§ 113.5

21 CFR Ch. I (4–1–14 Edition)

The criteria in §§113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or

capable of reproducing in the food under normal nonrefrigerated conditions of storage and distribution.

(f) Critical factor means any property, characteristic, condition, aspect, or other parameter, variation of which may affect the scheduled process and the attainment of commercial sterility.

(g) Flame sterilizer means an apparatus in which hermetically sealed containers are agitated at atmospheric pressure, by either continuous, discontinuous, or reciprocating movement, with impinging gas flames to achieve sterilization temperatures. A holding period in a heated section may follow the initial heating period.

(h) Headspace, gross is the vertical distance between the level of the product (generally the liquid surface) in an upright rigid container and the top edge of the container (the top of the double seam of a can or the top edge of a glass jar).

(i) Headspace, net of a container is the vertical distance between the level of the product (generally the liquid surface) in the upright rigid container and the inside surface of the lid.

(j) Hermetically sealed container means a container that is designed and intended to be secure against the entry of microorganisms and thereby to maintain the commercial sterility of its contents after processing.

(k) Incubation means the holding of a sample(s) at a specified temperature for a specified period of time for the purpose of permitting or stimulating the growth of microorganisms.

(l) Initial temperature means the average temperature of the contents of the coldest container to be processed at the time the thermal processing cycle begins, as determined after thorough stirring or shaking of the filled and sealed container.

(m) Lot means that amount of a product produced during a period of time indicated by a specific code.

(n) 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.

(o) Minimum thermal process means the application of heat to food, either before or after sealing in a hermetically sealed container, for a period of time and at a temperature scientifically determined to be adequate to ensure destruction of microorganisms of public health significance.

(p) Operating process means the process selected by the processor that equals or exceeds the minimum requirements set forth in the scheduled process.

(q) Retort means any closed vessel or other equipment used for the thermal processing of foods.

(r) Scheduled process means the process selected by the processor as adequate under the conditions of manufacture for a given product to achieve commercial sterility. This process may be in excess of that necessary to ensure destruction of microorganisms of public health significance, and shall be at least equivalent to the process established by a competent processing authority to achieve commercial sterility.

(s) Shall is used to state mandatory requirements.

(t) Should is used to state recommended or advisory procedures or to identify recommended equipment.

(u) Vacuum-packed products means those products that are sealed in a container under the vacuum specified in the scheduled process, the maintenance of which vacuum is critical to the adequacy of the scheduled process.

(v) Vents means openings through the retort shell, controlled by gate, plug cock, or other adequate valves used for the elimination of air during the venting period.

(w) Water activity ($a_w$) is a measure of the free moisture in a product and is the quotient of the water vapor pressure of the substance divided by the vapor pressure of pure water at the same temperature.

§ 113.5 Current good manufacturing practice.

The criteria in §§113.10, 113.40, 113.60, 113.81, 113.83, 113.87, 113.89, and 113.100 shall apply in determining whether the facilities, methods, practices, and controls used by the commercial processor in the manufacture, processing, or
packing of low-acid foods in hermetically sealed containers are operated or administered in a manner adequate to protect the public health.

§ 113.10 Personnel.

The operators of processing systems, retorts, aseptic processing and packaging systems and product formulating systems (including systems wherein water activity is used in conjunction with thermal processing) and container closure inspectors shall be under the operating supervision of a person who has attended a school approved by the Commissioner for giving instruction appropriate to the preservation technology involved and who has been identified by that school as having satisfactorily completed the prescribed course of instruction. This person shall supervise only in those areas for which a school approved by the Commissioner identifies the person as having satisfactorily completed training.

Subpart B [Reserved]

Subpart C—Equipment

§ 113.40 Equipment and procedures.

(a) Equipment and procedures for pressure processing in steam in still retorts—

(1) Temperature-indicating device. Each retort shall be equipped with at least one temperature-indicating device that accurately indicates the temperature during processing. Each temperature-indicating device shall have a sensor and a display. Each temperature-indicating device and each reference device that is maintained by the processor shall be tested for accuracy against a reference instrument for indicating the processing temperature. The temperature-indicating device—not the temperature-recording device—shall be the reference instrument for indicating the processing temperature.

(2) Temperature-recording device. Each retort shall have an accurate temperature-recording device. Each temperature-recording device shall have a sensor and a mechanism for recording temperatures to a permanent record, such as a temperature-recording chart. The temperature-recording device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder that emits steam continuously during the entire processing period.

(b) Temperature-indicating device.

(i) Each temperature-indicating device shall be accurate to 1 °F (0.5 °C). The temperature range of a mercury-in-glass thermometer shall not exceed 17 °F per inch (4 °C per centimeter) of graduated scale. A mercury-in-glass thermometer that has a divided mercury column shall be considered defective.

(ii) Records of the accuracy of the temperature-indicating device and of a reference device that is maintained by the processor shall be established and maintained in accordance with §113.100(c) and (d).

(iii) A temperature-indicating device that is defective or cannot be adjusted to the accurate calibrated reference device shall be repaired before further use or replaced.

(iv) A temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature recording device—shall be the reference instrument for indicating the processing temperature.

(v) Each temperature-indicating device shall be installed where it can be accurately and easily read. The temperature-indicating device sensor shall be installed either within the retort shell or in external wells attached to the retort. External wells or pipes shall be connected to the retort through at least a ¾-inch (2 centimeters) diameter opening and equipped with a 1/16-inch (1.5 millimeters) or larger bleeder opening so located as to provide a full flow of steam past the length of the temperature-indicating device sensor. The bleeders for external wells shall emit steam continuously during the entire processing period. The temperature-indicating device—not the temperature recording device—shall be the reference instrument for indicating the processing temperature.