

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS DIRECTIVE

7530.1
Revision 1

12/11/08

HANDLING A PROCESS DEVIATION OR ABNORMAL CONTAINER OF THERMALLY PROCESSED, COMMERCIALY STERILE CANNED PRODUCT

I. PURPOSE

This directive provides inspection program personnel (IPP) at thermal processing plants with updated procedures to follow when an abnormal container is found by either the IPP or the plant, or there is a process deviation during the production of thermally processed, commercially sterile (shelf stable) canned products. It also addresses the review of process deviations and abnormal containers by the Policy Development Division (PDD). This directive supplements but does not replace FSIS Directive 7530.2, Verification Activities in Canning Operations that Choose to Follow the Canning Regulations, which delineates the verification responsibilities of IPP during production of thermally processed, commercially sterile canned product.

Key Points

- *PDD will review evaluations of abnormal containers and selected process deviations.*
- *IPP are to verify that establishments are complying with the canning regulations.*
- *PDD canning specialists will carry out the responsibilities of what the regulations refer to as the "Program."*
- *IPP are to collect abnormal containers and submit them to the FSIS Western Laboratory in Alameda.*

NOTE: *OIA import inspectors are to contact HQ import inspection through their chain of command for guidance.*

II. CANCELLATION

FSIS Directive 7530.1, Handling Process Deviations and Abnormal Container Incidents for Shelf-Stable Canned Products, dated 11/10/94.

DISTRIBUTION: Electronic

OPI: OPPD

III. REASON FOR REISSUANCE

This directive is being reissued to provide updated instructions on how IPP are to handle process deviations and instructions on how to submit abnormal containers for microbial examination to the Western Laboratory. Additionally, IPP are being informed that PDD canning specialists will have responsibility for evaluating the information submitted by IPP and carrying out the responsibilities of what the regulations call the "Program."

IV. REFERENCES

FSIS Regulations, Sections 318.308, 318.309, 381.308, 381.309
FSIS Directive 7530.2, Verification Activities in Canning Operations that Choose to Follow the Canning Regulations, dated 10/20/05
FSIS Directive 7520.1, Procedures for Condition of Canned Product Container Examination, dated 5/12/88
FSIS Form 7500-1, Canned Food Sample Reporting Form
FSIS Form 10,000-2, Laboratory Report
FSIS Form 10,000-3, Abnormal Containers
FSIS Form 10,000-6, Process Deviations

V. BACKGROUND

Canned product is defined as a meat or poultry food product with a water activity above 0.85 that receives a thermal process either before or after being packed in a hermetically sealed container (9 CFR 318.300, 381.300). Thermally processed products are packed in a variety of different types of containers including rigid and semi-rigid containers, flexible pouches, glass jars, paperboard (e.g. Tetrapak), aseptically processed product and any other type container that may hold thermally processed, commercially sterile(canned) product.

VI. DEFINITIONS

A. Process Deviation: Whenever the actual process is less than the process schedule, or when any critical factor does not comply with the requirements for that factor as specified in the process schedule (9 CFR 318.308(a) and 381.308(a)).

B. Abnormal Container: A container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled (9 CFR 318.300(a) and 381.300(a)).

VII. RESPONSIBILITIES OF INSPECTION PROGRAM PERSONNEL

A. Process Deviations not requiring review by PDD.

Not all process deviations require review by PDD. This section sets out IPP responsibilities in all cases and identifies process deviations that do require review.

Whenever the actual process is less than that called for by the process schedule, or any critical factor does not meet the requirement for that factor as specified in the process schedule, such an event is considered to be a deviation in processing, and any deviation is to be handled in a manner to prevent the distribution of under-processed product. The regulations (9 CFR 318.308 and 381.308) specify the requirements for handling a deviation identified either in-process or through records review.

When IPP find a process deviation during their verification activities, or if they are notified by the establishment that a process deviation that requires review has occurred, they are to verify that:

1. establishment personnel handle the process deviation in accordance with regulations 9 CFR 318.308 and 381.308, whether identified in-process or through records review;
2. the establishment only reprocesses or repacks product using a process schedule authorized by the processing authority;
3. a deviation in a continuous retort, including, but not limited to, an emergency stop (jam or breakdown) or temperature drop, is handled according to regulatory requirements in 9 CFR 318.308/381.308(d)(1)(vi),
4. the establishment's process deviation file contains all of the records that relate to the handling of each deviation. The plant deviation file is required to contain, at a minimum, the following information:
 - the appropriate processing and production records,
 - a full description of the corrective actions taken,
 - the evaluation procedures and results, and
 - the disposition of the affected product.

B. Process Deviations requiring review by PDD

In certain situations, PDD will review a process deviation. Such situations include, but may not be limited to, the following:

- when the plant does not address microbial hazards in a HACCP plan or have an appropriate alternate documented procedure for handling a deviation, or
- when the deviation is identified by record review, or

- when the deviation occurs in a continuous system (e.g., including, but not limited to, an emergency stop, jam, breakdown, or temperature drop,) and the establishment does not follow 9 CFR 318.308/381.308(d)(1)(vi), or
- when the plant does not have procedures documented to handle a deviation as defined in 9 CFR 318.308 or 381.308.

For a deviation that the PDD reviews, IPP are to:

a. Verify that establishment management has held the product affected, and that the processing authority has evaluated the product to assess the safety and stability of the product. If the product is not held, this failure could result in a request for a recall.

b. Ensure that the establishment does not ship the affected product until PPD has reviewed the deviation and the processing authority's report. If necessary the inspector may use an official control action to retain the product.

c. Obtain copies of all information that the processing authority has given to the establishment, including;

- a complete description of the deviation along with all supporting documentation;
- a copy of the processing authority's evaluation report; and
- any product disposition actions, either taken or proposed.

d. Complete FSIS Form 10,000-6, Canned Foods--Process Deviation. Attach the data required in 3 above and send to PDD either by mail, fax, or through AskFSIS <http://askfsis.custhelp.com/>. When sending the information through AskFSIS the subject line is to read: canning deviation. Contact PDD at 800-233-3935 if you need assistance.

e. Send a copy of the completed FSIS Form 10,000-6, Canned Foods--Process Deviation, to the District Office and retain a copy in the government office file.

f. PDD will review the information and advise the District on whether to accept the establishment's proposed disposition. If the establishment has not proposed a disposition, PDD may recommend an action to the District. The District will decide what to do and inform the establishment of its decision.

C. Abnormal Containers.

The regulations on finished product inspection (9 CFR 318.309 and 381.309) require that the establishment notify FSIS inspection personnel of any abnormal container found, either by incubation or by some other means. IPP will verify, by reviewing records and performing inspection procedures, that any abnormal container is identified, and that container evaluation is being properly performed

by the establishment. If a production lot includes an abnormal container, IPP are to retain the lot.

1. When an abnormal container is found by the establishment during incubation, IPP are to:

- a. Retain the code lot represented by the incubation sample, if the establishment does not have adequate procedures to prevent shipment of product,
- b. Verify that the establishment has taken action to determine the cause of the abnormal containers under its HACCP plan or other documented procedure,
- c. Verify disposition of the lot by the establishment. Establishments that have a documented program for finished product are to dispose of product as outlined in their program.

2. When an abnormal container is found by inspection personnel or by the establishment by means other than incubation (e.g., product is found after incubation in the warehouse, when a plant does not incubate, etc.), IPP are to:

- a. Retain all production lots that have abnormal containers identified. Retain all like-coded products;

NOTE: The amount of product retained would be a minimum of 2 hours of continuous production, and there is no maximum. Depending on the cause, the establishment may need to consider additional product batch / lots cooked in one or more retorts.

- b. Inform plant management to place all abnormal containers under refrigeration to prevent rupture and to preserve their contents. Do not freeze either the abnormal containers or normal appearing containers.

- c. IPP are to contact the FSIS Western Laboratory at (510) 814-3000 regarding the need to submit samples for microbiological analysis. If the laboratory requests samples, the laboratory will provide guidance on the number of samples to be submitted and how they are to be submitted.

NOTE: If a swollen container is found, the lot is to be retained pending laboratory analysis.

NOTE: When multiple abnormal containers are available (more than requested by the FSIS Laboratory), IPP may share them with the processor upon request. IPP are to inform the FSIS microbiologist when they do so.

- d. If the FSIS Microbiology Laboratory requests samples:

- ❖ complete the following forms.
 - FSIS Form 10,000-2, Laboratory Report,
 - FSIS Form 10,000-3, Canned Foods--Abnormal Containers
 - FSIS Form 7500-1 Canned Food Sample Reporting Form
 - Any additional information the Laboratory may request.
- ❖ submit the original forms to the FSIS Laboratory.
- ❖ submit one copy of each form noted above to the District Office, PDD and retain a copy for the government office file.

NOTE: All forms (except 10,000-2) listed above are available in Outlook under Public Folders/All Public Folders/Agency Issuances/Forms.

3. Once the FSIS Laboratory has completed the analysis of abnormal containers submitted for microbiological and container evaluation, it will forward its findings to PDD. PDD will review the findings and issue a disposition recommendation. Final product disposition determinations will be made by the Office of Field Operations (OFO). IPP are to follow instructions from their District Office and Front Line Supervisor on the final disposition of affected product.

VII. FURTHER GUIDANCE

Refer questions regarding this directive to PDD through AskFSIS at <http://askfsis.custhelp.com/> or by telephone at 1-800-233-3935.



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