

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 en-

sure 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.