

Acidified Foods Manufacturing School

Next Steps

Process Evaluation by a Process Authority *21 CFR 114.83 / 108.25(c)(3)(i)* (Chapter 9)

Have your product(s) evaluated and receive a **scheduled process** by a process authority. The **scheduled process** specifies the maximum finished equilibrium pH of the product, thermal process and other critical factors that must be controlled to assure manufacture of safe acidified foods. You can find private laboratories/individuals, or many universities, like North Carolina State University, who can provide this service for you.

You can find more information on our website: <https://foodbusiness.ces.ncsu.edu/>

Records *21 CFR 114.100 / 108.25(g)* (Chapter 7)

You must decide what **records** are necessary to assure product safety and quality for human consumption, identify individual lots of foods in instances where questions arise as to safety or quality, aid in planning, scheduling, and decision-making, and comply with governmental regulations and then develop the necessary forms and procedures to be used. The types of records will vary with the product(s) being processed. At a minimum, critical factors stated in a scheduled process should be documented.

Examples of Records:

- Certifications of Personnel *21 CFR 114.10 / 108.25(f)*
- Thermal Processing *21 CFR 114.80(a)(1)*
- Equilibrated pH *21 CFR 114.80(a)(2) / 114.90*
- Container Closure/Seal Integrity Evaluation *21 CFR 114.80(a)(4)*
- Container Coding *21 CFR 114.80(b)*
- Deviations from the Scheduled Process *21 CFR 114.89*
- Calibration Records *21 CFR 114.90*
- Examinations of Raw Materials (Origin & Lot)
- Examinations of Packing Material (Origin & Lot)
- Examinations of Finished Products (Origin & Lot)
- Cleaning & Sanitizing Compounds (Origin & Lot)
- Lot Numbers & Number of Units Manufactured in Each Batch
- Initial Distribution Records
- Written Recall Plan *21 CFR 108.25(e)* (Chapter 8)
- HACCP Plan (Develop Food Safety Plan)

Required Equipment

You must read and follow all equipment supplier information. Purchase **equipment** to measure ALL critical factors as required by your scheduled process. These will include:

Potentiometric Method for Measuring Equilibrium pH *21 CFR 114.90* (Chapter 2)

- pH Meter
- Buffers (4.0 and 7.0) for calibration
- Distilled/Deionized water
- Extra sensor/Electrode
- Batteries

Method for Measuring Processing & Fill Temperature *21 CFR 114.80(a)(1)* (Chapter 5)

- Thermometer/Thermocouple (capable of being calibrated/digital)

Method for Measuring Time (Chapter 5)

- Stopwatch (capable of being calibrated/digital)

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Regulatory Steps

Federal Compliance

- **Current Good Manufacturing Practices** *FDA Food Safety Modernization Act (FSMA)*
<https://www.fda.gov/animal-veterinary/animal-food-feeds/food-safety-modernization-act-and-animal-food>
You can find more information about Preventive Controls for Human Food Courses on our website:
<https://units.cals.ncsu.edu/foodsafety/preventive-controls-human-foods-north-carolina-regional-courses>
- **Food Facility Registration (FFR)** *FD&C Act / Bioterrorism Act / FSMA*
Your facility must register before you begin manufacturing/processing, packing, or holding food for consumption in the United States. A food facility is required to submit an initial registration & renew its registration with FDA every other year during the period beginning on October 1 and ending on December 31 of each even-numbered year.
<https://www.fda.gov/media/161181/download>
- **Food Canning Establishment (FCE) Registration** *21 CFR 108.25(c)(1)* (FDA Form 2541)
<https://www.fda.gov/media/83914/download>
- **File EACH Acidified Food Scheduled Process** *21 CFR 108.25(c)(2)* (FDA Form 2541e)
<https://www.fda.gov/media/89918/download>
- **Adhere to the Scheduled Process** *21 CFR 108.25(c)(3)*

State Compliance

Contact your State Department of Agriculture to determine additional regulations/requirements.

Local Compliance

Check your local county/city/town/incorporation to determine additional regulations/requirements.

Additional Considerations

- File for a Tax Number
- Register Business Name
- Apply for a UPC Code
- Business Planning
- Marketing
- **Product Labeling** *21 CFR 101*
<https://www.fda.gov/media/81606/download>
 - Statement of Identity
 - Manufacturer Information (Name & Address)
 - Quantity Statement
 - Ingredient Statement
 - Allergen Labeling
<https://www.fda.gov/regulatory-information/search-fda-guidance-documents/guidance-industry-questions-and-answers-regarding-food-allergen-labeling-edition-5>
 - Nutritional Information
<https://www.fda.gov/food/food-labeling-nutrition/changes-nutrition-facts-label>
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