United States Department of Agriculture
Food Safety and Inspection Service

Thermally Processed Products FSA Tool VS3

This FSA tool is for establishments that produce product under the **THERMALLY PROCESSED COMMERCIALLY STERILE** HACCP processing category.

The FSA tool contains the following main sections:

- HACCP (TP1-TP18)
- Incoming Containers and Proper Closure (TP19-TP24)
- Process Schedules (TP25-TP30)
- Thermal Process Initiation (TP31-TP35)
- Retort Equipment (TP36-TP44)
- Process Deviations (TP45-TP49)
- Finished Product Inspections and Shipment (TP50-TP59)
- Thermally Processed Commercially Sterile Tool Summary (TP60)

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings.

A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could impact the establishment's ability to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).

References:

1. FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology*;
2. FSIS Directive 5000.2, *Review of Establishment Data by Inspection Personnel*;
3. FSIS Directive 7530.1, *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product;* and
4. FSIS Directive 7530.2, *Verification Activities in Canning Operations That Choose to Follow the Canning Regulations*.

For all questions in this FSA tool, please note that some FSA tool questions are not applicable questions for the processes being assessed and will only appear based on the answer responses provided. EIAOs are to copy and paste information into a text field if that answer was provided in a previous text field question within the tool, or another tool.

HACCP (TP1-TP18)

This section is designed to assess the establishment's HACCP system. The HACCP system includes hazard analysis, any supporting documentation, including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

All official establishments that produce thermally processed, commercially sterile meat and poultry products must meet the requirements in 9 CFR part 431. However, the establishment may choose to control biological hazards identified in the hazard analysis as reasonably likely to occur via the HACCP plan or via the controls in 9 CFR part 431 (see 9 CFR 417.2 (b)(3)).

9 CFR 417.2(b)(3) exempts canning establishments from having to address food safety hazards associated with microbiological contamination if the product is produced in accordance with the requirements of 9 CFR part 431.

When an establishment chooses to control biological hazards in its HACCP plan, the process schedule developed by the processing authority typically becomes the primary supporting document for the development of the HACCP plan. These two documents should be consistent with each other. It is also common to see establishments use retort manufacturer's instructions and the canning regulations as supporting documentation for their decisions. Chemical and physical hazards identified as reasonably likely to occur are to be addressed through the HACCP plan.

The EIAO is to document all relevant noncompliance and vulnerability findings regarding biological, physical, and chemical hazards.

TP1 Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4,000 characters).

☐Yes – Click here to enter text.
☐No – Click here to enter text.

TP2 Does the HACCP system include a prerequisite program or supporting documentation for any hazard that the establishment determines is "not reasonably likely to occur" (NRLTO) (9 CFR 417.5(a)(1))? Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

☐No, the establishment follows the canning regulations (9 CFR part 431) for biological hazards – Click here to enter text.

TP3 Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur" (RLTO) (9 CFR 417(a)(2))? Describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

☐No, the establishment follows the canning regulations (9 CFR part 431) for biological hazards – Click here to enter text.

TP4 Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product change, categorization change, or unforeseen hazard?

NOTE: Answer this question based on your review of the selected records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

☐Yes – If selected, answer the following question(s)

☐No

TP4a Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 5,000 characters).

Click here to enter text.

TP5 Reprocessing: Does the establishment have reprocessing or reconditioning procedures in place and implemented (if observed) that prevent cross contamination of product?

☐Yes – If selected, answer the following question(s)

☐No

TP5a Briefly describe the establishment's procedures for reprocessing or reconditioning. Include any vulnerability and any noncompliance with how the establishment's food safety system addressed reprocessing (limit 20,000 characters).

Click here to enter text.

TP6 Allergens: Does the establishment produce products that contain any of the "Big 8" allergens or other ingredients of public health concern? Big 8 allergens include: Wheat, Crustacean shellfish (e.g., crab, lobster, shrimp), Eggs, Fish, Peanuts, Milk, Tree nuts (e.g., almonds, pecans, walnuts), and Soy.

☐Yes – If selected, answer the following question(s)

☐No

TP6a Briefly describe any vulnerability and any noncompliance with how the establishment's food safety system addressed the identification, prevention and control, and declaration of allergens/ingredients. If applicable, address if the establishment has had a recall for undeclared allergens/ingredients in the past 6-months, and the corrective actions taken (limit 20,000 characters).

Click here to enter text.

HACCP System Validation

This section is designed to assess the establishment's validation of its HACCP system.

TP7 Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No, support does not relate – Click here to enter text.

☐No, establishment does not have support – Click here to enter text.

TP8 Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

TP9 Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part of validation – execution)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

TP10 Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).

Click here to enter text.

HACCP Monitoring, Verification, and Corrective Actions

This section is designed to assess the establishment's monitoring, verification, and corrective action procedures of those CCPs, prerequisite programs, or other programs.

TP11 Does the establishment conduct the monitoring and verification (procedure and frequency) as written in its HACCP program (i.e., HACCP plan, prerequisite program, or another program), including chilling/cooling procedures if the establishment slaughters? Noncompliances and vulnerabilities are to be described in TP13.

☐Yes

☐No, the establishment does not conduct monitoring and verification as written

☐No, the monitoring and verification are not written in its HACCP program

TP12 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in TP13.

☐Yes

☐No

TP13 Briefly describe any vulnerability and noncompliance finding with the establishment's monitoring and verification procedures and frequencies, including the support for its monitoring and verification procedures and frequencies in its program (i.e., HACCP plan, prerequisite program, or another program) (limit 20,000 characters).

Click here to enter text.

TP14 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or another program)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

TP15 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 417.3 over the last 60 days?

*If yes, note whether all applicable parts of 9 CFR 417.3 were met. If no, note why the establishment did not take appropriate corrective actions (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

☐N/A – The establishment has not had any deficiencies over the last 60 days.

TP16 Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

TP17 Based on your review of records and observation of operations, briefly describe any vulnerability and noncompliance findings not described in previous questions with the implementation of monitoring and verification procedures that affect the establishment's ability to produce safe, wholesome, and unadulterated products. Note if the records accurately reflect the process (limit 20,000 characters).

Click here to enter text.

TP18 HACCP Summary: Describe any HACCP design findings not described in the previous questions and how your findings impact the establishment's food safety system (limit 20,000 characters).

Click here to enter text.

Incoming Containers and Proper Closure (TP19-TP24)

This section is designed to assist EIAOs to assess whether the establishment meets the canning regulations for incoming containers and proper closure. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP19 Does the establishment follow a statistical sampling plan for evaluating incoming containers and rejection actions, if needed (9 CFR 431.2)? Noncompliances and vulnerabilities are to be described in TP24.

☐Yes

☐No

TP20 Does the establishment have procedures in place to ensure that empty containers, roll stock for container forming, and closure materials are received, stored, and handled in such a way that they are clean, unsoiled, and free from structural defects prior to filling (9 CFR 431.2))? Noncompliances and vulnerabilities are to be described in TP24.

☐Yes

☐No

TP21 Does the establishment have procedures in place to conduct container closure examinations according to the regulatory requirements and are such examinations conducted at a frequency to ensure proper closure (9 CFR 431.2)? Noncompliances and vulnerabilities are to be described in TP24.

☐Yes

☐No

TP22 Does the establishment have procedures in place to ensure containers are marked with a permanent, legible, identifying code mark per regulatory requirements (9 CFR 431.2)? Noncompliances and vulnerabilities are to be described in TP24.

☐Yes

☐No

TP23 Does the establishment have procedures in place to meet the maximum 2 hour time lapse between container closure and initiating thermal processing or follow an alternative procedure with supporting documentation on file and approved by the processing authority (9 CFR 431.2)? Noncompliances and vulnerabilities are to be described in TP24.

☐Yes

☐No

TP24 Provide your assessment of any vulnerability and describe any noncompliance with how the establishment receives, stores, and handles incoming containers and ensures proper closure and handling of containers after closure. Your assessment should include the type of closure examination and whether the establishment performs any tests as part of their closure examination (limit 20,000 characters).

Click here to enter text.

Process Schedules (TP25-TP30)

This section is designed to assist EIAOs to assess the whether the establishment's process schedules meet the canning regulations. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP25 Does the establishment have process schedules on file from the processing authority for each product produced that also include any subsequent communications describing the development process or authorized changes between the establishment and the processing authority (9 CFR 431.3)? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes

☐No

TP26 The process schedule provides direction to the establishment in developing monitoring and verification procedures and frequencies. Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes

☐No

TP27 Have there been any changes to the types of ingredients used in the preparation of the product formulation as specified in the process schedule (hydrated vs. not hydrated, acidified vs. not acidified, blanched vs. not blanched, slow set vs. rapid set starch, etc.)? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes – If selected, answer the following question(s)

☐No

TP27a With the changes that have been made to the types of ingredients used in the preparation of the product formulation, has the processing schedule been reviewed by a processing authority (9 CFR 431.3)? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes

☐No

TP28 Does the establishment have and follow procedures for measuring, controlling, and recording critical factors to ensure that these factors remain within the limits used to establish the process schedule (9 CFR 431.4)? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes

☐No

TP29 Does the establishment ensure that 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, particle size, etc.) of each ingredient (9 CFR 431.4)? Noncompliances and vulnerabilities are to be described in TP30.

☐Yes

☐No

TP30 Provide your assessment of any vulnerability and any noncompliance with how the establishment develops, implements, and monitors its process schedules and briefly describe the critical factors specified in the process schedule (limit 20,000 characters).

Click here to enter text.

Thermal Process Initiation (TP31-TP35)

This section is designed to assist EIAOs to assess whether the establishment meets the canning regulations for its thermal process initiation. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP31 Does the establishment have a system in place to prevent product from bypassing the thermal processing operation if critical factors at process initiation are not met (9 CFR 431.5)? Noncompliances and vulnerabilities are to be described in TP35.

☐Yes

☐No

TP32 Are the product traffic control procedures (e.g., heat sensitive indicators in each retort load) adequate to ensure unprocessed product due to system malfunction is not moved on to the next step in the process (9 CFR 431.5)? Noncompliances and vulnerabilities are to be described in TP35.

☐Yes

☐No

TP33 Does the establishment have written procedures on file for determining the initial temperature as specified in the process schedule to ensure that product does not fall below the minimum initial specified temperature during retort loading and the start of the thermal process (9 CFR 431.5)? Noncompliances and vulnerabilities are to be described in TP35.

☐Yes

☐No

TP34 Does the establishment have and maintain accurate devices to measure applicable thermal processing operation functions or events, such as process schedule time, come-up time, retort venting, and applicable product pH to ensure that all are achieved (9 CFR 431.5)? Noncompliances and vulnerabilities are to be described in TP35.

☐Yes

☐No

TP35 Provide your assessment of any vulnerability and any noncompliance with how the establishment has developed and implemented its thermal process initiation procedures (limit 20,000 characters).

Click here to enter text.

Retort Equipment (TP36-TP44)

This section is designed to assist EIAOs to assess whether the establishment meets the canning regulations for its retort equipment. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP36 Is each retort system equipped with at least one temperature indicating device that measures the actual temperature within the retort used as the reference for indicating process temperature, and at least one time/temperature recording device that provides a permanent record of temperatures within the thermal processing system (9 CFR 431.6)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP37 For atmospheric cookers (e.g., hot water bath), is each cooker equipped with at least one temperature/time recording device in accordance with the basic requirements described in 9 CFR 431.6(a)(2)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP38 Is each retort system installed, operated, and maintained as required to ensure proper control of water throughout the process, especially preventing leakage of water into the retort during the processing cycle (9 CFR 431.6)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP39 Is each retort system installed, operated, and maintained as required per 9 CFR 431.6 to ensure proper control of air throughout the process, such as effective air removal before thermal process is started and the use of globe valve or other equivalent type valve or system to prevent leakage of air into the retort during the process cycle? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP40 Is each retort system installed, operated, and maintained as required to ensure proper control of steam throughout the process to ensure adequate steam is present and maintained throughout the process cycle (9 CFR 431.6)? For example, each retort must be equipped with an automatic steam controller to maintain the retort temperature. Bleeders and vent mufflers are installed and operated according to the regulation (9 CFR 431.6). Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP41 Is each retort system installed, operated, and maintained in accordance with the specific requirements for the retort type per 9 CFR 431.6 (e.g., steam/air mix, batch still or agitating, continuous rotary, hydrostatic, etc.)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP42 Does the establishment have procedures in place to ensure the equipment is maintained on an on-going basis and do those records along with the annual thermal process system audit records indicate that the thermal process systems are functioning properly (9 CFR 431.6)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP43 Are recycled or reused container cooling waters 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 water (9 CFR 431.6)? Noncompliances and vulnerabilities are to be described in TP44.

☐Yes

☐No

TP44 Provide your assessment of any vulnerability and any noncompliance with how the establishment has installed, operated, or maintained its retort equipment. Include in your assessment whether there are repetitive process cycle stoppages due to faulty equipment and how that may impact the establishment's overall food safety system adequacy (limit 20,000 characters).

Click here to enter text.

Process Deviations (TP45-TP49)

This section is designed to assist EIAOs to assess whether the establishment meets the canning regulations for process deviations. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP45 Does the establishment have procedures in place to record the date of production, product name and style, container code, container size and type, and the process schedule, including the minimum temperature for each process cycle/batch of product (9 CFR 431.7)? Noncompliances and vulnerabilities are to be described in TP47.

☐Yes

☐No

TP46 Does the establishment have procedures where establishment personnel (no later than one working day after the actual process) review all processing and production records including deviation records to ensure completeness and to determine whether all product was processed in accordance with the process schedule (9 CFR 431.8)? Noncompliances and vulnerabilities are to be described in TP47.

☐Yes

☐No

TP47 Provide your assessment of any vulnerability and any noncompliance with how the establishment creates, reviews and maintains the records associated with each process cycle/batch of product (9 CFR 431.7 and 431.8) (limit 20,000 characters).

Click here to enter text.

TP48 Does the establishment have procedures in place to handle and document process deviations in accordance with the regulations, whether identified in-process or through records review (9 CFR 431.9)? Noncompliances and vulnerabilities are to be described in TP49.

☐Yes, through a HACCP plan for canned product that addresses hazards associated with microbial contamination

☐Yes, through alternative documented procedures that will ensure that only safe and stable product is shipped in commerce

☐Yes, following the regulatory requirements in 9 CFR 431.9(c)

☐No

TP49 Provide your assessment of any vulnerability and any noncompliance with how the establishment handles process deviations. Your analysis should include the procedures the establishment has in place along with how those procedures were implemented with each deviation over the past 60 days. Note whether there are repetitive deviations with the same root cause that have not been effectively corrected and whether the failure to correct the cause could impact the establishment's food safety system and its adequacy to produce safe product. Also note whether the establishment identified the deviation(s) via record review or during the operation (limit 20,000 characters).

Click here to enter text.

Finished Product Inspections and Shipment (TP50-TP59)

This series of questions is designed to assist EIAOs to assess whether the establishment meets the canning regulations for finished product inspections and shipment of product in commerce. The EIAO should have a copy of the canning regulations available as they answer these questions to ensure the details of the regulations are assessed.

TP50 Does the establishment have documented finished product inspection procedures to ensure only safe and stable product is shipped in commerce in accordance with the requirements in 9 CFR 431.10 (a)? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

TP51 Does the establishment's container incubation program comply with the required equipment specifications, time, temperature, range, sampling program, identification of product requiring incubation, checks, and records in accordance with the requirements of 9 CFR 431.10? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No, the establishment does not meet the requirements

☐No, the establishment does not follow 9 CFR 431.10 (b); they use alternative procedures – If selected, answer the following question(s)

TP51a Since the establishment does not follow 9 CFR 431.10 (b), describe the alternative procedures for the establishment's container incubation program (limit 5,000 characters). Noncompliances and vulnerabilities are to be described in TP59.

Click here to enter text.

TP52 If the establishment uses a reduced incubation rate, does it have controls for 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 (9 CFR 431.10)? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

☐N/A, the establishment does not use a reduced incubation rate

☐N/A, the establishment does not use an incubator

TP53 If the establishment uses a reduced incubation time, has the establishment adjusted the amount of product incubated (a percentage of the total lot rather than single container for still retorts or 1 per 1000 containers for continuous retorts) and narrowed the temperature range for incubation in accordance with the requirements of 9 CFR 431.10? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

☐N/A, the establishment does not use a reduced incubation time

☐N/A, the establishment does not use an incubator

TP54 If the establishment ships product without incubation, do they have a letter from their processing authority stating that its QC program or process schedule adequately provides for product safety and stability (9 CFR 431.10)? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

☐N/A, no product is shipped without incubation

TP55 Does the establishment implement alternative procedures such as a dud detection system, x-ray, or additional visual checks of finished product to ensure only normal-appearing containers are shipped? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

TP56 Does the establishment implement a written protocol for handling abnormal containers and disposition of lots containing abnormal containers to ensure only safe and stable product is shipped in commerce? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

TP57 Are all operators of thermal processing systems and container closure technicians 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 (i.e. the Better Process Control School) (9 CFR 431.11)? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

TP58 Does the establishment maintain a current procedure for the recall of all canned product per 9 CFR 431.12 and 9 CFR 418? Noncompliances and vulnerabilities are to be described in TP59.

☐Yes

☐No

TP59 Provide your assessment of any vulnerabilities and noncompliances with how the establishment conducts finished product inspections (limit 20,000 characters).

Click here to enter text.

Thermally Processed Commercially Sterile Tool Summary (TP60)

This question is designed to focus on the most significant noncompliance and vulnerability findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If an establishment that chooses to follow the canning regulations does not meet all the requirements in 9 CFR part 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). Summarize the findings that bear most directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The answer to this question is to be used to construct the Executive Summary.

TP60 Summarize any vulnerability or noncompliance findings identified in the Thermally Processed Commercially Sterile tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine an FSA recommendation (limit 20,000 characters). Describe the impact the findings have on the establishment's food safety system. Limit your response to three to five bullet points total.

Click here to enter text.