Food and Drug Administration, HHS

§ 113.60 Containers.

(a) Closures. Regular observations shall be maintained during production runs for gross closure defects. Any such defects shall be recorded and corrective action taken and recorded. At intervals of sufficient frequency to ensure proper closure, the operator, closure supervisor, or other qualified container closure inspection person shall visually examine either the top seam of a can randomly selected from each seaming head or the closure of any other type of container being used and shall record the observations made. For double-seam cans, each can should be examined for cutover or sharpness, skidding or deadheading, false seam, droop at the crossover or lap, and condition of inside of countersink wall for evidence of broken chuck. Such measurements and recordings should be made at intervals not to exceed 30 minutes. Additional visual closure inspections shall be made immediately following a jam in a closing machine, after closing machine adjustment, or after startup of a machine following a prolonged shutdown. All pertinent observations shall be recorded. When irregularities are
found, the corrective action shall be recorded.

(1) Teardown examinations for double-seam cans shall be performed by a qualified individual and the results therefrom shall be recorded at intervals of sufficient frequency on enough containers from each seaming station to ensure maintenance of seam integrity. Such examinations and recordings should be made at intervals not to exceed 4 hours. The results of the teardown examinations shall be recorded and the corrective action taken, if any, shall be noted.

(i) Required and optional can seam measurements:

(a) Micrometer measurement system:

<table>
<thead>
<tr>
<th>Required</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cover hook</td>
<td>Overlap (by calculation)</td>
</tr>
<tr>
<td>Body hook</td>
<td>Countersink.</td>
</tr>
<tr>
<td>Width (length, height)</td>
<td></td>
</tr>
<tr>
<td>Tightness (observation for wrinkle)</td>
<td></td>
</tr>
<tr>
<td>Thickness</td>
<td></td>
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</tbody>
</table>

(b) Seam scope or projector:

<table>
<thead>
<tr>
<th>Required</th>
<th>Optional</th>
</tr>
</thead>
<tbody>
<tr>
<td>Body hook</td>
<td>Width (length, height)</td>
</tr>
<tr>
<td>Overlap</td>
<td>Cover hook.</td>
</tr>
<tr>
<td>Tightness (observation for wrinkle)</td>
<td></td>
</tr>
<tr>
<td>Thickness by micrometer</td>
<td></td>
</tr>
</tbody>
</table>

(c) Can double seam terminology:
(1) "Crossover": The portion of a double seam at the lap.

(2) "Cutover": A fracture, sharp bend, or break in the metal at the top of the inside portion of the double seam.
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(3) “Deadhead”: A seam which is incomplete due to chuck spinning in the countersink.

(4) “Droop”: Smooth projection of double seam below bottom of normal seam.

(5) “False seam”: A small seam breakdown where the cover hook and the body hook are not overlapped.

(6) “Lap”: Two thicknesses of material bonded together.

(ii) Two measurements at different locations, excluding the side seam, shall be made for each double seam characteristic if a seam scope or seam projector is used. When a micrometer is used, three measurements shall be made at points approximately 120° apart, excluding the side seam.

(iii) Overlap length can be calculated by the following formula:

\[
\text{Theoretical overlap length} = CH + BH + T - W,
\]

where:

- \(CH\) = cover hook
- \(BH\) = body hook
- \(T\) = cover thickness, and
- \(W\) = seam width (height, length)

(2) For glass containers with vacuum closures, capper efficiency must be checked by a measurement of the cold water vacuum. This shall be done before actual filling operations, and the results shall be recorded.

(3) For closures other than double seams and glass containers, appropriate detailed inspections and tests shall be conducted by qualified personnel at intervals of sufficient frequency to ensure proper closing machine performance and consistently reliable hermetic seal production. Records of such tests shall be maintained.

(b) Cooling water. Container cooling water shall be chlorinated or otherwise sanitized as necessary for cooling channels and for recirculated water supplies. There should be a measurable residual of the sanitizer employed at the water discharge point of the container cooler.

(c) Coding. Each hermetically sealed container of low-acid processed food shall be marked with an identifying code that shall be permanently visible to the naked eye. When the container does not permit the code to be embossed or inked, the label may be legibly perforated or otherwise marked, if the label is securely affixed to the product container. The required identification shall identify in code the establishment where packed, the product contained therein, the year packed, the day packed, and the period during which packed. The packing period code shall be changed with sufficient frequency to enable ready identification of lots during their sale and distribution. Codes may be changed on the basis of one of the following: intervals of 4 to 5 hours; personnel shift changes; or batches, as long as the containers that constitute the batch do not extend over a period of more than one personnel shift.

(d) Postprocess handling. When cans are handled on belt conveyors, the conveyors should be so constructed as to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination. Automatic equipment used in handling filled containers should be so designed and operated as to preserve the can seam or other container closure integrity.

Effective Date Note: At 76 FR 11922, Mar. 3, 2011, § 113.60 was amended by revising paragraph (d), effective March 5, 2012. For the convenience of the user, the revised text is set forth as follows:

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(d) Postprocess handling. Container handling equipment used in handling filled containers shall be designed, constructed, and operated to preserve the can seam or other container closure integrity. Container handling equipment, including automated and non-automated equipment, shall be checked with sufficient frequency and repaired or replaced as necessary to prevent damage to containers and container closures. When cans are handled on belt conveyors, the conveyors should be constructed to minimize contact by the belt with the double seam, i.e., cans should not be rolled on the double seam. All worn and frayed belting, can retarders, cushions, etc. should be replaced
with new nonporous material. All tracks and belts that come into contact with the can seams should be thoroughly scrubbed and sanitized at intervals of sufficient frequency to avoid product contamination.

Subpart E—Production and Process Controls

§ 113.81 Product preparation.

(a) 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. Compliance with this requirement may be accomplished by receiving the raw materials and ingredients under a supplier’s guarantee that they are suitable for use, by examining them for their microbiological condition, or by other acceptable means.

(b) Blanching by heat, when required in the preparation of food for canning, should be effected by heating the food to the required temperature, holding it at this temperature for the required time, and then either rapidly cooling the food or passing it to subsequent processing without delay. Thermophilic growth and contamination in blanchers should be minimized by the use of adequate operating temperatures and by cleaning. If the blanched food product is washed before filling, potable water should be used.

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

(d) The exhausting of containers for the removal of air shall be controlled so as 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.

(e) 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. The methodology described in §114.90 of this chapter should be used.

(f) 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. 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. 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 nonrefrigerated conditions of storage and distribution.

§ 113.83 Establishing scheduled processes.

Scheduled processes for low-acid foods shall be established by qualified persons having expert knowledge of thermal processing requirements for low-acid foods in hermetically sealed containers and having adequate facilities for making such determinations. The type, range, and combination of variations encountered in commercial production shall be adequately provided for in establishing the scheduled process. Critical factors, e.g., minimum headspace, consistency, maximum fill-in or drained weight, $a_w$, etc., that may affect the scheduled process, shall be specified in the scheduled process. Acceptable scientific methods of establishing heat sterilization processes shall include, when necessary, but shall not be limited to, microbial thermal death time data, process calculations based on product heat penetration data, and inoculated packs. Calculation shall be performed according to procedures recognized by competent processing authorities. If incubation tests are necessary for process confirmation, they shall include containers from test trials and from actual commercial production runs during the period of instituting the process. The incubation tests for confirmation of the scheduled