

# Department of Food Science

## *Food Processing*

FSE 99-21

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### Scheduled Processes

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If acidified foods are improperly processed and distributed, the health of the consumer may be adversely affected. There is no adequate way to determine the harmful nature of the foods after they have been released into marketing channels. Therefore, the U.S. Food and Drug Administration (FDA) requires evidence that acidified foods destined for interstate commerce be manufactured and handled in such a manner as to assure safety to the consumer. A critical part of assuring acidified foods are safe is to manufacture products according to a scheduled process. A **scheduled process** is a process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food product that will not permit the growth of microorganisms having public health significance. Among other things the scheduled process specifies the pH and other critical factors that must be controlled to assure the manufacture of safe acidified foods. A scheduled process must be established by a qualified person or a competent process authority, with expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods. Scheduled processes must be followed during manufacture of the food, and critical factors must be monitored under the operating supervision of an individual who has attended and successfully completed a course and has become certified to supervise those operations.

The key to safe preservation of acidified foods is the maintenance of an adequately low pH in the finished product to prevent growth and toxin production by the deadly bacterium, *Clostridium botulinum*. A pH of 4.6 or below throughout the food will prevent this serious safety hazard. However, it may be necessary to prevent growth of other pathogenic and non-pathogenic microorganisms capable of growing at lower pH values by heating the product to kill vegetative cells of these microorganisms. Permitted preservatives may be used to inhibit **non-pathogenic** microorganisms, instead of thermal processing.

## REGISTRATION AND PROCESS FILING

A commercial processor, when first engaging in the manufacture, processing, or packing of acidified foods in any state **must** register with the FDA on Form FDA 2541 (Food Canning Establishment Registration; 21 CFR 108.25). This form **must** be filed not later than 10 days after the firm engages in operations.

In addition, the firm **must** file a scheduled process with the FDA on Form FDA 2541a not later than 60 days after registration, and before packing any new product. These forms are available from FDA. Firms already registered and engaged in the processing of acidified foods need only file Form FDA 2541a, for each new acidified food in each container size. Registration and process filing forms are available from FDA by writing:

LACF Registration Coordinator, HFS-618  
Food & Drug Administration  
Center for Food Safety & Applied Nutr.  
200 C Street, S.W.  
Washington DC 20204

The processor must fulfill all of the requirements for registration, as well as mandatory portions of 21 CFR 114, namely:

- 114.10 - Personnel
- 114.80 (a) (1) and (2), and  
(b) - Processes and controls
- 114.83 - Establishing scheduled processes
- 114.89 - Deviations from scheduled processes
- 114.100 (b), (c), and (d) – Records

The scheduled process **must** include information essential to produce a safe product, including the maximum equilibrium pH, and other critical factors, such as heat processing, and preservatives used, and their levels as appropriate.

## PROCESSES AND CONTROLS

The manufacturer **must** employ process and control procedures to ensure that the finished foods do not present a public health hazard. Acidified foods **must** have a finished equilibrium pH of 4.6 or lower, achieved within any time designated in the scheduled process (if such time is determined by the process authority to be a critical factor). Furthermore, a pH of 4.6 or lower **must** be maintained in all finished products. While pH 4.6 or lower is adequate to prevent growth and toxin production by *Clostridium botulinum*, it may not be adequate to prevent growth of other microbial pathogens. Thus, acidified foods **must** be thermally processed to an extent that is sufficient to destroy the vegetative cells of microbes of public health significance and those of non-health significance that can grow in the product under the conditions in which it is stored, distributed, and held by the consumer. Approved preservatives may be used instead of heat to prevent growth of non-pathogenic microorganisms. The product **must** be tested to insure an equilibrium pH of 4.6 or lower and the results recorded.

## PROCEDURES FOR ACIDIFICATION

It is important to remember that "acidified foods" are low-acid foods to which acids or acid foods have been added to obtain a finished equilibrium pH of 4.6 or below. It is essential that sufficient acid is added to ensure that pH 4.6 or lower is achieved after all of the components in the finished product have reached equilibrium. The following example procedures to properly acidify foods are mentioned in the regulation:

- (1) Direct acidification of individual containers
- (2) Direct batch acidification
- (3) Blanching in an acidified solution
- (4) Immersion of blanched products in an acid solution
- (5) Addition of an acid food to a low-acid food

Regardless of the acidification method used, it is important to establish if there are any critical factors for proper acidification, and if so, document their control during production.

**In all instances, when one or more containers of a given lot of acidified food is found to have an equilibrium pH above 4.6, it must be concluded that there has been a deviation from the scheduled process for the entire lot.**

Whenever the pH of any single container of a given lot of food approaches pH 4.6, a large number of containers should be sampled to assure that none of them exceeds this critical value. A processor of acidified foods must promptly report to FDA any instance of spoilage, process deviation, or contamination with microorganisms, the nature of which has potential health-endangering significance where any lot of such food has in whole or in part entered distribution in commerce.

Whenever deviations from scheduled processes occur, the re-working of the entire lot according to a scheduled process should

be quickly and carefully considered. While in many cases such deviations may not result in any public health hazard, they may have pronounced effects on the quality of the product. For example, if records indicate that there was a malfunction in a pasteurizer during a given period and, if pasteurization is in the scheduled process that was filed, then all product which may have been pasteurized during that period should be immediately re-processed according to the scheduled process. Failure to control other factors specified in the scheduled process, such as maximum pH, titratable acidity, salt and sugar concentrations, preservatives or drained weights of the finished products are deviations and the affected product must be set aside for evaluation or reprocessed according to pre-planned corrective action. Products with low vacuum or improper seals shall be treated similarly.

Records of all departures from scheduled processes **must** be maintained in a separate file for 3 years.

**Following are examples of critical factors for assuring proper acidification of foods; there may be others, depending upon the specific foods and processes:**

1. The pH and acidity of acidifying cover solutions or acid food must be sufficient to assure a final equilibrated pH of 4.6 or below for the entire container contents.
2. The ratio of solid foods (such as cucumbers, peppers, etc.) to acidifying cover solution must be controlled within limits to assure a final equilibrated pH of 4.6 or below.
3. Other unit operations in the process that affect the final equilibrated pH, such as lye peeling and piece size, must be properly controlled and the pH monitored.
4. If the product receives a heat treatment to destroy vegetative cells of microorganisms of public health and non-public health significance that may grow in the product, time and temperature must be controlled.
5. If a preservative such as sodium benzoate or potassium sorbate is used instead of, or in combination with heating, it must be present at the specified concentration.
6. The food containers must be properly closed, sealed, and handled in such a manner as to prevent leakage or contamination with pathogenic or spoilage microorganism.
7. The food container must be sealed to exclude air since oxygen in the air can permit growth of oxidative yeasts and molds which can utilize acids and result in an increase in pH above 4.6.
8. Analytical instruments, such as pH meters and titration devices, and standard solutions must be functioning properly and standardized frequently.
9. Samples of in-process product and/or finished products must be taken at regular intervals for measurement and verification of the intended pH and acidity.
10. Raw products must be properly handled to prevent growth and toxin production of harmful microorganisms prior to processing.
11. Personnel must be adequately trained and must perform proper pH and acidity measurements.
12. Adequate records must be kept and maintained to assure and document proper control of all critical factors in the process.