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

FSIS DIRECTIVE

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VERIFICATION ACTIVITIES IN CANNING OPERATIONS THAT CHOOSE TO FOLLOW THE CANNING REGULATIONS

I. PURPOSE

A. When an establishment that produces canned products conducts its hazard analysis as required by 9 CFR 417.2(a), it may choose to address the food safety hazards associated with microbiological contamination in its HACCP plan, or meet the requirements of the canning regulations. If the food safety hazards associated with microbiological contamination are addressed in its HACCP plan, the establishment is not required to meet the requirements of the canning regulations. If the establishment addresses the food safety hazards associated with microbiological contamination in its HACCP plan, inspection program personnel should follow the verification instructions in FSIS Directive 5000.1, Revision 1, Chapter II.

B. If the establishment elects not address the food safety hazards associated with microbiological contamination in its HACCP plan, the decision is that the food safety hazards are not likely to occur. The supporting documentation required in 9 CFR 417.5(a)(1) for the decision that the food safety hazards associated with microbiological contamination is not likely to occur is that the establishment will comply with the requirements of 9 CFR 318.300 – 318.311 or 381.300 – 381.311.

C. This directive provides inspection program personnel with instructions for verifying compliance with the regulatory requirements in Title 9 of the Code of Federal Regulations (CFR) part 417 in an establishment that does thermal processing (canning), and uses 9 CFR 318, subpart G, or part 381, subpart X (the canning regulations), as documentation to support a determination that food safety hazards associated with microbiological contamination are not reasonably likely to occur in its operations. In such cases, by serving as the supporting documentation required by 9 CFR 417.5 (a)(1) for the establishment's decision, the canning regulations are similar to a prerequisite program.

D. This directive also provides attached Questions and Answers to serve as additional guidance.

II. RESERVED

III. RESERVED

IV. REFERENCES

9 CFR Part 318, subpart G, Part 381, subpart X, and Part 417
FSIS Directive 5000.1, Revision 1

V. BACKGROUND

A. The regulations at 9 CFR 417.2(b)(3) state that HACCP plans for thermally processed/commercially sterile (canned) products do not have to address the food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X. "Canned product" is defined in 9 CFR 318.300(d) and 381.300(d) as a meat/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.

B. While all other ready-to-eat products have or will have to meet lethality performance standards, FSIS has made a decision that it is not required for establishments producing thermally processed/commercially sterile meat and poultry products to have lethality performance standards if the requirements of the prescriptive canning regulations are followed. Since the canning regulations were designed around these principles, the products produced meeting these requirements are eligible to bear the marks of inspection. If the establishment is not meeting the requirements of these regulations, it is not meeting the requirements of 9 CFR 417.5(a)(1). If the establishment is not meeting the requirements of 9 CFR 417.5, it may not be meeting the requirements of 9 CFR 417.2, and the HACCP system may be found to be inadequate as described in 9 CFR 417.6(a).

C. When an establishment chooses to follow the canning regulations instead of addressing the food safety hazards associated with microbiological contamination in its HACCP plan it is using the regulatory requirements of Subparts G and X as supporting documentation for the decision made in the hazard analysis that these hazards are not reasonably likely to occur. The establishment does this by documenting in its hazard analysis that food safety hazards associated with microbiological contamination are not reasonably likely to occur because it is using the canning regulations as supporting documentation for its HACCP system.

D. The establishment using the canning regulations in this way must have documentation demonstrating that the establishment is successful in meeting these regulatory requirements, thereby, resulting in safe product.

E. In those establishments that produce thermally processed/commercially sterile products and that do not address the food safety hazards in their HACCP plan, but determine in the hazard analysis that the hazards are not reasonably likely to occur, inspection program personnel have the responsibility of verifying that the requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X, are met. These regulatory requirements must be met in order for inspection program personnel to find that the decision made in the hazard analysis, and incorporated as part of the food safety system, is valid. Inspection program personnel verify that the regulatory requirements of 9 CFR 318, subpart G, or 9 CFR 381, subpart X are met in the same way that they verify that the requirements of the Sanitation Standard Operating Procedures (Sanitation SOP) regulations are met, when these regulations are used to support a decision in the hazard analysis.

F. The Agency recognizes that it generally utilizes Enforcement Investigation and Analysis Officers (EIAOs) to verify that prerequisite programs are successful in preventing identified food safety hazards from being reasonably likely to occur. When prerequisite programs without specific regulatory requirements are used to support the decisions in the hazard analysis that a food safety hazard is not reasonably likely to occur, EIAOs are the component of the Agency's workforce that assesses whether the design of these programs is adequate for the decision made. However, the Sanitation SOPs under 9 CFR 416, the canning procedures under 9 CFR 318.300 and 381.300, and the *Listeria monocytogenes* control procedures under 9 CFR 430, are regulations that can be used to support a decision made in the hazard analysis that a food safety hazard is not reasonably likely to occur. For the prerequisite programs for which there are explicit regulatory requirements, inspection program personnel verify compliance with the regulatory requirements. This directive details specifically the canning procedures under 9 CFR 318, subpart G, or Part 381, subpart X with respect to which inspection program personnel verify compliance.

G. A processing authority is defined in 9 CFR 318.300(q) and 381.300(q) as: *The person(s) or organizations(s) having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated in this subpart.* These persons or organizations have the knowledge and expertise to develop thermal processing schedules based on the critical factors associated with the products as well as the types of thermal processing systems used by the establishments. These thermal process schedules are designed using scientific formulae and, in most cases have safety allowances included.

VI. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES WHEN PERFORMING AN 03D01 PROCEDURE

A. Because there are numerous requirements in the canning regulations, inspection program personnel will need to verify some of these requirements each time a HACCP 01 procedure is performed. In addition to randomly selecting one or more of the other HACCP regulatory requirements (monitoring, verification, corrective action, and reassessment), inspection program personnel will need to verify that the establishment is meeting some of the canning regulatory requirements as part of verifying the HACCP recordkeeping requirement.

B. Verifying that the establishment is meeting the canning regulatory requirements can be performed by conducting the recordkeeping component, review and observation component, or a combination of these components when performing the 03D01 procedure. The majority of the time when the recordkeeping requirement is verified inspection program personnel use the recordkeeping component of the 03D01 procedure. In verifying some of the canning regulatory requirements, however, inspection program personnel will need to use the review and observation component.

C. For example, when verifying that the establishment is meeting the requirements of 318.305(a) or 381.305(a), inspection program personnel would have to go into the establishment and verify that each retort is equipped with at least one indicating

temperature device that measures the actual temperature within the retort, and that the indicating device, not the temperature/time recording device, is used as the reference instrument for indicating the process temperature. This cannot be determined by reviewing records. It requires direct observation of the process.

D. Inspection program personnel are to:

a. Randomly select for verification, one, or more of three of the HACCP requirements (monitoring, verification, and recordkeeping).

b. Select one (or more) of the sections of the canning regulations (e.g., 318.301, 381.301; 318.302, 381.302, etc.) for verification that the establishment is meeting the requirements of the regulation.

c. Determine which activity(review and observation or recordkeeping review) to perform in verifying each HACCP regulatory requirement and canning regulatory section selected.

d. Verify the HACCP regulatory requirements (monitoring, verification, recordkeeping) and also verify that the establishment is meeting the requirements of sections of the canning regulations selected to ensure the supporting documentation is implemented.

NOTE: If inspection program personnel have verified that the persons supervising the operators of the thermal processing systems and container closure technicians have completed the appropriate training (9 CFR 318.310, 381.310), and that there is a recall procedure on file (318.311, 381.311), these requirements would not have to be verified again unless there are supervisory changes or reason to believe that a recall procedure is no longer on file.

Example: There are 10 sections in the canning regulations (318.301 – 311, 381.301 – 311) and numerous requirements in each section to verify. The sections and the associated requirements for verification are listed below under B. Inspection program personnel would select two or more of the 10 sections and one or more of the requirements under each section for verification. Inspection program personnel might select 318.302, and 318.304, (C.2. and C.4. below) as the sections for verification. They also would select one or more requirements listed under the sections selected (e.g., B.1.a. and B.4.a.).

E. The following explains the regulatory requirements of the canning regulations and provides verification activities inspection program personnel should perform related to the regulatory requirements.

1. **9 CFR 318.301, 381.301 – Containers and Closures:** This section of the canning regulations requires that establishments ensure that empty containers and container materials are clean and free of structural defects and damage that may affect product or container integrity. Additionally, this section also specifies visual and physical examinations of closure or container defects are to be made, and that necessary corrective actions are to be performed when defects are found. Inspection program personnel should verify that:

a. the establishment has a statistical sampling plan for evaluating incoming containers and rejection actions, if needed;

b. the establishment is following its statistical sampling plan;

c. the establishment is ensuring that empty containers, roll stock for container forming, and lidding materials are clean and free from structural defects prior to filling;

d. the establishment's empty container handling practices (e.g., conveying, unscrambling, denesting, and manual handling) are adequate to prevent soiling and damage;

e. the containers are free of damage after filling;

f. the establishment is conducting container closure examinations;

g. the containers and closures (after closure) are protected from damage which could cause defects likely to affect the hermetic condition of the container;

h. corrective actions are taken in response to detection of improper container closure or damage;

i. the containers are marked with a permanent, legible, identifying code mark per regulatory requirements; and

j. the maximum time lapse between container closure and the initiation of the thermal process is two hours or less, unless otherwise approved.

2. **9 CFR 318.302, 381.302 – Thermal Processing:** This section of the canning regulations requires that all product be produced by the establishment is produced according to a process schedule developed by a process authority. Inspection program personnel should verify that:

a. the establishment verifies that it has process schedules/documents from the processing authority on file for each product produced;

b. the establishment ensures that no unauthorized changes are made to the process schedule in use (e.g., formulation, preparation, and process equipment); and

c. the establishment ensures that products are prepared according to the formulation and procedures specified in documents that the processing authority has developed.

3. **9 CFR 318.303, 381.303 – Critical Factors and the Application of the Process Schedule:** This section of the canning regulations requires that establishments ensure that the critical factors identified in the process schedule are measured, controlled, and recorded as specified in the process schedule. Factors that are often critical to process schedule adequacy may include: maximum fill or drained weight; arrangement of pieces in the container; container orientation; product

formulation; particle size; maximum thickness for flexible or semirigid containers during thermal processing; maximum pH; percent salt; ingoing nitrite level; maximum water activity, product consistency or viscosity; container filling sequence; minimum head space; retort conveyor or reel speed; steam/air ratio; and heating medium flow rate. Inspection program personnel should verify that:

a. the critical factors specified in the process schedule are measured, controlled and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule;

b. all measurements are within the limits used to establish the process schedule;

c. the establishment ensures that the types of ingredients (hydrated vs. not hydrated, acidified vs. not acidified, blanched vs. not blanched, slow set vs. rapid set starch, etc), as specified in the process schedule, are prepared or utilized in the product formulation; and

d. the establishment ensures that the product is prepared according to the formulation specified in the process schedule, including but not limited to the specified amount and characteristics (e.g., pH, cure, water activity, viscosity, etc) of each ingredient.

4. **9 CFR 318.304, 381.304 – Operations in the Thermal Processing Area:** This section of the canning regulations requires that establishments ensure that the process schedule (or operating process schedule) for daily products, including minimum initial temperatures and operating procedures for the thermal processing equipment, is posted near the thermal processing equipment, or available to the thermal processing system operator and inspection program personnel. Additionally, this section also states that establishments shall have product traffic control to prevent product from bypassing the thermal process, that the initial temperature of the contents of the coldest container to be processed shall be determined and recorded, that timing devices shall be adequate to time applicable thermal processing operation functions or events, and that measurement of pH shall be conducted using potentiometric electronic instruments (pH meters) unless other methods are approved. Inspection program personnel should verify that:

a. the process schedules (or operating schedules) for daily production, including minimum initial temperatures and operating procedures for thermal processing equipment, are posted in a conspicuous place near the processing equipment;

b. the establishment has a system in place for product traffic control to prevent product from bypassing the thermal processing operation;

c. establishment personnel are measuring the coldest container to be processed and recorded at the time the processing cycle begins to ensure that the temperature of the contents of every container to be processed is not lower than the minimum initial temperature specified in the process schedule;

d. the establishment is following its written procedures on file for determining the initial temperature;

e. measures are in place to prevent water from lowering the initial temperature below the prescribed minimum (if the establishment is placing containers in holding tanks or using water in the retort);

f. there are adequate product traffic control procedures (e.g., heat sensitive indicators in each retort load) to prevent unprocessed product from bypassing the system;

g. the establishment has accurate devices to time applicable thermal processing operation functions or events, such as process schedule time, come-up time, and retort venting to ensure that all such functions or events are achieved; and

h. the establishment uses potentiometric methods that employ electronic instruments for making pH determinations when a maximum pH value is specified as a critical factor in a process schedule.

5. **9 CFR 318.305, 381.305 – Equipment and Procedures for Heat Processing Systems:** This section of the canning regulations requires that the equipment and procedures used for heat processing systems be adequate to deliver a thermal process to product that renders it commercially sterile. This regulation identifies specific criteria or parameters for the various instruments, controls, and components of the various types of thermal processing systems, including retort design. The establishment must have the various items addressed in this section of the canning regulations, including but not limited to: temperature indicating devices; temperature/time recording devices; pressure recording devices; steam controllers; air valves and supplies; water inlets and valves; steam inlets and spreaders; bleeders and condensate removal systems (including vents and mufflers); crate supports; stacking equipment; retort/reel speed timing; conveyor speed; heat distribution systems; drain valves; and circulation systems for the various types of retort systems. Additionally, these regulations also address equipment maintenance, container cooling and cooling water, and post-process handling of containers. Inspection program personnel should verify that:

a. each retort system is installed, operated, and maintained as required;

b. each retort system is equipped with at least one temperature indicating device that measures the actual temperature within the retort;

c. the temperature indicating device, not the temperature/time recording device, is used as the reference instrument for indicating the process temperature;

d. the mercury-in-glass thermometers meet the requirements specified;

e. each thermal processing system is equipped with at least one temperature/time recording device to provide a permanent record of temperatures within the thermal processing system, and each retort is equipped with an automatic steam controller to maintain the retort temperature;

f. all air lines connected to retorts designed for pressure processing in steam are equipped with a globe valve or other equivalent-type valve or piping arrangement that will prevent leakage of air into the retort during the process cycle;

g. all retort water lines that are intended to be closed during a process cycle are equipped with a globe or other equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the process cycle;

h. the steam inlet to each retort is large enough to provide steam for proper operation of the retort, and enter at a point to facilitate air removal during venting;

i. steam spreaders, bleeders, stacking equipment, and divider plates are installed and used per the regulatory requirements;

j. vents are located in the portion of the retort opposite the steam inlet and designed, installed, and operated in such a way that air is removed from the retort before timing of the thermal process is started;

k. vents are not connected to closed drain systems without an atmospheric break in the line;

l. all instruments and controls are checked any time their functioning or accuracy is suspect;

m. maintenance records and the annual thermal process system audit records indicate that the thermal process systems are functioning properly;

n. recycled or reused container cooling waters are handled in systems that are designed, operated, and maintained so that there is no buildup of microorganisms, organic matter, and other materials in the systems and in the waters; and

o. containers are handled in a manner that will prevent damage to the hermetic seal area.

6. **9 CFR 318.306, 381.306 – Processing and Production Records:** This section of the canning regulations requires that establishments obtain and record all information necessary to demonstrate that the product is prepared, processed and handled in a manner that is in compliance with the regulations for commercially-sterile, hermetically-sealed shelf stable product. The records required by this part of the canning regulations include, but are not limited to: date of production; product name and style; container code; container size and type; process schedule, including the minimum initial temperature; measurements made to satisfy the requirements for the control of critical factors; and recorded information and data associated with the particular type of thermal processing system used to process the product. Inspection program personnel should verify that:

a. establishment personnel record the date of production, product name and style, container code, container size and type, and the process schedule, including the minimum initial temperature;

b. additional records are completed for the specific types of retorts in the establishment; and

c. establishment personnel review and maintain production records.

7. **9 CFR 318.307, 381.307 – Record Review and Maintenance:** This section of the canning regulations requires that establishments prepare processing and production records associated with the production of commercially- sterile, hermetically-sealed shelf stable product appropriately, review the records in a timely manner, and maintain them for a minimum of three years (one year at the establishment and an additional two years at the establishment or other location). Additionally, these regulations also specify that records must be maintained by the establishment that identify the initial distribution of the finished product, and that all records be made available to inspection program personnel for review. Inspection program personnel should verify that:

a. entries in records are made at the time the event occurs;

b. establishment personnel (no later than one working day after the actual process) review all processing and production records to ensure completeness and to determine whether all product was processed in accordance with to the process schedule; and

c. all records, including the temperature/time recorder charts and critical factor control records, are signed or initialed and dated by the person conducting the review.

8. **9 CFR 318.308, 381.308 – Deviations in Processing:** This section of the canning regulations requires that whenever the actual process is less than the process schedule, or any critical factor does not comply with the requirements for that factor as specified in the process schedule, such events are considered deviations in processing, and that deviations are to be handled in a manner to prevent the distribution of under processed product. These regulations specify the requirements for handling deviations identified either in-process or through records review. Inspection program personnel should verify that:

a. establishment personnel detect all deviations;

b. establishment personnel handle process deviations in accordance with these regulations, whether identified in-process or through records review;

c. the establishment only reprocesses or repacks product with a process schedule authorized by the processing authority;

d. deviations in a continuous retort, including, but not limited to, emergency stops (jams or breakdowns) or temperature drops, are handled according to regulatory requirements; and

e. the establishment's process deviation file contains full records regarding the handling of each deviation, including at a minimum, 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.

9. **9 CFR 318.309, 381.309 – Finished Product Inspection:** This section of the canning regulations is designed to ensure that only safe and stable product is shipped in commerce. This regulation specifies the finished product inspection procedures that the establishment must follow, including the handling of abnormal containers, to ensure that only normal-appearing, hermetically-sealed containers of product that are commercially sterile and shelf stable are distributed in commerce. Inspection program personnel should verify that:

a. the establishment has finished product inspection procedures that are in compliance with these regulations;

b. the establishment has documented procedures in place for finished product inspection;

c. the establishment has an incubator, when incubation is used, with an accurate recorder, accurate thermometer, a means for air circulation within the incubator, and a means to prevent unauthorized entry into the incubator;

d. the establishment's container incubation program, when applicable, complies with required time, temperature, range, sampling program, identification of product requiring incubation, checks, and records;

e. the establishment (when it uses a reduced incubation rate) has controls that include incoming container and closure examinations, packer's end double seam examinations, handling of filled and sealed containers, retort traffic control container cooling practices, recordkeeping and records review, and procedures for ensuring the container soundness of finished lots;

f. the establishment (when it uses a reduced incubation time) has adjusted the amount of product incubated (a percentage of the total lot rather than a single container for still retorts or 1 per 1000 containers for continuous retorts) and has narrowed the temperature range for incubation (e.g., from $\pm$ 5°F to $\pm$ 2°F);

g. the establishment (when it ships product without incubation) has a letter from its process authority stating that its QC program, or process schedule adequately provides for product safety and stability;

h. establishment personnel are performing incubation checks;

i. incubator records are maintained as required; and

j. abnormal containers are handled according to regulatory requirements.

10. **9 CFR 318.310, 381.310 – Personnel and Training:** This section of the canning regulations requires that all operators of the thermal processing systems within the establishment and all container closure technicians are under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations. Inspection program personnel should verify that:

a. all operators of thermal processing systems and container closure technicians are under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.

11. **9 CFR 318.311, 381.311 – Recall Procedures:** The purpose of this part of the canning regulations is for the establishment to ensure that it has prepared and maintains a current recall procedure for all canned product they produce that are covered by the canning regulations. Inspection program personnel should verify that:

a. the establishment has prepared and maintains current procedures for the recall of all canned product covered by the canning regulations.

VII. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES WHEN PERFORMING AN 03D02 PROCEDURE

A. Inspection program personnel should verify that the establishment is meeting the requirements specified in the canning regulations for the specific lot of production in question. The review and observation component, the recordkeeping component, or a combination of these components of the 03D02 procedure can be used for this verification as described in FSIS Directive 5000.1. Revision 1, Chapter II. The canning regulations have requirements that must be met for specific production to be determined commercially stable. Inspection program personnel should verify that:

1. this production received the appropriate process schedule for the containers and product;

2. the initial temperature was measured and recorded;

3. all critical factors associated with this production were met;

4. there was no unauthorized formulation change;

5. the product was prepared in accordance with the formulation in the processing authority's documents;

6. the required processing and production information was recorded;

7. all process deviations have been handled appropriately;

8. only normal containers were selected for incubation, and that only normal-appearing containers were shipped from an establishment, as determined by an

appropriate sampling plan; and

9. the regulatory requirements of 417.5(a)(3) were met if the establishment has HACCP plans addressing chemical or physical hazards.

B. Inspection program personnel should verify that the establishment is reviewing all processing and production records to ensure completeness and to determine whether all product received the process schedule no later than one working day after the actual produces. All records including the temperature/time recorder charts and critical factor control records are required to be signed or initialed and dated by the person conducting the review. The records required may vary slightly depending on the type of retorting system and the establishment's lotting system. The requirements of 9 CFR 318.307 and 9 CFR 381.307 are very similar to the requirements of 9 CFR 417.5(c). Therefore it is not necessary for the establishments that are following the canning regulations to conduct pre-shipment review as per 9 CFR 417.5. If the establishment does not conduct the records review in the manner described in 9 CFR 318.307 or 9 CFR 381.307, it would recordkeeping noncompliance.

VIII. CORRECTIVE ACTIONS

A. If any deviations in processing occur, the establishment must take corrective actions as described in 318.308 and 381.308. Because these regulations are very prescriptive concerning the establishment responding to deviations in processing, the establishment would not have to also meet the requirements of 9 CFR 417.3. If the deviation is identified prior to the completion of the intended processing schedule, the establishment can immediately reprocess the product using the full process schedule, use an appropriate alternate process schedule, or hold the product involved and have the deviation evaluated by a processing authority to assess the safety and stability of the product. Upon completion of the evaluation, the establishment is required to provide the inspection program employee with a complete description of the deviation along with all necessary supporting documentation, a copy of the evaluation report, and a description of the product disposition actions. If the deviations in processing are handled according to these requirements, there would be no noncompliance record written, and the deviation from processing would not be considered a deviation from a critical limit or an unforeseen hazard. If inspection program employees need assistance in assessing the supporting documentation or effectiveness of the corrective actions, the Technical Service Center (TSC) can be contacted.

B. On the other hand, if the deviation was not handled in accordance with the requirements of sections 318.308 or 381.308, it is regulatory noncompliance, and the establishment would also have to consider it as an unforeseen hazard. If the process deviation is considered to be an unforeseen hazard, the establishment must reassess it hazard analysis as required in 9 CFR 417.3(b) and have supporting documentation for the decisions made during the reassessment.

C. As stated in the Background section, process authorities are persons or organizations recognized as having the knowledge and expertise to develop thermal processing schedules. The decisions made by the process authorities generally are well documented and supported by science, and contribute significantly to the validation of the corrective actions. When there is a deviation in processing and the processing authority makes a disposition of the affected product, he/she should have supporting documentation for that decision. For example, if product were retorted short of the process schedule by one minute, the processing authority might be able to support the decision that the product is safe and will be stable because the process authority designed the system to have a safety factor and the support documentation shows that there is a safety factor of one minute designed into the process schedule. If FSIS inspection program personnel are not provided with the scientific basis for the decision made by the process authority in response to corrective actions, FSIS inspection program personnel should request a copy of the support documentation. If the support documentation appears to be inadequate (e.g., doesn't address the specific corrective action), there is noncompliance with the canning regulations and concerns with the safety and stability of the product. If inspection program personnel have reason to question the corrective actions taken by the establishment, they should contact their District Office (DO). The DO may send an EIAO to review the effectiveness of the corrective actions taken by the establishment. If inspection program personnel or EIAOs need assistance assessing the adequacy of the supporting data, they should contact the TSC.

IX. DOCUMENATION AND ENFORCMENT WHEN THE CANNING REGULATIONS SERVE AS PREREQUISITE PROGRAMS

A. Using the methodology in FSIS Directive 5000.1, Revision 1, when inspection program personnel find a regulatory noncompliance with the canning regulatory requirements they are to:

1. issue an non-compliance record (NR) under 03D01 or 03D02, as appropriate,

2. cite 9 CFR 417.5(a)(1) as the relevant HACCP regulation and cite the relevant canning regulation

3. record the non-compliance under the recordkeeping trend indicator because the establishment has failed to comply with the parameters of its supporting documentation (meeting the requirements of the canning regulations) for its hazard analysis.

B. Using the methodology in FSIS Directive 5000.1, Revision 1, inspection program personnel are to link NRs when there are any noncompliances with the canning regulations and are to:

1. reference the previous NR number and date, as well as the further planned action that was ineffective in preventing recurrence of the noncompliance,

2. discuss the linked NRs with plant management during the weekly meetings,

3. verify that the establishment understands that it made the decision to follow the canning regulations in lieu of addressing the food safety hazards associated with microbiological contamination associated with canning in its HACCP plan, and, therefore, it is the responsibility of the establishment to meet those regulatory requirements.

NOTE: The purpose of linking NRs is to provide notification to the establishment that the further planned actions have been ineffective, or have not been implemented in a way that was effective in preventing the noncompliance from recurring, and that if the trend continues; the repetitive NRs would support an enforcement action under the rules of practice regulations.

4. include in Block 10 of the NR that these discussions were held, and that the establishment was informed that continued failure to meet regulatory requirements can lead to enforcement actions described in 9 CFR 500.4.

C. Using the methodology in FSIS Directive 5000.1, Revision 1, when inspection program personnel determine that a trend of non-compliance exist, they are to contact, through supervisory channels, their DO and ask that it issue an Notice of Intended Enforcement (NOIE) to the establishment, as described in 9 CFR 500.4 and FSIS Directive 5000.1, Revision 1.

D. At any time when inspection program personnel find a noncompliance with the canning regulations that may result in the safety of the product being jeopardized, they are to contact, through supervisory channels, the DO. The DO may decide to issue an NOIE as described in 9 CFR 500.4 and FSIS Directive 5000.1, Revision 1.

E. At any time when inspection program personnel find that adulterated product has been produced and shipped, they are to contact, through supervisory channels, the DO. The DO may suspend the assignment of inspection program personnel as described in 9 CFR 500.3 and FSIS Directive 5000.1, Revision 1.

Assistant Administrator
Office of Policy, Program, and Employee Development

§ 318.301 and 381.300 – Definitions

1. **Question**: Are "pickled" or other low pH (e.g., spaghetti meat sauce) products covered by the canning regulations?

   Answer: Many pickled or other low pH products are considered "acidified low acid products" (as defined in sections 318.300(b) and 318.300(b)) because they are formulated or treated to yield a finished product with pH of 4.6 or lower. However, only those pickled or other low pH products where the product or any covering liquid is heated and filled hot into containers or receive a heat treatment (e.g., pasteurization or pressure process) after the container is filled and sealed are subject to these regulations. Products that are "cold filled" and receive no further heat treatment are not considered as "canned product" (as defined in section 318.300 (d)) and are not covered by these regulations.

§ 318.301 and 381.301 – Containers and Closures

2. **Question**: When an establishment performs a teardown examination on a double seam (as required in sections 318.301(b)(2) and 381.301(b)(2)) and a measurement does not meet the container specification guidelines for double seam integrity on file, is corrective action always necessary?

   Answer: The canning regulations require specifications for double seam integrity to be on file. Container specifications are most often provided by the container supplier or closing equipment supplier but sometimes are developed by a processor. Unlike critical limits associated with CCPs in HACCP, these specifications are guidelines, not absolute values. The length and thickness of the double seam, the body hook and cover hook lengths, and the amount of overlap of the body and cover hooks are measurements for the soundness of the double seam. The soundness of a double seam is dependant on the structure and formation of the seam, not necessarily on one individual measurement or component. The establishment must have a trained closure technician (as defined in sections 318.300(e) and 381.300(e)) review a measurement that does not meet the specifications to determine the impact on the soundness of the double seam. If corrective actions are not taken when the can manufacturer's specifications are not met, the closure technician should be able to support why the decision was made not to take corrective actions, and why despite not acting, there is no basis for concern about product safety.

3. **Question**: The requirements in sections 318.301(b)(2)(iii) and 381.301(b)(2)(iii) state that a side seam juncture rating be examined on the cover hook. When would this not be necessary?

Answer: Two-pieces cans (those with the bottom and side body formed from one continuous piece of metal (or plastic)) do not have a side seam. Therefore, the side seam juncture does not exist in two-piece cans, and as such, the juncture rating is not applicable. The regulations are applicable to all three-piece cans (those with the bottom and body made from two separate pieces of metal and joined together) but were written primarily for three-piece soldered cans, which are now seldom used in the USA. Even though three-piece cans with welded side seams have very little risk of developing droops at the side seam juncture, the juncture rating would still be done but would not be a primary concern in record review.

4. **Question**: If the time between closing and the initiation of thermal processing is longer than two hours as required in sections 318.301(f)(2) and 381.301(f)(2), what does an establishment do?

Answer: If the time between closing and the initiation of thermal processing is longer than two hours, microbial growth could occur. This could potentially result in spoilage of the product prior to processing. This situation should be reviewed by the establishment's processing authority to determine the suitability of the process and product. In most cases, the establishment will process the product, considering the matter a process deviation, and have the evaluation of the process completed by their processing authority per the processing deviation regulations specified in 318. 308(d)(1)(iii) and 381.308(d)(1)(iii). A copy of the documentation from the processing authority supporting a longer time between closure and start of thermal processing should be forwarded to the Technical Service Center for review if inspection program personnel have food safety concerns related to the longer time frame.

§ 318.302 and 381.302 – Thermal Processing

5. **Question**: Sections 318.302(a) and 381.302(a) require the establishment to have a process schedule for each canned product produced at the facility. Sections 318.302(b) and 381.302(b) require process schedules be developed by a process authority. Where does an establishment get a process schedule, and in what form might it appear? Who can be a process authority?

Answer: A process schedule is provided to the establishment by a processing authority – the person or organization having expert knowledge of thermal processing requirements for foods in hermetically sealed containers, having access to facilities for making such determinations, and designated by the establishment to perform certain functions as indicated. A processing authority can be an employee of the establishment (either at the facility or at a separate corporate facility) or of an outside organization or individual such as an equipment or container supplier, consulting firm, trade association, or university. An establishment may use different processing authorities for different products.

The process schedule may be provided as a letter, memo, report, S.O.P., or

other written communication or document. It may also be referred to in terms other than "process schedule" depending on the establishment. Regardless of whether the document uses the terms "process schedule" or "scheduled process," if it contains the thermal process (e.g., times and temperatures or minimum initial product temperature) and any specified critical factors for safety /stability of product, it would be considered the process schedule.

6. **Question**: Should inspection program personnel be expected to request from the establishment all records concerning the development or determination of each process schedule as stated in sections 318.302(b)(3) and 381.302(b)(3)?

   Answer: It depends. It may not be necessary to ask to see the data associated with determining the process schedule if the original communication from the processing authority outlining the process schedule adequately describes the basis/criteria (e.g., product and formulation parameters) upon which the process schedule was developed. However, if such information is not provided in the process authority communication (e.g. product formulation), then the complete records specified in sections 318.302(b)(3) and 381.302(b)(3) would need to be requested.

7. **Question**: Can a single process schedule be applied to more than one product?

   Answer: This depends. Process schedules are product and formula specific, affected by container size and type and the retorting system. If a single formula is packed and labeled with different brand names or label-types, the process schedules would apply to the different product brand names produced in the exact same size and type of package (because the formula is the same). In addition, the process authority determines if the same process schedule can be applied to more than one product

§ 318.303 and 381.303 – Critical Factors and the Application of the Process Schedule

8. **Question**: Sections 318.303 and 381.303 require that critical factors be measured, controlled, and recorded by the establishment. The establishment, however, monitors parameters that are not specified in the process schedule. When this happens, does it mean that the processing authority neglected to include these parameters as critical factors?

   Answer: No. The process authority has determined that certain characteristics of the product, product packing and handling procedure, or thermal process, are critical factors. An establishment will often monitor and control more parameters than are specified by the processing authority. **The establishment does so to control specific quality and economic, but not food safety, attributes associated with the product.** An establishment is still in compliance with this section of the regulation even if it does not monitor or meet its internal quality/economic specifications.

§ 318.304 and 381.304 – Operations in the Thermal Processing Area

9. **Question**: What is meant by the operating process schedule referenced in sections 318.304(a) and 381.304(a)?

Answer: A process schedule outlines the minimum conditions that must be met to ensure that a product will be rendered shelf stable/commercially sterile. An establishment will often set stringent process conditions that are over and above those outlined by the processing authority to prevent situations where the minimum conditions specified in the process schedule may not be met. These are referred to as "operating" process schedules. Varying from an operating process schedule does not mean that the there has been a process deviation if the parameters in the process schedule provided by the process authority are met.

10. **Question**: Sections 318.304(a) and 381.304(a) require that an establishment post the process schedule or make that information available to the thermal processing system operator and inspection program personnel. How can this be accomplished?

Answer: Each establishment will have its own method for posting or making a process schedule available. Some methods include: maintaining a bulletin board or notebook with all of the establishment's process schedules located by the thermal processing operations, providing a copy of the process schedule to the thermal processing system operators each production day, or providing "recipes" or schedules in a computer control system. These are just a few examples. The processes posted may be the operating processes rather than the minimum operating conditions specified in the process authority's process schedule.

11. **Question**: What actions should be taken if a temperature/time recording device does not agree within 15 minutes to the time of the day recorded on the corresponding written records? [318.304(d) and 381.304(d)]

Answer: The intent of this requirement in the regulations is to ensure that the recorder chart tracings accurately match the corresponding written records. If the temperature/time recording device does not agree to within 15 minutes of the time recorded on the written records, the establishment must be able to correlate the tracings and the records. However, FSIS would expect the establishment to bring the system into compliance with the regulations.

§ 318.305 and 381.305 – Equipment and Procedures for Heat Processing Systems

12. **Question**: What actions should be taken if a temperature/time recording device does not agree within 1°F of the indicating temperature device as stated in sections 318.305(a)(2) and 381.305(a)(2)?

Answer: An establishment may adjust the recording device to be in agreement with, but not be higher than, the reading on the indicating temperature device to ensure that they comply with sections 318.305(a)(2) and 381.305(a)(2), which require that the recording device not be higher than the known accurate indicating temperature device. If the temperature/time recording device requires more than one adjustment during the retort cycle, the retort operator should record the temperature indicated on the mercury-in-glass thermometer or temperature indicating device at 1 minute intervals for the duration of the process. After the completion of the retort cycle, the establishment must take the appropriate corrective action to ensure that the temperature/time recording device is functioning properly and will not require adjustment with subsequent retort loads.

13. **Question**: Sections 318.305 and 381.305 -- Equipment and Procedures for Heat Processing Systems -- make numerous references to “documentation shall be in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority.” Should inspection program personnel be expected to review the heat distribution data?

Answer: It depends. The written communication from the equipment manufacturer or processing authority outlining the thermal process operating procedures may adequately provide information demonstrating uniform heat distribution within the retort. If heat distribution data is not included in written communications, documentation in the form of heat distribution data or other documentation from the equipment manufacturer or processing authority would need to be provided by the establishment to Program employees for review.

14. **Question**: Are heat distribution data or other documentation always required to verify adequate temperature distribution within a retort or other thermal processing system?

Answer: Yes, except when "Batch, Still, Steam Retorts" (vertical or horizontal) are installed, equipped, piped, operated and vented exactly as described in sections 318.305(b)(1) and 381.305(b)(1) of the regulations. In that case, the establishment is not required to have any documentation attesting to the adequacy of air removal and temperature distribution within the retort(s).

15. **Question**: When an establishment is operating more than one retort, and heat distribution data or other documentation is required under sections 318.305(b) or 381.305(b) of the regulations, is separate documentation required for each individual retort?

Answer: Not necessarily. When two or more retorts are identical (e.g., size, dimensions, auxiliary equipment, operating procedures), there is no need to have documentation on file at the establishment demonstrating that each retort has

been individually tested. However, the documentation required under sections 318.305(b) and 381.305(b) that is maintained on file must clearly identify the acceptable (or limiting) retort operating conditions. For example, the information should address the range of container sizes; the use of retort crate divider plates (if applicable); and the number of retorts that could be simultaneously vented.

16. **Question**: Are processors required to keep actual ("raw") data and test results from retort heat distribution studies on file at the establishment?

Answer: It depends. Sections 318.305 and 381.305, which require that such records be maintained, qualify the requirement with "or other documentation from the equipment manufacturer or processing authority…." Therefore, the documentation requirement may be met by other documentation (e.g., letter or report) that recommends venting procedures or documents the uniformity of temperatures in the processing system, as long as this documentation contains sufficient information on the retort system to accurately describe the unit tested, and the conditions under which it can be operated. However, if the "other documentation" from the manufacturer or process authority is not provided, or if it does not adequately address the issue at hand, the heat distribution studies data and test results would need to be provided.

17. **Question**: What action should be taken by the retort operator if the chart recorder, as required by sections 318.305(a)(2) and 381.305(a)(2), fails to record the temperature within the thermal processing system?

Answer: The retort operator would record the temperature indicated on the mercury-in-glass thermometer or temperature indicating device at 1 minute intervals for the duration of the process. Such temporary temperature recording procedures would not be considered a process deviation by the Agency. However, the chart recorder must be repaired and operating properly before the retort can be used to process additional product.

18. **Question**: Sections 318.305(c)(1)(i) and 381.305(c)(1)(i) state that the bulb (or probe) of the indicating temperature device on "Batch, Still, Water Retorts" must extend a minimum of 2 inches into the water. Are there any exceptions to this requirement?

Answer: No. However, many establishments have "Batch, Agitating, Water Retorts" that are used in the still mode (no agitation). Even when operated in the still mode, these retorts are still agitating retorts which are covered by sections 318.305(c)(2) and 381.305(c)(2) of the regulations. These sections have no requirement regarding the distance that a bulb (or probe) must extend into the water. However, if these retorts are used in a still mode, the establishment must have a still retort process schedule.

19. **Question**: What requirements apply to the water used in "Hydrostatic Retorts"?

Answer: Because the water in a "Hydrostatic Retort" is being "reused" to thermally process canned product, section 416.2(g) of the regulations applies. This means that reused water must be for the original purpose, and that all equipment used to handle reused water must be constructed and installed so that it could be cleaned and drained, and be kept clean. If any portion of the retort's water that is considered "cooling water" is pumped from the retort (for example, from the outlet cooling leg to a cooling tower and back to the cooling leg), it is considered "recycled container cooling water" and is subject to the requirements of sections 318.305(h)(3) or 381.305(h)(3) of the regulations.

§ 318.308 and 381.308 – Deviations in Processing

20. **Question**: When a continuous rotary retort stoppage is of a short duration, and there is assurance that the temperature in the "cooker" shell has not dropped, may operation of the retort resume without any other action being initiated?

Answer: Yes, provided the establishment maintains documentation on file demonstrating that stoppages of short duration do not affect the adequacy of the thermal process. Thermal processing records, however, must provide assurance that the temperature in the "cooker" shell has not dropped, and entries must be made on the processing records regarding the handling of each stoppage. If the duration of the stoppage exceeds the time for which there is supporting documentation, product involved must be handled in accordance with sections 318.308(d)(1)(vi) and 381.308(d)(1)(vi).

§ 318.309 and 381.309 – Finished Product Inspection

21. **Question**: Sections 318.309 (d)(1) and 381.309 (d)(1) describe procedures for incubation of shelf stable canned product. Are establishments required to follow these procedures?

Answer: The intent of incubation is to ensure that only sound containers leave the establishment. An establishment may follow the incubation requirements of the regulation, use a modified procedure (e.g., increase the sample percentage of a lot incubated for less than 10 days), or release product without incubation. However, the establishment must ensure that the alternate procedures for incubation provide the same degree of safety and stability for the final product required in the regulations. To ship without incubation, a letter from a processing authority stating the HACCP plan, prerequisite program or process schedule adequately provides for safety and stability would be expected.

Assurance of the release of sound containers with a reduced incubation or without incubation may be demonstrated as follows:

- A reduction in the incubation sampling rate could be accomplished by a combination of controls. These controls include incoming container and closure examinations (sections 318.301(a) and 381.301(a)) and packer's end double seams (sections 318.301(b) and 381.301(b)), handling of filled and sealed containers (sections 318.301(f) and

381.301(f)), and retort control (sections 318.304(b) and 381.304(b)). Additional controls include container cooling practices (sections 318.305(h) and 381.305(h)), recordkeeping (sections 318.306 and 381.306), record review (sections 318.307 and 381.307), and procedures for assuring the soundness of finished lots (sections 318.309(d)(2)(i) and 381.309(d)(2)(i)).

- For reduced time of incubation (e.g., 3 days rather than 10 days), the establishment should consider both the amount of product incubated (e.g., a percentage of the total lot rather than a single container for still retorts or 1 per 1,000 containers in continuous retorts) and a narrowing of the temperature range (e.g., from 95±5°F to 96±2°F).

- To ship without incubation, the establishment must have a letter from a processing authority (sections 318.302 and 381.302) stating that their procedures adequately provide for safety and stability.

§ 318.310 and 381.310 – Personnel and Training

22. **Question**: Under sections 318.310 and 381.310, operators of thermal processing systems and container closure technicians must be “under the direct supervision of a person who has successfully completed a school of instruction that is generally recognized as adequate for properly training supervisors of canning operations.” Does this mean that the operator’s or technician’s immediate supervisor must have attended the training for supervisors of canning operations?

Answer: No. The word "direct" as used in sections 318.310 and 381.310 does not necessarily mean the immediate supervisor. Accordingly, if a trained supervisor's or manager's scope of authority extends to the thermal processing system operator or container closure technician, even if one or more levels of supervision exists between the trained supervisor and the operator/technician, the establishment would be in compliance with this requirement provided that the trained supervisor is on the premises during the times of operation.