Thermally Processed
FSA Tool VS2

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:

- **Hazard Analysis and HACCP System (Questions TP1 – TP13)**
- **Following Canning Regulations as Pre-Requisite Program to Prevent Biological Hazards (TP14 -50)**
- **Chemical and Physical Hazards (TP50 – end)**

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 contribute to 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***

NOTE: For all questions in this FSA tool, please note that some FSA tool questions are not required questions and will only appear based on the answer responses provided. Also, it is not necessary to copy and paste information into a text field that you've provided in a previous text field question within the tool.

Hazard Analysis and HACCP System (Questions TP1 – TP13)

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

Although thermally processed, commercially sterile (canning) processes are produced in a HACCP regulatory structure, that structure can appear differently depending on 1) whether the establishment chooses to address biological hazards as reasonably likely to occur and places controls within a HACCP plan or 2) whether the establishment addresses biological hazards as not reasonably likely to occur and creates a pre-requisite program modeled to meet the requirements of the prescriptive canning regulations (9 CFR 318 part 300 or 381 part 300) as appropriate for the product produced.

The EIAO is to document all relevant noncompliance and vulnerability findings.

TP1 **Does the establishment consider biological hazards as "reasonably likely to occur"?**

☐Yes, and the establishment places controls within a HACCP plan and complete the Chemical and Physical Hazards. If selected answer the following questions TP3,TP4,TP5,TP6,TP7,TP8,TP9,TP10,TP11,TP12,TP13

☐No, and the establishment has a prerequisite program modeled to meet the requirements of the canning regulations (9 CFR 318 part 300 or 381 part 300)

☐No, the establishment has not considered relevant biological hazards. If selected answer TP2

TP2 **Briefly describe the hazard(s) not properly considered. Briefly describe any vulnerability and cite any noncompliance. Assess and describe how your findings the impact the establishment's food safety system.**

Click here to enter text.

Using the HACCP plan to control Biological Hazards (Questions TP3 – TP13):

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 and these two documents should be consistent with each other. It is also common to see establishments use retort manufacturer's instructions as well as the canning regulations as supporting documentation for their decisions.

TP3 **Has the establishment properly developed and implemented a written HACCP plan to address biological hazards?**

☐Yes

☐No

TP4 **Does the establishment incorporate all appropriate critical operating parameters (critical factors) outlined in the validation documentation (process schedule and any additional validation documents) to address biological hazards?**

☐Yes

☐No

TP5 **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?**

☐Yes

☐No

TP6 **Does the establishment maintain support for the selected monitoring and verification procedures and frequencies?**
Note: The process schedule provides direction to the establishment in developing monitoring and verification procedures and frequencies.

☐Yes

☐No

TP7 **Does the establishment have procedures to ensure 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?**

☐Yes

☐No

TP8 **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?**

☐Yes

☐No

TP9 **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.)?

☐Yes

☐No

TP10 **If changes 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?**

☐Yes

☐No

TP11 **Provide your assessment of any vulnerability and describe any noncompliance with how the establishment has developed and implemented its process schedules.**

Click here to enter text.

TP12 **Does each prerequisite program and/or supporting document support the decisions made?**

☐Yes

☐No

TP13 **If no to the above question, describe any instances where the hazard analysis decision-making is not supported due to inadequate design, implementation, monitoring, verification, or recordkeeping. Briefly describe any vulnerability and cite any noncompliance.**

Click here to enter text.

Following Canning Regulations as Pre-Requisite Program to Prevent Biological Hazards (TP14 – TP50)

When an establishment chooses to follow the canning regulations (9 CFR 318 part 300 or 9 CFR 381 part 300) in order to address biological hazards, the establishment is in essence preventing the hazard from being likely to occur by meeting the requirements of the canning regulations. This series of questions is designed to assist EIAOs to assess the pre-requisite program(s) associated with meeting the canning regulations. The EIAO should have a copy of the canning regulations with them as they answer these questions to ensure the details of the prescriptive regulations are assessed.

TP14 **Does the establishment follow a statistical sampling plan for evaluating incoming containers and rejection actions, if needed? [9 CFR 318/381.301]**

☐Yes

☐No

☐No, statistical sampling plan

TP15 **Does the establishment have procedures in place to ensure that empty containers, roll stock for container forming, and lidding materials are received and handled in such a way that they are clean, unsoiled, and free from structural defects prior to filling? [9 CFR 318/381.301]**

☐Yes

☐No

TP16 **Provide your assessment of any vulnerability and describe any noncompliance with how the establishment receives and handles incoming containers.**

Click here to enter text.

TP17 **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 318/381.301]**

☐Yes

☐No

TP18 **Does the establishment have procedures in place to ensure containers are marked with a permanent, legible, identifying code mark per regulatory requirements? [9 CFR 318/381.301]**

☐Yes

☐No

TP19 **Provide your assessment of any vulnerability and describe any noncompliance with how the establishment ensures proper closure.**

Click here to enter text.

TP20 **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 318/381.302]**

☐Yes

☐No

TP21 **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?**

☐Yes

☐No

TP22 **Does the establishment have procedures to ensure 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? [9 CFR 318/381.303]**

☐Yes

☐No

TP23 **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 318/381.303(a)]**

☐Yes

☐No

TP24 **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.)?**

☐Yes

☐No

TP25 **If changes 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 318/381.302]**

☐Yes

☐No

☐No ingredient changes

TP26 **Provide your assessment of any vulnerability and any noncompliance with how the establishment has developed and implemented its process schedules.**

Click here to enter text.

TP27 **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 or 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 318/381.304]**

☐Yes

☐No

TP28 **Does the establishment have procedures in place to meet the maximum 2 h time lapse between container closure and initiating thermal processing or follow an alternative procedure that is on file and approved by the processing authority? [9 CFR 318/381.301]**

☐Yes

☐No

TP29 **Does the establishment have written procedures on file for determining the initial temperature as specified in the process schedule and ensure that product does not fall below the minimum initial specified temperature during retort loading and the start of the thermal process?**

☐Yes

☐No

TP30 **Does the establishment have 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 318/381.304]**

☐Yes

☐No

TP31 **Provide your assessment of any vulnerability and any noncompliance with how the establishment has developed and implemented its thermal process initiation procedures.**

Click here to enter text.

TP32 **Is each retort system equipped with at least one temperature indicating device that measures the actual temperature within the retort and used as the reference for indicating process temperature and at least one time/temperature device that monitors that the process is achieved? [9 CFR 318/381.305]**

☐Yes

☐No

TP33 **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 318/381.305]**

☐Yes

☐No

TP34 **Is each retort system installed, operated, and maintained as required to ensure proper control of air throughout the process such as effective air removal before thermal process is started and ensuring air does not leak into retort during the processing cycle? [9 CFR 318/381.305]**

☐Yes

☐No

TP35 **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 318/381.305]**

☐Yes

☐No

TP36 **Does the establishment have procedures in place to ensure the equipment is maintained on an on-going basis and those records along with the annual thermal process system audit records indicate that the thermal process systems are functioning properly? [9 CFR 318/381.305(g)(2) and (6)]**

☐Yes

☐No

TP37 **Provide your assessment of any vulnerability and any noncompliance with how the establishment has maintained its 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.

Click here to enter text.

TP38 **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 VFR 318/381.305(h)(3)]**

Yes

No

TP39 **Provide your assessment of any vulnerability and any noncompliance with how the establishment has installed, operated, or maintained its retort equipment.**

Click here to enter text.

TP40 **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 318/381.306]**

☐Yes

☐No

TP41 **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 products was processed in accordance with the process schedule? [318/381.307]**

☐Yes

☐No

TP42 **Provide your assessment of any vulnerability and any noncompliance with how the establishment creates and reviews the records associated with each process cycle/batch of product.**

Click here to enter text.

TP43 **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 318/381.308]**

☐Yes

☐No

TP44 **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. Are there repetitive deviations with the same route cause that have not been effectively corrected that could impact whether the establishment's food safety system is adequate to produce safe product on a daily basis.**

Click here to enter text.

TP45 **Does the establishment have documented finished product inspection procedures including abnormal containers that comply with the regulations? [9 CFR 318/381.309]**

☐Yes

☐No

TP46 **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? [9 CFR 318/381.309]**

☐Yes

☐No

☐No, the establishment does not use an incubator

TP47 **If the establishment uses a reduced incubation rate, does it have controls that include 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 318/381.309]

☐Yes

☐No

☐No reduced incubation rate

☐No, the establishment does not use an incubator

TP48 **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? [9 CFR 318/381.309]**

☐Yes

☐No

☐No reduced incubation rate

☐No, the establishment does not use an incubator

TP49 **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 318/381.309]**

☐Yes

☐No

TP50 **Provide your assessment of any vulnerability and describe noncompliance with how the establishment conducts finished product inspections.**

Click here to enter text.

Chemical and Physical Hazards (TP51 – end)

All establishments must properly address and control any chemical or physical hazards within their HACCP system regardless of whether they choose to follow the canning regulations as a pre-requisite program to address biological hazards.

TP51 **Has the establishment considered the relevant food safety hazards in regard to physical and chemical hazards throughout the HACCP system?**

☐Yes

☐No

TP52 **Briefly describe the hazard(s) not considered or identified. Briefly describe any vulnerability and any noncompliance. Provide an assessment of how your findings impact the establishment's food safety system.**

Click here to enter text.

TP53 **Has the establishment properly developed and implemented a written HACCP plan to address each physical and chemical hazard determined to be "reasonably likely to occur"?**

☐Yes

☐No physical or chemical hazards determined to be "reasonably likely to occur"

TP54 **Does the establishment incorporate all appropriate critical operating parameters outlined in the validation documentation into its CCP, prerequisite program, or other program to address chemical and physical hazards?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

TP55 **Does the establishment maintain adequate scientific support for the selected monitoring and verification procedures and frequencies in its CCP, prerequisite program, or other program?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

TP56 **Briefly describe any vulnerability and any noncompliance concerning HACCP design that was not mentioned in a previous answer in this section. Describe the impact your findings have on the food safety system.**

Click here to enter text.

TP57 **Does the establishment have monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program)?**

☐Yes

☐No

TP58 **Does the establishment have support for its monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program)?**

☐Yes

☐No

TP59 **Does the establishment implement monitoring and verification procedures as written?**

☐Yes

☐No

TP60 **Does the establishment properly conduct the pre-shipment review? (Including a review of records associated with each specific production of product or lots before shipment into commerce)**

☐Yes

☐No

TP61 **Has the establishment had a deviation in the previous 60 days?**

☐Yes - If selected, answer the following questions TP62

☐No

TP62 **Did the corrective actions meet the requirements of 417.3?**

☐Yes

☐No

TP63 **If no to any of the above HACCP implementation questions, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

TP64 **Does the HACCP system provide for a recordkeeping system that documents the monitoring of the critical control points and critical limits?**

☐Yes

☐No

☐The establishment does not have any critical control points

TP65 **Do establishment records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot?**

☐Yes

☐No

TP66 **Do the records document the verification procedures and results?**

☐Yes

☐No

TP67 **If no to any of the above HACCP recordkeeping questions, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

TP68 **Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product changes but the establishment did not reassess?**

☐Yes - If selected, answer the following questions TP69

☐No

TP69 **Was the hazard analysis and/or HACCP plan reassessed? If the reassessment showed that the HACCP plan or hazard analysis needed changes to meet regulatory requirements, was the HACCP plan or hazard analysis modified immediately?**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

Thermally Processed Commercially Sterile Tool Summary:

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. 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.

TP70 **Summarize in up to three bullets of 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 a FSA recommendation. Describe the impact the findings have on the establishment's food safety system.**

Click here to enter text.