

901:3-5-01

Criteria and definitions for processing acidified foods in hermetically sealed containers.

(A) Food processing establishments processing acidified foods in hermetically sealed containers shall comply with Chapter 901:3-5 of the Administrative Code and the applicable provisions of Chapter 901:3-17 of the Administrative Code.

(B) Definitions.

As used in Chapter 901:3-5 of the Administrative Code:

(1) "Acid foods" means foods that have a natural pH of 4.6 or below.

(2) "Acidified foods";

(a) Means low-acid foods that have a water activity (a_w) greater than 0.85 and have a finished equilibrium pH of 4.6 or below to which acids or acid foods are added.

(b) Does not include carbonated beverages, jams, jellies, preserves, acid foods such as standardized and nonstandardized food dressings and condiment sauces that contain small amounts of low-acid food and have a resultant finished equilibrium pH that does not significantly differ from that of the predominant acid or acid food, or foods that are stored, distributed, and retailed under refrigeration are excluded from the coverage of this chapter.

(3) "Lot" means the food product produced during a period indicated by a specific code.

(4) "Low-acid foods" means any foods, other than alcoholic beverages, with a finished equilibrium pH greater than 4.6 and a water activity (a_w) greater than 0.85. Tomatoes and tomato products having a finished equilibrium pH less than 4.7 are not classed as low-acid foods.

(5) "pH" is the symbol for the negative logarithm of the hydrogen ion concentration which is a measure of degree of acidity or alkalinity of a solution.

(6) "Scheduled process" means 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. It includes control of pH and other critical factors equivalent to the process established by a processing authority.

- (7) "A_w" means water activity which is a measure of the free moisture in a food and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

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Personnel training.

- (A) The operators of processing and packaging systems shall be under the operating supervision of a person who has attended a school for giving instruction in food-handling techniques, food-protection principles, personal hygiene, plant sanitation practices, pH controls, critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction.

- (B) The supervisor identified in paragraph (A) of this rule shall supply the director, upon request, a copy of their certificate of completion for the prescribed applicable course of instruction.

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Processes and controls.

(A) Processing operations.

The manufacturer shall employ appropriate quality control procedures to ensure that finished foods do not present a health hazard.

- (1) Acidified foods shall be so manufactured, processed, and packaged that a finished equilibrium pH value of 4.6 or lower is achieved within the time designated in the scheduled process and maintained in all finished foods. Manufacturing shall be in accordance with the scheduled process filed with the U.S. food and drug administration. Acidified foods shall be thermally processed to an extent that is sufficient to destroy the vegetative cells of microorganisms of public health significance and those of no health significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. In lieu of thermal processing, approved preservatives may be used to inhibit reproduction of microorganisms of no health significance.
- (2) Sufficient control, including frequent testing and recording of results, shall be exercised so that the finished equilibrium pH values for acidified foods are not higher than 4.6. If the finished equilibrium pH of the food is above 4.0, the measurement of the finished equilibrium pH shall be by a potentiometric method, and the in-process measurements by titration or colorimetry shall be related to the finished equilibrium pH. If the finished equilibrium pH is 4.0 or below, then the measurement of acidity of the final product may be made by any suitable method.
- (3) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:
 - (a) Blanching of the food ingredients in acidified aqueous solutions.
 - (b) Immersion of the blanched food in acid solutions provided the acid concentration is properly maintained.
 - (c) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.
 - (d) Direct addition of a predetermined amount of acid to individual containers during production provided care is taken to ensure that the proper amount of acid is added to each container.

(e) Addition of acid foods to low-acid foods in controlled proportions to conform to specific formulations.

(4) Testing and examinations of containers shall occur often enough to ensure that the container suitably protects the food from leakage or contamination.

(B) Coding.

(1) Each container or product shall be marked with an identifying code permanently visible to the naked eye.

(2) The required identification shall specify in code the establishment where the product was packed, the product contained therein, and the year, day, and period during which it was packed.

(3) The packing period code shall be changed often enough to enable ready identification of lots during their sale and distribution. Codes may be changed periodically on one of the following bases:

(a) Intervals of four to five hours;

(b) Personnel shift changes; or

(c) Batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

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Production and process controls.

(A) Scheduled processes for acidified foods.

(1) Processor shall supply upon request a copy of:

(a) Their FDA food canning establishment number.

(b) The scheduled process filed with the FDA including a list of critical control points.

(2) Complete records covering all aspects of the establishment of the process and associated incubation test shall be prepared and shall be permanently retained by the person or organization making the determination.

(B) Deviations from scheduled processes.

Whenever any process operation deviates from the scheduled process for any acidified food and/or the equilibrium pH of the finished product is higher than 4.6, the commercial processor of the acidified food shall either:

(1) Fully reprocess that portion of the food in accordance with the scheduled process filed with FDA;

(2) Thermally process it as a low-acid food under Chapter 901:3-3 of the Administrative Code; or

(3) Set aside that portion of the food involved for further evaluation as to any potential public health significance.

(a) The evaluation of the deviation shall be made to detect any potential hazard to public health.

(b) Unless the evaluation demonstrates that the food has undergone a process that has rendered it safe, the food set aside shall either be fully reprocessed to render it safe, or be destroyed.

(c) A record shall be made of the procedures used in the evaluation and the results.

(d) Upon completion of full reprocessing and the attainment of a safe food, or after the determination that no significant potential for public health

hazard exists, that portion of the food involved may be shipped in normal distribution.

(e) Food involved that has been determined to present a potential health hazard and not been reprocessed to render it safe shall be destroyed.

(C) A manufacturer shall promptly notify the director of any instance of spoilage, process deviation, or contamination with microorganisms when:

(1) There is a potential health endangering significance; and

(2) Where the lot of such food, in whole or in part, has entered distribution in commerce.

(D) A manufacturer shall prepare and maintain files on procedures which contains plans for the following:

(1) Recalling products;

(2) Identifying, collecting, warehousing and controlling products;

(3) Determining the effectiveness of recalls;

(4) Notifying the director of any recalls; and

(5) Implementing recall programs.

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Records.

- (A) Records shall be maintained of examinations of raw materials, packaging materials, finished products, and of suppliers' guarantees or certifications.
- (B) Processing and production records showing adherence to scheduled processes, including records of pH measurements and other critical factors intended to ensure a safe product, shall be maintained and shall contain sufficient additional information such as product code, date, container size, and product, to permit a public health hazard evaluation of the processes applied to each lot, batch, or other portion of production.
- (C) All departures from scheduled processes having a possible bearing on public health or the safety of the food shall be noted and the affected portion of the product identified; these departures shall be recorded and made the subject of a separate file or log identifying the appropriate data delineating them, the action taken to rectify them, and the disposition of the portion of the product involved.
- (D) Records shall be maintained identifying initial distribution of the finished product to facilitate, when necessary, the segregation of specific food lots that may have become contaminated or otherwise unfit for their intended use.
- (E) Copies of all records provided for in paragraphs (B), (C), and (D) of this rule shall be retained at the processing plant or other reasonably accessible location for a period of three years from the date of manufacture.