PROCEDURES FOR DOMESTIC CONDITION OF CANNED PRODUCT CONTAINER EXAMINATION

I. PURPOSE

This directive sets out the procedures inspection program personnel (IPP) are to follow when examining the condition of canned product containers that are domestically produced. This directive does not apply to reinspection of imported canned products, which is provided in FSIS Directive 9900.2, Import Reinspection of Meat, Poultry, and Egg Products. FSIS has rewritten this directive in its entirety to clarify the current procedures for condition of container examinations (COCE) for canned products. FSIS has updated the glossary for container defects and FSIS Form 7520-1, Condition of Container Examination Score Sheet. This directive also describes how to use the COCE tool for sample selection and lot disposition with updated examples in the attachment.

KEY POINTS:

- Updates regulatory citations with the consolidated canning regulations (9 CFR 431) published on 05/31/2018 (83 FR 25302)
- Changes the frequency of condition of canned product container examinations from routine to an ad hoc basis
- Clarifies the purpose of COCE procedure
- Streamlines the COCE procedure with the use of the COCE tool in FSIS Applications
- Updates container defect glossary and FSIS Form 7520-1

II. CANCELLATION

FSIS Directive 7520.2, Procedures for Condition of Canned Product Container Examination, 5/12/88

III. BACKGROUND

Thermally processed, commercially sterile (canned) products are required to be packed in hermetically sealed containers, which protect the contents against the entry of microorganisms during and after thermal processing. Abnormal containers may be caused by different reasons, such as under-processing, leakage, chemical reaction, or elevated storage temperature. Although some hermetically sealed containers (e.g., pouches and glass) used to package canned products are not technically “cans,” the term “canned product,” as defined in 9 CFR 431.1, describes all thermally processed, commercially sterile products regardless of actual packaging material. The COCE is intended to determine whether the canned product containers have any critical or major defects that may be indicators of under-processing of product, or whether the defects may substantially affect the integrity and hemetic seal of the containers.
IV. CONDITION OF CONTAINER EXAMINATION — STATIONARY LOT SAMPLING

A. IPP are to verify that only normal-appearing containers are shipped from an establishment (9 CFR 431.10 (c)(1)). During daily inspection, IPP are to stay alert concerning any evidence of container damage or abnormal containers in stationary lots (lots warehoused or ready for shipment). Wet or stained cases, damaged cases, odor, leaking containers, and swollen containers in the establishment’s storage areas may indicate problems with the hermetic condition of the sealed containers or potential process deviation. When IPP encounter production lots with abnormal containers, they are to follow the instructions in FSIS Directive 7530.1, Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product, and retain the affected lot if the establishment does not have control of the affected lot.

NOTE: When there is obvious forklift or transportation damage, IPP are to permit removal of the damaged containers without retaining the lot provided that the damage is not a prevailing condition throughout the lot.

B. The COCE helps IPP to evaluate the overall condition of the lot and determine whether the establishment has met the requirement in 9 CFR 431.10(c). IPP are to initiate the COCE only when there is reason to suspect the integrity of the containers in a lot or as directed by their immediate supervisor, Frontline Supervisor (FLS) or District Office (DO) on an ad hoc basis. For example, IPP may initiate a COCE when the establishment’s finished product inspection procedure (9 CFR 431.10(a)) is not conducted properly or when abnormal containers are observed in the lot. IPP may also initiate the COCE to evaluate a sorted, reconditioned or returned lot of product after the establishment has performed its corrective action in an abnormal container incident.

C. If IPP decide to conduct the COCE, they are to initiate a directed Thermally Processed, Commercially Sterile HACCP Task in the Public Health Information System (PHIS). IPP are to verify whether the establishment has met the regulatory requirement in 9 CFR 431.10(c)(1) and document the results in the HACCP task in PHIS.

D. If the establishment has an incubation program, IPP are to perform the COCE after the incubation period has elapsed. This will allow for potential microbial action and the resulting abnormal containers can be detected during the COCE.

V. SAMPLING PLAN

A. IPP are to complete Section A of FSIS Form 7520-1, Condition of Container Examination Score Sheet (available at InsideFSIS; users need an e-authentication account to access this form).

<table>
<thead>
<tr>
<th>Lot Size (immediate containers)</th>
<th>Sample Size (Immediate Containers)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td>Normal Sampling Plan</td>
</tr>
<tr>
<td>6,000 or Less</td>
<td>168</td>
</tr>
<tr>
<td>6,001 – 12,000</td>
<td>315</td>
</tr>
<tr>
<td>12,001 – 36,000</td>
<td>500</td>
</tr>
<tr>
<td>36,001 or More</td>
<td>800</td>
</tr>
</tbody>
</table>

Table 1. Sampling Plans for Condition of Container Examinations

Number of immediate containers in each shipping container | Number of immediate containers to be selected from each shipping container
B. Table 1 shows the number of sample units (immediate containers) to select based on the lot size and sampling plan, i.e., normal vs. tightened.

1. IPP are to use the normal sampling plan for initial COCE for any specific lot.

2. IPP are to use the tightened sampling plan for a lot that failed previous COCE or when directed. For a failed lot, IPP are to re-examine the lot at the request of the establishment only when there is evidence that the lot has been reconditioned or sorted by the establishment.

VI. SAMPLE SELECTION

A. IPP are to virtually designate numbers for each pallet and designate numbers for each case on the pallets using a predetermined pattern (see Example 1 in Attachment 2);

B. IPP are to use the COCE tool (Available at “FSIS Applications - Tools”) for sample selection.

C. IPP are to enter the lot information at the COCE tool “Input” section and click “Calculate”. The COCE tool will generate sampling information, such as the number of boxes to select, the number of immediate containers to select from each box and the locations of each box in the lot.

D. IPP are to draw samples from the lot according to the sampling information generated by the COCE tool.

NOTE: Two examples are provided in Attachment 2 to help IPP understand the sampling procedure using the COCE tool.

D. IPP are to draw samples from the lot according to the sampling information generated by the COCE tool.

VII. EXAMINATION, CLASSIFICATION AND RECORDING OF CONTAINER DEFECTS
A. IPP are to examine each sample unit visually and manually for the defects described in Section B of FSIS Form 7520-1.

**NOTE:** A glossary of the terms used on FSIS Form 7520-1 is provided in Attachment 1 to help IPP identify different types of container defects. Additional guidance on classification of container defects can be found in IPP Help – Condition of Containers Examination.

B. IPP are to remove the label when there is evidence of stains or damage or when container overwraps obscure visual examination.

C. IPP are to record all results on FSIS Form 7520-1 with the following rules in mind:

1. If two or more defects are found on the same sample unit and indicate the same cause, the defects are considered related and scored once. For example, if two locations are corroded, IPP are to score only once;

2. If more than one related defect is found and one is critical and the other is major, IPP are to score once as critical;

3. If the defects on the sample unit indicate different causes, IPP are to consider the defects unrelated and score as separate defects. For example, if a can is dented and has a sharp seam, IPP are to score two defects; and

4. Product containers with defects that are not part of the sample are to be removed and handled per Section VIII below. IPP are not to score these defects as part of the sample result.

D. IPP notice a recurrence of scorable or unscorable defects, they may note this in the Remarks box of the FSIS Form 7520-1 as a reminder to conduct further investigations.

**NOTE:** An unscorable defect is a defect often referred to as a minor defect. A minor or unscorable defect has no adverse effect on container integrity.

**VIII. DISPOSITION OF DEFECTIVE SAMPLE UNITS**

A. If abnormal containers (9 CFR 431.1) are found during the COCE and the containers exhibit no obvious mechanical defect, IPP are to retain the lot because this finding may indicate a potential process deviation or product adulteration.

B. IPP are not to allow abnormal containers with no obvious mechanical damage to be destroyed before completing the verification of establishment’s handling of the abnormal container incident according to the instructions in FSIS Directive 7530.1.

C. IPP are to verify that the establishment destroyed containers with critical defects.

D. IPP are to be aware that whenever any major defects are found in the sample, the establishment may decide on the disposition of these containers provided that the establishment ensures that only normal appearing containers are shipped in commerce (9 CFR 431.10(c)(1)).

**IX. DISPOSITION OF AFFECTED LOTS AND DOCUMENTATION**

A. IPP are to use Table 2 below to determine whether the overall condition of the lot is acceptable.
B. IPP are to follow the instructions in FSIS Directive 7530.1 to verify that the establishment handles the abnormal container incident appropriately in accordance with 9 CFR 431.10(a) even if the lot has passed the COCE according to Table 2.

C. IPP are to issue a noncompliance record (NR) citing 9 CFR 431.10 (c)(1) if the establishment fails the COCE. IPP are to document the COCE results in the description of the NR in a Thermally Processed, Commercially Sterile HACCP task in PHIS.

D. IPP are to verify that the disposition proposal from the establishment includes disposition of all defective containers in accordance with 9 CFR 431.10(c)(2).

E. If IPP need assistance in evaluating the supporting data and disposition of affected product, IPP are to forward the disposition proposal and supporting document to the Policy Development Staff (PDS) through askFSIS. When submitting a question, IPP are to complete the web form and select General Inspection Policy for the inquiry type.

F. IPP are to include their FLS’s contact information in the askFSIS case submission.

### TABLE 2. Disposition of lots

<table>
<thead>
<tr>
<th>LOT SIZE (CONTAINERS)</th>
<th>SAMPLE SIZE (CONTAINERS)</th>
<th>CRITICAL DEFECTS</th>
<th>TOTAL DEFECTS (CRITICAL + MAJOR)</th>
</tr>
</thead>
<tbody>
<tr>
<td></td>
<td></td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td></td>
<td></td>
<td>Pass</td>
<td>Fail</td>
</tr>
<tr>
<td>NORMAL PLAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6,000 or Less</td>
<td>168</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6,001 – 12,000</td>
<td>315</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12,001 – 36,000</td>
<td>500</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>36,001 or More</td>
<td>800</td>
<td>3</td>
<td>4</td>
</tr>
<tr>
<td>TIGHTENED PLAN</td>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>6,000 or Less</td>
<td>300</td>
<td>0</td>
<td>1</td>
</tr>
<tr>
<td>6,001 – 12,000</td>
<td>475</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>12,001 – 36,000</td>
<td>630</td>
<td>2</td>
<td>3</td>
</tr>
<tr>
<td>36,001 or More</td>
<td>800</td>
<td>3</td>
<td>4</td>
</tr>
</tbody>
</table>

G. The Policy Development Staff (PDS) is to review the proposal and supporting documents and issue a disposition recommendation to the DO through the FLS.

H. The DO is to review the disposition recommendation from PDS, make the final ruling on the disposition of the affected product, and notify the IPP through the chain of command.

X. QUESTIONS
Refer questions regarding this directive to your supervisor or as needed to the Office of Policy and Program Development through askFSIS or by telephone at 1-800-233-3935. When submitting a question, complete the web form and select General Inspection Policy for the inquiry type.

NOTE: Refer to FSIS Directive 5620.1, Using askFSIS, for additional information on submitting questions.

Assistant Administrator
Office of Policy and Program Development
Attachment 1: FSIS Form 7520-1 Glossary

A. General

**Defect Classifications**

1. **Critical Defect.** A defect which indicates that the container is not hermetically sealed (e.g., holes, fractures, leakage) or shows evidence that there may be spoilage of the container’s contents.

2. **Major Defect.** A defect that may affect the hermetic condition of the sealed container.

**Destination Examination.** An examination made at any location other than at the producing establishment.

**Hermetically Sealed.** Air-tight containers which protect the contents against the entry of microorganisms during and after thermal processing.

**Lot.** A collection of hermetically sealed containers of the same size, type, and style. Lots should be distinguishable by product name, code, formulation, and date of production.

**Origin Examination.** An examination made prior to shipment from the producing establishment.

**Random Sampling.** A process of selection whereby each container has an equal chance of being chosen.

**Related Defects.** Defects on a single container that may have resulted from a single cause.

**Sample.** A collection of sample units.

**Sample Size.** The number of sample units which are to be included in the sample.

**Sample Unit.** An individual hermetically sealed container.

**Stationary Lot Sampling.** The process of randomly selecting sample units from a lot that has been warehoused or prepared for shipment.

**Unrelated Defects.** Defects on a single container that may have resulted from separate causes.

B. External Container Defects

**Abrasion (cans).** A mechanical wearing of the metal plate, which results in the weakening of the metal plate making the abraded area susceptible to either fracture or corrosion.

**Abrasion/Scratch (pouch).** A scratch partially through the surface layers of the package caused by mechanical rubbing or scuffing. The abrasion will appear as streaks, some darker in color, on the container.

**Blister.** A void within the bonded seal. This defect will appear to resemble a bubble in the sealed area.

**Buckle or Peak.** A distortion of the container where the ends exhibit one or more permanent ridges extending into the countersink.

**Burning.** A milky white appearance on the seal is an indication of excess heat and pressure. Some appear as delaminating or small blisters on the seal, caused by incorrect heat, pressure, or dwell time.

**Burst.** A rupture of the container caused by excessive internal pressure. Burst usually occurs at the double seam over the side seam lap or in the middle of the side seam.
Cable Cuts. An abrasion at the top of the container double seam caused by the action of cable conveyors moving on stationary cans.

Channel Leaker. A patch of non-bonded area across the width of the seal creating a leak. This defect can sometimes be detected by the absence of a portion of the seal impression in a seal.

Cocked Cap. A condition of the lug-type cap that is caused by a lug failing to seat under the glass thread.

Compressed Seal. A seal formed by excessive pressure or heat and evidenced by cracking and delaminating. A milky white appearance on the seal is an indication of excess heat and pressure.

Contaminated Seal. Foreign matter in the seal area such as, but not limited to, water, grease, or food that results in a seal width of less than 3mm (3/32"). A pouch with contamination will have a noticeable raised area in the seal where the bar has sealed over the contamination.

Corrosion. A chemical deterioration of the container. Rusting is one form of corrosion.

Crooked, Short, or Misaligned Seal. A seal that is not parallel to the cut edge of the pouch. When on the edge of the pouch with a narrowing on one end, are not to be less than 3mm (3/32") wide. A hermetic seal that is on an angle with any amount of unsealed material above the closure seal will not be classified.

Crushed Package. Alteration of the package’s original dimensions caused by force.

Cut Seam. A cut through a layer of the double seam.

Deadhead, Spinner, Skidder or Skip Seam. A double seam which has not been completely ironed out.

Delamination. Any separation of laminate materials forming the package.

Dents. The pronounced mechanical distortion of the metal container resulting in deformity of the can end or body, the double seam, or the side seam.

Droop. A smooth crescent-like projection at the bottom of the double seam.

Fractured Glass. A glass container with any crack in the surface of the glass. The crack is usually shown by a silvery line in the container.

Incomplete Seam. A portion of the double seam where the body and cover hooks are not engaged.

Knocked Down Cover. A cover hook is not engaged with the body hook resulting in the cover curl extending below the double seam.

Knocked Down Flange. The flange is bent resulting in no engagement of the body and cover hooks.

Leakage. Loss of hermetic seal.

Mislocked Side Seam. Failure of the side seam hooks to interlock along their entire length.

Non-Bonding. Failure of two sealant films to combine during the sealing process. This can be detected visually by the sealing bar impression on a pouch. If it is in only one area, there will be a faint void in the seal. If it is in the whole seal, the seal impression will be very faint.

Notch Leaker. A leak at a manufactured notch used for easy opening.
Paneling. Flat side(s) on container body caused by internal vacuum and excessive external pressure developed during processing or cooling.

Seal Creep. Partial opening of the inner border of the seal. This problem is normally detected by applying some pressure upward toward the seal.

Sharp Seam. A sharp lip formed at the top inside edge of the double seam where no fracture of the seam is evident.

Swollen. A bulging of the container which may be due to the formation of gas.

1. **Burst**. A rupture of the container caused by excessive internal pressure. Burst usually occurs at the double seam over the side seam lap, or in the middle of the side seam.

2. **Hard Swell**. A container with both ends convex, rigid and not responding to medium hard thumb pressure.

3. **Soft Swell**. A container with both ends slightly convex. The container yields when moderate thumb pressure is applied but cannot be forced back to a normal condition.

4. **Springer**. A container with one end permanently convex. When sufficient pressure is applied to this end, it flips in but the other end flips out.

5. **Flipper**. A container that normally appears flat. When the end of the can is struck sharply on a flat surface, one end flips out but returns to its original appearance with mild thumb pressure (i.e., normal).

6. **Loose Tin**. A metal can which does not show evidence of full vacuum, but slight pressure reveals a looseness.

**NOTE:** Overfilled, overstuffed, or short vacuum may result in swelling and must be confirmed by laboratory analysis.

Vee or Spur. A projection at the bottom of the double seam which is shaped like the letter V.

Wrinkle (flexible containers). A fold of material in the seal area.
Attachment 2: Condition of Container Examination Examples

Example 1. A lot of 28,800 metal cans is to be examined under the normal sampling plan. The lot is palletized and cased — 2,400 cases (12 cans per case) arranged on 50 pallets each holding 48 cases. Each pallet has 6 layers and each layer has 8 cases. You want to use the COCE tool to sample the lot:

1. Enter the lot information in the “Input” section of the COCE tool and click “Calculate” to get the sample locations.

![Condition of Container Examination Tool](image)

2. The COCE tool will generate sampling plan containing information such as the number of boxes to select, the number of immediate containers to select from each box and locations of each box in the lot. Click “Export” button and print out the excel sheet generated by the tool.

![Output](image)

3. In the warehouse, virtually designate numbers for each pallet from 1 through 50 using a predetermined pattern.
4. Assign consecutive numbers from 1 through 6 for the layers on each pallet using a predetermined pattern.

5. Assign consecutive numbers from 1 through 8 for the shipping containers on each layer using a predetermined pattern.
6. Group the cans in each case into 2 adjacent sections of 6 cans. For example, the cans could be sectioned as follows:

```
Section 1
```

```
Section 2
```

7. Draw cans from designated sections of the case. For example, when drawing cans from the first case, you select cans from section 1. In the second case, you draw cans from section 2. The third case sample units may be from section 1 and the fourth case sample units from section 2. This cycle should be repeated until all sampling is completed.

If you have cases containing 24 cans each, you will need to select 12 cans from each case according to Table 1. The sectioning of the cans could be as follows:

```
Top Layer Section
```

```
Bottom Layer Section
```

The cycle could be as follows:

<table>
<thead>
<tr>
<th>Case No.</th>
<th>Samples to be examined</th>
</tr>
</thead>
<tbody>
<tr>
<td>Case 1</td>
<td>Top Section</td>
</tr>
<tr>
<td>Case 2</td>
<td>Lower Section</td>
</tr>
<tr>
<td>Case 3</td>
<td>Top Section</td>
</tr>
<tr>
<td>Case 4</td>
<td>Lower Section</td>
</tr>
<tr>
<td>etc.</td>
<td>etc.</td>
</tr>
</tbody>
</table>

8. Examine and score each sample unit for the defects on FSIS Form 7520-1. Record the results on the form.
9. To determine whether the lot passes the COCE, you can check Table 2 based on the numbers of defects found during the COCE, or you may enter the results of the COCE into the COCE tool and click “Sum Total” to get the result.

<table>
<thead>
<tr>
<th>Critical Defects</th>
<th>Major Defects</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swollen (Burst, Hard, Soft, Springer, Flipper, Loose Tin)</td>
<td>Corrosion (Severely Pitted, Not through Container Wall)</td>
</tr>
<tr>
<td>Incomplete Seam (False, Knocked Down Range/Cover)</td>
<td>Buckle Or Peak Into Seam (No Evidence Of Leakage)</td>
</tr>
<tr>
<td>Vee, Spur, Or Drop (Evidence Of Leakage)</td>
<td>Dents/Paneld (Body Crises/Affecting Seal/Score With No Cracks)</td>
</tr>
<tr>
<td>Side Seam Cracked Or Opened (Including Voids)</td>
<td>Cutover/Sharp Seam (No Evidence Of Leakage)</td>
</tr>
<tr>
<td>Corrosion (Evidence Of Leakage)</td>
<td>Cut Seam Or Abrasion (Cable Cut) Not Through One Layer Of Seam</td>
</tr>
<tr>
<td>Cut Through, Fractures, Holes, Or Punctures (Not On Seam Or Seal)</td>
<td>Vee, Spur, Or Drop (More Than 1/3 Seam Height, No Leakage)</td>
</tr>
<tr>
<td>Dents (Fractures Or Damage Impedes Exam)</td>
<td>Mislocked Side Seam (No Evidence Of Leakage)</td>
</tr>
<tr>
<td>Buckle Or Peak Into Seam (Evidence Of Leakage)</td>
<td>Other Major Defects – Explain (If No Other Criteria Apply)</td>
</tr>
<tr>
<td>Evidence Of Leakage (If No Other Criteria Apply)</td>
<td>Total 1</td>
</tr>
</tbody>
</table>

10. In this example, you have found no critical defect and only 1 major defect. The lot is acceptable.
Example 2. A lot of 28,800 metal cans is to be examined under the normal sampling plan. The lot is palletized and cased – 2,400 cases (12 cans per case) arranged on 40 pallets, each holding 60 cases. Each pallet has 6 layers and each layer has 10 cases. From Table 1, you have determined that the sample size should be 500 sample units (cans) and you need to draw 6 cans from each selected case. The selection of 500 cans for the first step proceeds as follows:

1. Enter the lot information in the “Input” section of the COCE tool and click “Calculate” to get the number of case and the locations.

2. Click “Export” and print out the sample location sheet. Bring it with you to the warehouse.

3. In the warehouse, virtually designate numbers for each pallet from 1 through 40 using a predetermined pattern.

4. Assign consecutive numbers from 1 through 6 for the layers on each pallet using a predetermined pattern.

5. Assign consecutive numbers from 1 through 10 for the shipping containers on each layer using a predetermined pattern.

6. Group the cans in each case into 2 adjacent sections of 6 cans.

7. Draw cans randomly from designated sections of the case.

8. Examine and score each sample unit for the defects on FSIS Form 7520-1. Record the results on FSIS Form 7520-1.

9. Enter the results of the COCE into the COCE tool and click “Sum Total” to get the COCE result.
10. Due to the findings of two swollen containers with no obvious mechanical damage, you decide to retain the lot and follow the instructions on FSIS Directive 7530.1 to verify that the establishment handles the abnormal container finding properly.