Ohio Administrative Code

Rule 901:3-5-04 Production and process controls.

Effective: June 29, 2015

(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.