



ACIDIFIED FOODS: OVERVIEW

This guide is intended to help current and prospective food processors understand the general requirements for producing acidified foods in Washington State. It is not meant to replace the food processor's responsibility for understanding and meeting the regulations themselves. Contact the Washington State Department of Agriculture (WSDA) Food Safety Program at 360-902-1876 with any questions.

Definitions of terms when discussing acidified foods:

- **CFR** is the Code of Federal Regulations, which sets the rules food processors must follow. Links to regulations relevant to acidified foods are listed in Appendix 3.
- **pH** is a term used to indicate how acidic or how basic a substance is. It is based on a logarithmic scale that goes from 0 to 14. A pH of 7 is neutral. Any value lower than 7 indicates that the substance is acidic. The lower the number, the more acidic (or higher the acid it has).
- **Water activity (a_w)** is the measure of the amount of free moisture available in a given substance. Water activity is given on a scale from 0 to 1. The closer to zero, the less free moisture is available in the food. Pure water has a water activity of 1.00.
- **Low-acid foods** are any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and an a_w greater than 0.85. (21 CFR Part 114.3(d)). These foods have their own special regulation.
- **Acidified foods** are low-acid foods to which acid(s) or acid food(s) are added. They have an a_w greater than 0.85 and have a finished equilibrium pH of 4.6 or below (21 CFR Part 114.3(b)). These foods have their own special regulation.

IN THIS GUIDE:

Overview	1
Licensing	3
Inspections	5
Common Violations	6
Frequently Asked Questions	8

APPENDICES

Appendix 1: Food Process Authorities	12
Appendix 2: Examples of Recordkeeping and Recall Forms	13
Appendix 3: Helpful Links	22
Appendix 4: Examples of Process Authority Letters	23

- **Acid foods** are foods that have a natural pH of 4.6 or lower (21 CFR Part 114.3(a)).
- **Homogenous products** are those where the ingredients are of uniform size, like many sauces.
- **Non-homogenous products** are those where the ingredients are different in size and consistency, such as pickled asparagus, for example.

Acidified foods are shelf-stable food products that have been thermally processed and hermetically sealed in a container. Some common acidified foods are pickled asparagus, dill pickles, bread and butter pickles, pickled green beans, barbecue sauces, hot sauces, and some pepper jellies.

Sometimes it is difficult to identify something as an acidified product or an acid food, such as with certain sauces or canned salsas. See Appendix 1 for more information on Process Authorities.

One of the main food safety concerns with hermetically sealed food products is the risk of botulism poisoning in improperly processed products that are stored in low-oxygen conditions, such as sealed jars or bottles. The main controls used to address this food safety hazard are pH control (through formulation) and sufficient thermal processing using cook times and temperature combinations.

Acidified foods are typically thermally processed using one of two methods: hot-fill hold method or water bath method. The hot-fill hold method is usually employed for homogenous products like barbecue and hot sauces. It involves cooking all product ingredients in one container to a specific temperature and length of time and then pouring the hot product into the final product container. After filling the container with hot product, the lids are applied and the containers are immediately flipped over for a couple of minutes.

The water bath method is typically used with non-homogenous products like pickled vegetables so a firm texture in the vegetable solids is maintained. In this method, a hot brine is prepared and poured over the vegetables and other ingredients. The containers are then capped and cooked for a specified time in a water bath.



LICENSING

To process and sell acidified food products in Washington State, you must be licensed with WSDA as a food processor. Due to the requirements of 21 CFR Parts 108 and 114, there are additional items that an acidified food processor must address. This section outlines the basic steps a firm must complete to legally process and sell acidified food products in Washington State. The steps do not have to occur in the order listed.

- Obtain a WSDA Food Processor License. Visit agr.wa.gov/FoodAnimal/FoodProcessors for information on obtaining a Food Processor License. The website includes information on facility requirements, laws and rules, and packaging and labeling. You can also download a licensing application packet. If you wish to consult with a WSDA Food Safety Compliance Specialist (FSCS) to talk over your facility and processing plans, you can contact the Olympia office at 360-902-1876 and ask them to give you the information for the FSCS that covers your area.
- Have your products evaluated by a qualified Food Process Authority. When you contact a process authority about your product evaluation(s), they will ask you to send them containers of your product as well as information about ingredients, processing, etc. They will then determine if your product falls under the definition of an acidified food product. After evaluation is complete, the process authority will send you a letter with their findings. For products classified as acidified foods, the letters will include minimum processing parameters such as maximum equilibrium pH, minimum processing time and temperature, minimum fill temperature, etc. These letters must be followed when making your product. Information on process authorities can be found in Appendix 1 of this guide and an example of a process authority letter is provided in Appendix 4 of this guide.
- Attend an FDA-approved Better Process Control School. This is a required class for acidified processors as stated in [21 CFR 114.10](#). The class may be taken in person or online. There are benefits and limitations to each type of class. A list of approved instructors is included in Appendix 3.
- Purchase equipment to measure the critical processing factors as required by the process authority letters. These will likely include an accurate watch to measure time, a thermometer that can be calibrated to measure processing temperatures, a pH meter to measure the

GETTING STARTED OVERVIEW:

- Obtain a WSDA Food Processor License
- Get your product evaluated by a process authority
- Attend a Better Process Control school
- Buy process monitoring equipment
- Register as an acidified processor with FDA
- File all of your product processing information with FDA
- Keep records
- File a license amendment with WSDA (only for previously licensed processors)

equilibrium pH, and buffer solutions to calibrate the pH meter. This is not an exhaustive list and a diligent processor will make sure to have all equipment necessary for taking required measurements.

- Register as an acidified processor with FDA.
- File a scheduled process with FDA for each of your acidified food products. We recommend filing electronically. Instructions for filing electronically can be found on FDA's website. The link to this portion of their website is provided in Appendix 3 of this guide.
- Keep records. Acidified foods processors are required to maintain records of several types of information. The following records are required for acidified foods processors.
 - Processing records (including the product codes)
 - Recall plan
 - Deviation log (for deviations from the Scheduled Process letter)
 - Distribution records
 - Process authority letters for each acidified product
 - Raw material examinations
 - Container examinations

Note: It is possible to include many of these records on one sheet. We have provided examples in Appendix 2 wherein the raw material, container, processing parameters, and deviations were all included in one log sheet.

- Apply for all your acidified products on your Food Processor License application. If you are already licensed by WSDA as a food processor, you will need to submit license amendment paperwork for each acidified product you wish to add to your license, if you are not currently licensed for acidified products.

If you are currently licensed for acidified products, you will not need to submit a license amendment for new acidified products—**unless your inspector directs you to file amendments for new acidified products in all cases.**

In most cases, you will need to have a new acidified product evaluated by a process authority, and file the processing information with FDA. You will also need to maintain mandatory records for the new product, and have the information on the new product available for your next WSDA inspection. Your inspector will work with you on licensing and amendment of products and you will be informed when your product has been approved by WSDA.

INSPECTIONS

In Washington State, there are several regulations covering the food product manufacturing. Processors of acidified foods also must comply with Chapter 21 of the Code of Federal Regulations (CFR) Parts 108 and 114.

All WSDA Food Safety inspections of food processors are a point-in-time glance at a firm's operations. Inspections always cover a firm's compliance with general good manufacturing practices (GMPs) in 21 CFR 110 or 21 CFR 117 Subpart B. These include, but are not limited to, the following.

- Personal cleanliness
- Safe food handling practices
- Cleanliness inside and outside the facility
- Effectiveness of pest control
- Suitable design and construction of the facility
- Water quality
- Maintenance of processing equipment
- Protected raw material storage
- Product labeling

With the added requirements for acidified foods processors in 21 CFR 108 and 114, you can also expect your Food Safety Compliance Specialist to look at the following:

- Your documentation related to acidified foods processing. They may want to see your Better Process Control School certificate, process authority records, deviation log, written recall plan, material examinations, and log of processing values (pH, temperature, hold time, etc.) Records will be checked for completion.
- Proof of your registration with FDA and that you filed your scheduled process for each acidified product.
- If a new acidified product not covered under your scheduled process letters is noted in the processing records, your FSCS will ask to see the process authority letter for that product to see what critical parameters, such as equilibrium pH, were provided for that product.

STAY READY FOR AN INSPECTION:

Producing a safe, quality product starts with giving attention to a few basic areas, that we call Good Manufacturing Practices.

Here are a few items that you should always keep in mind:

- **Wear clean garments.**
- **Wash hands thoroughly before starting to process and after any breaks.**
- **Make sure surfaces of the facility and your equipment are smooth, non-absorbent and easy to clean.**
- **Make sure you use approved, potable water that is protected from contamination.**
- **Store equipment and materials in a way that prevents them from becoming contaminated.**
- **Keep pests out of your facility and clear away debris that gives them a place to hide and multiply.**
- **Keep all required records and have them available for review.**

COMMON VIOLATIONS

The following is a list of violations commonly documented during WSDA inspections of acidified food processors. In most cases, these violations are considered critical violations.

A critical violation on an inspection will result in an automatic failing score. Failing scores result in the need for corrective action by the firm and possible compliance action by WSDA. In some cases, a violation may prompt WSDA to ask the firm to conduct a voluntary recall.

1. Failing to completely fill out required processing records.

Example: Ms. Smith is a part-time processor who makes pickled asparagus using the water bath method. Her process authority letter tells her to cook the canned product at 205F for 10 minutes and says the product must have an equilibrium pH of < 4.13. Ms. Smith records a processing temperature of 210F and a time of 11 minutes on her record sheet. She removes the product from the water bath and sets it on a counter to cool. Ms. Smith has errands to run, so she leaves the jars to continue cooling. The next day, Ms. Smith labels her jars, puts them into boxes and delivers them to her customer. However, she forgets to take the equilibrium pH from a jar of this batch and record it on her record sheet. When she has her inspection with WSDA, the Food Safety Compliance Specialist finds 6 different occasions when Ms. Smith failed to record the pH. Ms. Smith then fails her inspection due to a critical score for not recording required processing information.

2. Not having all required records.

Example: Mr. Williams has been processing pickled green beans for several months. He has done a great job of documenting all of his processing information like cook temperatures, hold times and equilibrium pH. He also has a well-considered written recall plan and a deviation log, though he hasn't had to use either one. However, during his first follow-up inspection with WSDA his Food Safety Compliance Specialist asks Mr. Williams to provide his distribution records and raw material examinations. Mr. Williams says that he always checks his supplies, but doesn't record anything. He also states that he only sells to two stores, so he knows where all of his product is. However, the FSCS informs Mr. Williams that the regulations require him to have records for this information. Mr. Williams fails his inspection due to a critical score for lacking all required records.

DON'T FORGET:

Paying attention to the following items will go a long way to making sure you are complying with the acidified foods regulations:

- Check that you are keeping all required records.
- Always make sure to completely fill in your records every time you process.
- Register as an acidified food processor with FDA and update the registration if you move to a new facility.
- File the processing information with FDA for every acidified product you make.
- Maintain a process authority letter for every acidified product.
- Always include a complete production code on every product container.
- Follow the instructions in your process authority letter.
- Consult with your process authority about reformulations and obtain new letters as required.

3. Not registering as an acidified processor with FDA.

All processors of acidified foods are required to register with FDA as an acidified processor within 10 days of start-up. Not registering as an acidified processor is a critical violation, which results in an automatic failing score.

4. Not filing the scheduled process with FDA.

In addition to registering with FDA as an acidified processor, you must file a scheduled process with FDA for each acidified product that you will be making. Failure to file a scheduled process for each acidified product is a critical violation on WSDA inspections and results in an automatic failing score.

5. Not having a process authority letter for an acidified product.

Every acidified product that a firm produces must have been evaluated by a process authority and have an accompanying letter.

Example: Mr. Reynolds has been producing dill pickles for which he has a process authority letter. He now wants to produce pickled beets. Mr. Reynolds is licensed as a processor of acidified vegetables, so he decides to start making and selling pickled beets. However, he did not have the new product evaluated by a process authority and therefore, does not have a process authority letter telling him what the critical processing parameters for the new product need to be to make a safe product (cook time, cook temperature, pH, etc.). During his next WSDA inspection, Mr. Reynolds receives a failing score and has to initiate a product recall for the pickled beets.

6. Failing to include a complete product code on the label of the acidified food.

Product codes are required to be on every acidified food container and must be permanently visible to the naked eye. The product code must include information on the establishment where the product was packed, the product in the container, and the year, day, and period (batch number) during which it was packed. Improper coding may result in a critical violation and failing score.

7. Changing an acidified product recipe without having the product reevaluated.

The letters provided by the process authorities for your acidified foods have specific processing parameters that are based on the recipe you initially provided. Changes to the recipe could affect what those parameters need to be to continue producing a safe product.

Example: Ms. Franklin had a new idea for her pickles, which hadn't been selling as well as she hoped. She thought that if she reduced the amount of vinegar, increased the garlic and added some red chili flakes, it would improve the flavor. She made the change and started processing and selling the new-and-improved pickles. However, at her next WSDA inspection, the FSCS noted that there was no documentation of an evaluation from a process authority. Ms. Franklin failed the inspection and had to recall all of the jars she had made using the new formulation.

8. Not following the process authority letter.

Each of a company's process authority letters for acidified products includes specific information on minimum processing parameters for producing a safe product. All products must adhere to these letters. For example, if a company has a letter with parameters for a hot-fill hold method, but is processing using a pressure cooker, that company has deviated from the process authority letter. This is a critical violation on a WSDA inspection and results in an automatic failing score.

FREQUENTLY ASKED QUESTIONS

1. I sell a refrigerated barbeque sauce. Am I covered by the acidified foods regulations?

Answer: No. The acidified foods regulations are for shelf-stable products. However, you must still be a WSDA-licensed firm. Be sure the labels clearly state that the product must be kept refrigerated, to distinguish your product from shelf-stable acidified products.

2. How do I know if my shelf-stable product has to be evaluated by a process authority?

Answer: There are several questions that you need to consider:

- Does my product contain more than 10 percent of low-acid ingredients like peppers, cucumbers, garlic or onions?
- Does my recipe call for adding significant amounts of acid and/or acidic foods like lemon juice, vinegar, or tomato sauce?
- Is my product typically referred to as a pickled product?

If you answer yes to any of these questions, you need to contact a process authority before proceeding. It is likely that you will need to have your product evaluated.

3. I want to produce a shelf-stable sauerkraut. Is this an acidified product?

Answer: Traditional sauerkraut is produced by a fermentation process that allows beneficial bacteria to naturally reduce the pH of a food product. Fermented products are not covered by the acidified foods regulation.

4. How long does a product evaluation take?

Answer: It depends. We recommend that when you are selecting a process authority, you ask them about expected turnaround times, costs, etc.

5. I had my product evaluated by a process authority in 1995. How long is the process authority letter good for?

Answer: While there is no specific expiration on a given process authority letter, new industry insights, regulatory changes, research findings, recall investigations, and other factors may create the need to have your product reevaluated. If you have any question about whether your process authority letter is still valid, ask your process authority if the information needs to be updated.

6. I received the results of my product evaluation from the process authority but they only gave me the pH results, not any information on what cook times and temperatures I have to use or what my maximum equilibrium pH is. What should I do?

Answer: Contact your process authority again and let them know that you were looking for this information. It may be that they thought you were only looking to have your

products tested to find out what the pH values were. Let them know that you were looking for processing information to conform to the acidified regulations and that you need the information in writing.

7. My process authority letter gives me two different times and temperatures to use for processing based on initial temperature. What does that mean?

Answer: Generally speaking, the initial temperature is mentioned in letters related to products that use the water bath method of processing where a hot brine is poured over cold or room-temperature ingredients (asparagus spears, for example) before being lidded and processed in a water bath. The time that you need to process the containers in the water bath depends on what the initial temperature of the solid, non-brine ingredients were before you closed the jars and started cooking them in the water bath. Commonly, process authority letters make the change from one time/temperature set to the other at an initial temperature of 70 F.

***Example:** You make a pickled asparagus product. After washing and trimming the asparagus, you place the asparagus spears and spices in a jar. Then you pour your hot brine over these solids. After a few seconds, you stick your thermometer directly into an asparagus spear in the middle of the jar. This temperature reading is considered your initial temperature. You then make sure to record this temperature on your processing records in the initial temperature column and select the correct cook time/temperature combination from your process authority letter based on that reading.*

8. Where can I find pH meters, pH strips, thermometers, etc.?

Answer: There are many suppliers of this equipment that can be found online. WSDA does not have a list of approved supplier websites or equipment manufacturers. It is up to the firm to find appropriate equipment.

9. Can I use pH strips to measure my equilibrium pH?

Answer: If the pH of your product is less than 4.0, you have the option to use pH strips. Otherwise, you must use a pH meter. If you can use pH indicator strips, choose a pH range that includes your target pH. That said, if the color of your product makes it difficult for you to compare the test strip to the color indicator chart, we recommend use of a pH meter instead because they are not affected by product color. Additionally, pH meters are more precise than pH strips.

10. How do I calibrate/standardize my equipment? How often does it need to be done?

Answer: The best thing you can do is read the instructions that come with your equipment and try to speak with the technical service representatives for the manufacturers of those devices for help. You can also contact a local laboratory or county extension office to see if they can show you how to calibrate and operate your device. With thermometers, the easiest thing to do is compare your thermometer to an NIST (National Institute of Standards and Technology) traceable thermometer at a temperature close to your minimum processing temperature and adjust your thermometer if necessary. There are also companies that offer calibration services for instruments like thermometers.

Calibration frequencies will depend on the manufacturer and device. It is good practice to do an accuracy check of your thermometer every day that you process. Generally, pH meters need to be calibrated/standardized before each use. When standardizing, you typically use two solutions of known pH, such as buffers with a pH of 4.0 and 7.0.

Make sure to document the results of your equipment calibrations and standardizations.

11. When is the best time to take an equilibrium pH reading on a finished container?

Answer: The best time depends on the type of product you are making. The time it takes for a product to reach equilibrium pH depends on factors like particle size, method of acidification, and product density. In many cases, it is sufficient to take the reading the day after processing, but less than 24 hours after bottling. In rare cases, a product might need several days to reach equilibrium pH. This would require refrigeration of the containers until a pH of 4.6 is reached. However, your process authority letter would contain specific information on what to do in these special instances.

12. Is there a difference in how I should take the pH of a barbecue sauce compared to a pickled asparagus product?

Answer: Yes. This is one of the items that is discussed in the Better Process Control School. The acidified regulation 21 CFR 114 also covers the general procedures for determining pH.

Homogenous products (where ingredients are uniform in size), like many sauces, can be easily measured by inserting the pH meter probe directly into the product. Non-homogenous products (ingredients are different in size and consistency) like pickled asparagus have several possible measurement options. The easiest method is to blend the entire contents of the jar together and then insert the pH meter probe into the evenly blended mix. With either product type, the measurements need to be taken when the product is at room temperature.

13. The equilibrium pH for my last batch of product was 4.4, but my process authority letter says that it is supposed to be 4.3 or less. Do I have to throw everything away?

Answer: This is a process deviation that must be documented in your records. While you may decide to throw away all the product, you also have the option to contact your process authority. The process authority can evaluate the issue and may be able to provide you with a letter that allows that batch of product to be sold. This deviation letter will be specific to that batch and cannot be used to justify the sale of other products that deviate from the scheduled process unless specifically stated by the process authority letter.

14. Can one person record all the processing information and then also sign off on the records as a reviewer?

Answer: Yes, as long as that person has taken and passed the Better Process Control School. Some small processors are one-person operations and have to do all the documentation and review themselves.

15. Are ditto marks (") and check marks allowed on processing records?

Answer: It depends on the record you are making. If you are taking a measurement like time, temperature or pH, then you must record an actual numerical value on your record, even if the measurement was identical to the value from the previous processing day. On the other hand, if you are documenting that you did a raw material examination, it is enough to simply record a checkbox to indicate that the activity was performed and the results were ok.

16. How long am I required to store my records for the production of acidified foods?

Answer: Keep records for three years, including records related to processing and production activities, deviations from the scheduled process and initial finished product distribution for potential recall purposes shall be made available at the processing plant or other reasonably accessible location.

17. Will FDA let me know that the scheduled processes for my products have been received and that they are ok?

Answer: It depends. If you are using a shared commercial kitchen, such as Grange Hall, to make your product and there is another acidified processor who uses the kitchen and had registered with FDA before you, you will not receive anything back if you file by mail. If you have your own facility or are the first to register at a shared commercial kitchen, you should receive confirmation of your filing. Also, it has been our observation that FDA will contact firms directly if they notice any errors in the scheduled process filings.

FDA also gives firms the ability to both register as an acidified processor and file scheduled processes electronically. **We recommend that you use the electronic registration/filing method.** Filing electronically creates an account for your firm that you can access in the future to reference process filings and to add new process filings.

18. Does my product code have to follow a specific format?

Answer: No. However, your product code must include information related to batch number, production date, location, and product identity. Some companies choose to use a Julian calendar date (1 for January 1st, 32 for February 1st, etc. through 365) instead of writing out the month and day of production. Some companies use letter codes to designate different product types. For example, a company uses 'A' for their pickled asparagus and 'B' for pickled green beans. However you write it, the code must contain all of the required information.

19. Where do I put the product code and how do I attach it to the container?

Answer: What is most important is that you have a product code on every container you make and that it is legible. There is no one way to label your product with a production code. Some companies print their own labels after each batch and include the product code information on the print out. Other companies have ink jet coding that is applied automatically to each container. Some very small producers handwrite the code onto their product labels. Other firms attach stickers with the product code to the lids of their jars or bottoms of the glass bottles.

APPENDICES

APPENDIX 1: Food Process Authorities

Acidified food products must be processed in accordance with 21 CFR Part 114. Examples of some acidified food products are pickles, sauces, dressings, and “non-standardized” jellies or jams (such as some pepper jellies). Unless a food processor intends to sell the food product refrigerated or the food product has a water activity of 0.85 or less, foods that have a pH of 4.6 or less and that contain more than 10 percent low-acid ingredients must obtain a food safety review by a qualified Process Authority to determine whether the food qualifies as an acidified or an acid food.

WSDA cannot recommend process authorities. However, here are some suggestions to help you locate one for your needs:

- Contact the food science departments at your local land grant university, such as Washington State University.
- Contact professional food industry trade organizations.
- If you search the internet, use key words such as process authority, process authority acidified, or other variations that may include the words certified or Washington State.

When you select a possible process authority, be sure to ask the firm about its experience writing scheduled processes for acidified foods and specifically for the type of food products you want to process.

APPENDIX 2: Examples of Recordkeeping and Recall Forms

The following pages (14-20) provide examples of forms to document process parameters, product sales and distribution, and process deviations. We also include an example of a written recall plan.

These are only examples. You may modify or create your own forms to document the information you need to track your compliance with regulations and manage your operations. But the form examples are designed to help you meet the regulations, so if you modify or create new forms, don't eliminate recordkeeping categories required by the regulations.

It is your responsibility to ensure that the recordkeeping forms you choose cover all the required regulatory parameters for your products and processes, that you record the required information on the forms, and that you record the information in a timely manner.



Thermometer and pH Checks

pH Meter

Date	pH meter standardized?	Reading of meter in 4.0 solution (must be +/- 0.1)	Actions Taken (if necessary)	Initials
5/20/17	Yes	4.2	Out of spec. Buffer cold. Re-standardized pH meter and retested with room temp buffer.	GDS
5/20/17	Yes	4.0		GDS

Thermometer

Date	Test temperature	Reading of NIST thermometer	Reading of my thermometer	Difference (must be +/- 1°F)	Actions Taken (if necessary)	Initials
5/20/17	205	205	204	1	N/A	GDS

Sales and Distribution Log

Date	Product Name	Product Code	Number of Units Sold	Customer	Comments

Sales and Distribution Log

Date	Product Code	Describe Process Deviation	Action Taken

Sample Recall Plan

In the event of a product recall, this company will take the following actions to ensure the product is quickly and effectively removed from the marketplace.

- 1. Start a report to document information about the recall.**
We will gather all information about the product name, batch/lot numbers that are part of the recall, and severity of the issue.
- 2. Review sales logs, processing logs and remaining inventory.**
We will find out how many containers of the product were produced and see which customers received those batches of product. We will then check inventory to confirm that the difference between the two numbers matches the amount of inventory onsite. Discrepancies will be investigated.
- 3. Contact customers.**
All customers identified by the review of the sales/distribution log will be contacted immediately to notify them of the recall and to have them pull the product from shelves.
- 4. Get product from customers.**
We will either pick up the recalled product from our customers or will arrange to have the recalled product sent back to our facility. All returns will be documented.
- 5. Quarantine product onsite.**
Product remaining in inventory will be separated from other products and clearly marked to indicate that they are not to be sold. Product that is returned from customers will also be stored in this quarantined area.
- 6. Contact regulatory authorities.**
We will call WSDA to notify them of the recall. For Class 1 recalls, we will also file a Reportable Food Registry report with FDA.
- 7. Create and distribute a recall notice.**
We will create a recall notice to be posted at sales locations and, when necessary, distributed to local news organizations. We will also post the recall notice on our website and social media pages. The notice will include our contact information as well as instructions on how to return product that has been purchased in the stores.
- 8. Investigate the problem.**
We will conduct a thorough investigation to determine the root cause of the problem. This will include a review of processing records, calibration records, raw materials, and other factors. The investigation may also include sending products to certified laboratories for analysis.
- 9. Generate and implement corrective actions.**
For any problems discovered during investigation, corrective actions will be implemented. These may include deep cleaning of the facility, retraining employees, evaluating new material suppliers, replacing equipment, etc.
- 10. Record all recall activities and close the recall.**

APPENDIX 3: Helpful Links

The following links provide additional information to help you get started with producing acidified foods and help your company stay in compliance with the acidified foods regulations.

Better Process Control Schools:

Washington State University Food Processing Extension & Research:
foodprocessing.wsu.edu/extension/training/bpcs

Oregon State University Food Science & Technology Extension Training:
oregonstate.edu/foodsci/fst-extension-schedule

University of California, Food Safety (only approved online course):
ucfoodsafety.ucdavis.edu/Better_Process_Control_School_Online

FDA Acidified Processor Registration and Product Filing:

FDA's main LACF and Acidified registration page:
www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/default.htm

To file registration document with FDA electronically (**recommended**):
www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007437.htm

Forms and instructions for paper submission of filing registration documents with FDA:
www.fda.gov/Food/GuidanceRegulation/FoodFacilityRegistration/AcidifiedLACFRegistration/ucm2007436.htm

Laws & Rules:

WSDA website with links to general food regulations:
agr.wa.gov/FoodAnimal/FoodProcessors/LawsRules.aspx

21 CFR Part 114, Acidified Foods:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=114&showFR=1

21 CFR Part 108, Emergency Permit Control:
www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcr/CFRSearch.cfm?CFRPart=108&showFR=1

APPENDIX 4: Examples of Process Authority Letters

Hot Water Bath Method:

Dear Ms. Jones,

The samples of your Pickled Sliced Garlic product has a finished equilibrium pH 3.72. Your product is an acidified food as formulated; therefore, it is subject to the appropriate low acid and acidified foods regulations as found in 21 CFR 108, 113, and/or 114. Copies of these regulations and other information can be found on our website www.howtomakeacidifiedfoods.com. Production of acidified foods also requires that certain aspects of the operation be under the operating supervision of a person who has satisfied the education requirements of the regulations. Let us know if you need information about related education programs.

Your product **must** have a **finished equilibrium pH 3.9 or lower**. Further, the entire contents of each closed finished container of the product **must be at or reach 180° F for at least 10 seconds** before the finished containers are cooled. This process can **only be accomplished using a water bath**. Following are the process parameters to achieve the above in jars with approximate dimensions 5.25 inches x 2.88 inches.

Water bath temperature **205 F** or greater.

Initial temperature **70 F** or greater.

Process time at **205 F** or greater for 9 minutes.

If the initial temperature is less than **70 F** but greater than **35 F**, the process time is **10 minutes**.

This letter is written in reference to the product samples that we received from you and the recipes and process information from you that we have kept on file. All information related specifically to your product is kept confidential.

Any changes that you make in the formulation of the product might result in a significant change in critical factors, which, in turn, could change the process parameters.

If the process above results in product qualities that you did not expect, please contact me to discuss these requirements.

If we can assist you further, please let me know.

Sincerely,

Michael Z. Smith
Food Processing Specialist
(555) 555-5555

Hot-Fill Hold Method:

Dear Mr. Jones,

The samples of your Jalapeno Sauce product has a finished equilibrium pH 3.53. Your product is an acidified food as formulated; therefore, it is subject to the appropriate low acid and acidified foods regulations as found in 21 CFR 108, 113, and/or 114. Visit howtomakeacidifiedfoods.com for copies of these regulations and other information. Production of acidified foods also requires that certain aspects of the operation be under the operating supervision of a person who has satisfied the education requirements of the regulations. Let us know if you need information about related education programs.

Your product **must** have a **finished equilibrium pH 3.7 or lower**. Further, you **must** fill the product into the finished containers at a temperature high enough to assure **175 F** when the lid is applied. The closed containers should be inverted immediately for 2-3 minutes and then cooled.

I also recommend that you become familiar with the Good Manufacturing Practices regulations (21 CFR 110), which apply to all processed food products. Pay special attention to the sanitation and employee practices in your processing facility.

This letter is written in reference to the product samples that we received from you and the recipes and process information from you that we have kept on file. All information related specifically to your product is kept confidential.

Any changes that you make in the formulation of the product might result in a significant change in critical factors, which, in turn, could change the process parameters.

If the process above results in product qualities that you did not expect, please contact me to discuss these requirements.

If I can assist you further, please let me know.

Sincerely,

Michael Z. Smith
Food Processing Specialist
(555) 555-5555