock new products in their warehouse or on retail shelves. The best shelf position is eye level to the consumer. Some products fail because of poor position. New products generally end up towards the bottom shelves.

<u>Product liability insurance</u> is a necessity. Buyers will not consider a product unless a policy is presented. Most expect the policy amounts to cover at minimum \$1 million per occurrence, and \$2 million per annual aggregate.

Another factor important to a buyer is the product's current distribution in retail stores. Again, this resembles the "chicken and the egg dilemma" because if the product were in distribution, you wouldn't be in the buyer's office seeking shelf space. Nonetheless, there are some things that you can do to show buyers your product has been accepted by consumers.

Once you have done your homework and compiled this information, you are ready for your sales pitch. You will need to have at least three to five jars or units of your product (with its final label) to sample at the meeting and leave behind for the rest of the grocery team to try, and provide your own complimentary pairings. For instance, when we first pitched our dulce de leche product to Whole Foods, we provided them with samples of dulce de leche paired with fresh local apples, gluten free crackers, and fresh French baguette slices layered with brie and dulce de leche. The idea was to highlight its versatile pairing nature with many other specialty food items that are also sold in the store. You will also want to leave behind a sell sheet. It is vital to have a sell sheet, which outlines the nuts and bolts of doing business with you. It should include the following information:

- The name of your company and contact information (include a website if you have one)
- 2 or 3 attributes that set your product apart—i.e.: local, handmade, gluten-free, preservative-free
- A short description of your product
- Pricing information that includes your product name, <u>UPC code</u>, unit size, case size, and price per unit and price per case. You should clarify whether this price includes delivery (most stores will require you include delivery costs in your product price)
- · Order information and required lead time

You make your pitch on the front side of the sell. It should outline the reasons your product is great: 3-5 bullet points that are easy to remember. Make sure your logo stands out and include

compelling pictures of your product, your production facility, ingredients, and so on. The back side of the sheet should have everything a store needs to know about doing business with you: pricing, delivery and ordering information, and your contact information. Make it clear and well organized.

Most sales don't happen the moment you make the pitch. They come later after the buyer has pondered your product, talked to co-workers, and looked at the items he or she wants to replace. While you can't be there during this process, your marketing materials can speak for you. They should be clear and comprehensive.

You also should include in your marketing packet copies of any media coverage you have received, and educational information if possible. For instance, if your product is high in antioxidants, include an article on health benefits. (Be careful about making direct <a href="health claims">health claims</a>.) If your product is made with fair trade ingredients, include a brochure about Fair Trade. Don't overdo it, but give retailers compelling reasons to buy your product instead of a competitor's.

After all of your careful planning you must remember to be patient. It is often said in sales that it takes six contacts with a buyer before he or she will buy. Some store buyers may buy the moment they see your product. Others are never going to buy—don't take it personally. Listen to what the buyers are telling you.

## Getting On (and Staying On) the Shelf

It is important to know how the competition gets on the shelf. They routinely offer free or deeply discounted cases of new products to any retailer. They offer sale prices three or four times a year, typically 20-30% off the retail price. They have teams of sales reps that not only promote products, but also offer merchandising assistance. They often restock their own shelf space. They may give stores equipment, split ad space with them in local newspapers and magazines, and provide product to give away at events. At large retail chains they may even pay for shelf space and end cap displays.

You may feel you can't compete with these tactics but don't panic. There are things you can do to get your product on the shelf. As discussed above, when approaching a store about selling your product, make an appointment to talk to the buyer. Grocery store buyers are very busy and showing up unannounced makes you look unprofessional. Once you have an appointment, be prepared to make your sales pitch. Have professional marketing materials with you at all times.

Be prepared to offer an introductory price or a discount on the first order. By doing this, the store can immediately put your product on sale. A sale sign in front of a new product draws attention and encourages customers to try something they haven't seen before. You can offer free shipping on the first order, as well as provide a sampling kit for the stores staff so they can familiarize themselves with your product.

Finally, you should arrange to provide several in-store demonstrations. You or a member of your team should put on a demonstration consisting of offering bite-sized samples to customers. These demonstrations are usually done on Friday and Saturday and a promotional price is often made available, as a discount off the regular price or a "buy one and get one free" offer. After the demonstrations, you should go into the store at least twice weekly to monitor your sales and inventory and make sure your product is being properly displayed. With careful planning you can get on the shelf, with a sale price, and customers will be able to taste your product before they buy it.

There are other affordable ways to build a good long term relationship with potential retail partners. As mentioned above, you can be available to give away samples at the store, offer shelf signage and recipe cards, and offer sample product for staff meetings. Ask if the retailer has a newsletter (email or print) and ask to be interviewed for it. If sales are slow, offer a discount on the next order. Ask the store to pass the savings on to consumers. Selling on a consignment basis, on the other hand, isn't recommended. This means that you still own the product while it is on the store shelf. If a retailer hasn't purchased your product outright they won't have the commitment required to truly sell it. Also you would have to accept back any unsold items. This does not work well with food items that are typically perishable.

Once you have landed shelf space, you have to diligently protect it, and your image. Finally, you need to begin to gage whether the cost of producing and selling your product can be justified by a profitable return and if your target market going to faithfully purchase it over time.

## **Brokers**

For most food startups, the food product distribution system makes no sense. It is also extremely difficult to break into. Herein lies the predicament, "What came first? The chicken or the egg?" As we mentioned above, a wholesale distributor typically won't give a small startup the time of day if they do not have presentation in several large retail grocery stores. On the other hand, a grocery chain often won't even consider placing a product on its shelves if it is not available

through a wholesale distributor. For those who need help in presenting their product or breaking into the industry, you may want to seek representation through a broker. Brokers will help you develop a retail price, promote marketing strategies to enhance your product's acceptance, and make sales presentations to the buyers of independent wholesalers and large retail food chains. Brokers' fees are usually about five percent of all sales made in the broker's territory.

## **Specialty Brokers**

If you seek broker representation, you may consider discussing your product with a "specialty" broker. These brokers specialize in representing products that fall into the specialty categories (relatively low volume products). The products may be gourmet foods, products produced by small processors who do not wish to enlarge their operation, or new products that do not suit the volume requirements of mass merchandisers.

There are fewer specialty brokers than "general" food brokers, who usually represent large national firms having well-known brand products. Specialty Food Resource publishes an online listing of specialty brokers by state. Members of the Specialty Food Association can also download a database of specialty food brokers.

# Ingredients and the Food Industry

Most specialty food startup companies start out with the intention and goal of keeping their label "clean" to ensure that their product has no preservatives, is all natural and uses fresh local ingredients. Herein lies the challenge, they also want their product to be <u>affordable</u> and <u>shelf</u> stable too!

Everyone wants their product to hit all the current trend buttons (natural, clean label, locally sourced, GMO Free, Organic), but sometimes you have to compromise in order to ensure that you are creating something that is both safe and affordable. Your ingredient selection process and the food supply chain you create to purchase your ingredients play a vital role in the success of your food startup. Below we offer a brief introduction that will get you thinking about your own food supply chain.

## **Sourcing Ingredients**

Sourcing, as they call it in the food business, is the process of getting your foods and other ingredients. Effectively sourcing ingredients can make or break a food startup. This especially poses a challenge to most startups when they begin to convert their home recipe to a scalable commercial formula. When scaling up a recipe, startups most evaluate the cost effectiveness of each ingredient to ensure their product(s) will produce healthy profit margins. In the beginning, many people do not realize their production costs. After determining the best market price for their product, most startups come to the immediate realization that they have to go back to the drawing board and adjust their recipe(s)/formula(s) accordingly. They can no longer purchase home-style ingredients from their local grocer at retail cost and, and must switch their ingredients for a cheaper alternative to lower production costs. In some cases, this merely means buying in bulk from a wholesaler. In other cases, some startups work with a food scientist to identify ingredients with specific functionality that may be used to replace home-style ingredients in scaled-up batches. An example of a cheaper alternative is replacing a thickening agent purchased at the store for a commercial gum. The important thing is to source the best ingredients at the lowest cost possible without compromising the quality of your product.

When it comes to efficiently sourcing ingredients, you must operate and think like a restaurateur—you need to determine your potential volume and buy accordingly. You always need to be planning in advance to shop or receive orders so that you're never out of necessities.

If you're cooking, make a detailed shopping list of ingredients. If you're buying food from wholesalers, know how much you need, how much you can safely keep fresh, and how much you can sell before any food goes bad. You're better off running out of food on a busy day than selling something that isn't fresh. Determining the right quantities to purchase is usually a matter of trial and error.

Shared buying can also help you lower your ingredients cost. When restaurateurs, food manufacturers and/or mobile food owners order foods together in bulk quantities, they can save money. According to economies of scale, the larger the order, the better the discount. So if you can find some noncompetitive entrepreneurs, you can ask if they want to team up and place orders with you, which is essentially how a food co-op is formed. A co-op is simply a group of individuals who come together for their mutual benefit, not unlike a credit union. Many commercial kitchen incubators offer shared-buying services that encourage food startups to band together and create a shared-buying network that allows them to source their products at greater discounts, thus lowering their production costs. This allows food startups to have a greater competitive edge against the big-box brands that dominate the food industry due to their massively lower production costs.

We suggest contacting <u>Pittsburgh's Food Policy Council</u> and/or the <u>Pennsylvania Association for Sustainable Agriculture (PASA)</u> to inquire about any local shared-buying networks in your area. In fact, we advise all local food startups to consider <u>joining PASA</u> as a member. The \$200 membership fee is well worth the cost as membership provides a guide to locating farm fresh foods, value-added products, cooperative connections, suppliers, restaurants and everything

local throughout Pennsylvania, as well as provides you access to the <a href="Buy Fresh Buy Local">Buy Fresh Buy Local</a> marketing program. PASA also manages the <a href="Local">1Local</a> online tool that helps food businesses assess their current local-food impact, communicate with consumers who share a commitment to strengthening their local food system and identify ways to improve their local efforts. We have found these



resources to be invaluable during our startup years, as PASA introduced us to <u>Le-Ara Farms</u>, one of the few Pittsburgh-area farms licensed to sell raw milk to consumers and small businesses. <u>Farm to Table Pittsburgh</u> also publishes an online directory for CSA's, Farmers Markets, Restaurants, Farms and other businesses that grow, produce or support local food in Western Pennsylvania.

Where to source your food can be a factor in planning your purchases, schedule and offerings. Below are some sources to consider:

#### 1. Local farm-to-fork suppliers.

There are several local food distributors in our area that specialize in farm-to-fork distributions. Penn's Corner Farm Alliance is a farmer-owned cooperative in southwestern PA that also provides wholesale services. Frankferd Farms is a family-owned operation in western Pennsylvania that distributed organic, local, bulk, and specialty foods to all sizes of companies...from large whole



foods operations to local neighborhood bakers and vendors. <u>Paragon Foods</u> is one of Pittsburgh's larger independently-owned fresh-foods distributors for our area's wholesale customers. The regional wholesale supplier, <u>Three Rivers Grown</u>, specializes in foods grown or produced within 250 miles of Pittsburgh. <u>Tiny Footprint Distribution</u> also distributes local and sustainable food products throughout the Midwest and offer a convenient ordering process for local and all natural food programs.

- **2. Wholesale food distributors.** You can find plenty of food choices by searching for "Pittsburgh Food Suppliers" on the larger search engines which will result in a large number of food and beverage suppliers. Some of the larger food wholesalers in our area include <u>Gordon Food Services</u>, and <u>Sysco</u>. <u>Aldo's Food Service</u>, <u>Nappies Food Service</u>, <u>Sherwood Food Distributors</u>, <u>Pennsylvania Macaroni Company</u>, <u>M<sup>c</sup> Aneny Brothers, Inc.</u>, and <u>Salonika Imports</u> are among Pittsburgh's locally based wholesale food suppliers. You can also find several distributors online. <u>Woodland Foods</u>, for instance, is a wholesaler of specialty food ingredients and spices that we often use.
- **3. Farmers markets.** Farmers markets and CSA's (Community Supported Agriculture farm shares) are also popular for sourcing seasonal, local, high quality ingredients. However, these

usually come at a higher cost. You have to determine whether it makes sense to incorporate farmers markets into your sourcing plan. Some startups, for instance, in particular mobile food vendors with carts and trucks are on a mission to reinvent popular food truck fare and sell the healthiest versions of the basic food truck favorites by sourcing from organic farms and greenmarkets. You'll have to charge a little more to cover the slightly higher costs, but you'll attract the health-conscious crowd, and that's a big demographic in some areas. PASA offers an online guide to our area's farmers markets. Visiting different markets provides you the opportunity to get to know area growers, talk to farmers and vendors at farmers' markets, and scout around carefully for whatever you need.

- **4. Manufacturers.** Most major food manufacturers should be easily reachable and, in many cases, will sell you what you need or point you in the right direction so you can find their products nearby. Start with their websites. There are thousands of big companies to consider. There are also numerous small companies and niche providers that can supply you with a tremendous number of tasty options. From apples to zucchini, someone is ready with the food you need. As is the case when buying anything, compare prices along with quality as you shop.
- **5. Shopping clubs.** Restaurant Depot, BJ's Wholesale Club, Sam's Club, Costco, and other shopping clubs have become very popular as the idea of buying quality food in bulk has caught on. Restaurant owners shop at these clubs, and so can you. Each requires a membership with an annual fee. Some also require you to have a business tax id. You can then stock up on many items you need at reasonable prices.

## Choosing a Supplier

As you begin develop your food supply chain and approach ingredient suppliers, you will need to request samples of the ingredients, as well as documentation for nutritional analysis, quality control and traceability. Work only with suppliers who can provide the following documentation:

- Nutritional information per 100 grams
- Allergen statements for both the ingredient and the facility
- Country of origin
- Ingredient statement
- Specification or "specs"—a document that provides the qualitative and quantitative measurements for that ingredient
- Organic certification (if needed)

- Kosher certification (if needed)
- Halal Certification (if needed)
- Non-GM0/GMO-free documentation (if needed)
- Certificate of Analysis—a document that provides the specific analytical measurements for a sample batch sent to you for either R&D or production purposes

Your operation supply chain may include growers, shippers, packers, manufacturers, distributors, and local markets. A number of factors go into selecting the right suppliers. Make sure suppliers can meet or exceed your standards and deliver safe food.

- Use approved and reputable suppliers. An approved supplier is one that has been inspected and is in compliance with local, state, and federal laws.
- Develop a relationship with your suppliers and get to know their food safety practices.
   Consider reviewing your supplier's most recent inspection from USDA and/or FDA.
   Also order and pick up your supplies occasionally so that you can do your own inspection of their facility.
- You must decide whether your priority is finding ingredients of the highest quality, items
  that provide the best value, or items that can be ordered the most efficiently. Using
  many suppliers will enable you to find those that specialize in specific product lines.
  However this could lead to more complicated ordering and delivery processes, because
  you'll have to coordinate several vendors. Pricing may be higher with specialized
  vendors, but the quality should also be higher.
- Arrange deliveries so they arrive one at a time and during off peak hours. Products should be delivered when your staff has time to make inspections. By establishing procedures for inspecting products, you can reduce hazards before they enter your establishment.
- Inspect deliveries properly and immediately. Assign responsibility to select employees
  to receive and inspect product. They should be trained to know proper temperature
  expiration dates and recognize the signs of thawing and refreezing.
- Plan ahead for shipments. Make sure there is enough space available in coolers, freezers, and storerooms prior to delivery.
- Inspect and store an entire shipment before receiving another shipment.
- Have correct information on hand. Receivers should have an order guide to cross reference with the suppliers invoice. Inspect each shipment immediately. Once you

sign for the product and the driver leaves, you are legally responsible for paying. File all packing documents and invoices.

- Put products away quickly and appropriately.
- Keep receiving area clean, sanitary, and well lighted to discourage pests.

### **Rejecting Shipments**

You have the right to refuse any product that does not meet your standards. This may put a crimp in your production schedule, but it will ensure that your product will remain consistent and of high quality.

Steps to rejecting a product include:

- Setting the rejected product aside.
- Explaining to the driver exactly what is wrong with the item. Do this as tactfully as possible; remember they are just the delivery person.
- Getting a signed adjustment or credit slip from the delivery person and attaching it to your invoice for processing.
- Tracking issues by vendor. This will help you decide if it may be time to change suppliers.

## Ingredient Function and Selection

The success of any new specialty product depends on the quality of its flavor, color and texture, its stability under various storage conditions and its safety. These factors are intimately related to the ingredients in the food product and to the physical processes and handling procedures to which it has been subjected. Often, additives may be needed to maintain or enhance product quality throughout and after processing. It also helps to understand that just because something sounds like it is not <u>natural</u>, doesn't mean that it isn't. Some supermarkets have lists of acceptable and unacceptable ingredients for products sold in their stores. If you know you want your product sold at <u>Whole Foods</u> production formula.

#### What is a Food Additive?

A food additive is an ingredient that is added to foods to aid in processing, preservation or quality improvement. The FDA defines a food additive is any substance used in the production, processing, treatment, packaging, transportation or storage of food (21 CFR 170.3 (a)). Additives should not be used to disguise faulty or inferior manufacturing processes or to conceal damage or

spoilage; only the minimum amount of an additive necessary to achieve desired results should be used. Government regulatory agencies such as the <u>FDA</u> and <u>USDA</u> closely monitor the use and levels of additives in food products.

A direct food additive is added to a food for a specific functional purpose. For example, <u>xanthan</u> <u>gum</u>—used in salad dressings, chocolate milk, bakery fillings, puddings and other foods to add texture—is a direct additive. Most direct additives are identified on the <u>ingredient label</u>. Indirect food additives are those that become part of the food in trace amounts due to its packaging, storage or other handling. For instance, minute amounts of packaging substances may find their way into foods during storage.

Thousands of food additives are added to food in the U.S. They are listed on the FDA webpage "Everything Added to Food in the United States" (EAFUS). The safety of food additives is constantly being reviewed, so food processors must pay close attention to current regulatory statutes governing particular additives. Listed below are descriptions of the functional use of each group of food additives.

- Acidulants are used to control tartness (by increasing the acidity) in fruit products and beverages, ensure proper gel formation in jams and jellies, and suppress bacterial and mold growth in baked goods and dairy products. They are an essential ingredient in sharp, zesty food products. These acids are what give fruit its characteristic tang, and most of those that are added to food products are common in nature. For example, citric acid occurs naturally in citrus fruits such as oranges and lemons, malic acid is found in apples, and tartaric acid in grapes. They are important in products such as jams, where the acidity of the fruit determines how it will set. Acids also have preservative and antioxidant properties.
- Antioxidants preserve food by retarding deterioration, rancidity or discoloration due to oxidation. They are used to prevent or inhibit the oxygen in air from causing taste and odor changes in fatty foods. Approved antioxidants that are commonly used are butylated hydroxyanisole (BHA), butylated hydroxy-toluene (BHT), propyl gallate (PG), ethoxyquim, and tertiary butylhydroquinone (TBHQ). Generally, no more than 0.02 percent by weight based on the fat content of the food is required. If an antioxidant is

incorporated into the packaging material, no more than 50 parts per million (ppm) of the antioxidant is allowed to become part of the food.

- Buffers, acids, alkalies and neutralizing agents are used to control the <u>pH</u> of a product or are added to change or maintain active acidity or basicity.
- **Emulsifiers** permit the dispersion of tiny particles or globules of one liquid in another liquid. Under ordinary circumstances, oil and vinegar will not mix; but with the addition of an emulsifier, the ingredients will mix to form an emulsion. Emulsifiers stabilize the fat component in chocolate candy, give uniform volume to baked goods, and help disperse essential oils and flavors that would not otherwise be water soluble in relishes, pickles, beverages and candy products.
- Flavoring agents are added to foods to create a desirable flavor or aroma, to supplement, modify or complement an existing flavor or to cover a less desirable flavor in a food product. These additives are available as condiments, spices, essential oils, extracts and single chemical substances. Flavor enhancers are substances that intensify or enhance the flavor of a food and are measured in parts per thousand. Flavor potentiators are potent flavor enhancers used in the parts per billion range. The most well-known is monosodium glutamate (MSG), which is found in frozen meats or fish, dry soup mixes and oriental foods. MSG is another additive that is on Whole Foods' banned ingredients list.
- Food colors are added to certain specialty foods to meet the expectation of the consumer in identifying the product (a grape-flavored drink is expected to be purple) or to enhance product color that may have been changed during processing or storage. They impart, preserve or enhance the color or shading of a food. These include color stabilizers, color fixatives, color-retention agents and so on. There are two categories of color additives: certified and uncertified. Certified colors are synthetic dyes labeled (FD & C Red No. 40; FD & C Yellow No. 5) and manufactured to meet government specifications. Uncertified colors are usually naturally derived substances such as paprika, turmeric or saffron. Natural colorants may cost ten to two hundred times more than certified dyes and may have stabilization problems during product storage.

- Humectants are used in the confectionery industry to prevent sugar crystallization and to provide a smooth, soft texture and moist, fresh taste. Humectants are used to keep moisture in certain foods. Glycerin, propylene glycol and sorbitol are the most commonly used humectants in the foods industry.
- Non-nutritive sweeteners are artificial sweeteners or sugar substitutes used in dietetic
  and low-calorie foods. They have less than 2% of the caloric value of sucrose per
  equivalent unit of sweetening capacity. Their unique chemical formulation gives them a
  sweetness potency several hundred times that of sucrose. Aspartame (NutraSweet<sup>®</sup>) is
  the most widely used high-potency sweetener in low-calorie foods and beverages
  today.
- Nutritional additives are necessary for the body's nutritional and metabolic processes.
- Phosphates have many uses in the food industry. In beverages, they are used for
  acidification and for complexing minerals responsible for off-flavors or loss of
  carbonation. Phosphates are used as dough conditioners (they improve texture and
  volume) in the cereal industry. They stabilize ice cream and milk pudding emulsions.
  Phosphates are used as antioxidants and promote moisture-binding and tenderness in
  meat products.
- Preservatives are antimicrobial chemical agents that preserve food by preventing growth of microorganisms and delay spoilage. Historically, natural preservatives, such as high levels of sugar, acid and salt, have prolonged the <a href="mailto:shelf-life">shelf life</a> of jams and jellies, pickled vegetables, and <a href="mailto:cured meats">cured meats</a>, respectively. However, chemical preservatives, such as sodium benzoate, sorbic acid salts, and nitrites, are used to extend the shelf life of products that cannot be highly sugared, salted or acidified. A list of preservatives and their approximate limits of use in food products is shown in the table below.

Properties and use limits of common preservatives*			
Agent	Optimum pH	Target Organisms	Use Limits
Sodium benzoate	2.5-4.0	yeasts and bacteria	not to exceed 0.1% by weight
Potassium sorbate	6.0 or less	molds and yeasts	not to exceed 0.1% by weight
Calcium propionate	5.0 or less	molds	not to exceed 0.3% by weight
Propyl parabens	7.0 or more	yeasts	not to exceed 0.1% by weight
Sulfites & Sulfur dioxide	4.5 or less	yeasts, molds and bacteria	depends on product
Nitrites & Nitrates	5.0-5.5	Clostridium botulinium	Nitrites: not above 200 ppm;
*0	ade tiene Title O4 fee deteiled infe	spores	Nitrates: not above 500 ppm

- \*Consult the Code of Federal Regulations, Title 21, for detailed information on the regulatory limits for specific food products.
  - Stabilizers and thickeners provide smooth, uniform textures to food products. They produce viscous solutions or dispersions to impart body, improve consistency or stabilize emulsions. This category includes suspending and bodying agents, setting agents, gelling agents and bulking agents, etc. Small amounts of natural gums derived from tree exudates, seeds, roots and seaweed extracts are added commercially to many foods, and pectin and starch are used to process foods in the home. Stabilizers are added to milk with cocoa to prevent separation in chocolate milk. Stabilizers are added to frozen dairy desserts to increase viscosity and prevent graininess of texture. Pectin and starch are added to ensure consistent gel formation and thickness in jams, jellies and sauces.
  - Sequestering agents are used to set aside or segregate, in an inactive chemical form, metallic substances present in some foods. If not inactivated, these minerals will lead to discoloration, rancidity and textural breakdown in food products. The most common sequestrants are salts of EDTA (ethylenediamine-tetracetic acid).

There are many definitions out there for "<u>natural food products</u>" and many opinions on what food additives to avoid. Many natural food retailers such as Whole Foods Market draw a line when it comes to hydrogenated fats and artificial colors, flavors, preservatives and sweeteners. As mentioned above, Whole Foods publishes a <u>guide</u> of ingredients they find unacceptable in food. It's a good idea to familiarize yourself with this guide. If your food product contains any of the ingredients listed on their list, Whole Foods, and likely other specialty food retailers, won't sell your brand in their stores. This is where ingredient selection becomes quite challenging.

Let's start with preservatives that act as mold inhibitors—anyone who wants their somewhat moist baked good to last on the shelf is going to have to keep mold at bay—and there are a wide variety of natural and synthetic versions. Potassium sorbate for example is a yeast and mold inhibitor that is fairly inexpensive and works in a wide variety of pH's and food bases—it is not natural, however, and is published on Whole Food's "Unacceptable Ingredients for Food" listing. Sodium benzoate is also a fairly inexpensive synthetic that prevents mold. It's also listed as an ingredient that Whole Foods will not allow on their shelves. There are more natural options that you can use—such as cultured dextrose. This is a cleaner label bacteria inhibitor that is created via the fermentation of milk and sugar with probiotic organisms and works in a wide variety of applications like salad dressings and cured meats, soups and dairy products. They cost more but allow you to maintain a natural claim on your label (assuming all other ingredients are natural as well). Of course you can use other preservation methods (i.e. canned foods and jarred shelf stable sauces often just rely on heat as a the preservation method—however any thermal process must be approved by your local PA Department of Agriculture Food Sanitarian) or you can work with a food scientist to research ways to preserve your product using salt or sugar, which also inhibit bacteria by lowering its water activity.

What about flavorings? No one in the specialty food industry wants to put artificial flavor in their products and that is understandable, but keep in mind that natural flavors are more expensive and less concentrated than artificial so you need to use more of them to get a flavor impact. If you want to flavor a lemon cake, you may only need 0.02% artificial flavor but would have to use 2 to 3% of a natural flavor to get the same effect—and that natural flavor is going to cost you more money. Some food manufacturers use a flavor called WONF (with other natural flavors) which is a blend of similar flavors used to make up the flavor you like but at a slightly reduced cost—you can tell your flavor supplier that you want an "off the shelf" flavor that they may already sell to several companies (a stock flavor) that they probably produce in bulk at a cheaper price. Talk to your flavor supplier about options.

While the FDA provides specific food labeling regulations of additives in section 21 CFR 101.22), it is very tricky, even for the experienced food scientist, to know when it's okay to call a product natural, naturally flavored, or made with natural ingredients. You should submit any product you intend to market for review by a regulatory expert who understands current FDA interpretations of the code and who can ensure that you don't accidentally break any labeling rules.

Artificial flavors, for instance, are substances that impart flavor but are not derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, fish, poultry, eggs, dairy products or fermentation products like yogurt or kimchi. A spice, on the other hand, is defined as any aromatic vegetable substance (in the whole, broken or ground form, except for those traditionally regarded as foods, such as onions, garlic and celery) whose significant function is seasoning/flavoring rather than nutritional. A natural flavor is the essential oil, oleoresin, essence or extractive, protein hydrolysate, distillate or any product of roasting, heating or enzymolysis, which contains the flavoring constituents derived from a spice, fruit or fruit juice, vegetable or vegetable juice, edible yeast, herb, bark, bud, root, leaf or similar plant material, meat, seafood, poultry, eggs, dairy products or fermentation products thereof. Their function is flavoring rather than nutritional.

Labeling a food product's flavoring as natural, artificial or WONF ("with other natural flavors") involves following a decision tree that can be found in <a href="CFR 101.22">CFR 101.22</a> Subsection (i). The rules for flavor labeling can get complicated, so it is advisable to consult a regulatory expert with the <a href="PA">PA</a> <a href="Department of Agriculture Bureau of Food Safety and Laboratory Services">Department of Agriculture Bureau of Food Safety and Laboratory Services</a> if you wish to list flavors in your product.

Even starches can fall in the natural or not natural category—if a starch is referred to as a "modified food starch" it is not a natural thickener—you need to ask your supplier to provide you with a natural "unmodified" food starch. There are also other ways to thicken a product via dehydration or evaporation of water—using tomato paste (if your product is tomato based), or experimenting with gums and hydrocolloids. Most hydrocolloids are natural like xanthan, gum Arabic, and gum acacia. Gum supplier websites like TIC (<a href="www.ticgums.com">www.ticgums.com</a>) have a wealth of information about gums and to use them to improve everything from particulate suspension to moisture retention in your food products.

There are always natural alternatives in the world of ingredients. It's just a matter of balancing out what you need with the right price point. In addition to striving to offer a food product that has fewer, clean ingredients, remember that "local" remains an important claim for specialty food products and "non-G.M.O." is among the top natural or ethical claim trending in today's specialty food industry.

# **About La Dorita Cooks**

La Dorita Cooks is a resource-based home for Pittsburgh's start-up and early-stage food makers. Our Kitchen Share Incubator Program is an exclusive co-working space for food that aims to break down the barriers to entry into the highly regulated food industry. We provide low-cost access to fully equipped and licensed commercial kitchen space and professional grade equipment in Sharpsburg, PA. Our space fills a need for Pittsburgh's burgeoning artisan and good-food community. It's a space to help small businesses thrive, but also one where people can get their feet wet when deciding if making food full time is for them. Whether a food maker is just starting out or looking to expand & grow his or her food business, La Dorita Cooks provides a service that is economically superior to building or leasing one's own commercial facility.

La Dorita Cooks' husband-and-wife founders, Gastón and Josephine Oría, are no strangers to food startups. As owners of La Dorita, LLC, an artisan maker of specialty dulce de leche products, the Oría's have an intimate understanding of the challenges of small-business ownership and the difficulties most face to make ends meet.

The model for Pittsburgh's first co-working space for food organically developed over the course of three years after Josephine was unable to secure licensed kitchen space to establish her own specialty food dulce de leche product line. Due to a lack of available co-working kitchen space in the Pittsburgh area, Gastón and Josephine Oría converted their dining room in their home into a licensed commercial kitchen. This considerable up-front investment put the Oría's far behind the eight-ball when starting their business. Now they hope to help other food start-ups avoid making the same mistakes.

Josephine launched La Dorita's Kitchen Share program in 2013, after successfully crowdfunding \$32,500 on Kickstarter.com. She envisioned a multi-purpose shared space where certain entrepreneurs would go on to open their own storefronts between one to two years, while others might be content to use the kitchen for years to come. Gastón and Josephine now draw from their own personal start-up experiences to provide industry-specific coaching, technical assistance, and food start-up workshops to members and Pittsburgh's underrepresented food start-ups.

## About Urban Innovation21

Urban Innovation21 (formerly known as the "Pittsburgh Central Keystone Innovation Zone") is a unique public-private partnership that is supporting the growth of entrepreneurship in our region's innovation economy and connecting that growth to disconnected communities and the residents who live in those communities. Urban Innovation21 believes that an inclusive innovation economy is key to increasing regional competitiveness and sustainability. Programs in the UI21 portfolio include the <a href="Pittsburgh Central Keystone Innovation Zone Program">Pittsburgh Central Keystone Innovation Zone Program</a>, <a href="Inclusive Innovation">Inclusive Innovation</a> Inclusive Innovation Equitable Development Program, <a href="Pittsburgh Wealth">Pittsburgh Wealth</a> Building Initiative, <a href="Placed Based Entrepreneurship Programs">Placed Based Entrepreneurship Programs</a>, and the <a href="Citizen Science Lab">Citizen Science Lab</a> to name a few. Urban Innovation21 is one of the first US-based organizations to work under the "inclusive innovation" economic development paradigm.

# About the PA Department of Community and Economic Development

The <u>Department of Community and Economic Development (DCED)</u> is committed to fostering opportunities for businesses to grow and for communities to succeed and thrive in a global economy. DCED's mission is to improve the quality of life for Pennsylvania citizens while assuring transparency and accountability in the expenditure of public funds.

# Disclaimer

La Dorita Cooks does not make any warranties regarding the accuracy or use of the materials in this guide. The contents of this resource guide offer only general background knowledge and in no way constitute expert advice intended for any specific situation or food product. While this guide contains links to third-party websites and names specific companies and events, La Dorita Cooks makes no endorsement or warranties in regard to their services, materials or opinions. Similarly, we have received no financial compensation for mentioning these organizations. As relevant food-industry laws and regulations change continuously, the reader should routinely verify all references to regulatory resources to ensure they are current.

