§ 114.5 Current good manufacturing practice.

The criteria in §§ 114.10, 114.80, 114.83, 114.89, and 114.100, as well as the criteria in parts 110 and 117 of this chapter, apply in determining whether an article of acidified food is adulterated:

(a) Within the meaning of section 402(a)(3) of the Federal Food, Drug, and Cosmetic Act in that it has been manufactured under such conditions that it is unfit for food; or

(b) Within the meaning of section 402(a)(4) of the Federal Food, Drug, and Cosmetic Act in that it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health.

[80 FR 56144, Sept. 17, 2015]

§ 114.10 Personnel.

All operators of processing and packaging systems shall be under the operating supervisions of a person who has attended a school approved by the Commissioner for giving instruction in food-handling techniques, food-protection principles, personal hygiene and plant sanitation practices, pH controls and critical factors in acidification, and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. The Commissioner will consider students who have satisfactorily completed the required portions of the courses presented under § 108.35 and part 113 of this chapter before March 16, 1979, to be in compliance with the requirement of this section.

Subparts B–D [Reserved]

Subpart E—Production and Process Controls

§ 114.80 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. 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 nonhealth significance capable of reproducing in the food under the conditions in which the food is stored, distributed, retailed and held by the user. Permitted preservatives may be used to inhibit reproduction of microorganisms of nonhealth significance (in lieu of thermal processing).

(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. Measurement of acidity of foods in-process may be made by potentiometric methods, titratable acidity, or colorimetric methods. 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. Special care should be taken when food ingredients have been subjected to lye, lime, or similar high pH materials.

(3) Procedures for acidification to attain acceptable equilibrium pH levels in the final food include, but are not limited to, the following:

(i) Blanching of the food ingredients in acidified aqueous solutions.

(ii) Immersion of the blanched food in acid solutions. Although immersion of food in an acid solution is a satisfactory method for acidification, care must be taken to ensure that the acid concentration is properly maintained.

(iii) Direct batch acidification, which can be achieved by adding a known amount of an acid solution to a specified amount of food during acidification.

(iv) Direct addition of a predetermined amount of acid to individual containers during production. Liquid acids are generally more effective than

solid or pelleted acids. Care must be taken to ensure that the proper amount of acid is added to each container.

(v) 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*. Each container or product shall be marked with an identifying code permanently visible to the naked eye. If the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, as long as the label is securely affixed to the product container. 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. 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: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers constituting the batch do not represent those processed during more than one personnel shift.

§ 114.83 Establishing scheduled processes.

The scheduled process shall be established by a qualified person who has expert knowledge acquired through appropriate training and experience in the acidification and processing of acidified foods.

§ 114.89 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: (a) Fully reprocess that portion of the food by a process established by a competent processing authority as adequate to ensure a safe product; (b) thermally process it as a low-acid food under part 113 of this chapter; or (c) set aside that portion of the food involved for further evaluation as to any potential public health significance. The evaluation shall be made by a competent processing authority and shall be in accordance with procedures recognized by competent processing authorities as being adequate to detect any potential hazard to public health. 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. A record shall be made of the procedures used in the evaluation and the results. Either 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. Otherwise, the portion of the food involved shall be destroyed.

§ 114.90 Methodology.

Methods that may be used to determine pH or acidity for acidified foods include, but are not limited to, the following:

(a) *Potentiometric method for the determination of pH*—(1) *Principles*. The term ''pH'' is used to designate the intensity or degree of acidity. The value of pH, the logarithm of the reciprocal of the hydrogen ion concentration in solution, is determined by measuring the difference in potential between two electrodes immersed in a sample solution. A suitable system consists of a potentiometer, a glass electrode, and a reference electrode. A precise pH determination can be made by making an electromotive force (emf) measurement of a standard buffer solution whose pH is known, and then comparing that measurement to an emf measurement of a sample of the solution to be tested.

(2) *Instruments*. The primary instrument for use in pH determination is the pH meter or potentiometer. For most work, an instrument with a direct-reading pH scale is necessary. Battery and line-operated instruments are available commercially. If the line voltage is unstable, line-operated instruments should be fitted with voltage regulators to eliminate drifting of