



Scheduled Process Guide for Acidified and Water Activity Controlled Foods

Processed foods are considered [acid, low acid, or acidified](#), or water activity-controlled. Low acid foods can be acidified in order to manufacture a non-refrigerated, shelf stable product. In the US, acidified and water activity-controlled shelf stable foods require a Scheduled Process. In New York and many other states, most acid foods being made shelf stable also need a Scheduled Process.

A [Scheduled Process](#) is a detailed recipe and procedure for your specific product. Your product and process are analyzed, reviewed, and approved by a [Processing Authority](#). A Scheduled Process ensures that a proper pH (4.60 or lower) OR proper water activity (0.91 or lower) is achieved in order to prevent the growth of *Clostridium botulinum*, and that a proper thermal or heat method is used to kill other pathogens and spoilage microorganisms of concern. For small- to mid-scale processors, this treatment combination for pH-controlled shelf stable products typically requires a pH further reduced to 4.20 or lower.

Whether you are manufacturing the product yourself or through a co-packer, the Scheduled Process must be followed diligently. Documentation of each batch is required to show that the Scheduled Process was followed and that the proper critical factors were achieved.

Any manufacturer of acidified or water activity-controlled foods must familiarize themselves with the following regulations:

1. [Title 21 Part 114 for FDA regulated acidified foods](#)
2. [Title 21 Part 113 for FDA regulated water activity-controlled foods](#)
3. [Title 21 Part 117 for Good Manufacturing Practices](#)
4. [FDA industry guidance for acidified foods](#)
5. [FDA industry guidance for low-acid canned foods \(water activity-controlled foods\)](#)

What you need to obtain a scheduled process:

1. Completed recipe with exact weights of all ingredients
2. Procedure of how the product is made including heat steps applied.
3. Contact a [Processing Authority](#) **after** the recipe prototype is created
4. Send relevant information based on Processing Authority submission requirements

A scheduled process through [Cornell University's Food Venture Center](#) costs \$85 with an expected 4-6 week turnaround. This process can be expedited to 2-3 weeks at a cost of \$170. To begin a Schedule Process with Cornell, contact the Cornell Food Venture Center at cfvc@cornell.edu.



The FDA regulates that all acidified foods destined for interstate commerce be manufactured under a Scheduled Process. Facilities used in manufacturing food products must be registered and Scheduled Processes filed with the FDA. If you are using a co-packer, they will usually take care of these requirements for you:

1. Register with the FDA on [Form FDA 2541](#) no later than 10 days after the firm engages in operations
2. File each new process requiring FDA registration using the appropriate form with the Food Facility Registration (Form FDA 2541):
 - a. acidified food process using [Form FDA 2541e](#)
 - b. water activity-controlled foods [Form FDA 2541f](#)
3. Complete a ["Better Process Control School"](#) training prior to commercial production