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OPI: IO/POS

HANDLING PROC. DEVIATIONS/ABNORMAL CONTAINER INCID...

HANDLING PROCESS DEVIATIONS AND ABNORMAL CONTAINER INCIDENTS FOR SHELF-STABLE CANNED PRODUCTS

I. PURPOSE

This directive provides current FSIS policy and procedures with respect to thermal process deviations or abnormal incidents that occur during the production of shelf-stable canned product. It also provides two new FSIS forms. This directive does not apply if all the requirements of Sections 318.308, 381.308, 318.309, and 381.309 of the MPI Regulations have been addressed through the implementation of an approved quality control program.

II. [RESERVED]

III. [RESERVED]

IV. REFERENCES

MPI Regulations, Sections 318.308, 318.309, 381.308, 381.309
FSIS Directive 7520.2, dated 5/12/88

V. POLICY

A. Process Deviations. MPI Regulations require that process deviations be:

1. Handled by an approved quality control program; or

2. Identified in-process and reprocessed, using the complete full process schedule; or

3. Reprocessed using a prior-approved alternate process schedule which is on file with the inspector; or

4. Held for evaluation by a processing authority.

B. Abnormal Containers. MPI Regulations state that, unless handled as part of an approved finished product quality control program, finding abnormal containers through incubation or other means requires that at least the code lot involved not be shipped.

VI. RESPONSIBILITIES

A. Process Deviations. Process deviations not handled in accord with the requirements described in items V.A.1, 2, or 3 of this directive require the following actions:

1. Establishment Management

a. Hold the product involved

b. Have the deviation evaluated by a processing authority.

2. Inspection Personnel

a. Assure that the affected product is not shipped until program approval for a proposed disposition is received.

b. Obtain copies of all information provided to the processing authority by the establishment.

c. Obtain a copy of the processing authority's evaluation report.

d. Complete FSIS Form 10,000-6, Canned Foods--Process Deviation; attach the data required in items VI.A.2.b. and c. above; and send to:

Processed Products Inspection Division
Thermal Processing Branch, FSIS, USDA
Washington, DC 20250-3700

e. Send a copy of the completed FSIS Form 10,000-6, Canned Foods--Process Deviation (do not include process records or the processing authority's report) to the Regional Office.

f. Retain a copy for the official file; NOTE: Additional information on procedures and distribution is shown on the reverse side of FSIS Form 10,000-6, Attachment 2.

g. When the final report is received from

headquarters, notify the establishment of the recommended action(s).

B. Abnormal Containers. Abnormal containers not handled as part of an approved finished product quality control program require the following actions:

1. Establishment Management

a. Notify FSIS inspection personnel of the findings(s).

b. Make available all abnormal containers for examination by FSIS inspection personnel.

2. Inspection Personnel

a. Retain like-coded product.

NOTE: The amount of product retained shall not represent less than 2 hours of continuous production.

b. Place all abnormal containers under refrigeration to prevent rupture and to preserve their contents.

c. Contact the appropriate FSIS Microbiology Laboratory regarding the need to submit samples for microbiological analysis. If samples are requested, the laboratory will provide guidance on the number and means of submission.

NOTE: When multiple abnormals are available, they may be shared with the processor upon request. The FSIS Microbiologist shall be informed when shared samples are given to the processor.

d. If the FSIS Microbiology Laboratory requests samples:

(1) Complete FSIS Form 10,000-2, Laboratory Report, according to directions contained on the form.

(2) Complete FSIS Form 10,000-3, Canned Foods--Abnormal Containers. Submit the original to the FSIS Laboratory along with the FSIS Form 10,000-2, Laboratory Report.

(3) Submit a copy to the Regional Office.

(4) Retain a copy for the official file.

NOTE: Additional information on procedures and distribution is shown on the reverse side of FSIS Form 10,000-3, Canned Foods--Abnormal Containers, Attachment 1.

e. When the final report is received from Washington, notify the establishment of the recommended actions(s).

VII. FURTHER GUIDANCE

Any questions regarding this directive should be referred to the next level of supervision.

Deputy Administrator
Inspection Operations

Attachments:

1--FSIS Form 10,000-3, Canned Foods--Abnormal Containers, dated 10/93 (See Hard copy FSIS Directive 7350.1)
2--FSIS Form 10,000-6, Canned Foods--Process Deviation, dated 10/93 (See Hard copy FSIS Directive 7350.1)

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