Appendix B

PUBLIC HEALTH RISK-BASED INSPECTION SYSTEM

FOCUSED INSPECTION PROMPTS AND QUESTIONS

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02; 318.6(a); 416.4(d) (multiple)

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

Potential Regulatory Citation(s):
310.22(d)(2) SRM Removal and Corrective Action
318.24 AMR
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT TWO

Prompt Description: Positive pathogen results from:

2.a - FSIS testing – O157:H7 – needs to be related to extended clean up – data from M2K

2.b- Salmonella – percent positive rate from M2K – failure to meet applicable performance standards

2.c.- Industry and other government testing (in profile) (TPC, generic E. coli, etc.) or trends in MOI (category on MOI form) [417.5(a)(1)]

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase

b.) Processing (Mixing, Grinding, Formulating, Needling, Marinating, Rework, Packaging)

a. Based on profile, does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?

b. Are there adequate controls to prevent pathogen lot- to-lot cross contamination? Are the controls being implemented?

c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):

310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP
318.24 AMR

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT THREE

Prompt Description: Temperature not controlled by CCP
(use as modifier to have different percentile for SSOPs – fewer SSOPs to trigger)

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing (Mixing, Grinding, Formulating, Needling, Marinating, Rework, Packaging)

a. Based on profile, does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?

b. Are there adequate controls to prevent pathogen lot- to-lot cross contamination? Are the controls being implemented?

c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP
318.24 AMR

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT FOUR

Prompt Description: Any HACCP NR with any 417 except 5(b) and 417.6

Threshold: one observation

Vulnerable Points & Question(s) to Answer:

a.) Labeling

a.) Does the establishment have controls to ensure the product is labeled appropriately for intended use? Are the controls implemented?
b.) Are all ingredients listed on the label?
c.) Does the plant have procedures in place to link outgoing lots to incoming lots?

Potential Regulatory Citation(s):

310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT FIVE

Prompt Description: Repetitive NRs over time for 416.13(c) and 416.14, 416.15. Distinguish between weekly versus daily up from profile/SSOPS (weekly would have lower significant threshold)

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Processing (Mixing, Grinding, Formulating, Needling, Marinating, Rework, Packaging)

a. Based on profile, does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?
b. Are there adequate controls to prevent pathogen lot- to-lot cross contamination? Are the controls being implemented?
c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP
318.24 AMR

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT SIX

Prompt Description: Observed SRM at receiving when not appropriate or handled improperly [03B01 or 03B02] (Beef Only) [310.22 in plants not intentionally receiving SRM]

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing (Mixing, Grinding, Formulating, Needling, Marinating, Rework, Packaging)

a. Based on profile, does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?

b. Are there adequate controls to prevent pathogen lot- to-lot cross contamination? Are the controls being implemented?

c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP
318.24 AMR

RAW GROUND (03B)
[INCLUDES GROUND, MARINATED, INJECTED, AND OTHERWISE COMMINUTED]

PROMPT SEVEN

Prompt Description: 04B04. Either 317.2(f) or 417, 381.1(18) for ingredient statements

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing (Mixing, Grinding, Formulating, Needling, Marinating, Rework, Packaging)

a. Based on profile, does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?

b. Are there adequate controls to prevent pathogen lot- to-lot cross contamination? Are the controls being implemented?

c. Does establishment control rework? Are the controls being implemented?

c.) Storage/Shipping

a.) Does the establishment maintain control of sampled product until results are obtained?

b.) Does the establishment have controls to ensure product temperature is controlled during storage or shipping? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(d)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen Hazard
417.4Validation and Verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?
b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

Potential Regulatory Citation(s):
310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT TWO

Prompt Description: Positive pathogen results from:

2.a - FSIS testing – O157:H7 – needs to be related to extended clean up – data from M2K

2.b- Salmonella – percent positive rate from M2K – failure to meet applicable performance standards

2.c.- Industry and other government testing (in profile) (TPC, generic E. coli, etc.) or trends in MOI (category on MOI form) [417.5(a)(1)]

Threshold: observation

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?

b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing

a. Does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?

b. During operational sanitation are there adequate controls to prevent pathogen lot to lot cross contamination? Are the controls being implemented?

c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):

310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT THREE

Prompt Description: Temperature not controlled by CCP.

Threshold: (number) observation during 03B01.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?
b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing

a. Does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?
b. During operational sanitation are there adequate controls to prevent pathogen lot to lot cross contamination? Are the controls being implemented?
c. Does establishment control rework? Are the controls being implemented?

c.) Storage/Shipping

a. Does the establishment maintain control of sampled product until results are obtained?
b. Does the establishment have controls to ensure product temperature is controlled during storage or shipping? Are the controls being implemented?
c. Does the establishment have controls to ensure product temperature controlled during storage or shipping? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT FOUR

Prompt Description: Product categorized incorrectly in Hazard Analysis.

Threshold: (number) observation during 04B04.

Vulnerable Points & Question(s) to Answer:

a.) Packaging/Labeling

a. Does establishment have controls to ensure product labeled appropriately for intended use? Are the controls being implemented?
b. If establishment produces AMR, does it have controls to ensure it is labeled appropriately? Are the controls being implemented?
c. Does the plant have procedures in place to link outgoing lots to incoming lots?

Potential Regulatory Citation(s):
310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT FIVE

Prompt Description: Preoperational equipment cleaning NR.

Threshold: (number) observation during 01B02.

Vulnerable Points & Question(s) to Answer:

a.) Processing

a. Does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?
b. During operational sanitation are there adequate controls to prevent pathogen lot to lot cross contamination? Are the controls being implemented?
c. Does establishment control rework? Are the controls being implemented?

Potential Regulatory Citation(s):
310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT SIX

Prompt Description: Observed SRM at receiving (Beef Only).

Threshold: (number) observation during 03C01 or 03C02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?
b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing

a. Does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?
b. During operational sanitation are there adequate controls to prevent pathogen lot to lot cross contamination? Are the controls being implemented?
c. Does establishment control rework? Are the controls being implemented?

c.) Packaging/Labeling

a. Does establishment have controls to ensure product labeled appropriately for intended use? Are the controls being implemented?
b. If establishment produces AMR, does it have controls to ensure it is labeled appropriately? Are the controls being implemented?
c. Does the plant have procedures in place to link outgoing lots to incoming lots?

Potential Regulatory Citation(s):

310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

RAW NOT GROUND (03C)
[INTACT PRODUCT AND AMR]

PROMPT SEVEN

Prompt Description: CNS or DRG found.

Threshold: (number) observation during 04A03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have controls, including corrective actions, to ensure product or carcass acceptability? Are the controls being implemented?
b. Does establishment documentation support ongoing effectiveness of any purchase specifications or offer pre-requisite programs in HACCP?

b.) Processing

a. Does establishment have mechanisms in place to control product temperature during processing? Are the controls being implemented?
b. During operational sanitation are there adequate controls to prevent pathogen lot to lot cross contamination? Are the controls being implemented?
c. Does establishment control rework? Are the controls being implemented?

c.) Packaging/Labeling

a. Does establishment have controls to ensure product labeled appropriately for intended use? Are the controls being implemented?
b. If establishment produces AMR, does it have controls to ensure it is labeled appropriately? Are the controls being implemented?
c. Does the plant have procedures in place to link outgoing lots to incoming lots?

Potential Regulatory Citation(s):
310.22(e)(2) SRM Removal and Corrective Action
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance and Monitoring
416.1 SSOP Corrective Action
417.2 Hazard Analysis
417.3(b) Unforeseen Hazard
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.4 Validation and verification of HACCP
318.24 AMR

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D)

PROMPT ONE

Prompt Description: Observe a process deviation.

Threshold: (number) observation during 03D01, 03D02, 04C03, 04C04, 06D01.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/ Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Are all meat and non-meat ingredients received from supplier list and in compliance with purchase specifications?
c. Are all the meat and non-meat ingredients the same as on the process schedule?
d. Are containers inspected and stored appropriately?

b.) Processing – Assembly/Filling

a. Does the plant ensure that the 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, etc.) of each ingredient?
b. Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that these factors remain within the limits used to establish the process schedule?
c. Have all changes made to the process schedule in use been authorized by the process authority?
d. Is there compliance with maximum fill-in weight or drained weight?
e. Is there compliance with minimum headspace?

c.) Processing – Sealing

a. Has the establishment addressed any abnormal containers identified?
b. Are closing machine verifications within limits (e.g., seams formed properly)?
c. Is the establishment generating records and maintaining records (e.g., samples, incubation, can teardown, equipment maintenance and auditing)?

d.) Thermal Processing and Cooling

a. Is meat “initial temperature” within plant specifications?
b. Did the establishment follow and meet its process schedule?
c. Is the processing schedule the same as approved by the process authority or an approved alternate?
d. Is there a proper amount of chlorine or other approved chemical in the cooling water?
e. If the establishment recycles water, are they handling the reused water in a maintained system?
f. Is the establishment addressing all processing deviations?
g. Does the plant handle process deviations appropriately, whether identified in-process or through records review?
h. Does the establishment reprocess product with a process schedule authorized by the processing authority?

e.) Storage/Shipping

a. Did the product receive required incubation prior to shipment?

Potential Regulatory Citation(s):
417.5(a)(1) – Hazard Analysis Decisions Not Supported
318.302/381.302 – Thermal Processing
318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D)

PROMPT TWO

Prompt Description: Observe any changes in product formulation, ingredients, or treatment that are not already incorporated in a process schedule and that may adversely affect either product heat penetration profile or sterilization value.

Threshold: (number) observation during 03D01, 03D02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Are all meat and non-meat ingredients received from supplier list and in compliance with purchase specifications?
c. Are all the meat and non-meat ingredients the same as on the process schedule?
d. Are containers inspected and stored appropriately?

b.) Processing – Assembly/Filling

a. Does the plant ensure that the 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, etc.) of each ingredient?
b. Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that these factors remain within the limits used to establish the process schedule?
c. Have all changes made to process schedule been authorized by the process authority?
d. Is there compliance with maximum fill-in weight or drained weight?
e. Is there compliance with minimum headspace?

c.) Thermal Processing and Cooling

a. Is meat "initial temperature" within plant specifications?
b. Did the establishment follow and meet its process schedule?
c. Is process schedule same as approved by the process authority or an approved alternate?
d. Is there a proper amount of chlorine or other approved chemical in the cooling water?
e. If establishment recycles water, are they handling reused water in a maintained system?
f. Is the establishment addressing all processing deviations?
g. Does the plant handle process deviations appropriately, whether identified in-process or through records review?
h. Does the establishment reprocess product with a process schedule authorized by the processing authority?

Potential Regulatory Citation(s):

417.5(a)(1) – Hazard Analysis Decisions Not Supported
318.302/381.302 – Thermal Processing
318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D

PROMPT THREE

Prompt Description: The plant not measuring, controlling and recording Critical Factors.

Threshold: (number) observation during 03D01, 03D02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/ Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Are all meat and non-meat ingredients received from supplier list and in compliance with purchase specifications?
c. Are all the meat and non-meat ingredients the same as on the process schedule?
d. Are containers inspected and stored appropriately?

b.) Processing – Assembly/Filling

a. Does the plant ensure that the 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, etc.) of each ingredient?
b. Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that these factors remain within the limits used to establish the process schedule?
c. Have all changes made to the process schedule in use been authorized by the process authority?
d. Is there compliance with maximum fill-in weight or drained weight?
e. Is there compliance with minimum headspace?

c.) Processing – Sealing

a. Has the establishment addressed any abnormal containers identified?
b. Are closing machine verifications within limits (e.g., seams formed properly)?
c. Is the establishment generating records and maintaining records (e.g., samples, incubation, can teardown, equipment maintenance and auditing)?

d.) Thermal Processing and Cooling

a. Is meat "initial temperature" within plant specifications?
b. Did the establishment follow and meet its process schedule?
c. Is the processing schedule the same as approved by the process authority or an approved alternate?
d. Is there a proper amount of chlorine or other approved chemical in the cooling water?
e. If the establishment recycles water, are they handling the reused water in a maintained system?
f. Is the establishment addressing all processing deviations?
g. Does the plant handle process deviations appropriately, whether identified in-process or through records review?
h. Does the establishment reprocess product with a process schedule authorized by the processing authority?

Potential Regulatory Citation(s):

417.5(a)(1) – Hazard Analysis Decisions Not Supported
318.302/381.302 – Thermal Processing

318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D

PROMPT FOUR

Prompt Description: No evidence of annual thermal process system audit records to indicate that the thermal process systems are functioning properly.

Threshold: (number) observation during 03D01, 03D02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/ Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Are all meat and non-meat ingredients received from supplier list and in compliance with purchase specifications?
c. Are all the meat and non-meat ingredients the same as on the process schedule?
d. Are containers inspected and stored appropriately?

b.) Processing – Assembly/Filling

a. Does the plant ensure that the 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, etc.) of each ingredient?
b. Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that these factors remain within the limits used to establish the process schedule?
c. Have all changes made to the process schedule in use been authorized by the process authority?
d. Is there compliance with maximum fill-in weight or drained weight?
e. Is there compliance with minimum headspace?

c.) Processing – Sealing

a. Has the establishment addressed any abnormal containers identified?
b. Are closing machine verifications within limits (e.g., seams formed properly)?
c. Is the establishment generating records and maintaining records (e.g., samples, incubation, can teardown, equipment maintenance and auditing)?

d.) Thermal Processing and Cooling

a. Is meat "initial temperature" within plant specifications?
b. Did the establishment follow and meet its process schedule?
c. Is the processing schedule the same as approved by the process authority or an approved alternate?
d. Is there a proper amount of chlorine or other approved chemical in the cooling water?
e. If the establishment recycles water, are they handling the reused water in a maintained system?
f. Is the establishment addressing all processing deviations?
g. Does the plant handle process deviations appropriately, whether identified in-process or through records review?
h. Does the establishment reprocess product with a process schedule authorized by the processing authority?

Potential Regulatory Citation(s):
417.5(a)(1) – Hazard Analysis Decisions Not Supported

318.302/381.302 – Thermal Processing
318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D)

PROMPT FIVE

Prompt Description: Abnormal containers identified.

Threshold: (number) observation during 03D01, 03D02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/ Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Are all meat and non-meat ingredients received from supplier list and in compliance with purchase specifications?
c. Are all the meat and non-meat ingredients the same as on the process schedule?
d. Are containers inspected and stored appropriately?

b.) Processing – Sealing

a. Has the establishment addressed any abnormal containers identified?
b. Are closing machine verifications within limits (e.g., seams formed properly)?
c. Is the establishment generating records and maintaining records (e.g., samples, incubation, can teardown, equipment maintenance and auditing)?

Potential Regulatory Citation(s):

417.5(a)(1) – Hazard Analysis Decisions Not Supported
318.302/381.302 – Thermal Processing
318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

THERMALLY PROCESSED/COMMERCIALLY STERILE (03D)

PROMPT SIX

Prompt Description: Dual jurisdiction plant recalls of non-amenable product – notice from FDA.

Threshold: (number) recalls

Vulnerable Points & Question(s) to Answer:

a.) Thermal Processing and Cooling

a. Is meat "initial temperature" within plant specifications?
b. Did the establishment follow and meet its process schedule?
c. Is the processing schedule the same as approved by the process authority or an approved alternate?
d. Is there a proper amount of chlorine or other approved chemical in the cooling water?
e. If the establishment recycles water, are they handling the reused water in a maintained system?
f. Is the establishment addressing all processing deviations?
g. Does the plant handle process deviations appropriately, whether identified in-process or through records review?
h. Does the establishment reprocess product with a process schedule authorized by the processing authority?

Potential Regulatory Citation(s):

417.5(a)(1) – Hazard Analysis Decisions Not Supported
318.302/381.302 – Thermal Processing
318.303/381.303 – Critical Factors and the Application of the Process Schedule
318.304/381.304 – Operation in the Thermal Process Area
318.305/381.305 – Equipment and Procedures for Heat Processing Systems
318.306/381.306 – Processing and Production Records
318.308/381.308 – Deviation in Processing
318.301 Containers and Closures
318.309 Finished Product Inspection

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving (threshold TBD).

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load?
c. Does the establishment have appropriate controls for returned product? Are controls being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT TWO

Prompt Description: Plant does not have fermentation and drying as CCPs for fermented products.

Threshold: Profile

Vulnerable Points & Question(s) to Answer:

a.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT THREE

Prompt Description: Plant does not have salting, equalization, and drying steps as CCPs for salt cured product.

Threshold: Profile

Vulnerable Points & Question(s) to Answer:

a.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT FOUR

Prompt Description: Positive pathogen results from Industry or FSIS testing or Total Plate Count above establishment action level.

Threshold: (number) observation during 03E01.

Vulnerable Points & Question(s) to Answer:

a.) Receiving

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load?
c. Does the establishment have appropriate controls for returned product? Are controls being implemented?

b.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

c.) Post-Processing (slicing and/or peeling for sausage products; boning/slicing/cutting for salt cured product (e.g., country cured ham); packaging)

a. Does plant control for pathogens? Are controls being implemented?
b. Does the plant have controls in place to ensure cross contamination does not occur? Are the controls being implemented?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT FIVE

Prompt Description: Plant has inadequate documentation to support that the product is shelf stable.

Threshold: (number) observation during 03E01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

b.) Labeling

a. Is product labeled appropriately for the intended use?
b. Does the product label have language on the principal display panel to indicate that it is NRTE and validated cooking instructions for shelf stable NRTE products?
c. Does the product need to be labeled “Refrigerate after Opening”? That is, does the shelf stability of the product depend on it being gas packed or vacuum packed in an oxygen impervious package?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT SIX

Prompt Description: For shelf stable NRTE products: The product's label does not have language on the principal display panel to indicate that it is NRTE and does not have validated cooking instructions.

Threshold: (number) observation during 04B04.

Vulnerable Points & Question(s) to Answer:

a.) Labeling

a. Is product labeled appropriately for the intended use?
b. Does the product label have language on the principal display panel to indicate that it is NRTE and validated cooking instructions for shelf stable NRTE products?
c. Does the product need to be labeled "Refrigerate after Opening"? That is, does the shelf stability of the product depend on it being gas packed or vacuum packed in an oxygen impervious package?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT SEVEN

Prompt Description: For shelf stable RTE products: The plant has no or insufficient documentation to demonstrate that the product achieves sufficient reductions for the bacterial pathogens of concern.

Threshold: (number) observation during 03E01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

NOT HEAT TREATED SHELF STABLE (03E)

PROMPT EIGHT

Prompt Description: Preoperational equipment cleaning NR (threshold TBD).

Threshold: (number) observation during 01B02.

Vulnerable Points & Question(s) to Answer:

a.) Processing (tempering, formulating, starter culture preparation, fermenting, salting, equalization, heating, drying, rework)

a. Is there evidence that the establishment controls temperature throughout the process?
b. Are rework and carry-over addressed in the Hazard Analysis?
c. Does the establishment have controls in place to ensure cross contamination does not occur? Are the controls being implemented?
d. Does the establishment have processes in place to ensure shelf stability? Are these processes being implemented?
e. Does the establishment control how they use starter cultures?
f. Does the establishment have proper procedures in place to follow-up positive *Listeria* results on food contact surfaces or environmental samples? Are these procedures being implemented?
g. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame? Are the controls being implemented?
h. For fermented products, does the process include a heat step for those processes with a higher pH (≥5.0), lower fermentation (70°F) temperature, or no starter culture?
i. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
j. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
k. Trichina addressed?
l. Does plant use certified pork as ingredient in combination product? Is combination product labeled appropriately?

b.) Post-Processing (slicing and/or peeling for sausage products; boning/slicing/cutting for salt cured product (e.g., country cured ham); packaging)

a. Does plant control for pathogens? Are controls being implemented?
b. Does the plant have controls in place to ensure cross contamination does not occur? Are the controls being implemented?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430.4(b) Control of Lm in post-lethality exposed RTE product

HEAT TREATED SHELF STABLE (03F)

PROMPT ONE

Prompt Description: Plant does not have fermentation and drying as CCPs for fermented products.

Threshold: (number) observation during 03F01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

HEAT TREATED SHELF STABLE (03F)

PROMPT TWO

Prompt Description: Plant does not have the lethality and drying steps as CCPs for heat dried products.

Threshold: (number) observation during 03F01.

Vulnerable Points & Question(s) to Answer:

b.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

HEAT TREATED SHELF STABLE (03F)

PROMPT THREE

Prompt Description: Positive pathogen or *Listeria* species results from Industry or FSIS testing or Total Plate Count above establishment action level.

Threshold: (number) observation during 03F01.

Vulnerable Points & Question(s) to Answer:

a.) Receiving

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? Are controls being implemented?
c. Does the establishment have appropriate controls for returned product)? Are controls being implemented?

b.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

c.) Post Processing (e.g. Slicing, Peeling & Packaging)

a. Does plant control for pathogens? Are controls being implemented?
b. Does the plant have controls in place to ensure cross contamination does not occur? Are controls being implemented?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

PROMPT FOUR

Prompt Description: Plant has inadequate documentation to support that the product is shelf stable.

Threshold: (number) observation during 03F01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

PROMPT FIVE

Prompt Description: For shelf stable RTE products: The plant has no or insufficient documentation to demonstrate that the product achieves sufficient reductions for the pathogens of concern.

Threshold: (number) observation during 03F01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

b.) Post Processing (e.g. Slicing, Peeling & Packaging)

a. Does plant control for pathogens? Are controls being implemented?
b. Does the plant have controls in place to ensure cross contamination does not occur? Are controls being implemented?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

HEAT TREATED SHELF STABLE (03F)

PROMPT SIX

Prompt Description: For shelf stable NRTE products: The product's label does not have language on the principal display panel to indicate that it is NRTE and validated cooking instructions

Threshold: (number) observation during 04B04.

Vulnerable Points & Question(s) to Answer:

a.) Labeling

a. Is product labeled appropriately for the intended use?
b. Does the product label have language on the principal display panel to indicate that it is NRTE and validated cooking instructions for shelf stable NRTE products?
c. Does the product need to be labeled "Refrigerate after Opening"? That is, does the shelf stability of the product depend on it being gas packed or vacuum packed in an oxygen impervious package?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

HEAT TREATED SHELF STABLE (03F)

PROMPT SEVEN

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? Are controls being implemented?
c. Does the establishment have appropriate controls for returned product)? Are controls being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

HEAT TREATED SHELF STABLE (03F)

PROMPT EIGHT

Prompt Description: Preoperational equipment cleaning NR.

Threshold: (number) observation during 01B02.

Vulnerable Points & Question(s) to Answer:

a.) Processing (Tempering, Formulating, Preparation, Fermenting, Drying, Rework, Heat)

a. If not a CCP, does plant achieve sufficient lethality?
b. Does the plant maintain sufficient humidity during the lethality step for heat dried product?
c. Does the plant have a low temperature heat step after fermentation if not a CCP?
d. Do they have temperature and humidity controlled during the lethality step in order to eliminate the bacterial pathogens of concern?
e. Is there evidence that the establishment controls temperature throughout the process?
f. Is rework and carry-over addressed in the Hazard Analysis?
g. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
h. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
i. Does the plant have controls in place to ensure cross contamination does not occur?
j. Does the establishment have processes in place to ensure shelf stability (e.g., monitoring of pH, brine or salt concentration, water activity)?
k. Does the establishment control how they use starter cultures?
l. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*)results on food contact surfaces or environmental samples?
m. During fermentation, does the establishment have controls to ensure appropriate pH is reached within the proper time frame?
n. Can establishment support selection of their alternative in *Lm* program?
o. Does establishment address foreign metal contamination through food safety system and are they implementing these controls?

b.) Post Processing (e.g. Slicing, Peeling & Packaging)

a. Does plant control for pathogens? Are controls being implemented?
b. Does the plant have controls in place to ensure cross contamination does not occur? Are controls being implemented?

c.) Storage/Shipping

a. Does the establishment have verifiable temperature controls in the storage? (e.g., if cooler goes down—need to know length of time)
b. Does the establishment monitor conditions in storage areas that would cause adulteration of product (over spray, dripping water, etc.)?

Potential Regulatory Citation(s):
416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)
430 *Listeria Control*
424.21(c) Regulatory limits for restricted ingredients

FULLY COOKED NOT SHELF STABLE (03G)

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? Are controls being implemented?
c. Does the establishment have appropriate controls for returned product? Are controls being implemented?
d. Does the establishment monitor product temperatures during storage?

Potential Regulatory Citation(s)

416.1 Failure to maintain sanitary practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported
417.3(b) Unforeseen Hazard
430.4(b) Control of Lm in post-lethality exposed RTE product
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.36 Interference with inspection
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)

FULLY COOKED NOT SHELF STABLE (03G)

PROMPT TWO

Prompt Description: Preoperational equipment cleaning NR.

Threshold: (number) observation during 01B02.

Vulnerable Points & Question(s) to Answer:

a.) Processing (mixing, formulating, grinding, tempering, molding, solution injection, rework, lethality step, stabilization)

a. If not a CCP, does plant achieve sufficient lethality?
b. Is rework and carry-over addressed in the hazard analysis?
c. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
d. Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented? (e.g., ventilation, movement of employees)
e. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*) results on food contact surfaces or environmental samples? Is plant carrying out follow up procedures?
f. Are establishments under Alternative II or III that are using sanitation programs adequately implementing the program and controls in sanitation program (not SSOP; spelled out in 430) adequate and followed?
g. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
h. Is establishment following cooling model? Is establishment checking temperature frequently enough to show criteria for cooling is being met?
i. Has establishment undergone recent construction and if so have they increased *Lm* monitoring? Do records show increase in *Lm* in environment?

Potential Regulatory Citation(s)

416.1 Failure to maintain sanitary practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported
417.3(b) Unforeseen Hazard
430.4(b) Control of Lm in post-lethality exposed RTE product
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.36 Interference with inspection
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)

FULLY COOKED NOT SHELF STABLE (03G)

PROMPT THREE

Prompt Description: Positive pathogen results from Industry or FSIS testing or Total Plate Count above establishment action level.

Threshold: (number) observation during 03G01, 03G02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are wholesome and safe? Are control measures being implemented?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? Are controls being implemented?
c. Does the establishment have appropriate controls for returned product? Are controls being implemented?
d. Does the establishment monitor product temperatures during storage?

b.) Processing (mixing, formulating, grinding, tempering, molding, solution injection, rework, lethality step, stabilization)

a. If not a CCP, does plant achieve sufficient lethality?
b. Is rework and carry-over addressed in the hazard analysis?
c. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
d. Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented? (e.g., ventilation, movement of employees)
e. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*) results on food contact surfaces or environmental samples? Is plant carrying out follow up procedures?
f. Are establishments under Alternative II or III that are using sanitation programs adequately implementing the program and controls in sanitation program (not SSOP; spelled out in 430) adequate and followed?
g. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
h. Is establishment following cooling model? Is establishment checking temperature frequently enough to show criteria for cooling is being met?
i. Has establishment undergone recent construction and if so have they increased *Lm* monitoring? Do records show increase in *Lm* in environment?

c.) Post-lethality Processes (e.g., slicing, peeling, packaging)

a. Are products post lethality exposed, if so, does establishment have *Lm* control program?
b. Does plant control for pathogens in the post-lethality processing environment (e.g., slicer, packaging equipment, and packaging)?
c. Does the plant have controls in place to ensure cross contamination does not occur?

Potential Regulatory Citation(s)
416.1 Failure to maintain sanitary practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported
417.3(b) Unforeseen Hazard
430.4(b) Control of Lm in post-lethality exposed RTE product
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.36 Interference with inspection
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)

FULLY COOKED-NOT SHELF STABLE (03G)

PROMPT FOUR

Prompt Description: Temperature not controlled by CCP.

Threshold: (number) observation during 03G01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (mixing, formulating, grinding, tempering, molding, solution injection, rework, lethality step, stabilization)

a. If not a CCP, does plant achieve sufficient lethality?
b. Is rework and carry-over addressed in the hazard analysis?
c. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
d. Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented? (e.g., ventilation, movement of employees)
e. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*) results on food contact surfaces or environmental samples? Is plant carrying out follow up procedures?
f. Are establishments under Alternative II or III that are using sanitation programs adequately implementing the program and controls in sanitation program (not SSOP; spelled out in 430) adequate and followed?
g. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
h. Is establishment following cooling model? Is establishment checking temperature frequently enough to show criteria for cooling is being met?
i. Has establishment undergone recent construction and if so have they increased *Lm* monitoring? Do records show increase in *Lm* in environment?

b.) Storage/Shipping

a. Does the establishment have verifiable temperature controls in the storage? (if cooler goes down—need to know length of time)
b. Does the establishment monitor conditions in storage areas that would cause adulteration of product (over spray, dripping water, etc.)?

Potential Regulatory Citation(s)

416.1 Failure to maintain sanitary practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported
417.3(b) Unforeseen Hazard
430.4(b) Control of Lm in post-lethality exposed RTE product
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.36 Interference with inspection
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)

FULLY COOKED-NOT SHELF STABLE (03G)

PROMPT FIVE

Prompt Description: Using an unvalidated cooling model to determine product disposition.

Threshold: (number) observation during 03G01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (mixing, formulating, grinding, tempering, molding, solution injection, rework, lethality step, stabilization)

a. If not a CCP, does plant achieve sufficient lethality?
b. Is rework and carry-over addressed in the hazard analysis?
c. Does the establishment have ingredients of public health concern and, if so, do they have proper controls in place to ensure levels do not exceed regulatory limits?
d. Does the plant have controls in place to ensure cross contamination including different species does not occur? Are controls being implemented? (e.g., ventilation, movement of employees)
e. Does the establishment have proper procedures in place to follow-up positive *Listeria* (*Lm*) results on food contact surfaces or environmental samples? Is plant carrying out follow up procedures?
f. Are establishments under Alternative II or III that are using sanitation programs adequately implementing the program and controls in sanitation program (not SSOP; spelled out in 430) adequate and followed?
g. Does the establishment have a means to ensure labeling for allergens is accurate and have a means in place to ensure no cross contamination of product?
h. Is establishment following cooling model? Is establishment checking temperature frequently enough to show criteria for cooling is being met?
i. Has establishment undergone recent construction and if so have they increased *Lm* monitoring? Do records show increase in *Lm* in environment?

Potential Regulatory Citation(s)

416.1 Failure to maintain sanitary practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported
417.3(b) Unforeseen Hazard
430.4(b) Control of Lm in post-lethality exposed RTE product
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.36 Interference with inspection
417.2(a)(2) Intended Use or Consumer
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Standards of Identity (Meat)
381.1 Standards of Identity (Poultry)

HEAT TREATED NOT SHELF STABLE (03H)

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Does the plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? If no, (b1) Does the finished product have cooking instructions? (b2) Are validation data available for the establishment's handling (cooking) instructions? (b3) Do the handling instructions include microwave cooking? (b4) Does the validation data show testing over a variety of microwave wattages?
c. Does the establishment reject or destroy returned products? (c1) Does the establishment have appropriate controls for returned product (e.g., handling instructions if kept in control of the producer versus if out of control of the producer)?
d. Does the establishment have adequate separation of the NRTE and RTE products in storage?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported 301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
424.21(c) Regulatory limits for restricted ingredients
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.10 Combination Product Labeling
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen hazard

HEAT TREATED NOT SHELF STABLE (03H)

PROMPT TWO

Prompt Description: Positive pathogen results from Industry or FSIS testing or Total Plate Count above establishment action level.

Threshold: (number) observation during 03H01, 03H02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome, and otherwise such as will not result in the product being adulterated?
b. Does the plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? If no, (b1) Does the finished product have cooking instructions? (b2) Are validation data available for the establishment's handling (cooking) instructions? (b3) Do the handling instructions include microwave cooking? (b4) Does the validation data show testing over a variety of microwave wattages?
c. Does the establishment reject or destroy returned products? (c1) Does the establishment have appropriate controls for returned product (e.g., handling instructions if kept in control of the producer versus if out of control of the producer)?
d. Does establishment have adequate separation of NRTE and RTE products in storage?

b.) Processing (mixing, formulating, grinding, breading, battering, tempering, molding, solution injection, rework, partial cooking, heating, smoking stabilization)

a. Does the establishment have adequate data (e.g., scientific research, in-house data) to support the heating step in the process?
b. Does the establishment control the heating step in the process?
c. Is rework and carry-over addressed in the Hazard Analysis?
d. Does the plant have controls in place to ensure cross contamination does not occur?
e. If the establishment has in-house testing of finished product or components, does the establishment follow their program and action limits when the results exceed their expected level?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported 301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
424.21(c) Regulatory limits for restricted ingredients
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.10 Combination Product Labeling
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen hazard

HEAT TREATED NOT SHELF STABLE (03H)

PROMPT THREE

Prompt Description: Temperature not controlled by CCP.

Threshold: (number) observation during 03H01.

Vulnerable Points & Question(s) to Answer:

a.) Processing (mixing, formulating, grinding, breading, battering, tempering, molding, solution injection, rework, partial cooking, heating, smoking stabilization)

a. Does the establishment have adequate data (e.g., scientific research, in-house data) to support the heating step in the process?
b. Does the establishment control the heating step in the process?
c. Is rework and carry-over addressed in the Hazard Analysis?
d. Does the plant have controls in place to ensure cross contamination does not occur?
e. If the establishment has in-house testing of finished product or components, does the establishment follow their program and action limits when the results exceed their expected level?

b.) Storage/Shipping

a. Does the establishment have appropriate temperature controls in storage?
b. Does the establishment have adequate separation of the NRTE and RTE products in storage that are not fully packaged?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported 301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
424.21(c) Regulatory limits for restricted ingredients
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.10 Combination Product Labeling
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen hazard

HEAT TREATED NOT SHELF STABLE (03H)

PROMPT FOUR

Prompt Description: Labeling incorrect.

Threshold: (number) observation during 04B04.

Vulnerable Points & Question(s) to Answer:

a.) Packaging/Labeling

a. If the product has the appearance of being fully-cooked, does the label provide adequate handling instructions?
b. Are ingredients of public health concern (e.g., allergens) listed on the label?
c. Does the plant have a sketch approval or generic approval of label?
d. Is product labeled appropriately for combination beef and pork product labeling (318.10(b))?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for operational sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis decisions not supported 301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
424.21(c) Regulatory limits for restricted ingredients
424.22(a)(b) or (c) Restrictions of products that require labeling
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
381.10 Combination Product Labeling
417.5(a)(1) Hazard Analysis Decisions Not Supported
417.3(b) Unforeseen hazard

PRODUCT WITH SECONDARY INHIBITORS-NOT SHELF STABLE (03I)

PROMPT ONE

Prompt Description: Observe damaged or unwholesome product at receiving.

Threshold: (number) observation during 06D01, 01C02, 04C04, 04C03.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome and otherwise will not result in the product being adulterated?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? If no, follow-on questions: (b1) Does finished product have cooking instructions? (b2) Are validation data available for establishment's handling (cooking) instructions? (b3) Do handling instructions include microwave cooking? (b4) Does validation data show a testing over a variety of microwave wattages?
c. Does establishment reject and/or destroy returned products? If no, (c1) Does the establishment have appropriate controls for returned product (e.g., handling instructions if kept in control of the producer versus if out of control of the producer)?
d. Does establishment have adequate separation of NRTE and RTE products in storage?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
430 Control of Lm In Post-Lethality Exposed RTE Product
424.21(c) Regulatory Limits for Restricted Ingredients
424.22(a)(b) or (c) Restrictions of products that Require Labeling

PRODUCT WITH SECONDARY INHIBITORS-NOT SHELF STABLE (03I)

PROMPT TWO

Prompt Description: Positive pathogen results from Industry or FSIS testing or Total Plate Count above establishment action level.

Threshold: (number) observation during 03I01, 03I02.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome and otherwise will not result in the product being adulterated?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? If no, follow-on questions: (b1) Does finished product have cooking instructions? (b2) Are validation data available for establishment's handling (cooking) instructions? (b3) Do handling instructions include microwave cooking? (b4) Does validation data show a testing over a variety of microwave wattages?
c. Does establishment reject and/or destroy returned products? If no, (c1) Does the establishment have appropriate controls for returned product (e.g., handling instructions if kept in control of the producer versus if out of control of the producer)?
d. Does establishment have adequate separation of NRTE and RTE products in storage?

b.) Processing (mixing, formulating, grinding, tempering, battering, breading, molding, solution injection, rework, cooking, partial cooking, heating, smoking stabilization)

a. Does the establishment have adequate data (e.g.,, scientific research, in-house) to support the cooking or heating step in the process?
b. Does establishment control the heating step in the process?
c. Is rework and carry-over addressed in the Hazard Analysis?
d. Does the plant have controls in place to ensure cross contamination does not occur?
e. If establishment has in-house testing of finished product or components, does establishment follow their program and action limits when results exceed expected level?
f. If solutions are reused, are there control programs in place to control reuse?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
430 Control of Lm In Post-Lethality Exposed RTE Product
424.21(c) Regulatory Limits for Restricted Ingredients
424.22(a)(b) or (c) Restrictions of products that Require Labeling

PRODUCT WITH SECONDARY INHIBITORS-NOT SHELF STABLE (03I)

PROMPT THREE

Prompt Description: Temperature not controlled by CCP.

Threshold: (number) observation during 03I01.

Vulnerable Points & Question(s) to Answer:

a.) Receiving/Storage

a. Does establishment have measures to ensure materials received are clean, sound, healthful, wholesome and otherwise will not result in the product being adulterated?
b. Does plant have controls on the incoming amount of microbes on product, or adjust their processes according to incoming load? If no, follow-on questions: (b1) Does finished product have cooking instructions? (b2) Are validation data available for establishment's handling (cooking) instructions? (b3) Do handling instructions include microwave cooking? (b4) Does validation data show a testing over a variety of microwave wattages?
c. Does establishment reject and/or destroy returned products? If no, (c1) Does the establishment have appropriate controls for returned product (e.g., handling instructions if kept in control of the producer versus if out of control of the producer)?
d. Does establishment have adequate separation of NRTE and RTE products in storage?

b.) Processing (mixing, formulating, grinding, tempering, battering, breading, molding, solution injection, rework, cooking, partial cooking, heating, smoking stabilization)

a. Does the establishment have adequate data (e.g.,, scientific research, in-house) to support the cooking or heating step in the process?
b. Does establishment control the heating step in the process?
c. Is rework and carry-over addressed in the Hazard Analysis?
d. Does the plant have controls in place to ensure cross contamination does not occur?
e. If establishment has in-house testing of finished product or components, does establishment follow their program and action limits when results exceed expected level?
f. If solutions are reused, are there control programs in place to control reuse?

c.) Storage/Shipping

a. Does the establishment have appropriate temperature controls in storage?
b. Does the establishment have adequate separation of the NRTE and RTE products in storage that are not fully packaged?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
430 Control of Lm In Post-Lethality Exposed RTE Product
424.21(c) Regulatory Limits for Restricted Ingredients
424.22(a)(b) or (c) Restrictions of products that Require Labeling

PRODUCT WITH SECONDARY INHIBITORS-NOT SHELF STABLE (03I)

PROMPT FOUR

Prompt Description: Labeling Incorrect.

Threshold: (number) observation during 04B04.

Vulnerable Points & Question(s) to Answer:

a.) Packaging/Labeling

a. If product has appearance of being fully cooked, does label provide adequate instructions (e.g., cooking)?
b. Are ingredients of public health concern listed on the label (e.g., allergens)?
c. Does the plant have a sketch approval or generic approval of label?
d. Is product labeled appropriately for combination beef and pork product labeling (318.10(b))?
e. If the product has cooking instructions, does establishment have validation data?

Potential Regulatory Citation(s)

416.1 Failure to Maintain Sanitary Practices
416.4(d) Sanitation
416.13 – Implementation
416.13(c) SSOP for Operational Sanitation
416.14 Maintenance, Monitoring
417.5(a)(1) Hazard Analysis Decisions Not Supported
301.2 Adulteration/ Misbranding
381.1 Adulteration/ Misbranding
430 Control of Lm In Post-Lethality Exposed RTE Product
424.21(c) Regulatory Limits for Restricted Ingredients
424.22(a)(b) or (c) Restrictions of products that Require Labeling

PORK SLAUGHTER (O3J)

PROMPT ONE

Prompt Description: Positive microbiological results (FSIS or industry).

Threshold: (number) observation during 05B02, 03J01.

Vulnerable Points & Question(s) to Answer:

a.) Scalding/Dehairing/Gambreling

a. Does establishment have controls in place to maintain scald temperature and are they implementing these controls?

b.) Dehiding (for Sows and Boars)

a. Does establishment have controls in place to prevent contamination (Wash after bleeding prior to skinning)

c.) Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

b. Is the bunging equipment available adequate for the line speed?

d.) Carcass Opening/Evisceration

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

Potential Regulatory Citation(s)

417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(1) Hazard Analysis
416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

PORK SLAUGHTER (O3J)

PROMPT TWO

Prompt Description: Slaughter food safety standard for visible feces, ingesta and milk contamination.

Threshold: (number) observation during 03J.

Vulnerable Points & Question(s) to Answer:

a.) Live Receiving/Pen Holding

a. Does establishment have control measures to limit the amount of time swine are in holding pen? Are control measures being implemented?

b.) Dehiding (for Sows and Boars)

a. Does establishment have controls in place to prevent contamination (Wash after bleeding prior to skinning)

c.) Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

b. Is the bunging equipment available adequate for the line speed?

d.) Carcass Opening/Evisceration

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

Potential Regulatory Citation(s)

417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(1) Hazard Analysis
416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

PORK SLAUGHTER (O3J)

PROMPT THREE

Prompt Description: Hazard Analysis**,** SSOP and SPS NRs.

Threshold: (number) observation during 03J01, 01B02, 01C02, 06B01.

Vulnerable Points & Question(s) to Answer:

a.) Scalding/Dehairing/Gambreling

a. Does establishment have controls in place to maintain scald temperature and are they implementing these controls?

b.) Dehiding (for Sows and Boars)

a. Does establishment have controls in place to prevent contamination (Wash after bleeding prior to skinning)

c.) Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

b. Is the bunging equipment available adequate for the line speed?

d.) Carcass Opening/Evisceration

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?

Potential Regulatory Citation(s)

417.5(a)(1) Hazard Analysis Decisions Not Supported
417.2(a)(1) Hazard Analysis
416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

POULTRY SLAUGHTER (O3J)

PROMPT ONE

Prompt Description: Exceeding half the standard for *Salmonella* or exceeding the standard for *Campylobacter* and *Generic E. coli* (FSIS or industry data).

Threshold: (number) observation during 05B02, 03J01.

Vulnerable Points & Question(s) to Answer:

a.) Live Receiving and Hanging

a. Does the establishment have controls to reduce cross contamination and are they being implemented? (e.g., ventilation)
b. Does the establishment itself or though its corporation have best practices programs for pre-harvest and are they being implemented?
c. Is establishment implementing prerequisite programs at live receiving and hanging, as per their hazard analysis? Is there adequate supporting documentation?

b.) Stunning and Bleeding

a. Does the establishment have controls and are they being implemented to prevent contamination at stunning and bleeding?
b. Is the establishment implementing prerequisite programs at stunning, as per their hazard analysis? Is there adequate supporting documentation?

c.) Scalding

a. Does the establishment have control mechanisms to reduce the amount of dirt and organic matter entering the chiller and are they being implemented?
b. Does the establishment have controls to maintain the optimum pH levels to reduce Salmonella?
c. Does the establishment have controls to maintain water temperature effective to reduce micro-organisms?
d. Is the establishment implementing prerequisite programs at scalding, as per their hazard analysis? Is there adequate supporting documentation?

d.) Picking

a. Does the establishment have controls reduce micro-organisms at this step and are they being implemented?
b. Is the establishment implementing prerequisite programs at picking, as per their hazard analysis? Is there adequate supporting documentation?

e.) Evisceration/On Line Reprocessing

a. Does the establishment have controls to maintain equipment to accommodate changes in bird size?
b. Does the establishment have controls in place to prevent cross contamination and are they implemented (ventilation, employee hygiene, equipment)?
c. Does the establishment have controls in place and are they implemented to maintain conditions of use for interventions?
d. Is there evidence that the establishment controls and monitors parameters unique to its OLR system or other antimicrobial intervention to have an effective system that reduces micro-organisms?
e. Is establishment implementing prerequisite programs at evisceration/on line reprocessing, as per their hazard analysis? Is there adequate supporting documentation?

f.) **Chilling**

a. For all Chillers:
    i. Does the establishment have controls to maintain a high flow rate (a half a gallon per bird) or alternate method?
    ii. Does the establishment use red water reuse to reduce microorganisms as per (416 (g) (3)?
    iii. Does the establishment have controls and are they being implemented to maintain effective chiller temperature?
b. For air chilling
    i. Does establishment have controls to prevent microbial load increase during chilling?
c. If using chlorine in a chiller
    i. Does the establishment control an effective pH?
    ii. Does the establishment monitor the effective level of free chlorine?
d. Does the establishment control the effective level of the antimicrobial?
e. If using another antimicrobial (than chlorine) in a chiller:
    i. Is there evidence that the establishment monitors/controls the effective level of the antimicrobial?
f. Does the establishment have post chill interventions and are they monitoring the effective level of that antimicrobial?
g. Is establishment implementing prerequisite programs at chilling, as per their hazard analysis? Is there adequate supporting documentation?

g.) Packaging/Labeling

a. Is establishment implementing prerequisite programs at packaging and labeling, as per their hazard analysis? Is there adequate supporting documentation?

h.) Storage and Shipping

a. Does the establishment monitor conditions in storage areas that would cause adulteration of product (over spray, dripping water, etc.)?
b. Is establishment implementing prerequisite programs at storage and shipping, as per their hazard analysis? Is there adequate supporting documentation?

Potential Regulatory Citation(s):

416.1 Failure to maintain sanitary conditions
416.13 Failure to implement SSOP
417.5 (a) (1)&(2) decisions in hazard analysis not supported
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

POULTRY SLAUGHTER (O3J)

PROMPT TWO

Prompt Description: Exceeding the critical limit for Slaughter food safety standard for visible feces contamination.

Threshold: (number) observation during 03J.

Vulnerable Points & Question(s) to Answer:

a.) Scalding

a. Does the establishment have control mechanisms to reduce the amount of dirt and organic matter entering the chiller and are they being implemented?
b. Does the establishment have controls to maintain the optimum pH levels to reduce Salmonella?
c. Does the establishment have controls to maintain water temperature effective to reduce micro-organisms?
d. Is the establishment implementing prerequisite programs at scalding, as per their hazard analysis? Is there adequate supporting documentation?

b.) Evisceration/On Line Reprocessing

a. Does the establishment have controls to maintain equipment to accommodate changes in bird size?
b. Does the establishment have controls in place to prevent cross contamination and are they implemented (ventilation, employee hygiene, equipment)?
c. Does the establishment have controls in place and are they implemented to maintain conditions of use for interventions?
d. Is there evidence that the establishment controls and monitors parameters unique to its OLR system or other antimicrobial intervention to have an effective system that reduces micro-organisms?
e. Is establishment implementing prerequisite programs at evisceration/on line reprocessing, as per their hazard analysis? Is there adequate supporting documentation?

c.) Chilling

a. For all Chillers:
    iv. Does the establishment have controls to maintain a high flow rate (a half a gallon per bird) or alternate method?
    v. Does the establishment use red water reuse to reduce microorganisms as per (416 (g) (3)?
    vi. Does the establishment have controls and are they being implemented to maintain effective chiller temperature?
b. For air chilling
    ii. Does establishment have controls to prevent microbial load increase during chilling?
c. If using chlorine in a chiller
    iii. Does the establishment control an effective pH?
    iv. Does the establishment monitor the effective level of free chlorine?
d. Does the establishment control the effective level of the antimicrobial?
e. If using another antimicrobial (than chlorine) in a chiller:
    ii. Is there evidence that the establishment monitors/controls the effective level of the antimicrobial?

f. Does the establishment have post chill interventions and are they monitoring the effective level of that antimicrobial?
g. Is establishment implementing prerequisite programs at chilling, as per their hazard analysis? Is there adequate supporting documentation?

Potential Regulatory Citation(s):
416.1 Failure to maintain sanitary conditions
416.13 Failure to implement SSOP
417.5 (a) (1)&(2) decisions in hazard analysis not supported
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

POULTRY SLAUGHTER (O3J)

PROMPT THREE

Prompt Description: SSOP and SPS NRs –threshold to be determined.

Threshold: (number) observation during 03J01, 01B02, 01C02, 06B01.

Vulnerable Points & Question(s) to Answer:

a.) Scalding

a. Does the establishment have control mechanisms to reduce the amount of dirt and organic matter entering the chiller and are they being implemented?
b. Does the establishment have controls to maintain the optimum pH levels to reduce Salmonella?
c. Does the establishment have controls to maintain water temperature effective to reduce micro-organisms?
d. Is the establishment implementing prerequisite programs at scalding, as per their hazard analysis? Is there adequate supporting documentation?

b.) Evisceration/On Line Reprocessing

a. Does the establishment have controls to maintain equipment to accommodate changes in bird size?
b. Does the establishment have controls in place to prevent cross contamination and are they implemented (ventilation, employee hygiene, equipment)?
c. Does the establishment have controls in place and are they implemented to maintain conditions of use for interventions?
d. Is there evidence that the establishment controls and monitors parameters unique to its OLR system or other antimicrobial intervention to have an effective system that reduces micro-organisms?
e. Is establishment implementing prerequisite programs at evisceration/on line reprocessing, as per their hazard analysis? Is there adequate supporting documentation?

c.) Chilling

a. For all Chillers:
   vii. Does the establishment have controls to maintain a high flow rate (a half a gallon per bird) or alternate method?
   viii. Does the establishment use red water reuse to reduce microorganisms as per (416 (g) (3)?
   ix. Does the establishment have controls and are they being implemented to maintain effective chiller temperature?
b. For air chilling
   iii. Does establishment have controls to prevent microbial load increase during chilling?
c. If using chlorine in a chiller
   v. Does the establishment control an effective pH?
   vi. Does the establishment monitor the effective level of free chlorine?
d. Does the establishment control the effective level of the antimicrobial?
e. If using another antimicrobial (than chlorine) in a chiller:
   iii. Is there evidence that the establishment monitors/controls the effective level of the antimicrobial?
f. Does the establishment have post chill interventions and are they monitoring the effective level of that antimicrobial?

g. Is establishment implementing prerequisite programs at chilling, as per their hazard analysis? Is there adequate supporting documentation?

Potential Regulatory Citation(s):
416.1 Failure to maintain sanitary conditions
416.13 Failure to implement SSOP
417.5 (a) (1)&(2) decisions in hazard analysis not supported
416.1 Sanitary Dressing
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

BEEF SLAUGHTER (O3J)

PROMPT ONE

Prompt Description: One positive *E. coli* O157:H7in plant or traced back to facility (i.e., an MT04, MT03, MT50, MT53, MT54, MT43 sample being requested).

Threshold: observation during 05B02.

Vulnerable Points & Question(s) to Answer:

a.) Live Receiving/Pen Holding

a. Does establishment have processes in place to control incoming microbial loads? Are control measures being implemented?

b.) Head Skinning and Removal

a. Does establishment have controls in place to limit cross contamination? (e.g., SOP for knife switching or dipping) Are controls being implemented?
b. Does establishment have control measures for SRM? Are control measures being implemented?
c. Are heads washed in sanitary manner and are heads removed in sanitary manner? Knife trimming, steam vacuum?

c.) Rodding the Esophagus/Hoof Removal

a. Are there controls in place to prevent cross contamination during rodding and hoof removal? Are control measures being implemented?

d.) Skinning and Related Operations

a. Are there controls in place to prevent cross contamination from hide to skin? (Including aerosolization of contaminants) Are control measures being implemented?

e.) Evisceration & Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?
b. Does establishment have control measures in place to prevent cross contamination during evisceration? Are control measures being implemented?

f.) Head and Cheek Meat Processing

a. Does establishment have procedures in place to cool head and cheek meat as quickly as possible? Are control measures being implemented?
b. Does establishment have control measures to prevent cross contamination? Are control measures being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
310.22 SRM
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

BEEF SLAUGHTER (O3J)

PROMPT TWO

Prompt Description: Positive microbiological results (Generic *E. coli*, *Salmonella)* by FSIS or industry [More than one required if not adulterant].

Threshold: observation during 05B02, 03J01] 310.25(a) , 310.25(b).

Vulnerable Points & Question(s) to Answer:

a.) Live Receiving/Pen Holding

a. Does establishment have processes in place to control incoming microbial loads? Are control measures being implemented?

b.) Head Skinning and Removal

a. Does establishment have controls in place to limit cross contamination? (e.g., SOP for knife switching or dipping) Are controls being implemented?
b. Does establishment have control measures for SRM? Are control measures being implemented?
c. Are heads washed in sanitary manner and are heads removed in sanitary manner? Knife trimming, steam vacuum?

c.) Rodding the Esophagus/Hoof Removal

a. Are there controls in place to prevent cross contamination during rodding and hoof removal? Are control measures being implemented?

d.) Skinning and Related Operations

a. Are there controls in place to prevent cross contamination from hide to skin? (Including aerosolization of contaminants) Are control measures being implemented?

e.) Evisceration & Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?
b. Does establishment have control measures in place to prevent cross contamination during evisceration? Are control measures being implemented?

f.) Head and Cheek Meat Processing

a. Does establishment have procedures in place to cool head and cheek meat as quickly as possible? Are control measures being implemented?
b. Does establishment have control measures to prevent cross contamination? Are control measures being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
310.22 SRM
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

BEEF SLAUGHTER (O3J)

PROMPT THREE

Prompt Description: Slaughter food safety standard for visible feces, ingesta and milk contamination.

Threshold: observation during 03J.

Vulnerable Points & Question(s) to Answer:

.) Live Receiving/Pen Holding

a. Does establishment have processes in place to control incoming microbial loads? Are control measures being implemented?

b.) Head Skinning and Removal

a. Does establishment have controls in place to limit cross contamination? (e.g., SOP for knife switching or dipping) Are controls being implemented?
b. Does establishment have control measures for SRM? Are control measures being implemented?
c. Are heads washed in sanitary manner and are heads removed in sanitary manner? Knife trimming, steam vacuum?

c.) Rodding the Esophagus/Hoof Removal

a. Are there controls in place to prevent cross contamination during rodding and hoof removal? Are control measures being implemented?

d.) Skinning and Related Operations

a. Are there controls in place to prevent cross contamination from hide to skin? (Including aerosolization of contaminants) Are control measures being implemented?

e.) Evisceration & Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?
b. Does establishment have control measures in place to prevent cross contamination during evisceration? Are control measures being implemented?

f.) Head and Cheek Meat Processing

a. Does establishment have procedures in place to cool head and cheek meat as quickly as possible? Are control measures being implemented?
b. Does establishment have control measures to prevent cross contamination? Are control measures being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
310.22 SRM
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

BEEF SLAUGHTER (O3J)

PROMPT FOUR

Prompt Description: Hazard Analysis**,** SSOP, and SPS NRs. (threshold TBD)

Threshold: observation during 03J01, 01J02, 01C02, 06D01.

Vulnerable Points & Question(s) to Answer:

a.) Live Receiving/Pen Holding

a. Does establishment have processes in place to control incoming microbial loads? Are control measures being implemented?

b.) Rodding the Esophagus/Hoof Removal

a. Are there controls in place to prevent cross contamination during rodding and hoof removal? Are control measures being implemented?

c.) Skinning and Related Operations

a. Are there controls in place to prevent cross contamination from hide to skin? (Including aerosolization of contaminants) Are control measures being implemented?

d.) Evisceration & Bunging

a. Does establishment have control measures to prevent contamination during evisceration? Are control measures being implemented?
b. Does establishment have control measures in place to prevent cross contamination during evisceration? Are control measures being implemented?

e.) Head and Cheek Meat Processing

a. Does establishment have procedures in place to cool head and cheek meat as quickly as possible? Are control measures being implemented?
b. Does establishment have control measures to prevent cross contamination? Are control measures being implemented?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
310.22 SRM
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination

BEEF SLAUGHTER (O3J)

PROMPT FIVE

Prompt Description: Observed SRM at establishment or receiving establishment.

Threshold: observation during 03B01, 03B02.

Vulnerable Points & Question(s) to Answer:

a.) Storage/Shipping

a. Does plant have controls to remove SRMS before product shipped?

Potential Regulatory Citation(s):

416.1 Failure to Maintain Sanitary Dressing
416.13 Failure to implement SSOP
310.22 SRM
416.13 Implementation and Monitoring
310.18 (a) Prevent and Remove Contamination