

Public Health Risk-Based Inspection System
for
Processing and Slaughter

**Appendix B – Within Establishment Prompts,
Vulnerable Points and Questions**

April 18, 2008

Raw Not Ground (03B)

Prompt	Data Source	Threshold
1.) Exceeding half the <i>Salmonella</i> standard	FSIS or Industry Data	Single Occurrence
2.) Positive <i>E. coli</i> O157:H7	FSIS or Industry Data	Single Occurrence
3.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
4.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
5.) Adulterated Product	FSIS Form 8140-1 sent to establishment	Single Occurrence
6.) SRM Noncompliance	FSIS NR Data (Regulatory Citations 310.22(a), 310.22(b), 310.22(d)(2))	Single Occurrence
7.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 301.2, 318.1)	Single Occurrence

Table 1. Raw Not Ground (03B) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Exceeding half the <i>Salmonella</i> standard		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?

Table 2 . Prompt 1 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 2: Positive E. coli O157:H7		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?

Table 3. Prompt 2 Vulnerable Points and Questions for 03B In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 3: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?
Storage/ Shipping	Does the establishment have control measures in place to prevent microbial growth or contamination?	1.) Does the establishment monitor temperature during storage as called for in its HACCP or prerequisite program? 2.) Does the establishment monitor conditions in storage areas that would cause product adulteration (e.g. over spray, dripping water)?

Table 4. Prompt 3 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	<p>1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs?</p> <p>2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products?</p> <p>3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?</p>
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program?</p> <p>2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program?</p> <p>3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?</p>

Table 5. Prompt 4 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 5: Adulterated Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?
Storage/ Shipping	Does the establishment have control measures in place to prevent microbial growth or contamination?	1.) Does the establishment monitor temperature during storage as called for in its HACCP or prerequisite program? 2.) Does the establishment monitor conditions in storage areas that would cause product adulteration (e.g. over spray, dripping water)?

Table 6. Prompt 5 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 6: SRM Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure hazard analysis decisions regarding SRM continue to be supported?	1.) Is the establishment implementing control measures to ensure SRMs are not accepted in received products, if the hazard analysis concludes that SRMs will not be reasonably likely to occur in received products? 2.) Does the establishment implement control measures to identify and remove SRMs in received products as described in the HACCP, SSOP, or prerequisite program?

Table 7. Prompt 6 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points:

Prompt 7: Misbranded or Mislabeled Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Labeling	Is the product labeled appropriately for indented use?	1.) Does the product label have language on the display window to indicate it is not ready to eat?

Table 8. Prompt 7 Vulnerable Points and Questions for 03B. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at the vulnerable point: Label is False or Misleading [301.2(1)].

Raw Ground or Otherwise Comminuted (03C)

Prompt	Data Source	Threshold
1.) Exceeding half the <i>Salmonella</i> standard	FSIS or Industry Data	Single Occurrence
2.) Positive <i>E. coli</i> O157:H7	FSIS or Industry Data	Single Occurrence
3.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
4.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
5.) Adulterated Product	FSIS Form 8140-1 sent to establishment	Single Occurrence
6.) SRM Noncompliance	FSIS NR Data (Regulatory Citations 310.22(a), 310.22(b), 310.22(d)(2))	Single Occurrence
7.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 301.2, 318.1)	Single Occurrence

Table 9. Raw Ground or Otherwise Comminuted (03C) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Exceeding half the <i>Salmonella</i> standard		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?

Table 10 . Prompt 1 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 2: Positive <i>E. coli</i> O157:H7		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs? 2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products? 3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program? 2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program? 3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?

Table 11. Prompt 2 Vulnerable Points and Questions for 03C In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 3: HACCP Noncompliance		
Vulnerable Point	Question	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	<p>1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs?</p> <p>2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products?</p> <p>3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?</p>
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program?</p> <p>2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program?</p> <p>3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?</p>
Storage/ Shipping	Does the establishment have control measures in place to prevent microbial growth or contamination?	<p>1.) Does the establishment monitor temperature during storage as called for in its HACCP or prerequisite program?</p> <p>2.) Does the establishment monitor conditions in storage areas that would cause product adulteration (e.g. over spray, dripping water)?</p>

Table 12. Prompt 3 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Sanitation Noncompliance		
Vulnerable Point	Question	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	<p>1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs?</p> <p>2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products?</p> <p>3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?</p>
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program?</p> <p>2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program?</p> <p>3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?</p>

Table 13. Prompt 4 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 5: Adulterated Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure materials received are clean, sound, healthful, and wholesome?	<p>1.) Is the establishment monitor temperature at receiving and during storage as called for by its HACCP or prerequisite programs?</p> <p>2.) Does the establishment documentation follow its purchase specifications or prerequisite programs for incoming products?</p> <p>3.) Is the establishment monitoring the incoming microbial load on products as called for in its HACCP or prerequisite programs?</p>
Processing	Does the establishment have control measures in place to prevent microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment test product, equipment, or the processing area for microbiological indicator organisms as called for in its HACCP, SSOP, SPS or prerequisite program?</p> <p>2.) Does the establishment have measures in place to control product temperature during processing and rework as called for in its HACCP or prerequisite program?</p> <p>3.) Does the plant have control mechanisms in place to prevent pathogen cross contamination (e.g. liquid recirculation, clean up between suppliers, rework) as called for in its HACCP, SSOP, SPS or prerequisite program?</p>
Storage/ Shipping	Does the establishment have control measures in place to prevent microbial growth or contamination?	<p>1.) Does the establishment monitor temperature during storage as called for in its HACCP or prerequisite program?</p> <p>2.) Does the establishment monitor conditions in storage areas that would cause product adulteration (e.g. over spray, dripping water)?</p>

Table 14. Prompt 5 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 6: SRM Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Receiving/ Storage	Does the establishment have control measures in place to ensure hazard analysis decisions regarding SRMs continue to be supported?	1.) Is the establishment implementing control measures to ensure SRMs are not accepted in received products, if the hazard analysis concludes that SRMs will not be reasonably likely to occur in received products? 2.) Does the establishment implement control measures to identify and remove SRMs in received products as described in the HACCP, SSOP, or prerequisite program?

Table 15. Prompt 6 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points:

Prompt 7: Misbranded or Mislabeled Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Labeling	Is the product labeled appropriately for indented use?	1.) Does the product label have language on the display window to indicate it is not ready to eat?

Table 16. Prompt 7 Vulnerable Points and Questions for 03C. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at the vulnerable point: Label is False or Misleading [301.2(1)].

Thermally Treated / Commercially Sterile (03D) Example

Prompt	Data Source	Threshold
1.) Abnormal containers identified	FSIS NR Data (Regulatory Citations 417.5(a)(1), 318.309, 381.309)	Single Occurrence
2.) Multiple Process Deviation Noncompliances	FSIS NR Data (Regulatory Citations 417.3, 417.5 (a)(1), 318.308 or 381.308)	TBD*
3.) Multiple Canning Regulation Noncompliances	FSIS NR Data (Regulatory Citations 318.3 , 381.3)	TBD*
4.) Multiple Maintenance Deviations Identified By Plant	Industry Data	TBD*

Table 17. Thermally Treated / Commercially Sterile Prompts (03D). FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Abnormal Containers Identified		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Assembly	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the plant ensure that the product is prepared according to the formulation specified in the process schedule (e.g. pH, cure, water activity, viscosity)?</p> <p>2.) Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that the factors remain within the limits used to establish the process schedule?</p> <p>3.) Have all changes made to the process schedule in use been authorized?</p>
Thermal Processing and Cooling	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the establishment follow and meet its process schedule?</p> <p>2.) Does the establishment have measures in place to handle process deviations? Has the establishment detected all process deviations?</p> <p>3.) Does the establishment reprocess product with a process schedule authorized by the processing authority?</p>

Table 18. Prompt 1 Vulnerable Points and Questions for 03D. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify at vulnerable points that the establishment is in compliance with the following regulations: Critical Factors and the Application of the Process Schedule [318.303/381.303], Processing and Production Records [318.306/381.306], Deviation in Processing [318.308/381.308].

Prompt 2: Multiple Process Deviation Noncompliances		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Assembly	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the plant ensure that the product is prepared according to the formulation specified in the process schedule (e.g. pH, cure, water activity, viscosity)?</p> <p>2.) Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that the factors remain within the limits used to establish the process schedule?</p> <p>3.) Have all changes made to the process schedule in use been authorized?</p>
Thermal Processing and Cooling	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the establishment follow and meet its process schedule?</p> <p>2.) Does the establishment have measures in place to handle process deviations? Has the establishment detected all process deviations?</p> <p>3.) Does the establishment reprocess product with a process schedule authorized by the processing authority?</p>

Table 19. Prompt 2 Vulnerable Points and Questions for 03D. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify at vulnerable points that the establishment is in compliance with the following regulations: Critical Factors and the Application of the Process Schedule [318.303/381.303], Processing and Production Records [318.306/381.306], Deviation in Processing [318.308/381.308].

Prompt 3: Multiple Canning Regulation Noncompliances		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Assembly	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the plant ensure that the product is prepared according to the formulation specified in the process schedule (e.g. pH, cure, water activity, viscosity)?</p> <p>2.) Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that the factors remain within the limits used to establish the process schedule?</p> <p>3.) Have all changes made to the process schedule in use been authorized?</p>
Thermal Processing and Cooling	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the establishment follow and meet its process schedule?</p> <p>2.) Does the establishment have measures in place to handle process deviations? Has the establishment detected all process deviations?</p> <p>3.) Does the establishment reprocess product with a process schedule authorized by the processing authority?</p>

Table 20. Prompt 3 Vulnerable Points and Questions for 03D. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify at vulnerable points that the establishment is in compliance with the following regulations: Critical Factors and the Application of the Process Schedule [318.303/381.303], Processing and Production Records [318.306/381.306], Deviation in Processing [318.308/381.308].

Prompt 4: Multiple Maintenance Deviations Identified By Plant		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Assembly	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the plant ensure that the product is prepared according to the formulation specified in the process schedule (e.g. pH, cure, water activity, viscosity)?</p> <p>2.) Are the critical factors specified in the process schedule measured, controlled and recorded by the plant to ensure that the factors remain within the limits used to establish the process schedule?</p> <p>3.) Have all changes made to the process schedule in use been authorized?</p>
Thermal Processing and Cooling	Does the establishment have control measures in place to ensure process schedule is followed?	<p>1.) Does the establishment follow and meet its process schedule?</p> <p>2.) Does the establishment have measures in place to handle process deviations? Has the establishment detected all process deviations?</p> <p>3.) Does the establishment reprocess product with a process schedule authorized by the processing authority?</p>

Table 21. Prompt 4 Vulnerable Points and Questions for 03D. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify at vulnerable points that the establishment is in compliance with the following regulations: Critical Factors and the Application of the Process Schedule [318.303/381.303], Processing and Production Records [318.306/381.306], Deviation in Processing [318.308/381.308].

Not Heat Treated, Shelf Stable Product (03E)

Prompt	Data Source	Threshold
1.) Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product	FSIS or Industry Data	Single Occurrence
2.) Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product	FSIS or Industry Data	Single Occurrence
3.) Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product	FSIS or Industry Data	Single Occurrence
4.) Post Lethality Noncompliance	FSIS NR Data (Regulatory Citation 430)	Single Occurrence
5.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
6.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
7.) Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
8.) Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
9.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 318.1)	TBD*

Table 22. Not Heat Treated, Shelf Stable (03E) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Postive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework, as called for in its HACCP or prerequisite program?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture?</p>

Table 23. Prompt 1 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 2: Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 24. Prompt 2 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 3: Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture?</p>

Table 24. Prompt 3 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Post Lethality Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 25. Prompt 4 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 5: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 26. Prompt 5 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 6: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 27. Prompt 6 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], (b), Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 7: Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<ol style="list-style-type: none"> 1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth? 4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation? 5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program? 6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<ol style="list-style-type: none"> 1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality? 2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality? 3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?

Table 28. Prompt 7 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], (b), Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 8: Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 29. Prompt 8 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 9: Product Misbranded or Mislabeled		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Labeling	Is the product labeled appropriately for indented use?	1.) Are not ready to eat products labeled appropriately and does the label contain validated cooking instructions?

Table 30. Prompt 9 Vulnerable Points and Questions for 03E. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Label is False or Misleading [301.2(1)].

Heat Treated, Shelf Stable Product (03F)

Prompt	Data Source	Threshold
1.) Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product	FSIS or Industry Data	Single Occurrence
2.) Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product	FSIS or Industry Data	Single Occurrence
3.) Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product	FSIS or Industry Data	Single Occurrence
4.) Post Lethality Noncompliance	FSIS NR Data (Regulatory Citation 430)	Single Occurrence
5.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
6.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
7.) Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
8.) Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
9.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 318.1)	TBD*

Table 31. Heat Treated, Shelf Stable (03F) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program?</p> <p>4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program?</p> <p>6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program?</p> <p>7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?</p>

Table 32. Prompt 1 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 2: Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 33. Prompt 2 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 3: Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program?</p> <p>4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program?</p> <p>6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program?</p> <p>7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?</p>

Table 34. Prompt 3 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Post Lethality Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 35. Prompt 4 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 5: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program?</p> <p>4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program?</p> <p>6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program?</p> <p>7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 36. Prompt 5 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 6: Sanitation Noncompliance

Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program?</p> <p>4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program?</p> <p>6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program?</p> <p>7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 37. Prompt 6 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 7: Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program?</p> <p>4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program?</p> <p>6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program?</p> <p>7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 38. Prompt 7 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 8: Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<ol style="list-style-type: none"> 1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) If applicable, is the establishment using antimicrobials during marination as called for in its HACCP or prerequisite program? 4.) Does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation? 5.) During heating, does the establishment follow the time, temperature and humidity specifications called for in its HACCP or prerequisite program? 6.) Does the establishment verify the water activity post drying to demonstrate the product has met the moisture protein ratio called for in its HACCP or prerequisite program? 7.) If a post drying heat step is used, does the establishment follow the time and temperature limits identified in its HACCP plan or prerequisite program?
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<ol style="list-style-type: none"> 1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality? 2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality? 3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?

Table 39. Prompt 8 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 9: Product Misbranded or Mislabeled		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Labeling	Is the product labeled appropriately for indented use?	1.) Are not ready to eat products labeled appropriately and are validated cooking instructions provided?

Table 40. Prompt 9 Vulnerable Points and Questions for 03F. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Label is False or Misleading [301.2(1)].

Fully Cooked, Not Shelf Stable (03G)

Prompt	Data Source	Threshold
1.) Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product	FSIS or Industry Data	Single Occurrence
2.) Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product	FSIS or Industry Data	Single Occurrence
3.) Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product	FSIS or Industry Data	Single Occurrence
4.) Post Lethality Noncompliance	FSIS NR Data (Regulatory Citation 430)	Single Occurrence
5.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
6.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
7.) Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
8.) Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
9.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 318.1)	TBD*

Table 41. Fully Cooked, Not Shelf Stable (03G) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Postive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program? 4.) Is the establishment following the cooling model in its HACCP or prerequisite program?

Table 42. Prompt 1 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 2: Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 43. Prompt 2 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 3: Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program? 4.) Is the establishment following the cooling model in its HACCP or prerequisite program?

Table 44. Prompt 3 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Post Lethality Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 45. Prompt 4 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 5: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program?</p> <p>4.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 46. Prompt 5 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 6: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program?</p> <p>4.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 47. Prompt 6 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 7: Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program?</p> <p>4.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 48. Prompt 7 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 8: Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment meeting the temperature, time and humidity specifications during cooking called for in its HACCP and prerequisite program?</p> <p>4.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p> <p>3.) Is the establishment applying post lethality treatments as called for in its HACCP or prerequisite program (pasteurization, radiant heating, high pressure processing)?</p>

Table 49. Prompt 8 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 9: Product Misbranded or Mislabeled		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Labeling	Is the product labeled appropriately for indented use?	1.) Are products labeled appropriately as to whether they are RTE or NRTE (e.g. If product is labeled as RTE, did it undergo a lethality treatment?)

Table 50. Prompt 9 Vulnerable Points and Questions for 03G. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Label is False or Misleading [301.2(1)].

Heat Treated, Not Fully Cooked, Not Shelf Stable Product (03H)

Prompt	Data Source	Threshold
1.) Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product	FSIS or Industry Data	Single Occurrence
2.) Positive <i>Listeria monocytogenes</i> test result for Product	FSIS or Industry Data	Single Occurrence
3.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
4.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
5.) Recall of Non-Amenable Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
6.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 318.1)	TBD*

Table 51. Heat Treated, Not Fully Cooked Shelf stable (03H) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Postive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) Is the establishment implementing sanitation SOPs to prevent contamination during solution injection, if used? 4.) Is the establishment following the time and temperature limits in its HACCP or prerequisite program for slow partial cooking processes? 5.) Is the establishment following the cooling model in its HACCP or prerequisite program?

Table 52. Prompt 1 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 2: Positive <i>Listeria monocytogenes</i> test result for Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment implementing sanitation SOPs to prevent contamination during solution injection, if used?</p> <p>4.) Is the establishment following the time and temperature limits in its HACCP or prerequisite program for slow partial cooking processes?</p> <p>5.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>

Table 53. Prompt 2 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 2: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment implementing sanitation SOPs to prevent contamination during solution injection, if used?</p> <p>4.) Is the establishment following the time and temperature limits in its HACCP or prerequisite program for slow partial cooking processes?</p> <p>5.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>

Table 53. Prompt 2 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 3: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) Is the establishment implementing sanitation SOPs to prevent contamination during solution injection, if used?</p> <p>4.) Is the establishment following the time and temperature limits in its HACCP or prerequisite program for slow partial cooking processes?</p> <p>5.) Is the establishment following the cooling model in its HACCP or prerequisite program?</p>

Table 54. Prompt 3 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: Recall of Non-Amenable Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time) 2.) Does the establishment have measures in place to control microbial contamination from rework? 3.) Is the establishment implementing sanitation SOPs to prevent contamination during solution injection, if used? 4.) Is the establishment following the time and temperature limits in its HACCP or prerequisite program for slow partial cooking processes? 5.) Is the establishment following the cooling model in its HACCP or prerequisite program?

Table 55. Prompt 4 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 5: Product Misbranded or Mislabeled		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Labeling	Is the product labeled appropriately for indented use?	1.) Is the product labeled as Not Ready to Eat and does it contain validated cooking instructions?

Table 56. Prompt 5 Vulnerable Points and Questions for 03H. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Label is False or Misleading [301.2(1)].

Product with Secondary Inhibitors, Not Shelf Stable (03I)

Prompt	Data Source	Threshold
1.) Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product	FSIS or Industry Data	Single Occurrence
2.) Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product	FSIS or Industry Data	Single Occurrence
3.) Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product	FSIS or Industry Data	Single Occurrence
4.) Post Lethality Noncompliance	FSIS NR Data (Regulatory Citation 430)	Single Occurrence
5.) HACCP Noncompliance	FSIS NR Data (Regulatory Citations 417)	TBD*
6.) Sanitation Noncompliance	FSIS NR Data (Regulatory Citations 416 except 416.2, 416.6)	TBD*
7.) Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
8.) Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination	Manual Prompt by District	Single Occurrence
9.) Product Misbranded or Mislabeled	FSIS NR Data (Regulatory Citations 318.1)	TBD*

Table 57. Product with Secondary Inhibitors, Not Shelf Stable (03I) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Positive <i>Salmonella</i> or <i>E. coli</i> O157:H7 in RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>

Table 58. Prompt 1 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 2: Positive <i>Listeria monocytogenes</i> in Post Lethality Exposed RTE Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 59. Prompt 2 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 3: Positive <i>Listeria monocytogenes</i> test result for Non Post Lethality Exposed Product		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>

Table 60. Prompt 3 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 4: Post Lethality Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 58. Prompt 1 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 5: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 59. Prompt 5 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 6: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post Lethality Process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 60. Prompt 6 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], (b), Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 7: Recall of Non-Amenable, Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 61. Prompt 7 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 8: Recall of Non-Amenable, Non Post Lethality Exposed Product from Dual Jurisdictional Plant due to product contamination		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Processing	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Does the establishment have measures in place to control product ingredient temperature during processing, as called for in its HACCP or prerequisite program? (e.g. refrigeration, short processing time)</p> <p>2.) Does the establishment have measures in place to control microbial contamination from rework?</p> <p>3.) For salt cured product, does the establishment have controls in place to ensure salting, equalization, and drying/ripening reduce water activity to the level identified in its HACCP or prerequisite program to inhibit microbial growth?</p> <p>4.) For dry/semi dry product, does the establishment address the degree hours concept in its HACCP or prerequisite program and is it meeting the needed time, temperature and pH limits during fermentation?</p> <p>5.) For dry/semi dry product, does the establishment dry and store product for the length of time and at the temperature called for in its HACCP and prerequisite program?</p> <p>6.) For dry/semi dry product, does the establishment use a heat step for fermentation processes with a pH greater than 5, temperature lower than 70 degrees F, or no starter culture.</p>
Post lethality process	Does the establishment have control measures and are they being implemented as per the hazard analysis to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to control microbial contamination post lethality?</p> <p>2.) Is the establishment implementing its sanitation SOPs or prerequisite programs to programs to prevent cross contamination post lethality?</p> <p>3.) Does the establishment follow its HACCP or other program for following up on positive <i>Listeria monocytogenes</i> results on food contact surfaces or environmental samples?</p>

Table 62. Prompt 8 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the

establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}], Control of *Listeria monocytogenes* in Post Lethality Exposed Product [430.4(b)].

Prompt 9: Product Misbranded or Mislabeled		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Labeling	Is the product labeled appropriately for indented use?	Are not ready to eat products labeled appropriately and does the label contain validated cooking instructions?

Table 63. Prompt 9 Vulnerable Points and Questions for 03I. In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Label is False or Misleading [301.2(1)].

Poultry Slaughter (03J)

Prompt	Data Source	Threshold
1.) Exceeding half the standard for <i>Salmonella</i>	FSIS or Industry Data	Single Occurrence
2.) Exceeding the standard for Campylobacter	Future	Single Occurrence
3.) Exceeding the standard for Generic <i>E. coli</i>	Future	Single Occurrence
4.) Sanitation Noncompliance	FSIS NR Data (any 416 Regulatory Citation except 416.2, 416.6)	TBD*
5.) HACCP Noncompliance	FSIS NR Data (and 417 Regulatory Citation)	TBD*

Table 64. Poultry Slaughter (03J) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the slaughter process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Questions
Scalding	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment meeting the time, temperature, and water flow specifications for scalding in its HACCP or prerequisite program? 2.) Is the establishment controlling the pH level during scalding as called for in its HACCP or prerequisite program?
Evisceration	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment implementing its SSOPs at evisceration to prevent microbial contamination (e.g. equipment sterilization, employee hygiene practices)? 2.) Is the establishment implementing and monitoring interventions at evisceration as called for in its HACCP or prerequisite program (e.g. inside outside bird wash)? 3.) Does the establishment adjust equipment when necessary to accommodate changes in bird size?
Chilling	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment controlling the chiller temperature, water flow, chlorine level, and pH according to its HACCP or prerequisite program? 2.) Is the establishment using antimicrobials during chilling as called for in its HACCP or prerequisite program? 3.) Is the establishment applying post chill interventions as called for in its HACCP or prerequisite programs?

Table 65. Vulnerable Points and Questions for Poultry Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Swine Slaughter (03J)

Prompt	Data Source	Threshold
1.) Exceeding half the standard for <i>Salmonella</i>	FSIS or Industry Data	Single Occurrence
2.) Sanitation Noncompliance	FSIS NR Data (416 except 416.2, 416.6)	TBD*
3.) HACCP Noncompliance	FSIS NR Data (417 except 5(b) and 417.6)	TBD*

Table 66. Swine Slaughter (03J) Prompts. FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the slaughter process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Examples
Scalding, Dehairing, & Gambirling	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	<p>1.) Is the establishment meeting the time, temperature, and water flow specifications for scalding in its HACCP or prerequisite program?</p> <p>2.) Is the establishment implementing its sanitation SOPs for dehairing equipment in order to prevent cross contamination?</p> <p>3.) Does the establishment meet the temperature and water flow specifications for dehairing in its HACCP or prerequisite program?</p> <p>4.) Does the establishment meet the temperature specifications in its HACCP or prerequisite program during singeing?</p>
Dehiding (Sows and Boars Only)	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment implementing sanitation SOPs to prevent cross contamination during dehiding?
Bunging	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?
Carcass Splitting & Evisceration	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment implementing its SSOPs at carcass opening and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices)?
Final Wash	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment applying final wash interventions (e.g. antimicrobial wash, steam) as called for in its HACCP or prerequisite program?
Chilling	Does the establishment have control measures and are they being implemented to limit microbial contamination or to reduce microbial levels?	1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?

Table 67. Vulnerable Points and Questions for Swine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Bovine Slaughter (03J) Prompts

Prompt	Data Source	Threshold
1.) Exceeding half the standard for <i>Salmonella</i>	FSIS or Industry Data	Single Occurrence
2.) Positive <i>E. coli</i> O157:H7 test result	FSIS or Industry Data	Single Occurrence
3.) Positive O157:H7 traced to establishment	MT04, MT05, MT53, or MT43 Sample Request for Establishment	Single Occurrence
4.) HACCP Noncompliance	FSIS NR Data (Any 417 Regulatory Citation)	TBD*
5.) Sanitation Noncompliance	FSIS NR Data (416 except 416.2, 416.6 Regulatory Citation)	TBD*
6.) SRM Noncompliance	FSIS NR Data (310.22 Regulatory Citation)	Single Occurrence

Table 68. Bovine Slaughter Prompts (03J). FSIS' new information technology system will continuously monitor inspection findings and laboratory results and will direct inspectors to examine vulnerable points in the slaughter process when the threshold for the prompt is reached.

*Statistical analyses will be carried out using historical FSIS inspection and laboratory verification data to determine prompt thresholds.

Prompt 1: Exceeding half the standard for <i>Salmonella</i>		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Skinning	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during skinning? 2.) Is the establishment following its sanitation SOPs for skinning to prevent cross contamination (prevent aerosolization of microbes, equipment sanitization, employee hygiene)?
Rodding the Esophagus	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during rodding? 2.) Is the establishment following its sanitation SOPs for rodding to prevent contamination (equipment sanitization, tie off esophagus, employee hygiene)?
Bunging	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during bunging? 2.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?
Splitting & Evisceration	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during splitting and evisceration? 2.) Is the establishment implementing its SSOPs at carcass splitting and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices) ?
Chilling	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?
Head & Cheek Meat Processing	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment following its sanitation SOPs for head and cheek processing to prevent cross contamination (equipment sanitization, employee hygiene)? 2.) Does the establishment follow guidelines for head and cheek meat cooling after processing per its HACCP or prerequisite program?

Table 69. Prompt 1 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 2: Positive <i>E. coli</i> O157:H7 test result		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Skinning	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during skinning? 2.) Is the establishment following its sanitation SOPs for skinning to prevent cross contamination (prevent aerosolization of microbes, equipment sanitization, employee hygiene)?
Rodding the Esophagus	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during rodding? 2.) Is the establishment following its sanitation SOPs for rodding to prevent contamination (equipment sanitization, tie off esophagus, employee hygiene)?
Bunging	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during bunging? 2.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?
Splitting & Evisceration	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during splitting and evisceration? 2.) Is the establishment implementing its SSOPs at carcass splitting and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices) ?
Chilling	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?
Head & Cheek Meat Processing	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment following its sanitation SOPs for head and cheek processing to prevent cross contamination (equipment sanitization, employee hygiene)? 2.) Does the establishment follow guidelines for head and cheek meat cooling after processing as stated in its HACCP or prerequisite program?

Table 70. Prompt 2 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 3: Positive O157:H7 traced to establishment		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Skinning	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during skinning? 2.) Is the establishment following its sanitation SOPs for skinning to prevent cross contamination (prevent aerosolization of microbes, equipment sanitization, employee hygiene)?
Rodding the Esophagus	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during rodding? 2.) Is the establishment following its sanitation SOPs for rodding to prevent contamination (equipment sanitization, tie off esophagus, employee hygiene)?
Bunging	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during bunging? 2.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?
Splitting & Evisceration	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during splitting and evisceration? 2.) Is the establishment implementing its SSOPs at carcass splitting and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices) ?
Chilling	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?
Head & Cheek Meat Processing	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment following its sanitation SOPs for head and cheek processing to prevent cross contamination (equipment sanitization, employee hygiene)? 2.) Does the establishment follow guidelines for head and cheek meat cooling after processing as per its HACCP or prerequisite program?

Table 71. Prompt 3 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 4: HACCP Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Skinning	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during skinning? 2.) Is the establishment following its sanitation SOPs for skinning to prevent cross contamination (prevent aerosolization of microbes, equipment sanitization, employee hygiene)?
Rodding the Esophagus	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during rodding? 2.) Is the establishment following its sanitation SOPs for rodding to prevent contamination (equipment sanitization, tie off esophagus, employee hygiene)?
Bunging	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during bunging? 2.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?
Splitting & Evisceration	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during splitting and evisceration? 2.) Is the establishment implementing its SSOPs at carcass splitting and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices) ?
Chilling	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?
Head & Cheek Meat Processing	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	1.) Is the establishment following its sanitation SOPs for head and cheek processing to prevent cross contamination (equipment sanitization, employee hygiene)? 2.) Does the establishment follow guidelines for head and cheek meat cooling after processing as per its HACCP or prerequisite program?

Table 72. Prompt 4 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 5: Sanitation Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Skinning	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during skinning?</p> <p>2.) Is the establishment following its sanitation SOPs for skinning to prevent cross contamination (prevent aerosolization of microbes, equipment sanitization, employee hygiene)?</p>
Rodding the Esophagus	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during rodding?</p> <p>2.) Is the establishment following its sanitation SOPs for rodding to prevent contamination (equipment sanitization, tie off esophagus, employee hygiene)?</p>
Bunging	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during bunging?</p> <p>2.) Is the establishment implementing its SSOPs at bunging to prevent microbial contamination (e.g. bagging the bung or equipment sterilization) ?</p>
Splitting & Evisceration	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment implementing its HACCP, prerequisite, and sanitation SOPs to control the sanitary dressing process during splitting and evisceration?</p> <p>2.) Is the establishment implementing its SSOPs at carcass splitting and evisceration to prevent microbial contamination (e.g. equipment sterilization, 2 knife system, employee hygiene practices) ?</p>
Chilling	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment meeting the critical limits for chilling stated in its HACCP or prerequisite programs?</p>
Head & Cheek Meat Processing	Does establishment have control measures in place to prevent cross contamination and to limit microbial contamination?	<p>1.) Is the establishment following its sanitation SOPs for head and cheek processing to prevent cross contamination (equipment sanitization, employee hygiene)?</p> <p>2.) Does the establishment follow guidelines for head and cheek meat cooling after processing as per its HACCP or prerequisite program?</p>

Table 73. Prompt 5 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: Equipment and Utensils [416.3 (a)(b) or (c)], Sanitary Operations [416.4 (a)(b)(c) or (d)], Employee Hygiene [416.5 (a)(b)(c)], Implementation of SSOPs [416.13 (a)(b) or (c)], Maintenance of SSOPs [416.14], SSOP Corrective Actions [416.15 (a) or (b) {1}{2}{3}], Hazard Analysis and HACCP Plan [417.2 (a){1}{3} or (e)], HACCP Corrective Actions [417.3(b)], HACCP Validation, Verification Reassessment [417.4 (a){2} or (b)], HACCP Records [417.5 (a){1}{2}{3}].

Prompt 6: SRM Noncompliance		
Vulnerable Point	Question (Response Options: Yes, No, Information Not Available)	Guidance Example
Head & Cheek Meat Processing	Does the establishment have controls in place to ensure hazard analysis decisions regarding SRM continue to be supported?	1.) Is the establishment implementing control measures to ensure SRMs are handled appropriately as described in its the HACCP, SSOP, or prerequisite program?
Splitting & Evisceration	Does the establishment have controls in place to ensure hazard analysis decisions regarding SRM continue to be supported?	1.) Is the establishment implementing control measures to ensure SRMs are handled appropriately as described in its the HACCP, SSOP, or prerequisite program?
Storage & Shipping	Does the establishment have controls in place to ensure hazard analysis decisions regarding SRM continue to be supported?	1.) Is the establishment implementing control measures to ensure SRMs are handled appropriately as described in its the HACCP, SSOP, or prerequisite program?

Table 74. Prompt 6 Vulnerable Points and Questions for Bovine Slaughter (03J). In response to a prompt, Inspectors will be automatically assigned a for cause procedure by the information technology system which will instruct them to respond to the vulnerable point questions. Inspectors will verify the establishment is in compliance with the following regulations at vulnerable points: SRM Removal Procedures [310.22(d)(1)], SRM Corrective Action [310.22(d)(2)], SRM Procedure Evaluation [310.22(d)(3)].