Developing a Food Safety Plan for Acid/Acidified Foods

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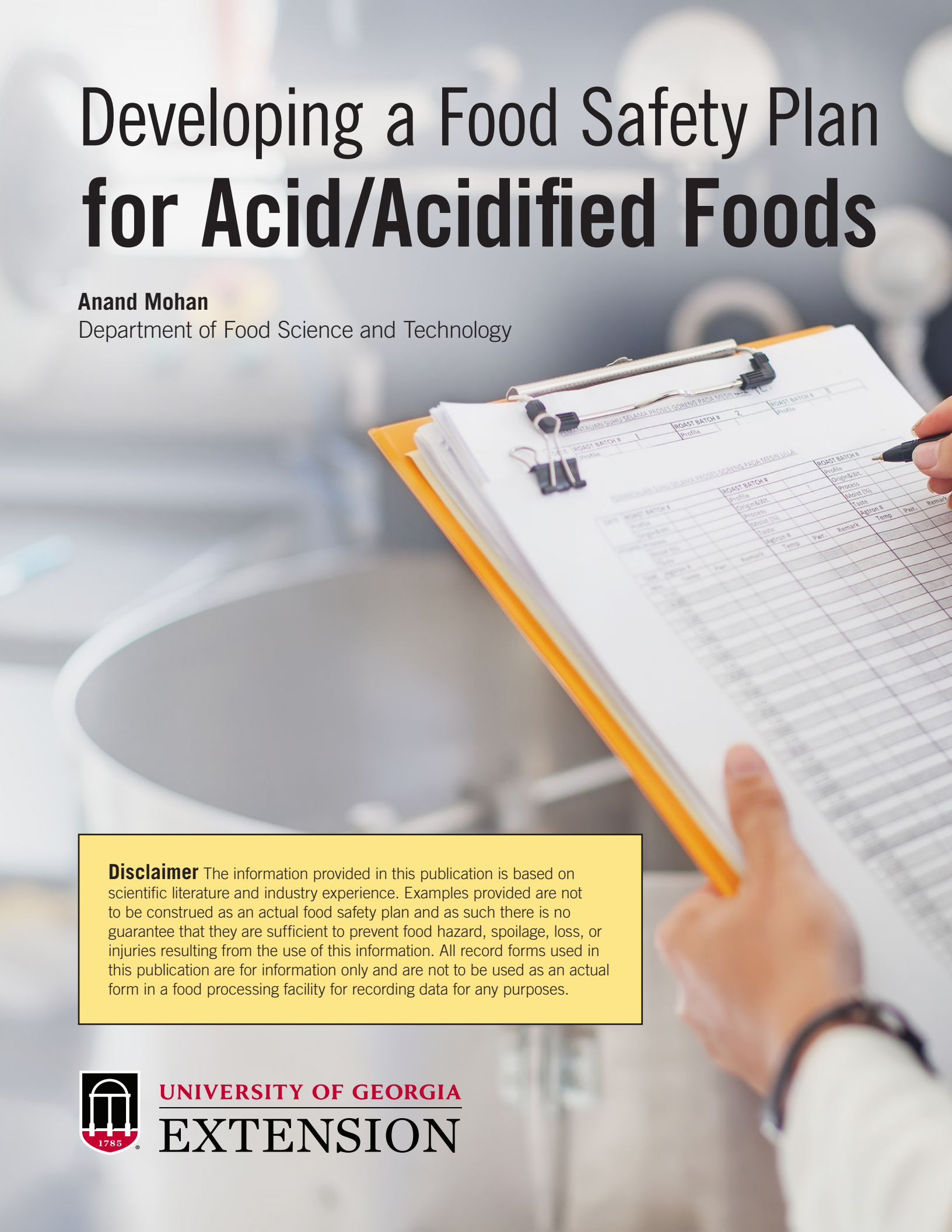

Disclaimer The information provided in this publication is based on scientific literature and industry experience. Examples provided are not to be construed as an actual food safety plan and as such there is no guarantee that they are sufficient to prevent food hazard, spoilage, loss, or injuries resulting from the use of this information. All record forms used in this publication are for information only and are not to be used as an actual form in a food processing facility for recording data for any purposes.

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Part I: Understanding the Food Safety Hazards Associated with Producing Acidified Foods

Creating a Food Safety Plan

The key to an effective food safety plan is to prevent occurrence of food safety hazards in the first place. Each hazard either will have a preventive control or it will be considered a critical control point. This food safety plan incorporates these principles by using a simplified multistep food safety plan for each hazard that may be encountered when producing acidified foods. Each hazard will have one of these four–step basic processes for creating a food safety plan.

For Preventive Controls

For Critical Control Points

Preventive Controls/Critical Control Points

Hazard	Preventive Controls	Critical Control Points
Allergen cross–contact	Allergen control program	
Contaminated raw ingredients	Supplier verification procedures	
Physical contamination of jars	Inspect jars before filling	
Pest infestation	Pest control program	
Pathogenic spores/bacteria		Cook time/temperature
Pathogenic spores/bacteria		Hold time/temperature
Pathogenic spores/bacteria		Acidify to a pH less than 4.6

Monitoring

When implementing preventive control measures, specific parameters MUST be established to prevent the occurrence of identified food safety hazards in acidified foods. For example:

and for each critical control point, critical limits are established. They must be followed and monitored with the production of each batch. Each hazard will have a detailed monitoring form that should be filled out every time the product is produced, without exception. Detailed records are needed to determine if the food safety plan is working, and to protect yourself and your customers in case of an issue.

Corrective Actions

Corrective actions may be necessary when there is a deviation from any preventive control or critical control point. The processing authority should determine the appropriate corrective action, and detailed records should be made whenever a corrective action is taken.

Allergen Cross–Contact

Hazard

If a facility produces allergen–containing foods and allergen–free foods, there is a risk of allergen cross–contact. Any food that comes in contact with an allergen, but is not labeled as containing it, can cause a serious health risk to consumers with an allergy.

Preventive Controls

Allergen ingredients or products should have an obvious label and be physically separated from allergen–free products. Allergen–free products should be produced before products containing allergens, or there must be cleaning sufficient to remove allergens between their production. After cleaning, allergen swabs should be used to make sure the cleaning was sufficient. Tools should be cleaned or separate tools should be used to produce food free from allergens. All food containing allergens must be labeled.

Monitoring

The specific parameter for allergen cross–contact will be the maximum allowable levels of allergen residues on food processing surfaces after cleaning and before production. Allergens should be tracked from the time they arrive in the facility through storage and production. Allergen cleaning should be confirmed with results from allergen swabbing on the preproduction preventive control log.

Corrective Actions

If a product that is not intended to contain allergens may have come in contact with an allergen, it is a deviation from the process. It should be recorded on the deviation form and the product must be destroyed.

Receiving Contaminated Raw Ingredients

Hazard

There are several hazards that can be encountered when receiving raw ingredients. These include microbial contamination, chemical contamination (allergens, pesticides), physical contamination (pests, metal pieces), and receiving a different product than expected.

Preventive Controls

Finding a trustworthy raw–ingredient supplier who operates with transparency is important for preventing hazards with raw ingredients. To select a supplier, you should inspect their facility, review their food safety plan, verify their certifications, and review the product specification forms. You should also make sure you will receive a specification form and letter of guarantee with each load, and make sure the distribution and transportation will be clean and consistent.

Monitoring

Specific parameters for receiving raw ingredients include acceptable temperatures to receive the product; pH or water activity of raw ingredients; and maximum allowed levels of microorganisms, which will be verified by your supplier in the product specification forms and letters of guarantee. Fill out the raw material inspection form every time you receive products. Keep all of your letters of guarantee and product specification forms as records so that you can trace the product back to the supplier, production facility, and distribution facility in case of a problem.

Corrective Actions

Do not accept the delivery if the product does not meet your expectations and what you agreed on with your supplier. Return the product to the supplier and make sure they correct the problem before you receive another load from them. If they are unable or unwilling to fix the problem, you may need to find a new supplier.

Physical Contamination of Jars

Hazard

Empty jars can become contaminated with debris or filth such as broken glass, plastic, wood chips, metal pieces, or dirt. If physical contaminants are consumed, they can present a serious health hazard to the consumer through choking, breaking a tooth, or lacerations of the mouth, tongue, throat, or intestines. Physical contaminants such as dirt or insect pieces may not harm the consumer, but they are aesthetically undesirable and can harm a brand's reputation.

Preventive Controls

All jars should be visually inspected before filling. If necessary, they should be inverted to allow debris to fall out, or they may need to be washed.

Monitoring

The preproduction preventive control log will have an area for employees to initial and date to confirm that all jars were inspected and were clean.

Corrective Actions

If debris is found in jars, they should be washed before using. If jars are already filled and staff later realize that no one confirmed that the jars were clean on the monitoring form, discard the product.

Pest Infestation

Hazard

Pests including mice, rats, birds, and insects can infest a food processing plant. These pests can cause a biological hazard by bringing in bacteria and viruses, or a physical hazard by contaminating product with feces or body parts. Pests can also damage structural elements of the facility and equipment through chewing, which can lead to serious production losses.

Preventive Controls

A pest control program should be implemented in which a pest control company comes to the facility on a regular basis. The frequency with which the pest control company should come will be based on the size of the facility and past occurrences. The pest control companies or in–house employees should implement regular monitoring of pest traps. Visual inspection for evidence of pests should take place every day before production.

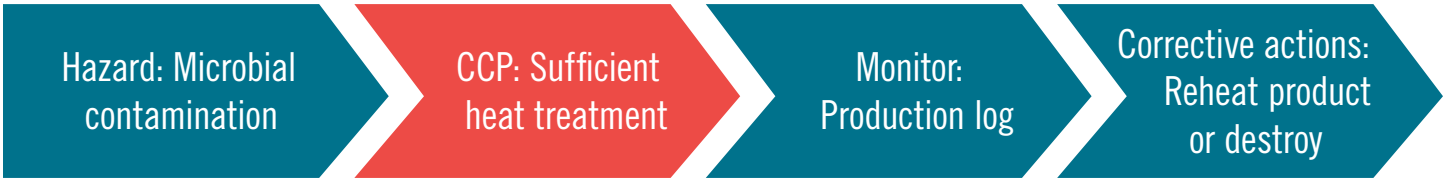
Monitoring

A record of each pest control visit should be kept, including when they came and what was completed during the visit. Regular checks of pest traps should be recorded with the results of what was or wasn't found. Before production each day, employees should visually check the processing area for pests and sign the preproduction preventive control log to confirm that no pests were sighted.

Corrective Actions

If a pest infestation occurs in an area not directly affecting food or food–contact surfaces, the pest control company should be contacted to determine the extent of the infestation and steps to take to eliminate the pests. If the pest infestation occurs in an area that affects food or food–contact surfaces, production should be halted. The pest control company should be contacted immediately to provide direction on how to eliminate the problem. If product was made during the infestation, it should be disposed of to avoid the risk of biological or physical contamination in the product.

Heat Treatment for Microbial Lethality



Hazard

Proper heat treatment will eliminate most microorganisms in a finished product. The minimum required temperature will depend on several factors, including the pH (a lower pH may require less heating). However, the container generally will require a minimum temperature of 180 °F to be sterilized, regardless of the product.

Critical Control Point

There are two general categories of heat treatment: direct (water bath or retort) and indirect (hot–fill–hold). Direct heating sterilizes the product and the container simultaneously, while indirect heating requires separate steps for sterilizing the product and the container.

Monitoring

The critical limit for heat treatment will be the minimum temperature that must be reached in cooking and the time the product must be held at that temperature. The production log must be filled out with the accurate time and temperature for each batch that is produced, along with the initials of the employee who is monitoring the process, date, and time.

Corrective Actions

Two types of deviations can occur with heat treatment: underprocessing or overprocessing. Overprocessing may affect the product quality, but won't be harmful to the product's safety, so it does not require a corrective action. Underprocessing means the product is not considered safe and will require a corrective action. If the process does not meet the minimum heat treatment specified in the scheduled process, immediately record it in the deviation log and then notify the processing authority or food safety manager. They will determine if the product can be reheated or if it needs to be destroyed.

pH Control for Microbial Lethality

Hazard

Acidified foods contain low–acid ingredients (pH > 4.6) that would allow for microbial growth if they are not properly acidified. The greatest concern for acidified foods is the growth of *Clostridium botulinum*, which can occur above a pH of 4.6 and will not be eliminated by heat treatment at the level required for acidified foods. Other microorganisms such as *Salmonella, E. coli 0157:H7*, and *Listeria monocytogenes* can grow at a pH below 4.6, but they will be eliminated by proper heat treatment. This is why a combination of heat treatment and pH control is important for the overall safety of your product.

Critical Control Point

Acidifying agents (vinegar, lemon juice, etc.) should be added to lower the pH to the level specified in the scheduled process to inhibit microbial growth.

Monitoring

The critical limits for pH control will be the minimum and maximum pH values allowed for the product after acidification. The production log should be filled out with every batch produced. Using a calibrated pH meter, measure the raw pH (pH taken before the acidifying agent is added) and the equilibrium pH (pH taken at least 24 hr after processing) and record them on the production log with the time, date, and employee's initials.

Corrective Actions

If the pH is above the target value specified in the process approval for that product, the product is unsafe and corrective actions are necessary. Add acidifier to bring the pH to the target level. All corrective actions should be recorded in the deviation log and the process authority or food safety manager should be notified. If the pH is below the target level the product is still considered safe, so corrective actions are not necessary.

Validation

The food safety plan must be validated to prove that it is effective. Find scientific data to support that the time and temperature used in processing are sufficient to make the product safe. This data may be provided by your process authority. Products also can go through microbial testing to make sure that the time and temperature used for processing is sufficient. Allergen plans can be validated by using allergen swabs to prove that the cleaning process is sufficient to remove all allergen residues.

Reanalysis

The plan should be reanalyzed:

- At least once every 3 years
- Whenever a major change is made in processing, equipment, or product formulation
- Whenever there is new information about a hazard related to acidified foods
- Whenever deviations occur that indicate the preventive controls are ineffective

Even if changes are not made to the food safety plan, the reanalysis should still be documented to demonstrate that reanalysis was conducted and all information was considered to decide that the plan is still effective.

Part II: Sample Forms and Documents

Preproduction Preventive Control Log

Instructions: For each production day, check each item and fill out the corresponding column.
✓= acceptable, X= unacceptable, NA= not applicable.

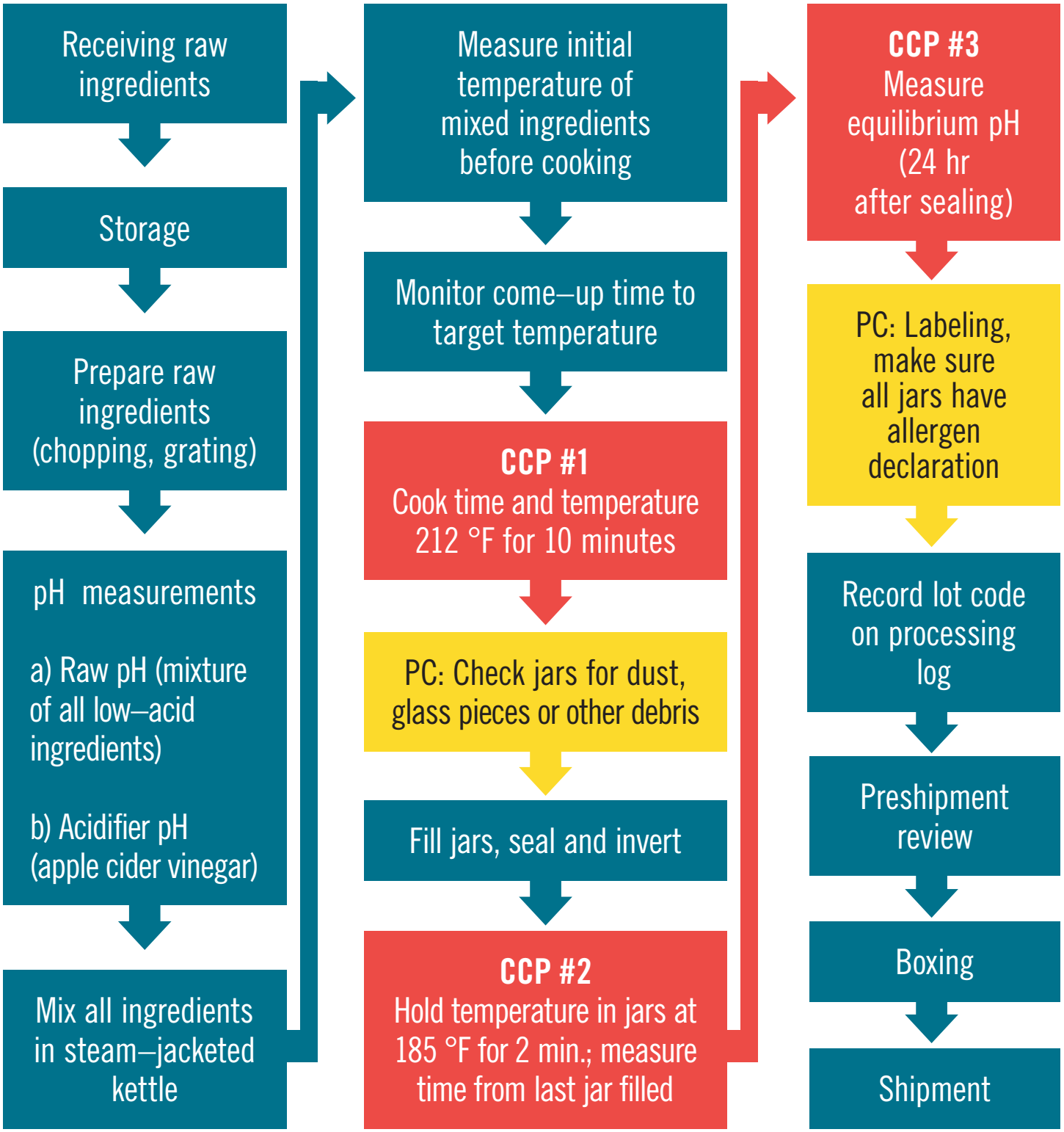
Product Made:	Lot Code/Batch #:		Date:
	Acceptable?	Comments	Initials
Equipment and utensils are clean and sanitary			
Tables and sink surfaces in the assigned work station are clean			
Visually inspect production area for pests			
Indirect food–contact surfaces (floors, cooler, etc.) are clean and in good working order			
Ingredient storage areas are clean and maintained to prevent cross contamination			
Jars have been checked for debris or filth			
All jars have been labeled with allergen declaration			
Employees have hair nets, smocks, and beard nets (if necessary)			
Employees that are handling food do not have an illness or open/infected wounds			
Has all equipment (pH meter, thermometer) been properly calibrated?			
Has allergen cleaning been completed with allergen swab results negative?			

Raw Material Inspection Form

Upon arrival of a delivery truck, stop the driver from unloading until you check through this list. As soon as the product has been unloaded, the product can no longer be rejected. Check yes or no for each question and make any necessary comments. Initial each column.

	Yes	No	Comments	Initials
Did the driver arrive within the expected time frame? *If not, then note how long the product has been on the truck*				
Do the ingredient specification forms match the product you are expecting?				
Do the specification sheets list the location of manufacture and distribution that you agreed upon with the supplier?				
Do you have the letter of guarantee for the product that you expected?				
Does the truck look clean inside?				
Is the product in the packaging that you agreed on with the supplier?				
Are all product containers in good condition (not broken or leaking)?				
If temperature–controlled items are being delivered, are they within the acceptable temperature range? *Note the temperature in the comments*				
Is the truck sealed or padlocked? *Note seal number in the comments*				
If you answered no to any of the above, notify the food safety manager or process authority before accepting the product.				

Sample Process Flow Diagram for Vidalia Onion Relish



NOTE: This process flow chart is provided only as an example and is not to be used or construed as applicable to any similar of different product. The use of specific times and temperatures are for example only.

Production Log

(Product Name)		Processing Log for _____(date)	
Lot code/batch #:	Quantity processed in this batch:	Released to ship/sell: (initials and date)	Number of jars shipped from this batch:

Temperature Measurements for this Batch					
Initial temperature of mixed ingredients (before cooking)	Target temperature for this product	Come–up time to reach target temp	CCP #1 Cook time and temperature (at least 212 °F for 10 min.)	CCP #2 Hold time and temperature in last jar (185 °F for 2 min.)	Initials of person making this record (date and time)

pH Measurements for this Batch			
pH of acidifying agent	pH of mixed low–acid ingredients before adding acidifying agent	CCP #3 Equilibrium pH taken 24 hr after sealing jars	Initials of person making this record (date and time)

Process deviation/corrective action/disposition of affected product:	

NOTE: This is not an actual form and is provided exclusively as an example. It is not to be used or construed as applicable to any product.

Recall Plan Checklist

If a recall becomes necessary, it is important to have the paperwork and procedures in place to help the process go smoothly and efficiently. Having the items in this list prepared and practiced will help you in the case of a recall.

- ☐ Assemble a Recall Team and delegate responsibilities so that each person knows what they are responsible for in the case of a recall.
- ☐ Formulate trace–back procedures to determine if contaminated ingredients could be the source of the problem.
- ☐ Formulate trace forward procedures to notify your customers and any secondary customers who may have received the affected product.
- ☐ Practice gathering all paperwork related to a certain batch code or production date.
- ☐ Figure out where product will be stored while it is "on hold" during the investigation.
- ☐ Figure out disposal procedures if the product must be destroyed.
- ☐ Create a contact list, including how to notify the FDA and state health and human services.
- ☐ Formulate a draft notice letter to send to your customers like the sample below:

URGENT RECALL NOTICE

Dear (Customer),

We regret to inform you that (XYZ product) is being recalled due to (reason for recall), which can cause a potential health concern if consumed. The product with the lot code (12345) and expiration date (1/31/2017) is the only batch that has been affected by the contamination. If you have any remaining product from this batch on hand, please place it on hold and do not distribute it under any circumstances. We will follow up shortly regarding compensation and instructions for either returning or disposing of the product. We sincerely apologize for this inconvenience. If you have any questions, please give us a call. Otherwise we will be in touch as soon as possible.

Sincerely,
(Company Representative)

Deviation Log

Important: Notify the food safety manager or process authority about any deviations to determine the proper corrective action.

Product	Batch code	What was the deviation?	What was done with the product?	Date and time	Employee initials

Reviewed by: _____ Date: _____

Preshipment Review Log for _____ Shipment date _____

In conducting this review, it has been determined that all product produced for the above–listed shipment date has met all established food safety requirements, ingredient specifications, and processing requirements, or that the appropriate corrective actions have been taken.

Product	Production date	Lot code/ batch number	Met ingredient specifications		Product remained within proper storage temperatures		Equilibrium pH reached		Reviewed by		Ship to
			Accept	Reject	Accept	Reject	Accept	Reject	Initials	Date	

Reviewed by: _____ Date: _____

Thermometer Calibration Log

Instructions: Calibrate thermometers as often as needed, with a minimum frequency of every 6 months. Specify if the calibration is done using the boiling water (hot) or ice water (cold) method. Thermometers are acceptable if within ±2 °F of the reference thermometer.

Date	Time	Thermometer ID number	Hot or cold calibration	Thermometer reading	Adjustment required (yes/no)	Initials

Reviewed by: _____ Date: _____

pH Meter Calibration Log

Instructions: Calibrate the pH meter each production day before use. Calibrate at pH 4 and pH 7.

Date	Time	Calibration (✓ = calibrated)		Comments	Initials
		pH 4	pH 7		

Reviewed by: _____ Date: _____

Food Safety Plan Checklist

- ☐ Create a flow chart of the process and identify points that could be hazards.
- ☐ Determine which hazards are critical control points and identify their critical limits.
- ☐ Determine which hazards are preventive controls and identify their specific parameters.
- ☐ Determine how each critical control point or preventive control will be monitored, and what the corrective action will be for a deviation.
- ☐ Create recordkeeping forms to monitor all critical control points and preventive controls.
- ☐ Create a batch/lot code system for easy trace–back of products.
- ☐ Establish corrective–actions procedures in case of a deviation.
- ☐ Establish cleaning and sanitizing procedures for preproduction and postproduction.
- ☐ Establish and practice recall procedures.
- ☐ Train employees on proper hygiene and recordkeeping procedures.
- ☐ Establish a pest control regimen and a system to keep records of pest control visits.
- ☐ Establish an organized way to maintain all supplier records (specification sheets, letters of guarantee).
- ☐ Establish an allergen–control plan and monitoring methods.
- ☐ Create your scheduled process with your process authority and maintain the records in a designated place.
- ☐ Establish a plan for handling allergen products. Make sure there is a protocol for corrective action if allergen swabbing comes back positive.

Appendix: Definitions

Acidified foods: Low–acid foods to which acid or acid foods are added, which have a water activity greater than 0.85 and a finished equilibrium pH of 4.6 or below.

Acidifying agents: Acid ingredients that are added to bring down the pH of low–acid ingredients. Examples are vinegar, apple cider vinegar, lemon juice, citric acid, and tomato.

Corrective action: Procedures followed when a deviation occurs.

Critical control point (CCP): A step at which control can be applied and is essential to prevent or eliminate a food safety hazard or reduce it to an acceptable level.

Cross–contact: The unintentional incorporation of a food allergen into a food.

Deviation: Failure to meet a critical limit or specific parameters.

Hazard: A biological, chemical, physical, or radiological agent that is reasonably likely to cause illness or injury in the absence of its control.

Hazard analysis: The process of collecting and evaluating information on hazards associated with the food to determine which need to be addressed in a food safety plan.

Preventive control (PC): Any measure put in place to significantly reduce or eliminate hazards identified under the hazard analysis.

Process authority: An expert on thermal processing of acidified foods. They are able to approve thermal processes and help in decision–making for process deviations.

Scheduled process: A process that has been determined by a process authority to be sufficient in making a product safe from microbiological contamination. This involves control of pH and thermal processing.

Validation: The element of verification focused on collecting and evaluating scientific and technical information to determine whether the food safety plan, when properly implemented, will effectively control the identified hazards.

Verification: Those activities, other than monitoring, that establish the validity of the food safety plan and that the system is operating according to the plan.

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