CHAPTER 11
SCHEDULED PROCESSES

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CHAPTER 11

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11.1 INTRODUCTION

Notes

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 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

The scheduled process must include all critical factors necessary to produce a safe food. It should not include processing steps unrelated to the safety of the product.

process. A *scheduled process* is the process selected by a processor as adequate for use under the conditions of manufacture for a food in achieving and maintaining a food that will not permit the growth of microorganisms having public health significance.

Among other things, the scheduled process specifies the maximum product pH and other critical factors that must be controlled to assure manufacture of safe acidified foods. Scheduled processes must be established by a qualified person or a competent processing 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 food, and critical factors must be monitored under the operating supervision of an individual who has attended and successfully completed a course such as the one you are attending.

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 the survival or growth of other pathogenic and non-pathogenic microorganisms at pH values of 4.6 or below by heating the product to kill vegetative cells of such microorganisms. Permitted preservatives

may be used to inhibit non-pathogenic microorganisms, but not cannot be relied upon to inhibit pathogens as a substitute for thermal processing.

The purpose of this chapter is to summarize the technical and regulatory bases of developing scheduled processes for acidified foods. Background information supporting this chapter appears in other chapters of this manual. The full text of the relevant regulations for acidified foods appears in Appendix A.

Notes

11.2 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 Section 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. Copies of these forms appear in Appendix B. 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.

The filed 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.

11.3 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 the 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*, researchers have determined that vegetative cells of acid-tolerant pathogens (*Escherichia coli*

The processor must fulfill all of the mandatory requirements of 21 CFR Section 108.25, as well as mandatory portions of 21 CFR Part 114, namely:

114.10 -	Personnel
114.80 -	Processes and controls
114.83 -	Establishing scheduled processes
114.89 -	Deviations from scheduled processes
114.100 -	Records

Notes

O157:H7, *Listeria O157:H7,Listeria monocytogenes,* and *Salmonella*) may survive (though they may not grow) for extended periods of time at pH levels below 4.6. If the equilibrated pH is 3.3 or lower and the temperature is held at 77°F (25°C) or higher for at least 48 hr, these acid-tolerant pathogens will die off. However, at pH values above 3.3, a thermal process as described in the previous chapter is required to assure killing of these pathogens.

11.3.1 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 procedures to acidify foods were discussed in Chapter 3 (section 3.9.1). Return to that section for more details.

(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.

11.3.2 Critical Factors for Acidified Foods

A critical factor is a point in the process at which a potential hazard can be eliminated, controlled, or reduced to a safe level.

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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 a 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 a heat process is required to assure killing of the vegetative cells of pathogenic organisms, an adequate time and temperature must be delivered to the slowest heating point in the product, and the process must be controlled to be sure that the intended heat process is delivered to every container.

(5) If an equilibrated pH ≤ 3.3 is to be used instead of a heat process to eliminate pathogenic bacteria from the product, the pH, holding temperature, and holding time required to ensure killing (48 hr at 77°F or 25°C) the pathogens must be controlled by the processor.

(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 microorganisms.

(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, standard solutions, and thermometers, must function properly and be 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 perform proper pH and acidity measurements.

(12) Adequate records must be kept and maintained to assure and document proper control of all critical points in the process.

11.4 PROCESS AUTHORITY

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The scheduled process must be established by a qualified person(s) who has expert knowledge acquired through training and experience in the acidification and processing of acidified foods. Expertise of the authority may be evidenced by data furnished to the FDA by the company, or by citing scientific publications that are accepted as authoritative by FDA and which deal specifically with the product and process in use. The source and date of the process establishment information must be listed on FDA Form 2541a. Examples of process filing forms and scientific publications that one can study and determine their suitability for a process filing are given in Appendix 3.

11.5 PROCESS DEVIATIONS

In the event that any process operation deviates from the scheduled process for any acidified food, or the equilibrium pH of the finished product is higher than 4.6, the processor has several options. The processor may:

(1) fully re-process that portion of the product as an acidified food using a process established by a competent processing authority for that purpose;

(2) thermally process the product (according to a filed process) as a low-acid food under 21 CFR Section 108.35 and Part 113; or

(3) set the product aside (usually under refrigeration) for evaluation by a competent process authority as to its safety;

(4) regardless of which option a manufacturer chooses, a record must be made of the procedures used to evaluate the food and the results.

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 pasteurization is specified by 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 critical 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 re-processed according to pre-planned corrective action. Products with low vacuum or improper seals should be treated similarly.

Records of all departures from scheduled processes must be maintained in a separate file. These will be discussed in Chapter 8.

11.6 SUMMARY

(1) "Scheduled processes" specify the critical factors, including maximum equilibrium pH, necessary to ensure that no microorganisms of public health significance will survive or grow in the food.

(2) A key to safe preservation of acidified foods is the achievement and maintenance of an adequately low pH (4.6 or below) in the finished product to prevent growth and toxin production by the deadly bacterium, *Clostridium botulinum*.

(3) An adequate thermal process is necessary to destroy vegetative cells of acid-tolerant pathogenic bacteria that may survive for considerable periods of time if the pH is greater than 3.3. For products with a pH $\leq$3.3, holding the product at 77°F (25°C) or higher for at least 48 hr prior to shipping may be used instead of a heat process to assure killing of acid-tolerant pathogenic bacteria.

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(4) In practice, manufacturers should **determine critical factors responsible for the safety** of each food product. Low-acid ingredients of acidified foods must not be held for extended periods under conditions which allow the growth of organisms of public health significance (see Chapter 2).

(5) A scheduled process **must** be filed on Form FDA 2541a not later than 60 days after registration and before packing any new product.

(6) The scheduled process must be established by a qualified person(s) who has adequate training and experience in the acidification and processing of acidified foods.

(7) Scheduled processes specify critical factors that must be controlled to assure that the spores of *Clostridium botulinum* will not germinate, grow, and produce toxin, and to assure that the vegetative cells of acid-tolerant pathogens are killed.

(8) Other critical factors may be established, such as solid/liquid ratios (drained weights) and the amount of acid per container, to ensure pH control and safety in many acidified foods.

(9) Any time that the equilibrium pH of any container of an acidified food lot is above 4.6, that lot of food must be considered to have been affected by a deviation from the scheduled process and should be dealt with according to pre-determined corrective actions.

(10) If any critical factors have deviated from the scheduled process, the affected product must be set aside and evaluated for public health significance, or re-processed using established corrective actions for process deviations.

(11) Detailed records must be maintained in a separate file for all instances of deviations from scheduled processes.