Task Identifier: FSA-M12612 P12612-2022-1

Establishment: Boar's Head Provisions Co., Inc. M12612 P12612

District: Raleigh, NC

General(GV6)

1. Q: FSA Recommendation

   A: NRs (no additional enforcement actions)

2. Q: If there are any NR(s) associated with this FSA, please include NR Numbers and a one line statement (maximum) to describe the NR (limit 10,000 characters).
   Note: This question is to be left blank if there are no NRs are associated with this FSA.
   A:

   1. NR#IDG1410104620 N/1 9 CFR 416.13(a), 9 CFR 416.13(c), and 9 CFR 416.16 (a)-SSOP/Pre-op Recordkeeping and Insanitary conditions.

   2. NR#IDG0210102920 N/1 9 CFR 416.4(b), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2)- SPS Insanitary conditions.

   3. NR#IDG1010105220 N/1 9 CFR 430.4(b)(3)(i)(D)-The establishment's Environmental Monitoring Program failed to list all possible Food Contact Surfaces (FCS) utilized in the Post-Lethality (PL) RTE room.

3. Q: FSA Executive Summary Supporting Recommendation (limit 8,000 characters)

   NOTE: The Executive Summary is a brief overview of the FSA report designed to give readers a quick overview of its recommendations and support.

A:

Boar's Head Provisions Co Inc. (M12612) located in Jarratt; VA is a large establishment with an approximate 219,182 square feet of workspace which was originally built in 1974. The most recent Grant of Inspection was issued on 01-26-2011. This establishment produces hams, franks, turkey, and bologna under the following HACCP process which is:

- Fully cooked not shelf stable

The last Food Safety Assessment (FSA) at Boar's Head Provision Co. Inc., Est. M12612 was completed in February 2016, resulting in SSOP and SPS design and implementation NRs. Due to it being over 6 years since the last FSA was completed and based on the monthly ODIFP priority list schedule for RLm sampling, a PHRE was assigned to be completed to analyze PHIS data, gather additional feedback from inspection personnel, and any changes to HACCP/SSOP and facilities.

A thorough analysis of the FSA findings supports a recommendation of the following NRs to be written by inspection program personnel (IPP):

- 9 CFR 416.13(a), 9 CFR 416.13(c), and 9 CFR 416.16(a)-SSOP/Pre-op Recordkeeping and Insanitary conditions. Multiple pre-op deficiencies were observed in the RTE and Raw areas. The establishment failed to document the EIAOs findings and corrective actions that the establishment took.
- 9 CFR 416.4(b), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2)-SPS Insanitary conditions. Numerous holes in the walls, damaged floors, loose caulking, product on floor, green mold, and rust were observed in the establishment.
- 9 CFR 430.4(b)(3)(i)(D)-The establishment's Environmental Monitoring Program failed to list all possible Food Contact Surfaces (FCS) utilized in the Post-Lethality (PL) RTE room.

With the exception of the non-compliances (NRs) discussed above, the establishment was following their written program that was adequately supported, therefore there were no additional food safety concerns. When not adequately addressed, these findings could impact the establishment ability to support the hazard analysis and the effectiveness of its programs.

Based on the observations as well as records reviewed during the assessment for Sanitation Program and the Fully Cooked-Not Shelf Stable HACCP written program indicates that the establishment is implementing their food safety system as per their written procedures. These programs were developed based on determinations made after conducting a hazard analysis to determine the food safety hazards reasonably likely to occur (RLTO) and not reasonably likely to occur (NRLTO) in each respective production process. The establishment has developed measures to control all hazards identified as RLTO. The CCPs, including the critical limits are supported, and validated. Overall, the EIAO's analysis supports the recommendation of these NRs to be written by in plant personnel (IPP) as a part of this FSA.

4. Q: Decision Making Analysis (limit 30,000 characters)
Provide an overall analysis of the FSA findings and the thought process used to arrive at the FSA recommendation. The support for the recommendation is derived from the sampling results (including the results from RLm, IVT, or IIT sampling), PHRE, in-plant observations, and the HACCP system design and implementation documented in the tools. Discuss and interpret the major findings and how that the findings impact the establishment's ability to produce safe, wholesome, and unadulterated product. This decision making analysis is important to provide context and support for a FSA recommendation that is supported by FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR). The EIAO is to summarize the analysis in an Executive Summary (Question G4).

   NOTE: The EIAO is to state whether follow up is necessary and is to contact the FLS within 30 days of the exit meeting to determine the status of the NR. Ensuring that an establishment has adequately addressed any noncompliance can reduce the likelihood of repetitive noncompliance in the future that could lead to public health events and additional FSAs.

   A:

   Boar's Head Provisions, Est. 12612M is a large Talmadge-Aiken (TA) plant located in Jarratt, Virginia. The plant was originally built in 1974. The establishment size is 219,182 square feet. They produce RTE hams, bologna, sausages, franks, and liverwurst. The above said products are produced under the following HACCP plan: Fully Cooked-Not Shelf Stable. This is a two-shift plant. The most recent grant of inspection was issued on 01/26/2011. The hours of operation are 0500 hours to 1330 hours (1st shift), and 1330 hours to 1000 hours (2nd shift) Monday through Friday.

   The establishment consists of the following inspected areas:

   Smoke house Addition room
   Battery charger room
   Freezer room
   Guard house room
   Stitch pump room
   Standardization room
   Spice room
   R&D office room
   R&D room
   Chemical room
   Chemical receiving room
   Liver Wurst room
   Head Cheese room
   Boxing room
   Boxing Mezzanine room
   Shipping room
   Shipping office room
   Bin Washroom
   RTE packaging room
   EQ5 room
   EQ6 room
   EQ7 room
   Smoke house Generator area room
   Blastcell (4) addition room
   Blastcell (3) addition room
   Pulled Pork room
   Franks Packaging room
   Franks Pack off room

Hi Temp Room (Browner)
Pre-Stage 1 room
Pre-Stage 2 room
New Process room
New Process Pickle room
New Process Receiving room
New Process Raw storage room
New Process Curing room
New Process Production office room
New Process Receiving office room
EQ1 room
EQ2 room
EQ3 room
EQ4 room
Cooler #5 room
Bologna Kitchen room
Netted Hams room
New Gourmet room
Stitch Pump II room
Receiving storage room
Raw storage room
Receiving room
Receiving office room
Holding cooler

This establishment samples for the following projects: [redacted] (b)(4)

The LIMS/PHIS sampling data results shows sampling for the date range reviewed of 04/20/2022 through 07/20/2022 as follows:

Sample for RTEPROD_RISK: Sampled on 06/10/2022 was negative/acceptable for *Listeria monocytogenes.*
Sample for RTEPROD_RISK: Sampled on 06/10/2022 was negative/acceptable for *Salmonella*.
Sample for RTEPROD_RISK: Sampled on 05/09/2022 was negative/acceptable for *Listeria monocytogenes.*
Sample for RTEPROD_RISK: Sampled on 05/09/2022 was negative/acceptable for *Salmonella*.

On 09/27/2022 through 10/04/2022, the EIAOs reviewed the Fully Cooked-Not Shelf Stable written programs, hazard analysis, and prerequisite programs. The Fully Cooked-Not Shelf Stable CCPs are the following:

- CCP-1A (Cooking for Nitrite and Non-Nitrite Products) (b)(4)
(b)(4)

- CCP-1B (Chilling for Nitrite Product Cured) (b)(4) (b)(4)
- CCP-1C (Chilling for Non-Nitrite Non-Cured Product) (b)(4) (b)(4)

The EIAO observed compliance with these CCPs. The EIAOs observed the plant's pre-operational procedure on 09/28/2022, 09/29/2022, and 10/04/2022 as well as operational sanitation procedure on 09/28/2022, 09/29/2022, and 10/04/2022. During the observations of the processing operations non-compliances were observed for the pre-operational and operational sanitation programs. An NR is being recommended for insanitary conditions throughout the facility. The SSOP records were completed and maintained daily but corrective actions of FSIS findings were not documented. This is documented in the recommended recordkeeping noncompliance in this question. The employee hygiene was acceptable throughout the process. The facility/structure was in good repair with no sign of rodent activity. The establishment has a pest control program which is being implemented with documented dates of their checks except for the non-compliances observed for beetles outside of bathroom. The establishment's recall plan complied.

The establishment supported the design of the HACCP plan and SSOP programs. Major deficiencies associated with the establishment's physical conditions were observed that could pose imminent threat to product. The EIAOs reviewed the Fully Cooked-Not Shelf Stable HACCP program on 09/27/2022 through 10/04/2022 and all CCPs complied. Review of records/direct observations of the HACCP, SSOP and other programs indicated the following Hazard Analysis and Critical Control Point (HACCP) noncompliance was observed by the EIAOs:

- On 09/28/2022 EIAOs (b)(6) and (b)(6) reviewed the Environmental Monitoring Program for Food Contact Surfaces (FCSs) Zone A which includes the following equipment: [redacted] The EIAOs observed operations on multiple days throughout the FSA, and the determination was made that the Environmental Monitoring Program failed to list the following sites: scissors, finger knives, white plastic tubs, stainless tub, knives, splitter belts, splitter blades, auto bagger, trees, associate sleeves, and cutting boards, all were confirmed to be a FCSs utilized in the Post-Lethality (PL) RTE room. The establishment failed to list all FCSs, as required by 9 CFR 430.4(b)(3)(i)(D).

Plant Management was notified of the above HACCP noncompliance.

The EIAO's observations from pre-operational verification on 09/28/2022, 09/29/2022, and 10/04/2022 showed that there were numerous insanitary conditions after the establishment completed their pre-op inspection, for example: on food contact product belts, plates, and conveyors of both the Raw and RTE processing rooms. Two product contact (FCS) pitch forks were observed contacting a non-food contact concrete wall and product contact bologna stick on the floor. All affected areas had numerous food contact findings and some failed rechecks (initial CAs) but were finally released after being cleaned and sanitized before use. Records were maintained but corrected actions for FSIS findings were not documented.

The EIAO's observations from operational sanitation verification on 09/28/2022 as acceptable. At least [redacted] a responsible person checks for sanitary conditions of food contact surfaces, equipment, utensils, and employee hygiene to prevent contamination and/or adulteration of product. The EIAOs observed that the establishment's own employees are responsible for daily sanitation. The daily pre- operational and operational sanitation records were completed showing findings and corrective actions of establishment findings only.

Based on the EIAO's walk through with plant management and IPP on 09/27/2022 to observe SPS procedures such as employee hygiene, sanitary conditions, facility conditions/construction, structural integrity, pest control, ventilation, and sanitary operations, the following non-compliances were observed:

- In the RTE room there were 5 clamps on the ceiling overhead piping, visually identified with rust on them, directly above product on line 3, a rusted bracket directly above the product zone of the tree wash area, a rust clamp directly above product in line 530, a rusted clamp directly above product in line 255, and 2 rusted clamps directly above product on line 1. The rust was thick and flaking on the clamps.
- In the Raw areas was a rusted conduit bracket temperature box in the pickle room on the east end, 2 rusted conduit brackets on the north wall of the pickle room, 3 rusted conduit brackets on the water line in the pickle room, 3 rusted valve handles on the north end of the pickle room, and 2 rusted conduit brackets on the south end of the pickle room. A rusted clamp, a rusted valve, and a rusted water pipe on the water line were found on the southwest corner of the tavern line.
- Beaded condensation beads (TNTC) were found on the doorway ceiling of the entrance holding cooler and condensation beads (TNTC) were found on the ceiling on the entrance door of frank stuffing.
- In the Cooler #5 room there was loose caulking (approximately 6" by 2" area) at the ceiling area in the northeast corner. Ceiling hot water supply line had loose tape hanging downward in the northwest corner. Cooler #5 had heavily beaded condensation (more than 50 beads on a 20' by 4" area) directly above RTE product. Another section of ceiling had loose tape (2- 2ft sections) hanging downward.
- The Blast cell hallway had loose caulking on the ceiling area hanging downward. There was a hole in the floor (approximately 3ft by 1.5" area) in the Blast cell hallway.
- In the Frank packaging RTE room the, EIAOs observed a 4" by 6" forming plate (product contact) on the floor. Dirt, screws, and trash were observed on the floor of the production area. The overhead cooling units had three sections of heavy rust (approximately 2ft. by 6" each) above the production area. Rust and grey flaking paint on the motor in line 255. Five holes and loose caulking on the northeast wall. The hot water line was leaking from the insulation around the pipe directly onto the floor.
- In the RTE Packaging room there were numerous (1/4" by 1/4" area) holes completely through the glass board wall behind the hot water line. The cold-water line had damaged insulation with loose

caulking at the exposed section (6" by 3" area) of the line. Loose caulking hanging downward was observed on the ceiling at the front of line 1. Hot water line had areas of peeling tape. Numerous holes (1/4" by 1/4" area) through the glass board wall north of line 1 shrink tunnel. Loose insulation tape coming off pipe 1 above shrink tunnel for line 3 creating insanitary conditions. Loose tape on grey water line above line 3. Damaged/exposed insulation around the hot water line. There was a gap in the insulation exposing the insulation around the steam line. Eleven holes (1/4" by 1/4" area) were observed on the north wall near line 3. Heavily beaded condensation (approximately 6ft by 1ft area) near steam exhaust line for the shrink tunnel area.

- EQ4 room had damaged/broken (approximately 2ft by 4 in area) floor area. There were numerous (greater than 20) holes (1/4" by 1/4" area), loose caulking, and tape on the door in EQ4. Missing and exposed insulation (approximately 4" by 4" area) on the cold-water line for unit 15.
- EQ3 room had hole in wall (approximately 2" by 6" area) of northeast corner. Duct tape on south door. Loose plastic on door. Numerous holes (approximately 20 and 1/4" by 1/4" in area) on the southwest wall.
- EQ2 room had loose/peeling paint and loose caulking (approximately 2" by 3' area). Peeling rust (approximately 6" by 20' area) on the wall pole.
- Smoke house addition room had loose caulking above the outside door of smokehouse #10. Loose caulking above smokehouse #20 hot water line.
- Entrance to Liver Wurst room had rust on the walls and ceiling. There was also rust and tape on the wall at the northeast corner. Loose caulking on the west wall in the Liver Wurst room. Rust on the floor of the east wall in Liver Wurst room. Loose caulking on the ceiling of the east wall. Holes and flaking paint on the east wall of Liver Wurst room. Numerous holes (more than 8 and 1/4" by 1/4" in area) on the east wall in Liver Wurst room. Loose caulking on overhead beam of the room. Product residue on the floor in Liver Wurst room. The Liver Wurst room strip tank window has rust on northeast wall.
- Breezeway to EQ1 room had hole in the floor (2ft by 6" area). Thick black smoke and soot were observed covering the ceiling area. EQ1 had a hole (approximately 1ft by 1" area) in the floor. Peeling paint (white and grey) on the wall in EQ1.
- Raw Smoke house room had peeling paint on the old steam pipe at south side of old smoke house. Numerous holes and loose caulking on the raw smoke house doorway. Missing trim and holes on the south wall. Cold water line had peeling paint. Loose caulking on the ceiling above smokehouse #14. Holes and rust above smokehouse #6.
- Smoke house generator area room had boards, wood, and trash on the floor area (approximately 10ft by 12ft area). Holes in the wall and holes in ceiling area of the Smoke house generator area room. Heavily beaded smoke on overhead pipes near the smokehouses. Heavily beaded condensation (approximately 30ft by 10ft area) on the ceiling above smoke house generator area room. Loose caulking, loose plastic, and heavily beaded condensation on the ceiling of the smoke house generator area room. Holes in the wall west of smoke house #14. Smoke house #2 had loose caulking hanging downward above the smoke house.
- Heavily beaded condensation on the ceiling area of the north entrance of holding cooler directly above product. Loose caulking above the holding cooler. Open vertical pipe near wall of the holding cooler. Loose caulking on floor and rust on south wall of the holding cooler. Heavily

beaded condensation on the ceiling area over product staging areas for trees. Numerous rusted holes on west wall.

- New Gourmet room had wall damage and numerous holes (1/4" by 1/4" area) on the north wall and doorway to the staging area for staging area for trees. Loose paint, holes, and loose caulking on the east wall. Heavily beaded condensation on the ceiling area near west wall. Holes (1/4" by 1/4" area) on the ceiling area near southeast wall. Loose caulking on south wall. Broken curbing and holes (1/4" by 1/4" area) in the floor before maintenance storage area. Condensation was dripping from the hot water line directly onto the floor area. Exposed insulation around the piping of the CRV machine.
- Head Cheese room had a product contact shovel hanging from a rusty pipe and its handle was directly contacting the wall (non-product contact surface). Another product contact shovel was hanging from the water line (non-product contact surface) and directly contacting the west wall (non-product contact surface). Loose caulking and holes in the west wall. Loose caulking on wall above 2nd cycle blending area. Loose caulking above cooling unit for netting hams above line 3.
- Franks stuffing room had numerous holes in walls and numerous areas of loose caulking. Standardization room had loose caulking on the south wall and numerous holes in the east wall. Rusted air filter to pump caulking on east door corner.
- Stitch pump II room had loose caulking on south wall. Numerous areas of green mold, large crack, and loose caulking on west wall.
- Pickle room had greater than 20 holes in the upper part of the west wall. Loose caulking at the bottom of west wall near door. Peeling paint on south wall. A hole (approximately 6" by 2" area) in the south wall.
- Live bugs (beetles) were observed on the floor the bathroom hallway.

The EIAOs observed pre-operational sanitation SOP procedures and noted several deficiencies after establishment personnel had completed pre-operational SSOP inspection and released the various areas for production.

- On 9/28/22 EIAO's observed: Beaded condensation (greater than 20 beads) above the dumper in the Netting room. Line 3A and Line 3B had a large black smear on the inside of the belts and a thick product residue build-up between the layers of belt. Product residue underneath the middle dumper in the rusted track are on floor. The metal supports of the dumper line had numerous areas of product residue. Strip belt had product residue (in five areas) on the product contact Teflon guides. The transfer belt had product residue (in three areas) on the metal bar that contacts the belt. The dumper belt had numerous areas of product residue on the Teflon rollers, metal guides, sprockets, belt supports, and product contact belt area. Bologna stick (product contact) was laying on the floor near the wall area. Numerous areas of product residue on the floor were observed. Two product contact pitch forks were hanging downward with the fork sections directly contacting the concrete wall. U.S Rejected tag# B 26 238183 was applied to the area at approximately 0541hrs and not removed until approximately 0646 hrs.

- On 9/29/22 EIAO's observed: Product residue was observed on the framework, inside

support bar (product contact surface) between belt layers, and in the product contact belt to the dumper belt in the Netting room. Crack in the roller for the middle transfer line. Product residue on cross bar (product contact surface) of transfer line. Product residue on belt of line 3A. Product residue on the underside table for 3A. Head Cheese room had product residue on the screen, and it was also damaged. Line 6B had product residue in the tub. Product residue on cutting board and on stuffing horn. Product residue on the east column of east wall.

- On 9/29/22 EIAO's observed: The underside of the metal detector in the RTE packaging area had numerous sections of coating was peeling and hanging downward above the belt. The Packaging area had numerous sections of product residue on the plates of the Line 1 (b)(4) machine, Line 2 (b)(4) machine, Line 3 (b)(4) machine, and Line 4 (b)(4) machine. Five of the white product contact tubs had product residue on the side edges and inside of them. They also were damaged and had white peeling plastic residue. The (b)(4) line 4 belt had numerus missing links in the belt. Product residue on frame to the dual infeed belt. EIAO's also observed numerous areas of product residue on the floor area around the equipment of all four lines. Stainless steel table on North end of Line 1 (b)(4) machine had product residue on product contact table. The inedible metal cart had numerous sections of product residue in it. Product residue on the splitter frame. The product contact storage cart had thick product residue on the underneath sides directly above product contact parts. The product residue area was dripping directly onto the product contact machine parts below. On the Line 1 Frank RTE area, the EIAO's observed product residue on the floor area around the machines. There was product residue on the incline belt to the (b)(4). Product residue on stripping arm of (b)(4) machine. The metal cover for the (b)(4) had product residue on the inside area. Conveyor belt leading to peeling room had product residue on the inside framework over the belt. There was a broken weld and product residue in-between the layers of belt to the conveyor to peeler room. Product residue on the outside frame of the conveyor leading to peeler room.

- On 10/4/22 EIAO's observed: Product residue on the (b)(4)-food contact guide and numerous meat scraps on the floor area of the New Gourmet room. The Beachwood line #1 had product residue on the conveyor belt. Syrup table had product residue on it. Conveyor belt #2 had product residue (1" by 4") of the guard.

- On 10/4/22 EIAO's observed: Frank RTE room had product residue on the inside support bars of the incline to (b)(4). Numerous chunks of franks were observed on the floor around the equipment near the wall and product residue around the drain. Two areas of product were observed on the floor around the vacuum pump. The RTE packaging area had product residue and wrapper stuck at roller area on the (b)(4) metal detector. Product residue on the floor around the (b)(4) line. Conveyor leading to the peeler room had product residue on the inside support bars. The establishment's SSOP states as follows: (b)(4)
(b)(4)

(b)(4)

Review of the establishment pre-operational SSOP records found that none of the deficiencies observed by the EIAO's, nor the corrective actions were documented on the SSOP record failing to meet the requirements of 9CFR 416.16(a).

The establishment failed to meet the regulatory requirements of 9 CFR 416.13(a), CFR 416.13 (c), 9 CFR 416.16(a), 9 CFR 416.4(b), 9 CFR 416.2(d), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2).

An analysis of the above stated NRs indicates when not adequately addressed, these findings could impact the establishment's ability to produce safe, wholesome, and unadulterated product. After a review of the Fully Cooked-Not Shelf Stable written programs, SSOP/SPS/SOP programs, pest control program, supporting documentation, and other records support the recommendation of these NRs to be issued for the FSA by IPP at the exit meeting. No follow up visit is necessary.

5. Q: Date of Entrance meeting (MM/DD/YYYY)

   A: 09/27/2022

6. Q: Attendees (Names and Titles) for Entrance Meeting:

   A:

   EIAO (b)(6) EIAO (b)(6), RTE Production Manager (b)(6), QA Manager (b)(6), Standardization Manager (b)(6), Receiving Department Manager (b)(6), Netted Hams Department Manager (b)(6) and Support Manager (b)(6).

7. Q: Date of Exit Meeting (MM/DD/YYYY)

   A: 10/20/2022

8. Q: Attendees (Names and Titles) for Exit Meeting:

   A: EIAO (b)(6) EIAO (b)(6) IIC (b)(6), RTE Production Manager (b)(6), QA Manager (b)(6), Smokehouse Manager (b)(6), Safe Quality Foods Manager (b)(6) Facility Manager (b)(6), Assistant Plant Manager (b)(6), Plant Manager Michael Kneeland, Senior Manufacturing Manager (b)(6), Smokehouse Supervisor (b)(6) Receiving Department Manager (b)(6) (b)(6) Netted Hams Department Manager (b)(6), and Support Manager (b)(6).

9. Q: Did the FSA extend beyond 5 -7 production days?

   A: No

10. Q: Does this FSA require a follow-up for NR corrective actions or vulnerability identified during the FSA?

    A: No

11. Q: Provide your assessment of any vulnerability and any noncompliance associated with the condition of the structure (Sanitation Performance Standards) that would hinder the establishment's ability to maintain sanitary conditions (limit 5,000 characters).
    If there are no vulnerabilities or noncompliances, leave the free text box blank.

A:

Based on the EIAO's walk through with plant management and IPP on 09/27/2022 to observe SPS procedures such as employee hygiene, sanitary conditions, facility conditions/construction, structural integrity, pest control, ventilation, and sanitary operations, the observed non-compliances which are documented in question G5 were too many characters to fit into this answer. Please review the SPS NRs in question G5. A summary of the SPS observations is listed below.

9 CFR 416.4(b), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2)-SPS Insanitary conditions. Numerous holes in the walls, damaged floors, loose caulking, product on floor, green mold, and rust were observed in the establishment.

12. Q: Are there any conditions associated with the equipment or implemented Sanitation SOP that would hinder the establishment's ability to maintain sanitary conditions (optional text box has 2,000 character limit)?

    A: Yes

    The EIAOs observed pre-operational sanitation SOP procedures and noted several non-compliances associated with equipment and implemented Sanitation SOP that would hinder the establishment's ability to maintain sanitary conditions, after establishment personnel had completed pre-operational SSOP inspection and released the various areas for production. These non-compliances exceeded the number of characters allowed in the answer. Please refer to the previously documented SSOP NR in question G5 to review these observations.

13. Q: Provide your assessment of any vulnerability and any noncompliance with the Sanitation SOPs. Include concerns with: 1) whether all sanitation procedures are incorporated into the Sanitation SOPs, 2) if the procedures of the Sanitation SOPs address the cleaning of FCSs, and 3) if the Sanitation SOPs specify the frequency of each procedure and identify the establishment employee responsible for implementation and maintenance of each procedure (limit 5,000 characters).

    A:

    The EIAOs observed pre-operational sanitation SOP procedures and noted several non-compliances after establishment personnel had completed pre-operational SSOP inspection and released the various areas for production. These non-compliances exceeded the number of characters allowed in the answer. Please refer to the previously documented SSOP NR in question G5 to review these observations. A summary of the SSOP observations is listed below.

    9 CFR 416.13(a), 9 CFR 416.13(c), and 9 CFR 416.16(a)-SSOP/Pre-op Recordkeeping and Insanitary conditions. Multiple pre-op deficiencies were observed in the RTE and Raw areas on product contact surfaces. The establishment failed to document the EIAOs findings and corrective actions that the establishment took.

14. Q: Provide your assessment of any vulnerability and any noncompliance with employee hygiene training procedures, training materials, written documents, and employee adherence to Good Manufacturing Practices (GMPs) (limit 5,000 characters).

    A: None

15. Q: Provide your assessment of any vulnerability and any noncompliance with the sanitizer(s) used, sanitizer rotation cycle (if applicable), and maintaining sanitizer(s) at a level that is both safe and effective (limit 5,000 characters).

    A: None

16. Q: Does the establishment have less than daily (LTD) cleaning procedures, including poultry chillers, if applicable (limit 4,000 characters)?
    *If yes, provide your assessment of any vulnerability and any noncompliance with the establishment's LTD cleaning program. Include concerns with how the establishment ensures that: 1) sanitary conditions are maintained and wholesome product is produced, 2) the program is comparable to daily cleanup, and 3) pathogens are effectively addressed as described in FSIS Directive 5000.5.

    A: N/A - Establishment does not have LTD cleaning procedures

17. Q: Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 416.15(a) over the last 60 days (limit 2,000 characters)?
    *If yes, note whether all applicable parts of 9 CFR 416.15(b) were met. If no, note why the establishment did not take appropriate corrective actions.

    A: Yes

    EIAOs (b)(6) and (b)(6) observed that the corrective actions meet all parts of 9 CFR 416.15(b).

18. Q: Describe any vulnerability and any noncompliance not described above that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If none, leave the free text box blank (limit 20,000 characters).

    A: None

19. Q: Sanitation Summary: Considering the questions in the sanitation section, and the establishment's sanitation program as a whole, please provide your assessment of any additional vulnerability and describe any noncompliance not previously documented (limit 20,000 characters).

    A: None

20. Q: Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4000 characters).

    A: Yes

    The EIAOs observed that the establishment did consider the relevant food safety hazards throughout the HACCP system. No noncompliance or vulnerability was observed.

21. Q: Does the establishment utilize normal consumer-cooking practices to support hazard analysis decision-making?

    A: Yes

22. Q: 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 4000 characters).

    A: Yes

    The EIAOs observed that the HACCP system does include prerequisite programs and supporting documentation for any hazard that the establishment determines is "not reasonably likely to occur"(NRLTO). No vulnerability or noncompliance was observed.

23. Q: 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 4000 characters).

    A: Yes

    THE EIAOs observed that the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur" (RLTO). No vulnerability or noncompliance was observed.

24. Q: 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 selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

    A: No

25. Q: Does the establishment apply antimicrobial treatments or additives that support decisions in the hazard analysis (e.g., CCPs, pre-requisite programs, or other programs)?

    A: No

26. Q: 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, including chilling/cooling if the establishment slaughters (1st part – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

    A: Yes

    The EIAOs observed that the establishment maintains adequate scientific and technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis, including chilling/cooling for the 1st part design. No vulnerability or noncompliance was observed.

27. Q: Does the establishment's scientific support demonstrate the process meets the performance standards or targets (i.e., pathogen reduction level) identified in the hazard analysis for each food safety system (limit 4,000 characters)?

    A: Yes

    The EIAOs observed that the establishment's scientific support demonstrates that the process meets the performance standards and targets identified in the hazard analysis for each food safety system. No vulnerability or noncompliance was observed.

28. Q: Does the establishment use multiple interventions, including antimicrobial interventions, to meet the overall performance standard or target (i.e., Multi-Hurdle effect)?

    A: No

29. Q: Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits (limit 4,000 characters)?

    A: Yes

    The EIAOs observed that the establishment does incorporate the critical operating parameters in the scientific support into its CCP limits, prerequisite programs, and other program limits. No vulnerability or noncompliance was observed.

30. Q: 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 – execution) (limit 4,000 characters)?

    A: Yes

    The EIAOs observed that the establishment maintains in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part-execution). No vulnerability or noncompliance was observed.

31. Q: 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).

    A: None

32. Q: 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 G40.

    A: Yes

33. Q: Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in G40.

    A: Yes

34. Q: 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).

    A: None

35. Q: 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).

    A: Yes

    THE EIAOs observed that the establishment does have corrective action procedures in its written program (HACCP plan). No vulnerability or noncompliance was observed.

36. Q: 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).

    A: N/A - The establishment has not had any deficiencies over the last 60 days

    The EIAOs observed that the establishment has not had any deficiencies over the last 60 days, so no corrective actions have been taken. No vulnerability or noncompliance was observed.

37. Q: 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).

    A: Yes

    The EIAOs observed that the records include the actual times, temperatures, and other quantifiable values, and include the product codes, product name and identity. No vulnerability or noncompliance was observed.,

38. Q: 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).

    A: None

39. Q: 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).

    A: None

40. Q: Waiver: Does the establishment have alternative procedures associated with waivers (e.g., Salmonella Initiative Program (SIP) program, no objection letters)? Current establishment waivers and letters may be found under the Establishment Profile column => "Waivers & Letters" tab. If the establishment provides documentation of a waiver or NOL, but it is not in PHIS, please correlate with OPPD via askFSIS to determine if the waiver or NOL is current.

    NOTE: The EIAO is to review alternative procedures associated with waivers (e.g., Salmonella Initiative Program (SIP) program, no objection letters) during the assessment of the establishments overall food safety system.

    A: No

41. Q: Was sampling performed as part of the FSA (e.g., RLm, or IVT)?

    A: Yes - If selected, answer the following question G49

42. Q: Briefly describe the implemented sampling plan, the sample sites, and results. Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

    NOTE: If there were positive results, include in your response the establishment's corrective actions.

    (Do not document IIT sampling if associated with this FSA document unless directed by your supervisor)

A:

MOIs
1.RLm MOI dated 09-22-2022
2.Product on HOLD MOI dated 09-22-2022

On September 22, 2022, EIAOs (b)(6) and (b)(6) conducted a three-unit RLm sampling. The 10 FCS sites for unit 1 were the following: finger knife, large stainless-steel table, cutting board, south auto bagger, knife, north auto bagger, headcheese tree, associate glove, inside of white plastic tub, and inside small white pan. The 5 non-FCS sites for unit 1 were the following: yellow boot, stainless steel table wheel, maintenance cart tools, red drop hose airline, and drain. The 5 product samples for unit 1 were the following: 5 samples of Lower Sodium Bologna.

The 10 FCS sites for unit 2 were the following: finger knife, stainless steel table, splitter belt, north auto bagger, splitter belt, south auto bagger, stainless steel table, associate glove, finger knife, and inside large white plastic tub. The 5 non-FCS sites for unit 2 were the following: brace for water hose, blue hose, yellow boot, drain, and stainless-steel table wheel. The 5 product samples for unit 2 were the following: 5 samples of Tavern Ham.

The 10 FCS sites for unit 3 were the following: package, associate glove, north stainless-steel table, stainless steel tree stick, south stainless-steel table, frank tree, inside of large white plastic tub, inside package film, associate scissors, and inside small white plastic pan. The 5 non-FCS sites for unit 3 were the following: ink machine cover, vacuum pump, shrink tunnel hot water line, shrink tunnel, and drain. The 5 product samples for unit 3 were the following: 5 samples of Beef Frankfurters. On September 24, 2022, all results posted negative in LIMS.

43. Q: 3rd Party Audit: Has the establishment received a 3rd Party Audit in the last 60 days that revealed any direct food safety related weaknesses?

    A: No 3rd Party Audit in the last 60 days

44. Q: Sampled Lot Definition: Considering rework, returned product, carry-over, commingling, and cross-contamination during processing, does the establishment have a supportable basis for its sampled lot definition (microbiological independence)?

A: Yes

45. Q: Describe the establishment's sample lot definitions, the support and rationale for lot independence, and any flaws in the process that would question the establishment's microbiological independence determination (limit 20,000 characters).

    A:

    A lot for this establishment is defined as one day's production: from cleanup to cleanup. Cleanup is conducted daily after production.

46. Q: Based on the products the establishment produces and a review of the laboratory sampling results obtained from the PHRE report, is the in-plant team receiving the appropriate sampling tasks through PHIS according to the establishment's products and production volume?

    NOTE: If the EIAO identifies that the appropriate sampling tasks are not being assigned to the in-plant team, he or she is to contact the FLS.

    A: Yes

47. Q: Recall Procedure: Does the establishment have a documented recall procedure as required by 9 CFR part 418 to ensure all products could be recalled? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

    A: Yes

    EIAOs (b)(6) and (b)(6) observed that the establishment has a 24-hour security service at the guarded entrance. There are (b)(4) employees working in a 219,182 square foot area and no through traffic is allowed in the establishment's operation areas. Water supply emergency contacts are in place should there be a water source issue and the municipal water has a shutoff valve for emergencies.

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

    A: Yes - If selected, answer the following question G57

49. Q: 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 5,000 characters).

A:

The EIAOs observed that the establishment had individual sinks in the Raw and RTE departments designated to recondition product that has fallen on the floor. An establishment employee would take the product, to be reconditioned, to the meat wash sink, remove their current personal protective equipment (PPE) and put on new PPE before reconditioning the product. The reconditioned RTE products are already packaged. Reconditioned product would be placed back on the production line and the responsible employee would then change out PPE again. Certain products at the establishment cannot be reconditioned due to the injection process performed in the Stitch Pump department. No noncompliance or vulnerability was observed.

50. Q: 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 Soybeans.

    A: Yes - If selected, answer the following question G59

51. Q: Briefly describe any vulnerability and cite 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 5,000 characters).

    A: The EIAOs did not observe any vulnerability or noncompliance with the establishment's food safety system addressing the identification, prevention, control, and declaration of allergen/ingredients.

52. Q: Non-Inspected Production: Considering dual jurisdiction, retail exempt processing, and custom exempt processing, are there any non-FSIS inspected production practices that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.unadulterated product.

    A: No

53. Q: Food Defense: Does the establishment have a functional food defense plan? Note: a food defense plan is functional if it meets all four of the following conditions: 1) written/developed (the plan is documented and signed), 2) implemented (preventive measures are implemented to ensure a base level of "common sense" security, 3) tested (security measures are monitored), and 4) reviewed and maintained (the plan is reviewed at least annually and revised as needed).

    A: Yes

54. Q: Supplemental: Based on your experience, expertise, and knowledge of industry practices, describe any additional questions that came up during the FSA that you sought answers to, based on the unique characteristics of the establishment's process. Document the answers of your additional investigation (limit 20,000 characters).

    A: None

55. Q: Summarize in three to five bullets of any vulnerability or noncompliance findings identified in the General 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 (limit 20,000 characters).

    A:

    Based on the EIAO's walk through with plant management and IPP on 09/27/2022 to observe SPS procedures such as employee hygiene, sanitary conditions, facility conditions/construction, structural integrity, pest control, ventilation, and sanitary operations, the observed SPS non-compliances are summarized below.

    The EIAOs observed pre-operational sanitation SOP procedures on 09/28/2022, 09/29/2022, and 10/04/2022 and noted several non-compliances after establishment personnel had completed pre-operational SSOP inspection and released the various areas for production. These SSOP non-compliances are summarized below.

    - 9 CFR 416.4(b), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2)-SPS Insanitary conditions. Numerous holes in the walls, damaged floors, loose caulking, product on floor, green mold, and rust were observed in the establishment.
    - 9 CFR 416.13(a), 9 CFR 416.13(c), and 9 CFR 416.16(a)-SSOP/Pre-op Recordkeeping and Insanitary conditions. Multiple pre-op deficiencies were observed in the RTE and Raw areas. The establishment failed to document the EIAOs findings and corrective actions that the establishment took.

    When not adequately addressed, these previously documented findings could impact the establishment's ability to produce safe, wholesome and unadulterated product. It is the EIAO's recommendation that these NRs be issued by IPP at the exit meeting.

Ready-To-Eat(RTEV2)

1. Q: Has the establishment considered the relevant food safety hazards throughout the HACCP system?

   A: Yes

2. Q: Describe the hazard(s) not properly considered or identified. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

   A: None

3. Q: Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur"?
   *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 free text box blank.

   A: Yes

4. Q: Has there been a change that could affect the hazard analysis or HACCP plan during the previous 60 days?
   NOTE: Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1

   A: No

5. Q: HACCP Summary: If applicable, describe additional HACCP design or implementation of the establishment's HACCP system findings that are not described in the previous questions. Describe any vulnerability or noncompliance. Provide an assessment of how your findings impact the establishment's food safety system.

   A: None

6. Q: Does the establishment achieve lethality of its RTE products in the fully cooked, not shelf stable HACCP category by cooking and stabilization by cooling or hot holding?

   A: Yes

7. Q: Did the establishment identify all appropriate hazards as part of its hazard analysis at the cooking step?
   *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 free text box blank.

   A: Yes

8. Q: Did the establishment identify a performance standard or target to be met by the HACCP system during cooking?
   *If the answer is no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If the answer is yes, leave the free text box blank.

A: Yes

9. Q: Does the establishment identify CCP critical limits, prerequisite program or other program limits for the cooking process?
*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 free text box blank.

   A: Yes

10. Q: Does the establishment maintain adequate scientific support for the design of its cooking CCP critical limit or prerequisite program or other program design?

    *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 free text box blank.

    A: Yes

11. Q: Does the scientific support relate to the establishment's actual process, product, and hazard identified in the hazard analysis?
*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 free text box blank.

    A: Yes

12. Q: Does the establishment's scientific support demonstrate the process meets the performance standards or targets identified in the hazard analysis for each food safety hazard?
*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 free text box blank.

    A: Yes

13. Q: Does the establishment incorporate the critical operational parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits for the cooking process?
*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 free text box blank.

    A: Yes

14. Q: Does the establishment incorporate humidity into the cooking process?
*If yes, leave the text box blank unless based on your assessment, you have findings. Briefly describe any vulnerability and any noncompliance with the establishment's support.
*If no, describe if the establishment has support for why humidity is not a critical operational parameter and include your assessment of any vulnerability and describe any noncompliance

    A: Yes

15. Q: Does the establishment's in-plant validation adequately support the cooking process?
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
*If there are findings of any vulnerability or noncompliance, describe them in the free text and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.

    A: Yes

16. Q: Does the establishment have monitoring and verification procedures and frequencies in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooking.
*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 free text box blank.

    A: Yes

17. Q: 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) for cooking?
*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 free text box blank.

    A: Yes

18. Q: Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooking?
*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 free text box blank.

    A: No

    EIAOs (b)(6) and (b)(6) were informed that product would be recooked or reworked first and then discarded, as a last option, if there was a cooking deviation. No vulnerability or noncompliance was observed.

19. Q: If applicable, describe additional findings regarding lethality monitoring, verification, corrective action design for cooking RTE product that are not described in the previous questions and how your findings impact the establishment's food safety system. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

    *This question is to be left blank if there are no additional findings.

    A: None

20. Q: Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for the cooking process step?

    NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed. Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1

    *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 free text box blank.

    A: Yes

21. Q: As part of its ongoing verification of the cooking process, does the establishment conduct end product testing for biological hazards other than Listeria?
    *If yes, provide your assessment of whether the establishment took appropriate corrective actions in response to any positives during the previous 6 months. If no, leave the free text box blank.

    A: Yes

    EIAOs (b)(6) and (b)(6) observed that the establishment did not have a [redacted] end product test result in the past 6 months, so no corrective actions were implemented.

22. Q: Did the establishment identify all appropriate hazards as part of its hazard analysis during the cooling step?
    *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 free text box blank.

    A: Yes

23. Q: If the establishment fully cooks the product and then applies additional heating and cooling steps that do not achieve full lethality (e.g., an oil browning step or pasteurization treatment), does it identify all appropriate hazards as part of its hazard analysis at those steps?

    *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 or if the establishment does not apply additional steps, leave the free text box blank.

    A: Establishment does not apply additional heating and cooling steps that do not achieve full lethality

24. Q: If the establishment fully cooks the product and then applies additional heating and cooling steps that do not achieve full lethality, does the scientific support address the cumulative growth of spore-formers (e.g., C. perfringens, C. botulinum) across the first cooling and subsequent heating and cooling steps?
*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 or if the establishment does not apply additional steps, leave the free text box blank.

    A: Establishment does not apply additional heating and cooling steps that do not achieve full lethality

25. Q: Did the establishment identify a performance standard or target to be met by the HACCP system during cooling? Provide your assessment of any vulnerability and describe any noncompliance.
*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 free text box blank.

    A: Yes

    The EIAOs observed that the establishment did identify a performance standard and target to be met by the HACCP system during cooling. No vulnerability or noncompliance was observed with this process.

26. Q: Does the establishment identify CCP critical limits, prerequisite program or other program limits for the cooling process?
*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 free text box blank.

    A: Yes

27. Q: Does the establishment maintain adequate scientific support for the design of its cooling CCP critical limit or prerequisite program or other program design?
*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 free text box blank.

    A: Yes

28. Q: Does the scientific support relate to the establishment's actual process, product and hazard identified in the hazard analysis?
*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 free text box blank.

    A: Yes

29. Q: Does the establishment's scientific support demonstrate that the establishment's process meets the performance standards or targets it identified in the hazard analysis for each food safety hazard?
*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 free text box blank.

    A: Yes

30. Q: Does the establishment incorporate the critical operational parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits for the cooling process.
*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 free text box blank.

    A: Yes

31. Q: If the establishment is using scientific support other than an FSIS guideline or regulation (e.g., journal article or challenge study), does establishment's study design adequately support the cooling process?
*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 or if the establishment is not using other support, leave the free text box blank.

    A: The establishment is not using support other than FSIS guidelines or regulations.

32. Q: Does the establishment's in-plant validation data adequately support the cooling process?
NOTE: Until further notice, EIAOs are to note any lack of data in the FSA but are not to use the lack of data as the only reason for noncompliance.
*If there are findings of any vulnerability or noncompliance, describe them in free text and assess the impact your findings have on the food safety system. If yes, leave the free text box blank.

    A: Yes

33. Q: If the establishment hot-holds the product, does it have controls and appropriate labeling to ensure that the temperature will be maintained throughout storage, distribution, and sale?

    *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 free text box blank.

    A: The establishment does not hold product

34. Q: If the establishment hot-holds the product, does the establishment adequately address hot-holding in the hazard analysis, supporting documentation, CCPs or prerequisite programs, and validation?

    *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 free text box blank.

A: The establishment does not hot-hold product

35. Q: Does the establishment have support for its monitoring and verification procedures and frequencies in its written program for cooling (i.e., HACCP plan, 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 free text box blank.

    A: Yes

36. Q: Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or other program) for cooling?
*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 free text box blank.

    A: Yes

37. Q: If applicable, describe additional findings regarding stabilization monitoring, verification, corrective action design for cooking RTE product that are not described in the previous questions and how your findings impact the establishment's food safety system. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

    * This question is to be left blank if there are no additional findings.

    A: None

38. Q: Based on your review of records and observation of operations, do the establishment's records accurately reflect that the establishment is implementing the monitoring and verification procedures as designed for product stabilization?

    NOTE: For deviations in the last 60 days, provide your assessment of whether all parts of 9 CFR 417.3 were addressed. Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

    *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 free text box blank.

    A: Yes

39. Q: Cooking and Cooling Summary: Provide a summary of your findings regarding the establishment's cooking and cooling process RTE product. Briefly describe how your findings impact the establishment's food safety system. Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system.

A: None

40. Q: Does the establishment achieve lethality by processes other than cooking alone (e.g., heat treated, shelf stable; not heat treated, shelf stable; and secondary inhibitors, not shelf stable)?
A: No

41. Q: Does the establishment add non-meat ingredients (e.g., sauces, spices, glazes, etc.) to any RTE products after the final lethality step?
A: No

42. Q: Does the establishment produce post-lethality exposed RTE products?

A: Yes

43. Q: Which alternative does the establishment use to produce post-lethality exposed RTE products?

A: Alternative 3 (sanitation alone, does not use PLT or AMAP)

44. Q: Does the establishment minimize cross-contamination and maintain separation of raw and RTE product. Include in your assessment traffic patterns, controlling movement of equipment, maintaining physical separation (if applicable), and restricting use of garments or utensils to specific areas.
*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 free text box blank.
A: Yes

The EIAOs observed that the establishment minimized cross-contamination by maintaining separation of raw and RTE product. Traffic patterns, controlling movement of equipment, maintaining physical separation, and restricting the use of garments and utensils to specific areas. No noncompliance or vulnerability was observed.

45. Q: Are conditions that may contribute to product and FCS contamination corrected as soon as possible?

*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 free text box blank.
A: Yes

46. Q: If applicable, describe any additional findings regarding establishment or facility conditions that could lead to Lm cross-contamination that were not previously addressed. Note: Your assessment may include conditions (e.g., condensation, holes in wall, air flow, rusty or pitted equipment). Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

    *This question is to be left blank if there no additional findings of vulnerability or noncompliance.

    A:

    The EIAOs observed the following facility insanitary conditions throughout the facility summarized in the following SPS NR summary listed below.

    9 CFR 416.4(b), 9 CFR 416.2(a), 9 CFR 416.2(d), and 9 CFR 416.2(b)(2) SPS Insanitary conditions. Numerous holes in the walls, damaged floors, loose caulking, product on floor, green mold, and rust were observed in the establishment.

47. Q: Has the establishment had any Listeria positive tests other than FCS sites?
    NOTE: If yes, assess whether the establishment conducted follow-up testing in response to positive test results.

    * Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system in the free text box. If there are no vulnerabilities or noncompliance, leave the free text box blank.

    A: No

48. Q: Provide your assessment of any vulnerability and describe any noncompliance with hold-and-test procedures being implemented as written. If there are no findings, leave the free text box blank.

    A: None

49. Q: Does this establishment conduct food contact surface (FCS) testing?
    NOTE: FCS testing is required for alternatives 3 and 2b. It is optional for alternatives 2a and 1.

    A: Yes as REQUIRED by the Listeria rule for Alt. 3 and Alt. 2b; or OPTIONALLY under Alt. 1 and Alt. 2a

50. Q: Is FCS testing designed to verify sanitation in the post-lethality environment?
    *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 free text box blank.

    A: Yes

51. Q: Does the FCS testing design include hold and test procedures following a positive FCS testing?
*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 free text box blank

A: Yes

52. Q: Does the FCS testing design include the frequency of FCS testing, identification of the location of sites for sampling, and the size of sites to be sampled?
*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 free text box blank.

A: Yes

53. Q: Are all possible FCS sampling sites identified?
*If no, identify all FCS sites not identified by the establishment. Also, 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 free text box blank.

A: No

On 09/28/2022 EIAOs (b)(6) and (b)(6) reviewed the Environmental Monitoring Program for Food Contact Surfaces (FCSs) Zone A which includes the following equipment: [redacted] etc." The EIAOs observed operations on multiple days throughout the FSA, and the determination was made that the Environmental Monitoring Program failed to list the following sites: scissors, finger knives, white plastic tubs, stainless tub, knives, splitter belts, splitter blades, auto bagger, trees, associate sleeves, and cutting boards, all were confirmed to be a FCSs utilized in the Post-Lethality (PL) RTE room. The establishment failed to list all FCSs, as required by 9 CFR 430.4(b)(3)(i)(D).

54. Q: Is the FCS testing design sufficient, 1) to ensure effective control of Listeria-like, Listeria spp, or Listeria monocytogenes, and 2) to detect low numbers of Lm or indicator organisms, if present?
NOTE: Assess the laboratory analysis method and sample collection method.
*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 free text box blank.

A: Yes

55. Q: Based on your observation of the sampling procedure, does the establishment collect samples according to the design of the FCS testing?
NOTE: Consider weaknesses in the implemented sampling program, which may hinder the establishment's ability to ensure that effective control of Lm or indicator organisms is maintained.
*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 free text box blank.

A: Yes

56. Q: Has the establishment had any initial FCS positive tests in the past 6 months?
NOTE: If yes, assess whether the establishment conducted of follow-up testing on FCS sites.
* Briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system in the free text box. If there are no vulnerabilities or noncompliance, leave the free text box blank.

A: (b)(4)

EIAO's (b)(6) and (b)(6) were informed that the establishment has a [redacted]. For corrective actions they inspected the table for possible harborage areas, cracks, and rough wells. All stainless tables were baked in the smoke house after cleaning and then heavily sanitized. An audit of associate GMPs was also conducted. No vulnerability or noncompliance was observed.

57. Q: Does this establishment utilize or apply a post-lethality treatment (PLT)?

A: No, the establishment does not produce products under Alt. 1 and Alt. 2a

58. Q: Does this establishment utilize or apply an Antimicrobial Agent or Process (AMAP)?

A: No, the establishment does not produce products under Alt. 1 and Alt 2b

59. Q: Summarize in up to three bullets of any vulnerability or noncompliance findings identified in the RTE Processed Products 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.

A:

Based on EIAOs (b)(6) and (b)(6) in-plant observations and records review of the Fully Cooked Not Shelf Stable HACCP process the following noncompliance was observed.

The establishment's Environmental Monitoring Program failed to list all possible Food Contact Surfaces (FCS) utilized in the Post-Lethality (PL) RTE room as required by 9 CFR 430.4(b)(3)(i)(D).

Besides the above observed noncompliance, the establishment's monitoring and verification activities support the absence of any immediate food safety concern and the adequacy of the design of their food safety system. The establishment is maintaining all documentation to demonstrate the proper implementation and effectiveness of their program's design as required by 9 CFR Part 417. It is the EIAO's recommendation that this NR be issued by IPP at the exit meeting.