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(v) *Thermal process*. The heat treatment necessary to achieve shelf stability as determined by the establishment's processing authority. It is quantified in terms of:

(1) Time(s) and temperature(s); or

(2) Minimum product temperature.

(w) *Venting*. The removal of air from a retort before the start of process timing.

(x) *Water activity*. The ratio of the water vapor pressure of the product to the vapor pressure of pure water at the same temperature.

§ 381.301 Containers and closures.

(a) *Examination and cleaning of empty containers*. (1) Empty containers, closures, and flexible pouch roll stock shall be evaluated by the establishment to ensure that they are clean and free of structural defects and damage that may affect product or container integrity. Such an examination should be based upon a statistical sampling plan.

(2) All empty containers, closures, and flexible pouch roll stock shall be stored, handled, and conveyed in such a manner that will prevent soiling and damage that could affect the hermetic condition of the sealed container.

(3) Just before filling, rigid containers shall be cleaned to prevent incorporation of foreign matter into the finished product. Closures, semirigid containers, preformed flexible pouches, and flexible pouch roll stock contained in original wrappings do not need to be cleaned before use.

(b) *Closure examinations for rigid containers (cans)*. (1) Visual examinations. A closure technician shall visually examine the double seams formed by each closing machine head. When seam defects (e.g., cutovers, sharpness, knocked down flanges, false seams, droops) are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken. In addition to the double seams, the entire container shall be examined for product leakage or obvious defects. A visual examination shall be performed on at least one container from each closing machine head, and the observations, along with any corrective actions, shall be recorded. Visual examinations shall be recorded. Visual examinations shall be conducted with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician at the beginning of production, immediately following every jam in the closing machine and after closing machine adjustment (including adjustment for changes in container size).

(2) *Teardown examinations*. Teardown examinations of double seams formed by each closing machine head shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing head shall be examined on the packer's end during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have container specification guidelines for double seam integrity on file and available for review by Program employees. A teardown examination of the can maker's end shall be performed on at least one container selected from each closing machine during each examination period except when teardown examinations are made on incoming empty containers or when, in the case of self-manufactured containers, the containers are made in the vicinity of the establishment and the container plant records are made available to Program employees. Additional teardown examinations on the packer's end should be made at the beginning of production, immediately following every jam in a closing machine and after closing machine adjustment (including adjustment for a change in container size). The following procedures shall be used in teardown examinations of double seams:

(i) One of the following two methods shall be employed for dimensional measurements of the double seam.

(*a*) *Micrometer measurement*. For cylindrical containers, measure the following dimensions (Figure 1) at three

points approximately 120 degrees apart on the double seam excluding and at least one-half inch from the side seam juncture:

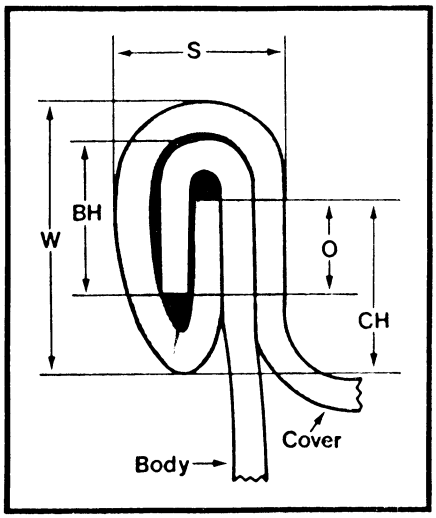
(*1*) Double seam length—W;

(*2*) Double seam thickness—S;

(*3*) Body hook length—BH; and

(*4*) Cover hook length—CH.

Maximum and minimum values for each dimensional measurement shall be recorded by the closure technician.



(*b*) *Seamscope or seam projector*. Required measurements of the seam include thickness, body hook, and overlap. Seam thickness shall be obtained by micrometer. For cylindrical containers, at least two locations, excluding the side seam juncture, shall be used to obtain the required measurements.

(ii) *Seam tightness*. Regardless of the dimensional measurement method used to measure seam dimensions, at a minimum, the seam(s) examined shall be stripped to assess the degree of wrinkling.

(iii) *Side seam juncture rating*. Regardless of the dimensional measurement method used to measure seam dimensions, the cover hook shall be stripped to examine the cover hook droop at the juncture for containers having side seams.

(iv) *Examination of noncylindrical containers*. Examination of noncylindrical containers (e.g., square, rectangular, ''D''-shaped, and irregularly-shaped) shall be conducted as described in paragraphs (b)(2) (i), (ii), and (iii) of this section except that the required dimensional measurements shall be made on the double seam at the points listed in the establishment's container specification guidelines.

(c) *Closure examinations for glass containers*—(1) *Visual examinations*. A closure technician shall visually assess the adequacy of the closures formed by each closing machine. When closure defects, such as loose or cocked caps, fractured or cracked containers and low vacuum jars, are observed, necessary corrective actions, such as adjusting or repairing the closing machine, shall be taken and recorded. In addition to the closures, the entire container shall be examined for defects. Visual examinations shall be made with sufficient frequency to ensure proper closure and should be conducted at least every 30 minutes of continuous closing machine operation. Additional visual examinations shall be made by the closure technician and the observations recorded at the beginning of production, immediately following every jam in the closing machine, and after closing machine adjustment (including adjustment for a change in container size).

(2) *Closure examinations and tests*. Depending upon the container and closure, tests shall be performed by a closure technician at a frequency sufficient to ensure proper closure. These examinations should be made either before or after thermal processing and at intervals of not more than 4 hours of continuous closing machine operation. At least one container from each closing machine shall be examined during each regular examination period. Examination results along with any necessary corrective actions, such as adjusting or repairing the closing machine, shall be promptly recorded by the closure technician. The establishment shall have specification guidelines for closure integrity on file and available for review by Program employees. Additional closure examinations should be made at the beginning of production, immediately following every jam in the closing machine and

after closing machine adjustment (including adjustment for a change in container size).

(d) *Closure examinations for semirigid and flexible containers*—(1) *Heat seals*—(i) *Visual examinations.* A closure technician shall visually examine the seals formed by each sealing machine. When sealing defects are observed, necessary corrective actions, such as adjusting or repairing the sealing machine, shall be taken and recorded. In addition to examining the heat seals, the entire container shall be examined for product leakage or obvious defects. Visual examinations shall be performed before and after the thermal processing operation with sufficient frequency to ensure proper closure. These examinations should be conducted at least in accordance with a statistical sampling plan. All defects noted and corrective actions taken shall be promptly recorded.

(ii) *Physical tests.* Tests determined by the establishment as necessary to assess container integrity shall be conducted by the closure technician at a frequency sufficient to ensure proper closure. These tests shall be performed after the thermal processing operation and should be made at least every 2 hours of continuous production. The establishment's acceptance guidelines for each test procedure shall be on file and available for review by Program employees. Test results along with any necessary corrective actions, such as adjusting or repairing the sealing machine, shall be recorded.

(2) Double seams on semirigid or flexible containers shall be examined and the results recorded as provided in paragraph (b) of this section. Any additional measurements specified by the container manufacturer shall also be made and recorded.

(e) *Container coding.* Each container shall be marked with a permanent, legible, identifying code mark. The mark shall, at a minimum, identify in code the product (unless the product name is lithographed or printed elsewhere on the container) and the day and year the product was packed.

(f) *Handling of containers after closure.* (1) Containers and closures shall be protected from damage which may cause defects that are likely to affect the hermetic condition of the containers. The accumulation of stationary containers on moving conveyors should be minimized to avoid damage to the containers.

(2) The maximum time lapse between closing and initiation of thermal processing shall be 2 hours. However, the Administrator may specify a shorter period of time when considered necessary to ensure product safety and stability. A longer period of time between closing and the initiation of thermal processing may be permitted by the Administrator.

(Approved by the Office of Management and Budget under control number 0583–0015)

§ 381.302 Thermal processing.

(a) *Process schedules.* Prior to the processing of canned product for distribution in commerce, an establishment shall have a process schedule (as defined in § 381.300(n) of this subpart) for each canned poultry product to be packed by the establishment.

(b) *Source of process schedules.* (1) Process schedules used by an establishment shall be developed or determined by a processing authority.

(2) Any change in product formulation, ingredients, or treatments that are not already incorporated in a process schedule and that may adversely affect either the product heat penetration profile or sterilization value requirements shall be evaluated by the establishment's processing authority. If it is determined that any such change adversely affects the adequacy of the process schedule, the processing authority shall amend the process schedule accordingly.

(3) Complete records concerning all aspects of the development or determination of a process schedule, including any associated incubation tests, shall be made available by the establishment to the Program employee upon request.

(c) *Submittal of process information.* (1) Prior to the processing of canned product for distribution in commerce, the establishment shall provide the inspector at the establishment with a list of the process schedules (including alternate schedules) along with any additional applicable information, such as