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

FSIS DIRECTIVE

7530.2
Rev. 1

8/20/18

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

I. PURPOSE

This directive is rewritten in its entirety to refer to the updated canning regulations published on 05/31/2018 (83 FR 25302). This directive updates and provides instructions to inspection program personnel (IPP) on how to verify compliance with the canning regulations in canning establishments that choose to follow the canning regulations per 9 CFR 417.2(b)(3). This directive also supplements instructions in FSIS Directive 5000.1 *Verifying an Establishment's Food Safety System,* for verifying compliance with 9 CFR 417 and 9 CFR 431 in those canning establishments. The supplemental instructions are updated to provide additional verification instructions and to address processes that are unique to canning establishments.

NOTE: If the establishment addresses the food safety hazards associated with microbiological contamination in its Hazard Analysis and Critical Control Point (HACCP) plan, IPP are to follow the verification instructions in FSIS Directive 5000.1.

KEY POINTS:

- *Updates the regulatory citations based on the consolidated canning regulations (9 CFR 431.1–431.12)*
- *Provides IPP with instructions for performing the Thermally Processed - Commercially Sterile HACCP task in canning establishments that choose to follow the canning regulations*
- *Provides instructions to IPP regarding verification of the regulatory requirements in 9 CFR 431.1–431.12*

II. CANCELLATION

FSIS Directive 7530.2 *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations*, 10/20/05

III. BACKGROUND

A. FSIS published the consolidated canning regulations (9 CFR 431) in the final rule "*Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations*" on 05/31/2018 with an effective date of 07/30/2018.

B. Official establishments that produce thermally processed, commercially sterile meat and poultry products are subject to the HACCP regulations in 9 CFR part 417 and are required to conduct a hazard analysis for all such products. The HACCP regulations at 9 CFR 417.2(b)(3) exempt these establishments from having to address food safety hazards associated with microbiological contamination if the

establishments comply with the canning regulations in 9 CFR 431. However, canning establishments that identify other non-microbiological (chemical or physical) food safety hazards as reasonably likely to occur (RLTO) are to address those hazards in their HACCP plan, per the HACCP regulations.

C. If an establishment that chooses to follow the canning regulations under 9 CFR 417.2(b)(3), any records required by the regulations in 9 CFR 431 and the establishment's associated process documentation would be required to be kept under 9 CFR 417.5(a)(1).

D. If an establishment that chooses to follow the canning regulations does not meet all the requirements in 9 CFR 431, 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(a)(1), 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).

E. "Canned product" is defined in 9 CFR 431.1 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.

F. A processing authority (PA) is defined in 9 CFR 431.1 as a 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 PA can be an employee of the establishment (either at the facility or at a separate corporate facility) or an outside organization or individual such as an equipment or container supplier, consulting establishment, trade association, or university. An establishment may use different PAs for different products.

G. A process schedule is defined in 9 CFR 431.1 as the thermal process and any specified critical factors for a given canned product required to achieve shelf stability. A process schedule developed by a PA is a supporting document. It may also be referred to in terms other than "process schedule," such as "scheduled process," depending on the establishment. If it contains the thermal process (e.g., processing time, retort temperature and minimum initial product temperature) and any specified critical factors for safety and stability of the product, FSIS would consider the document a process schedule.

IV. IPP RESPONSIBILITIES WHEN PERFORMING A THERMALLY PROCESSED - COMMERCIALLY STERILE HACCP TASK

A. IPP are to schedule and perform the PHIS Thermally Processed, Commercially Sterile HACCP Task as described in FSIS Directive 13000.1 Rev. 1 *Scheduling In-Plant Inspection Tasks in the Public Health Information System (PHIS)*. IPP have the responsibility to verify that the requirements of 9 CFR 431 are met in establishments that choose to follow the canning regulations.

B. IPP are to be familiar with the establishment's hazard analysis, HACCP plan, and any prerequisite programs according to instructions in FSIS Directive 5000.1.

C. In the canning establishments, IPP are to select a specific production lot to perform the Thermally Processed – Commercially Sterile HACCP task. If an establishment produces both low acid and acidified low acid canned products, IPP are to consider the number of products in each category and the production volume when selecting the specific production lot. IPP are to give priority to canned products with more critical factors to control, but are also to ensure that they verify all product types produced in the establishment over the course of a calendar year. IPP are to ensure that all types of thermal processing system equipment (e.g., aseptic processing systems or retorts) used by an establishment receive inspection at least once during the calendar year.

D. IPP are to verify that:

1. Process schedules (or operating process schedules) for daily production are posted in a conspicuous place near the thermal processing equipment or available to operator and the inspector (9 CFR 431.5(a));

2. Appropriate process schedule for the product and type of container was used (9 CFR 431.3(a));

3. There was no unauthorized change in product formulation, equipment or treatment that was not already incorporated in the process schedule (9 CFR 431.3(b));

4. The initial temperature was measured and recorded by the establishment (9 CFR 431.5(c));

5. All critical factors associated with this production were met (9 CFR 431.4);

6. The required processing and production information was correctly recorded (9 CFR 431.7);

7. Any process deviation was handled appropriately (9 CFR 431.9(b));

8. Only normal containers were selected for incubation (if applicable), and only normal appearing containers were shipped from the establishment, as determined by an appropriate finished product inspection program (9 CFR 431.10(a) and (c)); and

9. The establishment reviewed all processing and production records no later than one working day after the actual process, to ensure the completeness of the records and to determine whether all products received the process schedule. 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 (9 CFR 431.8);

D. IPP are to select at least one additional requirement in one of the 11 sections in canning regulations (e.g., 9 CFR 431.6(a)) and verify whether the establishment is complying with that section of the regulations. IPP are to give priority to sections in the regulations with which the establishment has a history of noncompliance. IPP are to verify establishments meet all canning regulations at least once during the calendar year.

NOTE: There are 11 sections in the canning regulations and numerous requirements in each section that IPP may select to verify. The last section (9 CFR 431.12) covers recalls and can be met through compliance with Part 418. If IPP have verified that the persons supervising the operators of the thermal processing systems and container closure technicians have completed the appropriate training (9 CFR 431.11), and that there is a recall procedure on file (9 CFR 418.3), IPP do not need to verify these requirements again during the year unless there are supervisory changes or reason to believe that a recall procedure is no longer on file.

E. IPP are to follow the methodology in FSIS Directive 5000.1 and verify whether the establishment meets all HACCP regulatory requirements, including monitoring, verification, recordkeeping (including preshipment review), and corrective action for all CCPs that apply to the specific production lot.

NOTE: If the establishment reviewed all processing and production records no later than one working day after the actual process, per 9 CFR 431.8(a), it is not required for them to review those records again, per 9 CFR 417.5(c).

F. IPP are to verify whether any prerequisite programs or other programs that apply to the specific production lot have been effectively implemented. Examples: purchasing programs, allergen control programs, foreign material control programs, and finished product inspection programs.

G. IPP are to verify whether the corrective action requirements in 9 CFR 417.3 are met when there is a deviation from a critical limit or an unforeseen hazard occurs.

H. IPP are to document findings of compliance or noncompliance and consider the implications of any noncompliance, per FSIS Directive 5000.1.

I. IPP are to schedule a directed Thermally Processed - Commercially Sterile HACCP task when an abnormal container is found by IPP or the establishment, or a process deviation occurs, to verify whether the establishment's corrective actions meet regulatory requirements. IPP are to follow FSIS Directive 7530.1, *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product,* and document their findings in PHIS.

V. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING CONTAINERS AND CLOSURES DURING HACCP TASKS

A. IPP are to verify that:

1. The establishment is following its statistical sampling plan (9 CFR 431.2(a)(1)) if the establishment uses a statistical sampling plan for evaluating incoming containers and rejection actions;

2. The water used to clean containers is potable and compressed air used for cleaning containers is filtered (9 CFR 431.2(a)(3));

3. A trained closure technician (as defined in 9 CFR 431.1) conducts container examinations and evaluates measurements and conditions to determine the impact on container integrity and that examination results along with any necessary corrective actions are promptly recorded by the closure technician (9 CFR 431.2(b) for rigid, (c) for glass, and (d) for semirigid and flexible containers);

4. Containers and closures are handled properly to protect from damage which could cause defects likely to affect the hermetic condition of the container (9 CFR 431.2(a)(2) and 431.2(f)(1)); and

5. The maximum time lapse between container closure and the initiation of the thermal process is two hours or less, unless data are available from the establishment's PA demonstrating that an alternative time period is safe and will not result in product spoilage (9 CFR 431.2(f)(2)). When IPP are provided with supporting data for the alternative time lapse from the establishment and need assistance in evaluating the data, they are to submit the supporting documents to Policy Development Staff (PDS) for review through askFSIS. For each askFSIS question, IPP are to select **Processing**, then select **Thermal Processing** from the drop-down menu as stated in Section XIV.

B. The supporting data provided by the PA should be product specific. When an establishment chooses to use alternative time lapses for different products, data for each product are to be provided.

VI. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING PROCESSING SCHEDULES AND CRITICAL FACTORS DURING HACCP TASKS

IPP are to verify that:

1. The products were produced according to a process schedule developed by a PA (9 CFR 431.3(a) and (b)) and all the critical factors were met (9 CFR 431.4). IPP are to be aware that process schedules are product and formula specific, affected by container size and type and the retorting system. However, in some cases, a single process schedule may be applied to more than one product;

EXAMPLE: If a single formula is packed and labeled with different brand names or label-types, one process schedule could apply to the different product brand names produced in the exact same size and type of package (because the formula is the same). The PA determines if the same process schedule can be applied to more than one product.

2. No unauthorized changes (e.g., product formulation, ingredients, treatments or process equipment) are made to the process schedules in use (9 CFR 431.3(b)(2)). Any change in product formulation, ingredients, or treatments that are not already incorporated in the process schedule are required to be evaluated by the PA who is to amend the process schedule when necessary. If the process schedule is evaluated and approved by the PA, that would meet the requirement in 9 CFR 431.3(b)(2);

3. They have access to the process schedules (including alternate schedules) along with any additional applicable information such as heat distribution, heat penetration and product specific critical factor information (9 CFR 431.3(c)(1));

4. They have access to letters or other written communication from the PA and the establishment's written procedures for measuring, controlling, and recording critical factors (9 CFR 431.3(c)(2)); and

5. The establishment has written procedures and frequencies for calibration of any instruments used to measure the critical factors (e.g., initial temperature, pH, viscosity) (9 CFR 431.3 (c)(2)). Calibration methods should be in accordance with accepted procedures or manufacturer instructions (with supporting documentation in either case).

VII. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING OPERATIONS IN THE THERMAL PROCESSING AREA DURING HACCP TASKS

IPP are to verify that:

1. 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 (9 CFR 431.5(a)). Each establishment may have its own method for posting or making a process schedule available.

EXAMPLE: The establishment may be 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. The processes posted may be the operating processes rather than the minimum operating conditions specified in the PA's process schedule.

2. The establishment has a system in place for product traffic control (e.g., heat sensitive indicators in each retort load) to prevent product from bypassing the thermal processing operation (9 CFR 431.5(b));

3. The temperature/time recording devices correspond within 15 minutes to the time of day recorded on written processing records (9 CFR 431.5(d)). The purpose of this requirement is to ensure that the time recordings on the temperature/time recording devices accurately match the time recordings on processing records in case the product needs to be segregated and held. Under these regulations, the establishment is to be able to correlate the recorder tracings and the processing records. If the temperature/time recording device does not agree to within 15 minutes of the time recorded on the written processing records, FSIS would require the establishment to make adjustments to the recording device to bring it into compliance with the regulations; and

4. The establishment uses potentiometric methods (i.e., pH meters) to make pH determinations when the pH value is specified as a critical factor in a process schedule (9 CFR 431.5(e)). The potentiometric methods are to ensure that the pH is achieved in every component of the finished product.

EXAMPLE: If pH is used as a critical factor in acidified canned products such as pickled sausage or pig's feet, the interior of the sausage or feet would need to be acidified to the pH limit listed in the process schedule within 24 hours or other time period demonstrated as safe by the establishment's PA (9 CFR 431.1).

VIII. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING EQUIPMENT AND PROCEDURES FOR HEAT PROCESSING SYSTEMS DURING HACCP TASKS

A. IPP are to verify that temperature indicating devices, temperature/time recording devices, steam spreaders, steam controllers, valves, bleeders, vents, stacking equipment, and divider plates are installed and used, per the regulatory requirements (9 CFR 431.6).

EXAMPLE: During verification, IPP note that the divider plates of the steam still retorts are in poor repair – solid metal patches have been welded in place or a bilayer (metal/rubber) plate has separated and shifted, blocking some of the holes. IPP are to ask questions as to how this affects the retort's heat distribution and if the establishment's PA has evaluated this change in the condition of the divider plates. Any change to divider plates that may adversely affect the heat distribution is a change that requires evaluation by a PA (9 CFR 431.6(b)(2)(iv)(B)).

B. IPP are to verify that the establishment checks all instruments and controls any time their functioning or accuracy is suspect, and that maintenance records and the annual thermal process system audit records indicate that the thermal process systems are functioning properly (9 CFR 431.6(g)).

IX. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING CORRECTIVE ACTIONS

A. IPP are to verify that the establishment takes corrective actions as described in 9 CFR 431.9 if a process deviation occurs.

B. If the deviation in processing is handled according to the requirements in 9 CFR 431.9, IPP are to be aware that the establishment would not have to also meet the requirements of 9 CFR 417.3, there would be no noncompliance record (NR) written, and the deviation from processing would not be considered an unforeseen hazard. The establishment would still need to maintain full records regarding the handling of each deviation in a process deviation file. Such records are to include, at a minimum, the appropriate processing and production records, a full description of the deviation and corresponding corrective actions taken, the evaluation procedures and results, and the disposition of the affected product (9 CFR 431.9 (d)).

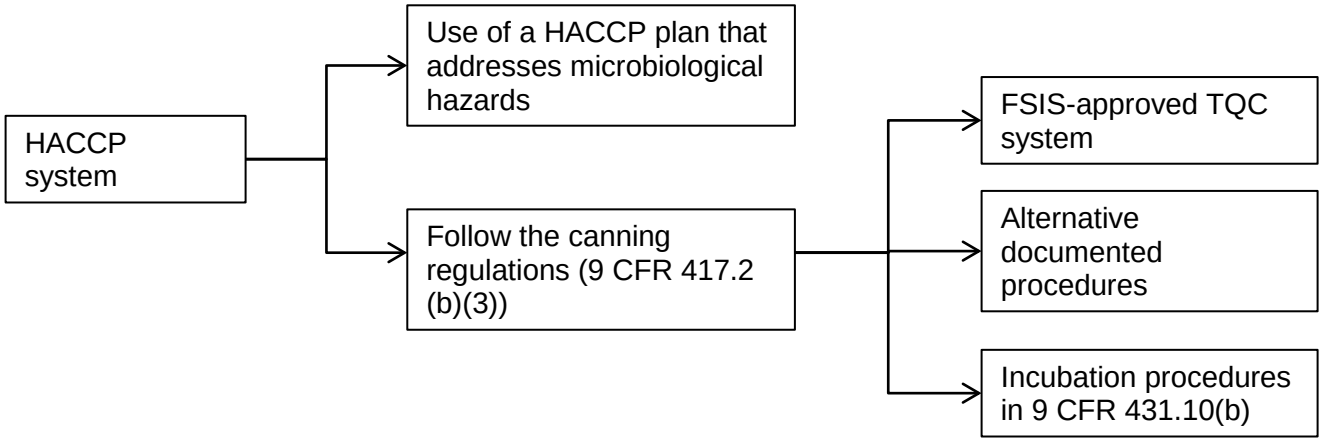
C. On the other hand, if the process deviation was not identified by the establishment or covered in the documented procedures in accordance with the requirements of 9 CFR 431.9, it is regulatory noncompliance. In this situation, IPP are to issue an NR and cite 9 CFR 431.9 and 9 CFR 417.5(a)(1) and consider the process deviation as an unforeseen hazard. IPP are to verify that the establishment reassesses the hazard analysis and HACCP plan as required in 9 CFR 417.3(b). IPP are to also verify that the establishment documents the results of the reassessment and maintains supporting documentation for the decisions made during the reassessment.

D. IPP are to follow the instructions in FSIS Directive 7530.1 regarding the verification of deviations in processing. If IPP need assistance in assessing the establishment's supporting documentation or the effectiveness of its corrective actions, they are to contact the PDS in the Office of Policy and Program Development (OPPD) through askFSIS.

X. SUPPLEMENTAL INSTRUCTIONS FOR VERIFYING FINISHED PRODUCT INSPECTION

A. IPP are to refer to Figure 1. below to determine the type of finished product inspection program the establishment implements and to verify whether the establishment is implementing its procedures as written. The type of finished product inspection program will determine the required inspection verification activities.

Figure 1. Finished product inspection in an establishment's HACCP system



B. When the establishment chooses to follow the canning regulations per 9 CFR 417.2(b)(3), IPP are to verify that the establishment is following a FSIS-approved total quality control (TQC) system, the incubation program as outlined in 9 CFR 431.10(b), or an alternative documented procedure.

1. **Incubation program as outlined in 9 CFR 431.10(b):** IPP are to verify that the incubator has an accurate recorder, accurate thermometer and a means for air circulation within the incubator, and a means to prevent unauthorized entry into the incubator. The establishment's container incubation program is to comply with time, temperature, range, sampling program, identification of product requiring incubation, checks, and records requirements listed in 9 CFR 431.10(b).

2. **Alternate incubation procedures:** IPP are to verify that the incubator has an accurate recorder, accurate thermometer and a means for air circulation within the incubator, and a means to prevent unauthorized entry into the incubator. If the establishment uses a reduced incubation rate, IPP are to verify that it 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 as detailed in the canning regulations. If the establishment uses a reduced incubation time, IPP are to verify that it has adjusted the amount of product incubated (a percentage of the total lot rather than a single container for batch retorts or 1 per 1000 containers for continuous retorts) and that it has narrowed the temperature range for incubation. For example, the establishment has chosen to narrow the temperature control from $\pm$ 5°F to $\pm$ 2°F, reduce the incubation time, and incubate a percentage of the total lot rather than a single container for still retorts or 1 per 1,000 containers for continuous retorts. Documentation would be expected to support the reduced incubation time.

3. **No incubation of containers:** If the establishment has documented finished product inspection procedures and ships product without incubation, IPP are to verify that the establishment's PA has provided documentation either through a letter or other documented finished product inspection procedures that ensures safety and stability that is at least equivalent to what incubation provides (9 CFR 431.10), such as a TQC system or other equivalent documented procedure. IPP are to verify that the PA has provided clear identification information on the product, size, process, vendor

information in the documentation. IPP are to review the dates of the supporting documents and verify that any changes the establishment has made since these dates were also documented and reviewed by its PA (9 CFR 431.3(b)(2)). For example, introduction of experimental or new products, maintenance, emergencies, new equipment and new employees are all changes in the establishment that can adversely affect the delivered thermal process since the dates of the supporting documents and would need to be documented. IPP are to verify that a protocol for handling abnormal containers is included in the alternative procedure. These alternative procedures are permitted only if the establishment can ensure the same degree of safety and stability required in the canning regulations.

NOTE: If IPP need assistance in assessing the establishment's supporting documentation for alternative procedures, they can contact PDS through askFSIS.

C. IPP are to verify that only normal-appearing containers are shipped from the establishment as determined by an appropriate sampling plan or other means acceptable to program employees (9 CFR 431.10(c)(1)). IPP are to be aware that the establishment is required to notify IPP when abnormal containers are detected by any means other than incubation (9 CFR 431.10(c)(2)). Whenever an abnormal container is found by IPP or the establishment, IPP are to schedule a directed Thermally Processed - Commercially Sterile HACCP task as necessary to verify the establishment's corrective actions. IPP are to follow FSIS Directive 7530.1 for findings of abnormal containers and document their findings in PHIS.

XI. DOCUMENTATION AND ENFORCEMENT

A. Using the methodology in FSIS Directive 5000.1, when IPP find a regulatory noncompliance with the canning or HACCP regulatory requirements, they are to:

1. Initiate a HACCP task as a directed task as necessary to respond to findings of noncompliance (e.g., stumble on finding while performing a different task) or as instructed by their immediate supervisor, frontline supervisor (FLS), District Office (DO), or Headquarters personnel;

2. Issue an NR under the Thermally Processed - Commercially Sterile HACCP task, as appropriate; and

3. Cite the canning regulation that was not met and any HACCP regulations that were not met. For example, IPP note that a new employee is formulating a chili product with starch B instead of starch A as stated on the recipe. Starch B was not approved to be used in this chili product according to the process schedule. The establishment is following the canning regulations per 9 CFR 417.2(b)(3). In this case, IPP are to cite the applicable canning regulation (9 CFR 431.3(b)) and 9 CFR 417.5(a)(1) on the NR.

B. Using the methodology in FSIS Directive 5000.1, IPP are to associate NRs when there is similar cause and are to reference the previous NR number and date, as well as the further planned action that was ineffective in preventing recurrence of the noncompliance. For example, when an establishment following the canning regulations does not meet the requirements in multiple situations, IPP are to document and associate the NRs because the establishment fails to meet the canning regulations.

NOTE: The purpose of associating 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 (9 CFR 500).

C. At any time when IPP find a noncompliance with the canning regulations that results in the safety of the product being jeopardized, they are to contact the DO. The DO may decide to issue a Notice of

Intended Enforcement (NOIE) as described in 9 CFR 500.4 and FSIS Directive 5000.1 and may initiate a recall if misbranded or adulterated product entered commerce.

D. At any time when IPP find that adulterated product has been produced and shipped, they are to contact the DO. The DO may suspend the assignment of IPP as described in 9 CFR 500.3 and FSIS Directive 5000.1.

XII. SUPERVISORY PROGRAM PERSONNEL RESPONSIBILITIES

A. The supervisor is to ensure that all 11 sections in the canning regulations (9 CFR 431.2 – 431.12) are being verified and that all regulatory requirements in each section are verified at least once during the calendar year.

B. The supervisor is to instruct inspectors to add directed verifications tasks, as needed, to the task list in response to certain events that indicate that the establishment may not be maintaining control of its HACCP system (e.g., abnormal containers found outside of an incubation procedure or a process deviation found by IPP during record review).

XIII. DATA ANALYSIS

The FSIS Office of Data Integration and Food Protection (ODIFP), in conjunction with the Office of Field Operations (OFO) and OPPD will analyse the data collected from the Thermally Processed – Commercially Sterile HACCP verification task to help inform food safety policies. These data may also be used to inform Agency sampling priorities.

XIV. QUESTIONS

Refer questions regarding this directive to PDS through askFSIS or by telephone at 1-800-233-3935. When submitting a question, use the Submit a Question tab, and enter the following information in the fields provided:

Subject Field:	Enter **Directive 7530.2.**
Question Field:	Enter your question with as much detail as possible.
Product Field:	Select **General Inspection Policy** from the drop-down menu.
Category Field:	Select **Processing**, then select **Thermal Processing** from the drop-down menu.
Policy Arena:	Select **Domestic (U.S.) Only** from the drop-down menu.

When all fields are complete, press **Continue** and at the next screen press **Finish Submitting Question.**

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

Assistant Administrator
Office of Policy and Program Development