Ohio Administrative Code
Rule 901:3-3-17 Production and process controls.

Effective: July 4, 2015

(A) Product preparation.

(1) Before using raw materials and ingredients susceptible to microbiological contamination, the processor shall ensure that those materials and ingredients are suitable for use in processing low-acid food.

(2) The filling of containers, either mechanically or by hand, shall be controlled to ensure that the filling requirements specified in the scheduled process are met.

(3) The exhausting of containers for the removal of air shall be controlled to meet the conditions for which the process was designed. Compliance with the requirement may be accomplished by heat exhausting, mechanical exhausting, hot brining, or steam injection.

(4) When the maintenance of pH above 4.6 of a normally low-acid food is a basis for a scheduled process, there shall be careful supervision to ensure that the equilibrium pH of the finished product meets that of the scheduled process.

(5) When the scheduled process sets forth critical factors to prevent the growth of microorganisms not destroyed by the thermal process, the factors shall be carefully controlled to ensure that the limits established in the scheduled process are not exceeded.

(6) When normally low-acid foods require sufficient solute to permit safe processing at low temperatures, such as in boiling water, there shall be careful supervision to ensure that the equilibrium water activity ($a_w$) of the finished product meets that of the scheduled process.

(7) The scheduled thermal processes for foods having an $a_w$ greater than 0.85 and less than the $a_w$ that would allow the growth of spores of microorganisms of public health significance shall be sufficient to render the food free of microorganisms capable of reproducing in the food under normal

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nonrefrigerated conditions of storage and distribution.

(B) Scheduled processes for low acid 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 listing 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.

(C) Operations in the thermal processing room.

(1) Operating processes and retort venting procedures to be used for each product and container size being packed shall either be posted in a conspicuous place near the processing equipment or be made readily available to the retort or processing system operator and any duly authorized employee of the Ohio department of agriculture. Scheduled processes must be made readily available to the supervisor and any duly authorized employee of the Ohio department of agriculture.

(2) A system for product traffic control in the retort room shall be established to prevent unretorted product from bypassing the retort process.

(a) Each retort basket, truck, car, or crate used to hold containers in a retort, or one or more containers therein, shall, if it contains any retorted food product, be plainly and conspicuously marked with a heat-sensitive indicator, or by other effective means that will indicate visually, to thermal processing personnel, those units that have been retorted.

(b) A visual check shall be performed to determine whether or not the appropriate change has occurred in the heat-sensitive indicator as a result of retorting for all retort baskets, trucks, cars, or crates, to ensure that each unit of product has been retorted.
(3) The initial temperature of the contents of the containers to be processed shall be determined and recorded with sufficient frequency to ensure that the temperature of the product is no lower than the minimum initial temperature specified in the scheduled process. For those operations that use water during the filling of the retort or during processing, provision shall be made to ensure that the water will not, before the start of each thermal process, lower the initial temperature of the product below that specified in the scheduled process.

(4) Timing devices used in recording thermal process time information shall be accurate to ensure that the processing time and venting time specified in the scheduled process are achieved. A pocket or wrist watch is not considered satisfactory for timing purposes. Digital clocks may be used if the operating process and the venting schedule have a one minute or greater safety factor over the scheduled process.

(5) The steam supply to the thermal processing system shall be adequate to the extent needed to ensure that sufficient steam pressure is maintained during thermal processing, regardless of other demands of steam by the plant.

(6) If mufflers are used on bleeders or vent systems, evidence that the bleeders or vents are operated in a manner that does not significantly impede the removal of air shall be kept on file. This evidence may be in the form of heat distribution data or other satisfactory evidence.

(D) Deviations in processing, venting, or control of critical factors.

(1) Whenever any process is less than the scheduled process or when critical factors are out of control for any low-acid food or container system as disclosed from records by processor check or otherwise, the commercial processor of that low-acid food shall either:

(a) Fully reprocess that portion of the production involved, keeping full records of their processing conditions; or

(b) Must set aside that portion of the product involved for further evaluation as to any potential public health significance.
(i) The evaluation shall be made to detect any potential hazard to public health.

(ii) Unless this evaluation demonstrates that the product had been given a thermal process that rendered it free of microorganisms of potential public health significance, the product set aside shall be either fully reprocessed to render it commercially sterile or destroyed.

(2) A record shall be made of the evaluation procedures used and the results. Either upon completion of full reprocessing and the attainment of commercial sterility or after the determination that no significant potential for public health hazard exists, that portion of the product involved may be shipped in normal distribution. Otherwise, the portion of the product involved shall be destroyed.

(3) All process deviations involving a failure to satisfy the minimum requirements of the scheduled process, including emergencies arising from a jam or breakdown of a continuous agitating retort necessitating cooling the retort for repairs, shall be recorded and made the subject of a separate file or a log identifying the appropriate data detailing those deviations and the actions taken.

(E) A manufacturer shall promptly notify the director or the director's designee 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.

(F) 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.