My Food Venture
Risk Management Plan
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This publication includes resources from:
OSU Fact Sheet AEX-253-05, What can you Do to Be Ready for a Recall? By Dr. Gonul Kaletunc and Dr. Ferhan Ozadahi, The Ohio State University Extension.

WSU Food Processing Website, Hazard Analysis Critical Control Points (HACCP), found at http://foodprocessing.wsu.edu/haccp/

North Carolina State University Department of Food Science Website, HACCP Principles. By J.E. Rushing and D.R. Ward, found at http://foodprocessing.wsu.edu/haccp/

Food Allergens: Food Safety for the Non-Food Scientist By Dr. Aurora A. Saulo, University of Hawaii at Manoa, found at http://www.ctahr.hawaii.edu/aurora/downloads/FoodAllergensAug08.pdf

Iowa State University Fact Sheet, On-Farm Food Safety: Guide to Good Agricultural Practices (GAPs), by Jason Ellis, Dan Henroid, Catherine Strohbehn, and Lester Wilson, found at http://www.extension.iastate.edu/Publications/PM1974A.pdf

This publication is available in alternative media on request.

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Planning to Manage Risk in a Food Venture

Although individual food items may vary a great deal, there is a consistent set of steps that each person must go through to develop a value-added product. On this page, and the ones that follow, the actions taken are in “usual chronological order,” but you may find that some steps occur simultaneously to speed the process from start-up to production. Facility design may happen at the same time you are creating the business plan or ordering/producing raw materials — all prior to having the facility pass final inspection. You should refer to this description as an approximation for your operation, as all facilities and products have unique aspects. You may be planning to produce your own product or co-pack a product for someone else. If you are planning to co-pack for another business, they will need to be involved in the planning process.

Create a business plan. If you plan to produce a value-added product from your own production or by purchasing the raw materials from others, your first step should be to create a detailed business plan. By starting with this activity, you will research the steps necessary to begin a new venture. You go through the route of deciding your processing procedures, marketing strategies, risk management strategies, inventory control, and product recall procedures. If the plan shows that the venture will be feasible as a viable business, you can then begin the process of designing your facility — purchasing and installing the necessary equipment — or seeking out a shared kitchen.

Choose Your Facility. If you choose to use a shared kitchen facility, the equipment that an individual kitchen offers will already be designated. However, you will need to schedule your time, sign the necessary contracts, and provide all necessary documentation required by the facility. You will need to have on-hand both proof of insurance and advance payment for the facility.

If you are creating a facility for your own business you may frequently need to remodel an existing structure. Be sure to contact your local municipality to determine if you are able to manufacture a product at the location chosen and stay within their zoning plan. If not, you may need to apply for a zoning variance or decide to locate your facility elsewhere. Design the facility to make the maximum use of space and create the most efficient work flow needed to produce your product. You will need to share this site plan with the sanitarian from Pennsylvania Department of Agriculture to ensure that their requirements for your facility and processes are met. Even if you researched the facilities requirements as you prepared your business plan, by the time you are ready to
set up, the regulations may have changed, necessitating your having plans that now match what is allowable for food businesses.

Beyond the floor plan, you must arrange for adequate and appropriate equipment (including but not limited to steam kettles, stove tops, exhaust fans, steel countertops, etc.) to take your product from the basic ingredients to a customer-ready product. When doing this planning, remember that not all equipment is in the kitchen — your business resources may include delivery vehicles. Now is the time to secure these vehicles since any modifications should be made prior to the time that you begin to make sales and the actual delivery schedules are set.

**Have facility inspected.** To double-check what you are doing, your facility inspection is one of the most important steps in the process. Get your (potentially) long-term relationship off on the right foot by courteously listening to, and following, all of your inspector’s recommendations. Once your facility has passed inspection and you have the necessary documentation, you may then begin to do several short test runs to make sure everything is in working order before starting full-scale production. Be sure to track all processes in your record keeping system as actual production costs may differ from those in your estimated partial budget that was part of your business plan. Allocate your fixed expenses to the cost of the process to determine your total cost of production, which will play a role in your selling price. If you are a farmer/grower adding value, be sure to assign a realistic value to the ingredients that you have grown, to help insure all costs are fully documented.

**Securing additional ingredients.** If you are growing your own ingredients, you can begin the processing of those materials into your finished product as soon as they are harvested. However, you will probably not be able to produce all of the ingredients just-in-time for many food items, so having purchased and stored the necessary materials slightly ahead of time will insure you are ready to begin processing your trial runs and to complete first orders. Make sure all materials are stored correctly so the possibility of contamination is reduced. Make certain your record keeping process is adequate to track all products and costs of those products, as well as the time of storage, refrigeration or freezing for good pre-inventory control.

**Personnel.** If your plan shows that you will need to hire employees, you should begin the search and hiring processes. This will insure that when you are ready to begin production, you will have all of the necessary personnel to do so.

**Marketing.** Contact any wholesale and retail customers and inform them that you are ready for production. Set your current selling price and inform the customers of any changes to the product or price since your initial contact with them. You can begin taking orders for product and determining processing schedules based on delivery needs.
Production. At this milestone, your dream of having a food business is well underway! However, it is really at this point that much of the hard work will begin. Your production will be both market, and employee, driven. You do not want to over-produce what the market (and your storage facility) will bear. If your product is a perishable item, needing to discard a significant amount of food items because they are past shelf life becomes very expensive. Such costs may be ones you cannot recoup. You will also need to factor in the number of employees that you have, and the hours it will take for them to complete production lots, making full use of their time while avoiding costly overtime (when possible). This is because paying overtime for production or delivery adds to the total product cost. Remember that long hours for employees not only result in financial challenges, but may also affect morale.

You will need to track all product inputs (home grown and purchased ingredients) to be sure they are manufactured and stored to your specifications and standards. If you are using organically produced products, make sure the supplier has all documentation and certificates to allow you to advertise an organic product, and that what you do in adding value does not compromise the organic certification of the finished product.

You should constantly monitor all processes and procedures to maintain quality and reduce possible product contamination. Your monitoring should consist of checking temperatures throughout the process. If you are producing a product that requires heat to seal containers, make sure they are rated adequately to allow for the process to which you subject them. Check samples from each batch to be sure containers are completely sealed. If your food product requires cold temperatures for storage, closely monitor storage facilities to make sure that a consistent, correct temperature is maintained.

Equipment maintenance is another critical aspect of production. Well maintained equipment will generally last longer and reduce the possibility of parts or pieces being shed into the food product. Use high quality food-grade grease on any equipment where it may come in contact with food. A good procedure to follow is checking equipment at the end of the production session, while cleaning. Problems found at this time will allow for more detailed maintenance procedures before the next processing begins. Keeping good equipment maintenance records will serve you well. Delivery personnel and their vehicles are not exempt from routine inspection and maintenance practices.

Selling your product. Visit your wholesale buyers frequently to maintain good customer relations. By seeing where they place your food items in their establishment, you can make sure your products are stored correctly and displayed to the best advantage. It is also beneficial to observe customers while they are purchasing your products at the retail level, to discern what, if any, improvements need to be made. If you are the primary marketer, talk to customers directly to get feedback about the product, and make corrections or improvements.
Inventory Control. The first-in-first-out (FIFO) is frequently the best inventory policy, especially for a perishable product (or one with relatively short shelf life). Even the most shelf-stable preserved products may turn color if stored too long, making them unsalable. FIFO ensures that the first products off the manufacturing line are the first products sold. Maintain your storage facility so that the oldest containers are rotated to the front, rather than buried, so this procedure works for you. Verify that FIFO is working by recording batch numbers when product enters storage, and again when it is shipped to the customer.

Good product record keeping is a key step in being able to conduct a product recall procedure, if it is ever necessary. Knowing when the a food item was manufactured and where it was distributed is essential to contain a recall to the fewest units possible. Every food manufacturer hopes that he/she never has to conduct a recall, but if and when the occasion arises, your recall procedure must be already set up to reduce the cost of revenues and PR associated with “something going wrong.”

Following all of the steps covered in this section of the workbook — or reviewing your steps (if you have been in business for a while) to ensure that you did not miss anything important, will help your operation run smoothly and provide peace of mind that you are doing all you can, to ensure that your product is the best you can provide. Quality sells, and producing and maintaining the image of a quality product should be every food business owner’s goal.
Food safety concerns start in the field where the “ingredients” are grown. Illness-causing microorganisms that were once unheard of have become more prevalent, and products previously considered safe are now causing an increasing number of illnesses each year. Even though fruits, vegetables and herbs were once thought of as “safe” products, they have recently come under fire as the causes of major food borne illnesses. These illnesses are primarily caused by bacteria, viruses, parasites, and fungi.

Beyond plant products, these microorganisms, often referred to as pathogens or biological hazards, are also associated with ground beef, poultry, eggs, and seafood. Cooking is a common method of easily killing most pathogens in those foods. However, since fresh produce is often consumed raw, other steps must be taken to ensure that both final products and ingredients are safe.

Good Agricultural Practices (GAPs) take into consideration that produce is exposed to naturally occurring, biological hazards in the soil, water, and air and that the potential risk for contamination is increased by certain production practices such as using manure for fertilizer and human handling of products.

It is incumbent upon all value-added and local foods producers/manufacturers to develop a safety plan that enables the management of the safety component of an agricultural operation by organizing the action steps identified as key to reducing key identifiable risks. Documenting of current practices and any changes over time is the first step that allows for monitoring the safety of the food product.

GAPs focus on four primary components of production and processing: soil, water, hands, and surfaces.

Soil—Maintaining “clean soil,” reduces the risk of contaminating the food grown in it with illness-causing microorganisms that naturally occur in the soil during stages of growth and harvesting. Improper manure management and application has the potential for increasing the populations of these microorganisms tremendously. It is important to remember that pathogens are found in ALL manure. Some pathogen levels in the soil will decrease over time due to competition from other bacteria in the soil or because of less-than-desirable conditions.
“Clean soil,” which minimizes the risks from manure, is attained by:
- Reducing the risk of physical contamination from rain or irrigation splash by incorporating manure or using cover mulch after application.
- Using high temperature, aerobic composting to reduce microbes
- Applying manure to cover crops in the fall.
- Applying manure in the spring two weeks before planting.
- Allowing 120 days or more between manure application and the harvest of fruit or vegetables.

**Water**—All water used for irrigation, cooling, processing, or for cleaning equipment and facilities should be free of microbial contaminants. Municipal water usually has the best quality because of previous testing and safety requirements, but it is rare for farms to have this water source. Ground or well water will have fewer pathogens than surface water (such as ponds, streams, or rivers) because there is less chance of contamination. By regularly testing water sources, an agricultural producer can document that water is not a source of contamination. The recommended frequency of water testing is dependent on the type of water source and the time of year. It is important to be more vigilant as harvest approaches and the water has increased contact with the product. The level of contribution that water has to product contamination also varies, based on the method and timing of water use. For example, use of drip irrigation (rather than sprinklers) helps to prevent water-based contamination because there is less soil splash.

**Hands**—There is a human element involved in food safety during production and processing, referred to as “clean hands.” Poor worker hygiene and health, unclean clothing or shoes, or unsafe practices can threaten food safety. The farmer must provide clean and appropriately stocked restroom and hand washing facilities to field and processing employees, to reduce the incidence of product contamination. Skimping on restrooms, or not effectively training workers in their use, results in unnecessary product contaminants in the field.

**Surfaces**—Food items will have physical contact with many surfaces (including harvest equipment and containers, transport bins, knives and other utensils, sorting and packaging tables, product packaging, and storage areas) during harvest and processing. Basic GAPs to help ensure clean surfaces are:
- Keeping potential contaminants (i.e., soil and manure) out of the processing area or facility.
- Discarding soiled produce in the field and damaged produce prior to processing.
- Using plastic containers and totes that can be routinely, efficiently cleaned and sanitized.
- Cleaning and sanitizing equipment and facilities daily.
- Including a sanitizer in produce rinse water to reduce bacteria.
- Controlling animal contamination (from pets, wildlife, birds, insects, and rodents).
- Developing guidelines for product storage and transportation.
Identify Your GAPs/GHPs Exposure

Whether you are an agricultural producer, or the manufacturer of a food product that depends on local inputs, the agricultural and harvest practices that are used have potential to increase the risk to your business. Take time to consider how much the GAPs and GHPs related to the ingredients you use will impact on your business. Describe this impact in the space provided:
If you are an agricultural producer, you will need to create a Food Safety Plan. Use this grid to begin taking the steps toward that important document.

<table>
<thead>
<tr>
<th>Action Step</th>
<th>What does this mean for your farm?</th>
<th>Potential Level of Risk: Low, medium, or high?</th>
<th>Amount of time/resources needed to do this step:</th>
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<td>Identify each distinct fruit, vegetable or herb that you will grow for value-added products.</td>
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<td>List the steps you take, from preparation for planting to post-packaging of product</td>
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<td>Identify the areas where product quality and food safety may be affected</td>
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<td>Identify how you can measure or monitor each risk factor identified</td>
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<td>Identify the way your practices need to change to eliminate or reduce the risks identified</td>
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<td>Assess the costs (financial, time, etc.) of each of these practice changes</td>
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<td>Take time to document all steps of the changes, including former practices, the changes that were made, and how you plan to measure/monitor the potential risk</td>
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<td>Plan to do a yearly update during the off-season, of all monitoring records to figure out how to change what you do in subsequent years to make your food safety plan work for you.</td>
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</table>
List here your top 3 sources of risk associated with GAPs and GHPs, and then identify 1-2 strategies to manage each of these:

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<th>Risk 1:</th>
<th>Strategy 1:</th>
<th>Strategy 2:</th>
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<th>Strategy 1:</th>
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<th>Risk 3:</th>
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Identify the one strategy you will use in the next 6 months, and list 1 step you will take to implement that strategy:

Strategy 1:

Step 1:
Hazard Analysis Critical Control Points (HACCP) is a useful tool in the prevention of food safety hazards. HACCP is not a stand alone program—instead, it is only one part of a multi-component food safety system. Other parts must include: good manufacturing practices, sanitation standard operating procedures, and a personal hygiene program (similar to the GAPs and GHPs discussed previously.

In the past, periodic plant inspections and sample testing were used to ensure the quality and safety of food products. Inspection and testing,. However, these spot-checks were like a photographic snapshot, because they provided information about the product that was relevant only for the inspection or testing time. They did not cover what happened before or after, so these traditional methods offered little production or assurance from a public health and safety point of view.

HACCP was introduced as a system of continuous control in food safety as the product is manufactured, rather than trying to detect problems by testing the finished product. This new system is based on assessing the inherent hazards or risks in a particular product or process and designing a system to control them. Specific points where the hazards can be controlled in the process are identified.

Since its inception, HACCP has shown itself to be a system that fits well with modern quality and management techniques — in addition to supporting the consumer expectations of safe food. It is especially compatible with the ISO quality assurance system and Just-in-time delivery of ingredients. Because of HACCP, manufacturers are assured of receiving quality products that meet their specifications, without having to conduct special receiving tests.

HACCP is incorporated in the food production process as follows:

- A flow diagram of the complete food manufacturing process is created, to identify hazards (biological, chemical and physical) that may pose an unacceptable health risk to the consumer. analysis.
- The significant hazards associated with each specific step of the manufacturing process are listed.
• Preventive measures (temperature, pH, moisture level, etc.) to control the hazards are also listed.
• Critical Control Points (that is, steps at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels) are identified. Examples would be cooking, acidification or drying steps in a food process.
• Critical, measurable limits of acceptability are designated for each of these CCPs and the ways to monitor them are assigned within the routine process for manufacture of the specific food. If the critical limit criteria are not met, the process is considered to be "out of control", because food safety hazards are not being prevented, eliminated, or reduced to acceptable levels, and the potential for business liability risk is increased.
• Monitoring of these CCPs is accomplished through a planned sequence of measurements or observations to ensure the product or process is in control (critical limits are being met). It allows processors to assess trends before a loss of control occurs, because adjustments can be made as the process continues, assuming the monitoring interval is adequate to ensure reliable control of the process.
• There must be pre-planned and written steps in place for disposition of the product and for correction of the process. If, for instance, a cooking step must result in a product center temperature between 165°F and 175°F, and the temperature is 163°F, the corrective action could require a second pass through the cooking step with an increase in the temperature of the cooker.
• The HACCP system requires the preparation and maintenance of a written HACCP plan together with other documentation. This must include all records generated during the monitoring of each CCP and notations of corrective actions taken. Usually, the simplest record keeping system possible to ensure effectiveness is the most desirable.
• After engaging the HACCP plan, there must be several verification steps taken:
  • The scientific or technical validity of the hazard analysis and the adequacy of the CCP's in ensuring food safety should be documented.
  • The effectiveness of the HACCP plan also needs to be gauged and documented.
• To be of the best effect, the system should be subject to periodic revalidation using independent audits or other verification procedures.

By adhering to HACCP, a food manufacturer has a continuous and systematic approach to assure food safety, and thus reduce liability. As additional food safety related incidents occur, there is a renewed interest in HACCP from a regulatory point of view. Both FDA and USDA have proposed umbrella regulations which require HACCP plans of industry. As a small food manufacturer, you will do well to adopt HACCP approaches to food safety whether or not it is required for your specific venture.
Identify Your Food Production Risks

For every food product, there are specific points at which some oversight, testing, and recording of results would be warranted. Consider how HACCP applies to your food venture, and describe how it might reduce risk. Then evaluate who will take the lead in incorporating HACCP — you, your suppliers, and/or your co-packer. Write what you have discovered in the space below:
Regardless of who will be in the key position to develop and adopt HACCP for your food product, it will be important that the standard steps are taken to put an effective food safety monitoring system in place. Use the following grid to consider and launch an appropriate HACCP plan for your food venture.

<table>
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<tr>
<th>Action Steps</th>
<th>Who will do this</th>
<th>Timetable for adoption</th>
<th>Likelihood of business risk: Low, medium, or high?</th>
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<tr>
<td>Create a flow diagram of the food manufacturing process.</td>
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<tr>
<td>Identify the CCPs (steps at which control can be applied and a food safety hazard can be prevented, eliminated or reduced to acceptable levels).</td>
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<td>Identify preventative measures that can be taken for each CCP.</td>
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<td>Identify all specific measurements or observations needed to ensure the product/process stays in control.</td>
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<td>Identify how the measurements or observations will reveal trends that may require changes to the process.</td>
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<td>List the definite steps that must be taken for disposition of the product and for correction of the process (if errors are found).</td>
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<td>Create a simple recordkeeping system to keep track of all HACCP actions.</td>
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<td>Build ways to gauge that HACCP is working, and that the CCPs are appropriate to the product or process.</td>
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Strategies to Manage Food Safety Risk

We have discussed that there are several ways that HACCP is part of a food venture. A food manufacturer can take the responsibility him/herself, studying the process, conferring with experts, and developing the flow diagram and resulting plan. In other instances, the control for HACCP will be with the supplier of ingredients, or with a co-packer who manufactures a packaged product. What strategies will you need to use, in order to assure that your food product is safe for consumers?
List here your top 3 sources of HACCP-related risk, and then identify 1-2 strategies to manage each of these risks.

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Identify the one strategy you will use in the next 6 months, and list 1 step you will take to implement that strategy:

**Strategy 1:**

**Step 1:**
Every producer of a value-added product should carry product liability insurance. If you are planning to produce the product in your home kitchen, you first need the kitchen inspected and approved by the Pennsylvania Department of Agriculture (PDA). Your current home owner’s policy carries no product liability insurance so you will need to purchase a commercial or business policy and you may wish to add additional product liability insurance. Most business, commercial, or farm owner’s policies include a minimum coverage level of $300,000 protection. Food product liability insurance only covers claims of injured parties and not any costs incurred for a product recall. There are several types of products to cover these expenses and others. More information about these products is covered in the Insurance Coverage Options for Fresh Produce Growers fact sheet from the North Carolina State University A & T which is contained in this informational workbook. When purchasing any insurance, you should consider the level of coverage based on what you are willing to pay out to satisfy a claim awarded to someone. You should then cover the remainder of your assets with an insurance product.

The premium for product liability is based on several factors. If you are just beginning, you will need to estimate the amount of sales you will have during the year. The more sales you have or predict, the greater the premium. It will not benefit you to underestimate this figure to reduce premiums. In the event of a claim, your insurance company will audit your records and any discrepancy may reduce coverage. If you have been in business, you can use your sales history to determine this figure.

There is an experience factor when pricing a product liability policy. This means that if you do not have several years of experience your premium may be higher than someone with three or more year’s experience. This is because insurance companies determine that experience reduces risk, much the same as insurance for a young driver is higher than for an older more experienced driver. Most policies for food manufacturers contain $300,000 product liability coverage. If you determine that you need additional coverage, it will cost an additional 3% on average to move to $500,000 coverage. This increase in coverage may be necessary depending on your situation. If you determine that $500,000 is not enough coverage for your business, the average increase to move to $1M is 10% more than the initial $300,000 coverage level. Many farmers markets are now requiring this $1M coverage level before you can participate at the market. Some producers are also increasing coverage to more than $1M.
There are many items you will need to provide to your insurance agent to allow that person to adequately assess your insurance needs. These include the following:
* The entity description
* Address including post office box
* Locations of operations and satellites if any
* Additional individuals/entities insured with addresses and their interests
* Loss Payees & Lien-holders
* Mortgagees
* All available phone numbers & contacts
* Values of product, buildings, stock, vehicles
* List of all licensed operators of vehicles with pertinent information
* Written description of operation
* Radius of operation
* Fire & Burglary Protection
* Number of employees & work experience
* License information & safety certificates
* Estimated gross receipts

Another method of reducing risk when producing a food product is your business structure. You may think that when just starting the enterprise that you can operate as a sole-proprietorship to reduce start-up costs. This may be an acceptable business structure for a business with less inherent risks however; a food based business carries a higher level of risk than producing a crop. You will be taking steps to process raw products and ingredients into a finished product and each step increases your level of risk. Because of these additional levels of risk, you should consider a business structure that may reduce the risk exposure to your personal assets. Consult your accountant and legal advisor to determine which structure best fits your operation.

There are three types of claims a food manufacturing company may face because of someone becoming injured from a product. These are:
* Manufacturing or production flaws. This claim will state that some part of the production process created an unsafe defect in the final product. An example of this type of claim may be that a piece of glass was present in a product you produced and could harm a consumer if ingested.
- Design defect. This claim states that the design of the product caused someone harm. An example of this claim may be that your product or packaging design harmed a consumer.

- Defective warnings or instructions. This claim states that you failed to warn your consumer that something in the product may harm them. An example of this claim would be that you used tree nuts or peanuts (or other allergen), in the ingredients and did not include a warning on the product label.

Pennsylvania laws follow the “stream of commerce” model of liability. This means that anyone placing any component of a product into the stream of commerce is liable in the event of damages. The person who grew the raw product, the person who added value to the raw product, and any business that produced any of the inputs are liable. However, the business that combined the raw product and all other inputs is the most liable since that business created the end product. If you are producing a baked good, the person who grew the wheat will be listed in court documents but that person’s level of liability will be smaller than yours because you processed the final product.

When producing a food product, there are requirements of what must be included on the label. You must follow these requirements and you may consider adding other elements that may reduce your risk level. You must list ingredients, nutritional information, size (net weight for example), and the company’s name. There are additional items that may be included that will reduce your risk exposure.

For example, if your product contains any peanuts or peanut oil, you should include an allergy warning on the label. This will show that you attempted to inform the consumer that an allergy attack is possible. You should research all possible allergies and your ingredients to determine what you may need to include. We have all seen the warnings on hot beverages due to the McDonalds™ incident with coffee. These warning will at least demonstrate “good faith” to warn consumers of possible injury causing possibilities.

Your record keeping system for tracing a product back to the date it was produced is also a key item in risk management. When you discover that a food product may be contaminated, being able to trace that item throughout the entire process from production to consumption will be invaluable. You may be able to recall only that batch of product thus reducing the amount of potential consumers injured by your product and product destroyed. Being able to trace back products may reduce the risk level for your business.
There are many court cases that have been argued against food manufacturers. These cases provide many scenarios for attorneys to use to prove damages to their clients. Under strict liability the product itself is the focus and the manufacturer is liable for all processes involved in making that product. If the product is defective or contaminated the producer of the product is liable even if they are not negligent while making the product.

Because of all the issues mentioned above, you should not operate without product liability insurance and a comprehensive risk management plan. You should tell your insurance provider before you begin a food based business. You will need to work with that person to determine your level of risk exposure and how you want to protect your personal assets. Having protection in place before it is needed is always the best procedure. The best business people know that insurance is an integral part of doing business. Insurance will be in the top five items of your yearly expenses however, doing business without insurance coverage is not recommended.
Develop Your Plan to Address Product and Business Liability

To develop your risk management plan, you need to identify the legal actions that you need to take for your food venture. Once you have a clear picture of what needs to be done to reduce legal risk, you can identify the tools you’ll use to address the risks.

<table>
<thead>
<tr>
<th>Action Steps</th>
<th>Describe risk to your food venture, if not done/gotten</th>
<th>Potential Legal Exposure: Low, medium, or high?</th>
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</thead>
<tbody>
<tr>
<td>Compliance with PDA and FDA food regulations.</td>
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<tr>
<td>Adequate/appropriate Insurance coverage for your products and activities</td>
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<tr>
<td>Appropriate business structure to address the business and product related risk.</td>
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<tr>
<td>On-going monitoring of manufacturing/production integrity</td>
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<td>Identification/creation of design problems/defects</td>
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<td>Inclusion of appropriate consumer warnings</td>
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<tr>
<td>Ability to trace a product back to the date it was produced /harvested</td>
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**Strategies to Manage Legal Risk**

Having adequate insurance, keeping vigilant about court decisions related to food liability, and ensuring that your business structure is effective are all ways to manage your legal risk. Which one will be the most important to your business, and why?

How does your legal strategy interface with any of the other four areas (GAPs/GHPs, HACCP, allergen notification, and proactive recall planning) that were discussed in the workshop?
List here your top 3 sources of legal risk, and then identify 1-2 strategies to manage each of these risks.

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Identify the one strategy you will use in the next 6 months, and list 1 step you will take to implement that strategy:

**Strategy 1:**

**Step 1:**
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Food Allergens

Food allergic reactions can range from mild oral symptoms to severe anaphylactic shock in which multiple body systems react simultaneously. An estimated 30,000 episodes of food related anaphylaxis occur each year in the U.S., resulting in approximately 2000 hospitalizations and 150 deaths.

The main preventative recommendations for people with food allergies are to carefully read product labels and carry medications in case of a reaction. Therefore, it is extremely important that product labels be accurate and credible. The Food Allergen Labeling and Consumer Protection Act of 2004 (FALCPA) required that the top eight allergens be bolded on food labels or be listed in a “contains (allergen)” statement at the end of the ingredient list. A 2008 Eastern Michigan University study showed that, in the two years immediately after the FALCPA was passed, the annual accidental food allergen ingestion rate of adults decreased by a significant 24.4%. Additionally, the percent of accidental food allergen ingestion events due to store-bought food decreased. Therefore, food manufacturers should be diligent about indicating the presence of any of the top eight allergens in their products — not only because of the law, but also because of the effectiveness of these notices in reducing consumer allergy incidents.

The eight (8) major food allergens include:

- Milk
- Eggs
- Peanuts
- Tree nuts (like walnuts or pecans)
- Fish
- Shellfish
- Wheat (this includes gluten)
- Soy

To reduce the risk of individuals accidentally consuming any of these, it is important to not only list their presence when they are an intended ingredient in a food product, but also to test food products that have been made in the same kitchen where other foods with these allergens were made, or when the same equipment has been used to make other foods which do contain one or more of the above allergens.
In general, allergen warnings must be put on all foods even if the products that carry these allergen risks are listed in the ingredient list. The allergen warning must say: Warning: this product contains foods that may cause an allergic reaction. This product contains (name product/s). If a food product is made from ingredients manufactured by another supplier, the labels of prepared ingredients must be checked, and applicable allergen alerts must be included on the resulting product’s label.

As an example, Nut Warnings must be put on: any food containing nuts or nut derivatives (including almond extract, peanut oil, walnut oil or other nut oils). These warnings must also be placed on the package of any food that has been prepared with chocolate or other prepared food that has a nut warning on it (e.g. cookies prepared with M&Ms in them OR any food that has been prepared in the same kitchen at the same time foods with nuts were prepared (e.g., one batch of brownies was made with nuts, the other without). In all these instances, the Nut Warnings must say:

Warning: This product contains ground nuts or tree nuts or ingredients derived from nuts. OR

Warning: Nuts. This product was made in the same facility as other products containing nuts or where nuts are handled. (ONLY if there are no nuts directly in the product.)

The resulting Sample Label of such a product would read:

Chocolate Chip Cookie
Ingredients: Wheat flour, sugar, butter, vegetable shortening, eggs, chocolate (contains cocoa solids, cane sugar, lecithin, vanilla), pure vanilla extract, salt.

Warning: This product contains foods that may cause an allergic reaction. This product contains wheat, milk products, eggs, and was made in the same facility where products containing nuts were made or where nuts were handled.

In relation to strict liability, case law suggests that, although restaurants are generally not liable for failing to warn food allergic consumers about the presence of allergens in restaurant food, those same restaurants may have some duty to warn consumers about food allergens. Section 402(A), comment j, of the Restatement (Second) of Torts has been adopted by courts:

In order to prevent the product from being unreasonably dangerous, the seller may be required to give directions or warning, on the container, as to its use. The seller may reasonably assume that those with common allergies, as for example to eggs or strawberries, will be aware of them, and he is not required to warn against them. Where, however, the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known, or if known is one which the consumer would reasonably not expect to find in the product, the seller is required to give warning against it, if he has knowledge.
Therefore, it is important for all food manufacturers and restauranteurs/caterers to:

- Carefully review the ingredients of their products, noting the intentional presence of any allergens.
- Design warnings (on packaging or in menus) that ensure that these ingredients are known by consumers, so that they can make an informed selection.
- Carefully assess products that do not, in themselves, have an allergen as an ingredient, to determine whether they still might come in contact with equipment, or facilities, where the allergen is present.
- In cases where food might have unintentional allergen content, it is important to test the product for residue (using a standard enzyme-linked-immunosorbent-assay (ELISA) process) and notify the public that the product “is made in the same facility where (named allergens) are present.”

In this way, food business risk is lessened, through clear consumer information, and your profile as a vigilant, caring manufacture is enhanced.
**Develop Your Allergen Notification Plan**

To develop your allergen notification plan, you need to assess your food product(s) for the intentional use of any of the 8 food allergens. You need to check with suppliers for the contents of their items that you include in your food products. You also need to assess your facility, equipment, and practices to determine whether unintentional allergen content may be in the food that you sell. Which of these sources of allergen will be the most significant one for your product(s)?
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<td>Determine if the Food Allergen Labeling and Consumer Protection Act (FALCPA) applies to your product(s)</td>
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<td>Evaluate your food products for presence of any of the 8 allergens</td>
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<td>Evaluate your food process for “hidden allergens” which are part of a food item</td>
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<td>Evaluate your cooking processes for possible cross-contact</td>
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<td>Develop a labeling plan to make clear what allergens are present</td>
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<td>Separate non-allergen foods from those that contain allergens in storage</td>
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<td>Improve sanitation protocols and train all staff</td>
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<td>Qualify your suppliers; ask them to label the items with allergens and include that info on the spec sheets</td>
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Strategies to Manage Food Allergen Related Risk

The amount of risk associated with allergen-related incidents continues to rise for food ventures. Regardless of whether a business creates packaged products (where the allergens must be acknowledged in writing) or serves ready-to-eat items that may contain allergens (as a restaurant or caterer), it is incumbent upon the food manufacturer to make sure that contents or contact with any of the 8 allergens is clear to the consumer. How active do you believe that you will need to be, in identifying and dealing with allergens?
List here your top 3 concerns related to food allergen risk, and then identify 1-2 strategies to manage each of these risks.

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Identify the one strategy you will use in the next 6 months, and list 1 step you will take to implement that strategy:

**Strategy 1:**

**Step 1:**
The term “food recall” can mean a wide variety of activities — but in essence, it is any corrective action by a company needed to protect consumers from potentially adverse effects of a contaminated, adulterated, or misbranded product. Recalls are voluntary actions, initiated by a recall decision made by the company management. In some cases, if the company does not initiate a recall, the government agency responsible for the particular product category may request that the company do so. Recalls are conducted by industry in cooperation with federal and state agencies.

No food business hopes for a recall. By employing Good Manufacturing Practices (GMP) and Hazard Analysis Critical Control Points (HACCP) plans, businesses seek to prevent recalls. However, even the best managed businesses can make occasional mistakes. It is important to be ready for a recall well before a problem occurs, with company management integrated into the recall plan and team. It is not enough to just rely on product liability insurance! While liability insurance might cover a portion of the losses due to recall, it will not cover the expense of product retrieval and most importantly, liability insurance will not help the company regain one of its biggest assets for sustainability — customer trust.

Despite the undesirable nature of a recall event, it is in the best interest of the manufacturing company to complete the recall quickly. Because the manufacturer is responsible for all of the costs involved in this process, it is critical to have a plan to cover recall expenses, to expedite the process without creating negative public opinion, and to prevent down time. How this all will come about should be well-thought-out ahead of time, because when crisis hits, it is too late to work on the recall plan. Generally, recall events should be included in the Crisis Management and Emergency Contingency Program for a company (a document that few businesses seem to have).

Factors prompting a food recall include but are not limited to:
- unsafe, contaminated, or mislabeled product,
- nonconformities to manufacturer’s specifications, and
- missing allergen or other hazard warnings.
Although a recall may be perceived as a failure, as long as a proactive, rather than reactive, approach is taken, the company’s reputation can be recovered and even improved as they demonstrate a commitment to consumer safety and service. The recall process includes withdrawal of an unsafe or substandard product from the market and distribution channels, as well as the return of already purchased product from consumers. Rapid removal of products from the market requires a well-documented product code and tracking system be in place. The need for a recall is determined by the potential health hazards of a product, and the extent of recall is implemented according to the classification of hazard.

Starting from the year 2000, USDA requires a press release to be issued for every recall even if the product had not yet reached consumer channels. To notify the public in the event of a product recall, the press release and the Recall Notification Report are posted on web sites maintained by federal agencies, as well as state health agencies.

**Purpose of a Recall**

A company’s food safety policies, ethical understanding, regulatory requirements, and financial constraints all determine the recall concept that is adopted. An effective recall procedure will protect not only the consumer, but also the company. A smooth recall process can save a company’s name and prevent further damage due to negative publicity. Destroying, replacing, or altering the product are the three main corrective actions. A recall plan should strive to achieve the following goals:

- Protect consumer health
- Comply with existing rules and regulations
- Minimize the cost of the recall
- Regain and improve the company’s reputation

**Outline of a Successful Recall Process**

Although each business may have variations on who does what activities within the recall and how the process will be carried out, all successful recalls have these things in common:

- **Planning ahead**: A successful recall process depends on planning of the recall management well before a problem occurs.
- **Acting quickly**: The sooner harmful or misleading events are prevented, the faster the negative publicity and financial burden are eliminated.
- **Effective communication during a recall**: The firm should immediately provide recall instructions to everyone in the product distribution channels.
- **Recall assessment**: Post-recall assessment is extremely important in determining the effectiveness of the recall plan in order to improve the efficacy of potential future recalls. The current recall plan also should be evaluated through simulated recalls.
What can you do to be prepared for a recall?
The actions necessary to be ready to implement a recall are:
• Select a recall coordinator and establish a recall committee.
• Prepare a recall action plan.
• Keep the contact information in the recall plan up-to-date.
• Conduct mock recalls to test the effectiveness and promptness of the recall plan.
• Revise the recall plan based on mock recalls.
• Establish a product identification and tracking system.
• Conduct timely stock rotations, and maintain good records for the supplied products, invoices, and bills for purchased and sold products.

Develop a customer inquiry and complaint database to identify major problems. The questionnaire for collection of information from consumers should be designed to get as much information as possible regarding the problem. The frequency of the calls related to the same problem should be recorded. To be able to implement the necessary actions in the event of a recall, you need to have a well-considered recall plan.

What should you include in a recall plan?
A recall plan is prepared in order to act quickly and effectively to locate the product, to remove the product from the market, to quarantine the product, to identify and to correct the root cause in order to prevent recurring, and to reassure the consumers about the establishment’s commitment to consumer safety. Therefore, the recall plan should describe in detail the procedures that the establishment will follow and the responsibilities of individuals during the recall. The recall committee selected and managed by the recall coordinator prepares the recall plan.

A recall plan should include the following items:
I. **Purpose**: This step includes statements defining the company objective for preparing the recall plan. It should define the scope of the products covered under the recall plan. As a starting point, all products produced under a single HACCP plan, including cleaning and sanitation procedures, could be included in the recall plan. The scope of the recall may expand or contract from this point.

II. **Definitions**: In this section, the terms related to the recall and the level of recalls are defined. The terms include: recall, market withdrawal, stock recovery, recall classification, class I, class II, and class III recalls.

III. **Responsibilities**: The roles and responsibilities of every individual participating in the execution of the recall should be clearly specified in the recall plan. The recall plan should include all current contact information (office and home telephone numbers, fax numbers, mobile phone numbers, e-mail addresses) for members of the recall committee and their deputies and should be updated frequently.
iv. Fact gathering about the defective product:
   A. Internal discovery: A defective product may be spotted internally (company plants, warehouses, co-packers). The seriousness of the problem should be rapidly evaluated by the plant manager and the quality assurance manager in the plant and/or the supply chain. If the problem is considered to be serious, the recall coordinator should be alerted immediately.
   B. External discovery: Every complaint about a product should be investigated by consumer services, sales and marketing department, and regional technical management to evaluate the seriousness of the problem. If the problem is judged to be serious, or even if there is an element of doubt, the recall coordinator should be alerted immediately.
   C. Health hazard evaluation and recall classification: The recall plan should state the potential defects and hazards for the products in scope of the recall plan and the corresponding recall class. At a minimum, this evaluation should take into account whether any disease or injuries have already occurred from the use of the product, an assessment of how serious the health hazard is, an assessment of the immediate and long-range consequences of the hazard, and an assessment of the ability to identify and quantify the defective product in the marketplace.

v. Identification of the regulatory agency: After the recall coordinator makes the decision to initiate the recall, he or she contacts the regulatory agency. Therefore, the contact information for the individual in the appropriate regulatory agency should be included in the recall plan. The recall coordinator provides the Product ID (name, code number, lot number, size), the reason for recall, how the problem was discovered, the quantity of product that was manufactured and distributed, the distribution records for the affected product, a copy of any recall communication that has been issued, the recall strategy and depth, and a public warning.

vi. Recall communications: Appropriate and effective communication during recall is essential for a successful recall process. The recall plan should include a generic press release, a generic communication letter for affected affiliates, information specifying how contact will be made with media, and a name and contact info for the designated spokesperson.

vii. Recall status reports: The recall plan should include a policy to document the number of consignees notified, number of responses versus non-responses, and quantity of product accounted for, all of which are necessary for recall effectiveness checks.

viii. Not Returned product: The recall plan should include the following statements to clearly define the strategies regarding the returned product:
   - Returned products will be quarantined until the termination of the recall.
   - Quarantined products will be reprocessed or disposed of after receiving the approval of technical management.
   - FDA will be notified for approval of planned method of disposition because FDA may wish to witness final destruction of Class I articles.
ix. **Recall termination:** The recall plan should clearly define the policy to be implemented to end the recall process.

x. **Appendices:** The suggested appendices include a press release template and a sample press release from FDA, a product withdrawal for template, and the recall plan flow sheet.

Once a recall plan is established, the recall team should conduct practice or “mock” recalls to ensure the plan’s effectiveness and to detect pitfalls in the plan. Mock recalls should be conducted without prior knowledge of the personnel involved. A mock recall assesses the recall team’s ability to use the plan to conduct a review of records related to processing, raw product, ingredients, and containers, and to determine the distribution of the product with the given lot code. Such exercises can also determine the distributors’ (including brokers) ability to locate product rapidly. If there are major problems or it is taking too long to obtain the necessary information, it is strongly suggested that the recall team get help from external organizations and/or consultants.
**Develop Your Product Recall Plan**

The entire food manufacturing process is centered around a series of activities that should lead to quality, safe products. However, sometimes things get out of control, and a faulty batch, or erroneous labeling may occur. When that happens, it is important to protect the integrity of your company’s name and reputation by quickly owning up to the error and “making good.” Being able to act in an emergency is enabled by making plans ahead of time, and running drills to make sure that the plans are sound. Think about the actions that you can take, now, to be ready for the unexpected, and jot them down here.
When a recall must occur, it is just as important that WHO will be involved is known ahead of time as WHAT they must do to resolve the problem. Use the chart below to identify the people involved, and the areas they represent.

<table>
<thead>
<tr>
<th>Area Represented</th>
<th>Primary Member (Name, Title, Phone#)</th>
<th>Alternate Member (Name, Title, Phone#)</th>
<th>Function during a Recall</th>
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<td>Recall Coordinator</td>
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The Flowchart for Recall Related Emergencies

This flow chart can be used to ensure that a logical pattern is followed in the event of an emergency:

RECALL PLAN FLOW SHEET

1Internal finding or external complaint
List here the top 3 sources of risk most apt to result in recall within your business, and then identify 1-2 strategies to manage each of these risks.

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**Step 1:**