HACCP 03D Thermally Processed, Commercially Sterile

Version Type: Working **Version #:** 2

General Hazard Analysis, Flow Diagram and HACCP

H1	**Based on your scientific knowledge of the process information in the Hazards Guide, Agency guidance documents, and the establishment's supporting documentation, did the establishment consider all appropriate hazards and determine those hazards that are reasonably likely to occur?**
	No
	Yes
H2	**Are all decisions made in the hazard analysis supported with documentation on file?**
	No
	Yes
H3	**Why did you come to the conclusions in H1 and H2? Briefly explain how the answers in H1 and H2 were determined by describing the hazards considered by the establishment and their thought process in determining those reasonably likely to occur. Include the names of documents and cite any non-compliances.**
	Editor
H4	**Does the plant use a prerequisite program(s)?**
	Yes
	No
H4a	**If yes to H4, list the names of all the prerequisite programs used as part of the HACCP category and briefly describe the hazards each prerequisite program is preventing along with the monitoring procedures and records generated.**
	Editor
H4b	**Are there any prerequisite programs lacking adequate supporting documentation that the hazard is not likely to occur?**
	No
	Yes
H4c	**Why did you come to this conclusion? Briefly describe the reasoning why these prerequisite program(s) lack adequate support and how this may affect the production of safe product. Cite any non-compliances.**
	Editor
H4d	**If yes to H4, with the records reviewed, has the plant had a deviation from compliance with a prerequisite program?**
	Yes
	No
H4e	**If yes to H4d, did it constitute a trend, and did the plant reassess?**
	Yes
	No
H4f	**Is the establishment monitoring and keeping adequate records for each of the prerequisite programs?**
	Yes
	No
H4g	**Why did you come to this conclusion? Describe the observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor

H4h	**Describe any additional findings regarding prerequisite programs and briefly describe your analysis of how the prerequisite programs impact the food safety system.**
	Editor
H5	**Are all steps in the process(s) included in the flow diagram?**
	Yes
	No
H6	**Briefly discuss any regulatory noncompliance associated with the flow diagram.**
	Editor
H7	**Does the HACCP plan(s) adequately address each of the hazards that appear reasonably likely to occur based on the hazard analysis(s) by identifying a point in the process that will prevent eliminate, or reduce to acceptable levels for each?**
	Editor
H7a	**Briefly discuss any hazards that are not adequately addressed and the thought process behind the conclusion. Cite any non-compliances.**
	Editor
H8	**Does the HACCP plan list the monitoring procedures and frequencies that are used to monitor each of the CCPs to ensure compliance with the critical limits?**
	Yes
	No
H8a	**Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-complainces.**
	Editor
H9	**Are the monitoring procedures being performed as described in the HACCP plan?**
	No
	Yes
H10	**Are the monitoring procedures being performed at the frequencies specified for the CCPs listed in the HACCP plan?**
	No
	Yes
H11	**For H9 and H10, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H12	**Does the HACCP plan contain procedures and frequencies for the calibration of the process-monitoring instruments?**
	No
	Yes
H13	**Does the HACCP plan contain procedures and frequencies for direct observations of monitoring activities and corrective actions?**
	No
	Yes
H14	**Does the HACCP plan list procedures and frequencies for the review of records generated and maintained in accordance with 9 CFR 417.5(a)(3)?**
	Yes
	No

H15 **For H12-H14, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**

Editor

H16 **Does the HACCP plan list product sampling as a verification activity?**

Yes

No

H16a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

H17 **Are process-monitoring instrument calibration activities conducted as per the HACCP plan?**

Yes

No

H18 **Are direct observation verification activities conducted as per the HACCP plan?**

Yes

No

H19 **Are records generated in accordance with 9 CFR 417.5(a)(3) being reviewed by the establishment?**

No

Yes

H20 **For H17-H19, why did you come to this conclusion? Describe your observations and/or documents used to reach the decisions and cite any non-compliances.**

Editor

H21 **Does the HACCP plan set out a recordkeeping system that documents the monitoring of the CCP?**

Yes

No

H22 **Does the HACCP plan recordkeeping system provide for documenting actual values and observations obtained during monitoring?**

No

Yes

H23 **For H21 and H22, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**

Editor

H24 **Does the establishment have all scientific support documentation for initial validation (first part) on file?**

Yes

No

H24a **Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.**

Editor

H25 **Does the establishment have the decision making documents associated with the selection of each CCP?**

No

Yes

H26 **Do the documents explain why the establishment selected that location for the CCP?**

Yes

No

H27	**For H25 and H26, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H28	**Does the establishment have scientific, technical, or regulatory support for the critical limit?**
	No
	Yes
H29	**Does the support appear credible?**
	Yes
	No
H30	**For H28 and H29, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H31	**Does the establishment have documents supporting the monitoring procedures and frequencies listed in the HACCP plan?**
	Yes
	No
H32	**Does the establishment have documents supporting the verification procedures and frequencies listed in the HACCP plan? Do the documents support what the establishment has done?**
	No
	Yes
H33	**If the establishment has supporting documents for these decisions, does the documentation support the decisions?**
	No
	Yes
H34	**For H31-H33, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H35	**Do the records document the monitoring of CCPs and their critical limits?**
	No
	yes
H36	**Do the records include actual temperatures, times, concentrations or other quantifiable values, as prescribed in the establishment's HACCP plan?**
	No
	Yes
H37	**Do the monitoring, verification, and corrective action records include product codes, product name or identity, or slaughter production lot, or a means by which the records can be associated with a specific production, along with the date and time the record was made?**
	Yes
	No
H38	**Are the verification procedures and results of those procedures documented including time and date record was made?**
	yes
	No

H39	**Are the process-monitoring calibration procedures and results being recorded?**
	No
	yes
H40	**Was each entry on the record made at the time the event occurred?**
	No
	Yes
H41	**Was each entry on the monitoring, verification, and corrective action records signed or initialed by the establishment employee making the entry?**
	No
	Yes
	No
	Yes
H42	**For H35-H41, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H43	**Are the records being maintained for the required amount of time, e.g., 1 year for slaughter and refrigerated products and 2 years for frozen, preserved, or shelf-stable products?**
	Yes
	No
H44	**Are the records kept on-site for 6 months?**
	Yes
	No
H45	**If the records are stored off-site after 6 months, can they be retrieved in 24 hours?**
	No
	Yes
	Establishment does not store any records off-site
H46	**For H43-H45, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.**
	Editor
H47	**Has the establishment reviewed the records associated with the production of the product, prior to shipment?**
	No
	Yes
H47a	**Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H48	**Does the establishment list corrective actions in its HACCP plan that meet the requirements of 417.3?**
	No
	Yes
H49	**Is a responsible party assigned to perform corrective actions?**
	Yes
	No

H50	**If corrective actions have been taken by the plant, were those corrective actions effective? If no corrective actions in the past 60 production days, verify the last time the establishment took corrective actions.**
	No
	Yes
H51	**How many times within the last 60 days did the establishment have deviations from CCPs?**
	0 times
	1-2 times
	3-5 times
	>5 times
H52	**For H48-H51, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H53	**Has a reassessment been conducted to meet the annual reassessment requirement?**
	Yes
	No
H53a	**Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliance.**
	Editor
H54	**Did the establishment consider any significant developments that have occurred in the plant or that have occurred with respect to the types of products produced by the plant, in its analysis?**
	Yes
	No
	No significant developments occured
H54a	**Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor
H55	**Has change occurred that could affect the hazard analysis or HACCP plan?**
	Yes
	No
H55a	**Did the establishment reassess?**
	No
	Yes
	No changed occured
H55b	**If the reassessment revealed that the HACCP plan no longer meets regulatory requirements, was the HACCP plan modified immediately?**
	No change occured
	Yes
	No
H55c	**For H55-H55b, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision and cite any non-compliances.**
	Editor

General

G1	**List all HACCP 03D plans, products produced using those plans, CCPs, critical limits, monitoring procedures, and verification procedures associated with those plans using the template provided. NOTE: Establishments who address biological hazards through a canning regulations prerequisite program, the HACCP plan will reflect chemical and physical hazards. For establishemnts using HACCP Plan to address all hazards, the HACCP plan will include controls for biological, chemical, and physical.**
	Editor

Microbial Hazard Requirements Under 9 CFR 318.300

MH1	**In the last 12 months were there deviations from the validated process schedule?**
	Yes
	No
MH1a	**What was the cause of the deviation(s)?**
	Formulation
	Inadequate Thermal Process
	Equipment Failure
	Container Integrity
	Other
MH1a1	**Please specify.**
	Editor
MH1b	**If yes, were enforcement actions taken?**
	Yes
	No
MH1c	**Were the corrective actions effective in preventing recurrence of the deviation?**
	Yes
	No
MH1d	**For MH1 and MH1c, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**
	Editor
MH2	**Have there been repetitive noncompliance reports (NR) for the same reason in the last 12 months?**
	Yes
	No
MH2a	**Why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**
	Editor
MH3	**Was enforcement action in the last 12 months (e.g., enforcement actions include Notice of Intended Enforcement (NOIE), 30-day letter, and suspension)?**
	Yes
	No

MH3a	**If yes, what was the reason for the enforcement action or NR? Check all that apply.**
	Process deviation
	Container Integrity
	Finished Product Testing
	Non-food safety deviation (e.g., undeclared allergen, mislabeling)
	Sanitation deviation
	Others
MH3a1	**Please specify.**
	Editor
MH4	**Has the establishment recalled product in the last 12 months?**
	Yes
	No
MH4b	**If the product was recalled, what was the reason for recall? Check all that apply.**
	Underprocessing
	Non-food safety related deviation (e.g., undeclared allergen, mislabeling)
	Abnormal Containers, not food safety related
	Other
MH4c	**Please specify.**
	Editor
MH5	**Is the thermal processing system examined at least once a year by an individual not involved in the daily operations to ensure the equipment is operating as designed?**
	Yes
	No
MH5a	**What, if anything, did the annual examination recommend?**
	Editor
MH5b	**Were these recommendations followed?**
	Yes
	No
MH5c	**For MH5-MH5b, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**
	Editor
MH6	**Were any abnormal-appearing containers found within the last 12 months?**
	Yes
	No
MH6a	**If yes, how often were abnormal-appearing containers found?**
	1 – 2 times
	3 – 5 times
	more than 5 times

MH6b **Was the finding of abnormal-appearing containers reported to FSIS inspection personnel?**

Yes

No

MH6c **For MH6-MH6b, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH7 **Does the establishment have a statistical sampling plan for evaluating incoming containers and rejection actions, if needed?**

Yes

No

MH8 **Is the establishment following its statistical sampling plan?**

Yes

No

MH9 **Does the establishment ensure that empty containers, roll stock for container forming, and lidding materials are clean and free from structural defects prior to filling?**

Yes

No

MH10 **Does the establishment ensure that empty containers, roll stock for container forming, and lidding materials are clean and free from structural defects prior to filling?**

Yes

No

MH11 **Is the establishment's empty container handling practices (e.g., conveying, unscrambling, de-nesting, and manual handling) adequate to prevent soiling and damage?**

Yes

No

MH12 **Are containers free of damage after filling?**

Yes

No

MH12a **For MH7-MH12, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH13 **Does the establishment conduct container closure examinations?**

yES

nO

MH14 **Was a visual inspection performed on at least one container from each closing machine head?**

Yes

No

MH15 **Are the containers and closures (after closure) protected from damage which could cause defects likely to affect the hermetic condition of the container?**

Yes

No

MH16 **Are the corrective actions taken in response to detection of improper container closure or damage?**

Yes

No

MH17 **Are the containers marked with a permanent, legible, identifying code mark per regulatory requirements?**

Yes

No

MH18 **Does the plant meet the maximum time lapse between container closure and the initiation of the thermal process of two hours?**

Yes

No

MH19 **Were the observations recorded?**

Yes

No

MH20 **Were examinations conducted at sufficient frequency to ensure proper closure? (At least every 30 minutes of continuous closing machine operation or other frequency that is documented.)**

Yes

No

MH21 **If the establishment exceeds the two hour maximum time lapse between container closure and the initiation of the thermal process does the establishment have an alternative procedure on file that is approved by the processing authority?**

Yes

No

MH21a **For MH13 and MH21, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH22 **Does the establishment have process schedules on file from the processing authority for each product produced?**

Yes

No

MH23 **Have authorized changes been made to the process schedule in use (e.g., formulation, preparation, and process equipment)?**

Yes

No

MH23a **If yes, has the process schedule been updated?**

Yes

No

MH24 **Are the products being prepared according to the formulation and procedures specified in documents that the processing authority have developed?**

Yes

No

MH25 **Are appropriate letters/communications from the processing authority on file?**

Yes

No

MH26 **Are the critical factors specified in the process schedule measured, controlled, and recorded by the establishment to ensure that these factors remain within the limits used to establish the process schedule?**

Yes

No

MH27 **Are all measurements of the critical factors within the limits used to establish the process schedule?**

Yes

No

MH28 **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

MH28a **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

MH29 **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

MH30 **Are the process schedules (or operating schedules) for daily production, including minimum initial temperature and operating procedures for thermal processing equipment, posted in a conspicuous place near the processing equipment?**

Yes

No

MH30a **For MH22-MH30, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH31 **Does the establishment have a system in place to prevent product from bypassing the thermal processing operation?**

Editor

MH32 **Are establishment personnel measuring the coldest container to be processed and recording 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?**

Yes

No

MH33 **Does the establishment follow their written procedures on file for determining the initial temperature?**

Yes

No

MH34 **Are thermal processing systems which subject the filled and sealed containers to water at any time before process timing begins operated to assure that such water will not lower the temperature of the product below the minimum initial temperature specified in the process schedule?**

Yes

No

MH35 **Are the product traffic control procedures (e.g., heat sensitive indicators in each retort load) adequate to prevent unprocessed product from bypassing the system?**

Yes

No

MH36 **Does the establishment have 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?**

Yes

No

MH36a **For MH31-MH36, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH37 **Does the process schedule for the product being verified specify a maximum pH value as a critical factor?**

Yes

No

MH37a **If the process schedule does specify a maximum pH value as a critical factor, does the establishment use potentiometric methods that employ electronic instruments for making pH determinations?**

Yes

No

MH37b **For MH37 and MH37a, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH38 **Is each retort system installed, operated, and maintained as required?**

Yes

No

MH39 **Is each retort system equipped with at least one temperature indicating device that measures the actual temperature within the retort?**

Yes

No

MH40 **Is the temperature indicating device (the temperature/time recording device) used as the reference instrument for indicating process temperature?**

Yes

No

MH41 **Does the mercury-in-glass thermometer(s) or other temperature indicating device meet the requirements specified in the regulations?**

Yes

No

MH42 **Is each thermal processing system equipped with at least one temperature/time recording device?**

Yes

No

MH42a **For MH38-MH42, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH43 **Do water valves comply with 9 CFR 318.305 and 381.305?**

Yes

No

MH44 **Is each retort equipped with an automatic steam controller to maintain the retort temperature?**

Editor

MH45 **Are all air lines connected to retorts designed for pressure processing in steam 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?**

Yes

No

MH46 **Are all retort water lines that are intended to be closed during the process cycle equipped with a globe valve or equivalent-type valve or piping arrangement that will prevent leakage of water into the retort during the processing cycle?**

Yes

No

MH47 **Is the steam inlet to each retort large enough to provide steam for proper operation of the retort, and enter at a point to facilitate air removal during venting?**

Yes

No

MH48 **Are the steam spreaders, bleeders, stacking equipment, and divider plates installed and used per the regulatory requirements?**

Yes

No

MH49 **Are the vents 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?**

Yes

No

MH50 **If vents are connected to a closed drain system, is there an atmospheric break in the line?**

Yes

No

Not connected to closed drain system

MH50a **For MH43-MH50, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH51 **Are all instruments and controls checked any time their functioning or accuracy is suspect?**

Yes

No

MH52 **Do the maintenance records and the annual thermal process system audit records indicate that the thermal process systems are functioning properly?**

Yes

No

MH52a **For MH51 and MH52, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH53 **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?**

Yes

No

MH54 **Is potable water used for cooling, except as provided for in 9 CFR 318.305(h) and 381.305(g)?**

Yes

No

MH55 **Is cooling canal water chlorinated or treated with a chemical appropriate for this use?**

Yes

No

MH56 **Are cooling waters that are recycled or reused handled in systems so designed for such use?**

Yes

No

MH57 **Is system equipment such as pipelines, cooling towers, and holding tanks constructed and installed so they may be easily cleaned and inspected?**

Yes

No

MH57a **For MH53-MH57, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH58 **Does the establishment record the date of production, product name and style, container code, container size and type, and the process schedule, including the minimum temperature?**

Yes

No

MH59 **Are additional records completed for the specific type of retorts in the establishment?**

Yes

No

MH60 **Do establishment personnel review and maintain production records?**

Yes

No

MH61 **Are entries in records made at the time the event occurs?**

Yes

No

MH62 **Do 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 the process schedule?**

Yes

No

MH63 **Are all records, including the temperature/time recorder charts and critical factor control records, signed or initialed and dated by the person conducting the review?**

Yes

No

MH63a **For MH58-MH63, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH64 **Do establishment personnel detect all deviations?**

Yes

No

MH65 **Do establishment personnel handle process deviations in accordance with the regulations, whether identified in-process or through records review?**

Yes

No

MH66 **Does product that is reprocessed or repacked only processed with a process schedule authorized by the processing authority?**

Yes

No

MH67 **Are deviations in a continuous retort, including, but not limited to, emergency stops (jams or breakdowns) or temperature drops, handled according to regulatory requirements?**

Yes

No

MH68 **Does the establishment's process deviation file contain 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?**

Yes

No

MH68a **For MH64-MH68, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH69 **Does the establishment have finished product inspection procedures that are in compliance with the regulations?**

Yes

No

MH70 **Does the establishment have documented procedures in place for finished product inspection?**

Yes

No

MH70a **For MH69 and MH70, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH71 **Does the establishment have an incubator?**

Yes

No

MH71a **When incubation is used, is the recorder and thermometer accurate?**

Yes

No

MH71b **Is there air circulation within the incubator?**

Yes

No

MH71c **Is the incubator designed to prevent unauthorized entry?**

Yes

No

MH71d **Does the establishment's container incubation program comply with the required time, temperature, range, sampling program, identification of product requiring incubation, checks, and records?**

Yes

No

MH71e **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?**

Yes

No

No reduced incubation rate

MH71f **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?**

Yes

No

No reduced incubation rate

MH71g **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?**

Yes

No

MH71h **Are the establishment personnel performing incubation checks?**

Yes

No

MH71i **Does the establishment maintain incubator records?**

Yes

No

MH71j **Does the establishment handle abnormal containers according to the regulatory requirements?**

Yes

No

MH71k **For MH71-MH71j, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**

Editor

MH72	**Are all establishment personnel who operate the thermal processing systems under the direct supervision of a person who has successfully completed a program/course recognized as adequate for properly training of supervisors of canning operations?**
	Yes
	No
MH73	**Does the establishment have a current recall procedure for all canned product they produce, subject to the canning regulations?**
	Yes
	No

Analysis

A1	**Has the plant had a third party audit of its food safety system?**
	Yes
A1a	**Did the establishment implement any of the recommendations?**
	Yes
	No
A1b	**For A1 and A1a, why did you come to this conclusion? Describe your observations and/or documents used to reach the decision.**
	Editor
A2	**Briefly describe any additional findings which were not addressed by any of the proceeding questions.**
	Editor
A3	**Analysis and Summary: Please discuss findings and any regulatory noncompliances associated with HACCP 03D plans at this establishment using the relevant data gathered above. Include in your discussion how the findings impact the establishment's ability to meet the requirements of the FMIA/PPIA and that impact on food safety.**
	Editor