

UNITED STATES DEPARTMENT OF AGRICULTURE
FOOD SAFETY AND INSPECTION SERVICE
WASHINGTON, DC

FSIS NOTICE

65-07

10/12/07

NOTICE OF REASSESSMENT FOR *ESCHERICHIA COLI* O157:H7 CONTROL AND COMPLETION OF A CHECKLIST FOR ALL BEEF OPERATIONS

NOTE: FSIS will be mailing one hardcopy of the full notice with attachments to the management official at the establishment and one to the Inspector-in-Charge (IIC). The IIC also will receive a CD copy of training material related to implementation of this notice.

I. PURPOSE

The purpose of this notice is to make inspection program personnel aware of a number of significant developments involving *Escherichia coli* O157:H7 (*E. coli* O157:H7) in beef products that occurred since the beginning of the high prevalence season for this pathogen in April. These developments raise questions about the adequacy of the interventions and controls that beef operations (i.e., official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting beef products such as with marinades) are employing to address this pathogen. Because these developments have come so swiftly, however, it seems likely that most establishments are not aware of the full extent of the problems evidenced by these developments. As a result, many establishments have not considered the implications of these developments for their Hazard Analysis and Critical Control Points (HACCP) systems.

This notice summarizes these significant developments and instructs inspection program personnel to meet with the establishment, to review the developments at that meeting, and to advise the establishment that these developments constitute changes that could affect the establishment's hazard analysis or cause the establishment to alter its HACCP plan. Inspection program personnel are to inform the establishment management that, given these facts, under 9 CFR 417.4(a)(3), it has an obligation to reassess its HACCP system to determine whether any changes are necessary in response to these developments (see Attachment 1). This notice also instructs inspection program personnel to determine what changes, if any, the establishment made on the basis of its reassessment. Inspection program personnel are to document their findings in the Responses to the Reassessment found in Attachment 3.

In addition, inspection program personnel at official establishments that slaughter,

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OPI: OPED

fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting beef products such as with marinades are to complete an on-line checklist on how the establishment addresses *E. coli* O157:H7 (see draft checklist Attachment 5). For the purposes of this notice, such establishments are considered beef operations. The section of the checklist titled "Raw Beef Food Safety System" identifies a set of best practice measures that, while not required, the Agency considers to be essential to controlling *E. coli* O157:H7. The remainder of the checklist describes known control measures and activities employed by beef operations that may affect the level of control employed by the establishment. FSIS is capturing all this information for each establishment and will use the information to determine targeted approaches for the risk-based verification testing program by FSIS and to assist in prioritizing the scheduling of Food Safety Assessments by the Enforcement, Investigation, and Analysis Officer (EIAO) in each District Office (DO).

Before inspection program personnel submit the online checklist to the Policy Analysis Division, Office of Policy, Program, and Employee Development (PAD/OPPED), they are to share a copy with a management official at the establishment. The management official will be given the opportunity to correct any response for which a change can be substantiated. If the Front-line Supervisor has concerns or changes to the checklist, it may be modified and re-submitted to PAD/OPPED. Also, periodically, FSIS will instruct inspection program personnel to review the checklist data and update it.

II. BACKGROUND

FSIS has issued two FR Notices since 2002 specifically mandating the reassessment of HACCP plans related to *E. coli* O157:H7 control measures. In October 2002, FSIS issued a FR Notice that outlined adulteration considerations regarding intact and non-intact beef products. This reassessment was a consequence of new scientific data identifying the increased prevalence of this pathogen on live cattle coming to slaughter and the results from FSIS' *E. coli* O157:H7 testing program since FSIS began using a new testing method. In addition, this 2002 FR Notice described at length the Agency's expectations regarding the appropriate use of prerequisite (or purchase specification) programs (see: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/00-022N.pdf> or for hard copy only Attachment 6 -- 67 FR 62325, October 7, 2002).

In May 2005, FSIS again issued a FR Notice that outlined adulteration considerations regarding mechanically tenderized and enhanced beef products. This 2005 FR Notice informed beef operations about three known outbreaks associated with such products (see: <http://www.fsis.usda.gov/OPPDE/rdad/FRPubs/04-042N.pdf> or for hard copy only Attachment 7 -- 70 FR 30331, May 26, 2005).

Beginning at least with the high prevalence season for *E. coli* O157:H7 in April 2007, some control measures for *E. coli* O157:H7 implemented by beef operations have proven to be inadequate. During this period, there has been an increased number of positives in Agency sampling for *E. coli* O157:H7, compared to the preceding three years, a couple of outbreaks attributed to this pathogen and beef products, and a number of large recalls. This situation requires a broad reassessment of how beef operations and FSIS are assessing this pathogen.

III. INSPECTION PROGRAM PERSONNEL RESPONSIBILITIES

A. Awareness Meeting

1. Within one week of receipt of the initial receipt of this notice, inspection program personnel at all beef operations are to conduct an awareness meeting with a management official of the establishment. At the meeting, inspection program personnel are to discuss:

a. the developments identified in Attachment 2, Developments That Support That There Is A Need For Establishments To Reassess Their HACCP Plans;

b. the documents referenced in this notice, including the Response to the Reassessment and the *E. coli* O157:H7 Checklist. Inspection program personnel are to inform the management that the *E. coli* O157:H7 Checklist (Attachment 5) is a draft of the checklist and there will be differences between it and the final version that will be completed by inspection program personnel; and

c. that the reassessment of the HACCP plan should be conducted by **October 26, 2007**.

2. Inspection program personnel are to prepare a memorandum of interview for the awareness meeting, documenting the following:

a. who was present at this initial awareness meeting;

b. the date and time of the meeting;

c. what was discussed, and

d. any documents that were shared with the management official.

3. Inspection program personnel are to maintain a copy of the memorandum in the official government file and provide a copy to the establishment management.

B. Verification Responsibilities

1. At the next weekly meeting after October 26, 2007, inspection program personnel are to ascertain whether and how the establishment reassessed. Inspection program personnel are to complete the questions in Attachment 3, Responses to the Reassessment, and submit the answers by no later than **November 2, 2007**.

2. Inspection program personnel are to complete the reassessment questions in

Attachment 3 in lieu of performing a food safety 01 or 02 procedure. To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment 4. Procedures for products with the lowest risk factor are to be replaced first.

3. Inspection program personnel are to save the answers to Attachment 3 in a Word document. Inspection program personnel are to maintain a copy of Responses to the Reassessment in the official government file, provide a copy to the establishment management, and, e-mail the Word document to:

a. the Front-line Supervisor,

b. District Analyst in the District Office, and

c. PAD/OPPED at: O157H7EstablishmentPractices@fsis.usda.gov or at: O157H7 Establishment Practices (found in Outlook).

NOTE: If inspection program personnel or the FLS have concerns regarding the reassessment, they may contact the DO. The DO will determine whether to schedule a Comprehensive Food Safety Assessment at the establishment.

4. OPPED will develop a summary report, by District, listing completed and pending Responses to the Reassessment and provide that to the OFO management for their follow up.

C. Completing *E. coli* O157:H7 Checklist

1. Although a draft copy of the checklist is Attachment 5, inspection program personnel are not to complete this checklist because there will be changes. Inspection program personnel are only to review this checklist to determine whether they have any questions. Inspection program personnel are to direct any questions to the Policy Development Division.

2. After inspection program personnel have reviewed the *E. coli* O157:H7 Checklist, they are to complete the training regarding the *E. coli* O157:H7 Checklist on the provided CD. Inspection program personnel are allotted up to two hours of 01 time to complete the training. After completing the training, inspection program personnel will take a test on Aglearn. The Resources Management Analyst will run a weekly training report for the Deputy District Managers to verify that inspection program personnel have completed the training.

3. Inspection program personnel will receive an email containing instructions for completing the checklist, an attached copy of the checklist in Word format that can be completed, printed and saved, and a link to an Intranet site where they are expected to complete the online checklist.

4. Inspection program personnel are first to complete the checklist in a Word document (**NOTE:** printing it and completing it on a printed hardcopy may be helpful because some of the information will be available only from reviewing records).

5. Inspection program personnel are to share a printed or electronic copy with the establishment management and provide them 48 hours to correct any responses for which it can substantiate the changes.

6. Inspection program personnel are to save the Word document and e-mail it to their District Analyst.

7. Inspection program personnel are to go to the provided link and enter the information from the completed checklist online for official submittal of the results.

NOTE: The instructions for the checklist will explain how to complete the checklist in multiple shift establishments.

8. Inspection program personnel are to complete steps 1-7 by **November 30, 2007**. Inspection program personnel are to use result code "U-Performed PE/Checklist" to indicate when they have completed the *E. coli* O157:H7 PERSEUS checklist in lieu of performing a food safety 01 or 02 procedure. To determine the product for which the scheduled 01 or 02 will not be performed, inspection program personnel are to use the chart in Attachment 4. Procedures for products with the lowest risk factor are to be replaced first.

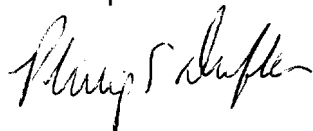
9. After completing the *E. coli* O157:H7 Checklist, inspection program personnel are to maintain a copy of it in the official government file and provide a copy to the establishment management.

10. Before **November 30, 2007**, Front-line Supervisors are to check that inspection program personnel have accurately completed the checklist. If the Front-line Supervisor finds inconsistencies in a checklist, he or she should contact PDD to discuss how to submit a revised checklist.

11. OPPED will have weekly reports developed by district, listing the establishments for which they have received completed *E. coli* O157:H7 checklists and establishments for which they have not received the checklist. OPPED will provide those weekly reports to OFO management.

12. Periodically, FSIS will instruct inspection program personnel to review the prior submitted checklist and to update it, if appropriate, and ensure that the updated information is submitted to PAD/OPPED.

Refer questions to the Policy Development Division at 1-800-233-3935.



Assistant Administrator
Office of Policy, Program, and Employee Development

Sec. 417.4 Validation, Verification, Reassessment.

(a) Every establishment shall validate the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis, and shall verify that the plan is being effectively implemented.

(1) Initial validation. Upon completion of the hazard analysis and development of the HACCP plan, the establishment shall conduct activities designed to determine that the HACCP plan is functioning as intended. During this HACCP plan validation period, the establishment shall repeatedly test the adequacy of the CCP's, critical limits, monitoring and recordkeeping procedures, and corrective actions set forth in the HACCP plan. Validation also encompasses reviews of the records themselves, routinely generated by the HACCP system, in the context of other validation activities.

(2) Ongoing verification activities. Ongoing verification activities include, but are not limited to:

- (i) The calibration of process-monitoring instruments;
- (ii) Direct observations of monitoring activities and corrective actions; and

(iii) The review of records generated and maintained in accordance with Sec. 417.5(a)(3) of this part.

(3) Reassessment of the HACCP plan. Every establishment shall reassess the adequacy of the HACCP plan at least annually and whenever any changes occur that could affect the hazard analysis or alter the HACCP plan. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; personnel; packaging; finished product distribution systems; or, the intended use or consumers of the finished product. The reassessment shall be performed by an individual trained in accordance with Sec. 417.7 of this part. The HACCP plan shall be modified immediately whenever a reassessment reveals that the plan no longer meets the requirements of Sec. 417.2(c) of this part.

(b) Reassessment of the hazard analysis. Any establishment that does not have a HACCP plan because a hazard analysis has revealed no food safety hazards that are reasonably likely to occur shall reassess the adequacy of the hazard analysis whenever a change occurs that could reasonably affect whether a food safety hazard exists. Such changes may include, but are not limited to, changes in: raw materials or source of raw materials; product formulation; slaughter or processing methods or systems; production volume; packaging; finished product distribution systems; or, the intended use or consumers of the finished product.

Developments That Support That There Is A Need For Establishments To Reassess Their HACCP Systems

A. Adverse trend in percent positive rate in FSIS verification testing

1. FSIS monitors the percent positive rate (i.e., the percentage of raw ground beef samples analyzed by FSIS that are found positive for *E. coli* O157:H7). In addition, FSIS has established a maximum target percent positive rate of 0.200% at any time in the calendar year (CY) or fiscal year (FY). Generally, FSIS reports the percent positive rate in two ways. For the public, FSIS has reported a CY status at the end of the CY. For internal budget considerations, FSIS reports the percent positive rate on a FY quarter and annual basis. FSIS believes that by tracking the day-to-day changes in the percent positive rate, whether by CY or FY, the data provide useful indications about changes in beef operations. In addition, FSIS uses these data to measure changes in the degree of control exerted by beef operations for ensuring that *E. coli* O157:H7 is non-detectable in verification samples collected by FSIS.

2. In CY2002, the percent of positive rate from raw ground beef samples collected by FSIS in Federal plants, retail stores, and at import houses was 0.787% (55 positives in 6,986 samples). Thereafter, there was a remarkable decrease in the percent positive rate for similarly collected samples. In CY2003, the percent positive rate dropped to 0.305% (20 positives in 6,553 samples, albeit slightly fewer samples than the prior CY). Since then through CY2006, there has been a persistent decrease in the percent positive rate even with a steady increase in the number of similar samples analyzed. Moreover, the maximum target percent positive rate of 0.200% has not been exceeded in any of the recent prior CYs.

3. However, thus far in CY2007, through October 10, 2007, FSIS found 20 *E. coli* O157:H7 positive samples, compared to twenty positive results for the entire CY06, as of today, the percent positive rate is 0.208. The last year that the percent positive rate exceeded the maximum percent positive target rate was CY2003. This uptick in the percent positive rate is cause for concern.

B. Unusual number of positive samples in a short span of time

In July 2007, FSIS found five positives in a span of three days. There was no linkage amongst the samples and no evidence of FSIS laboratory contamination. This is believed to be a rare event in the 13 year history of verification testing by FSIS for this pathogen. This finding presents a basis for concern that the control measures implemented by beef operations may not be adequate to address the degree of contamination by *E. coli* O157:H7.

C. Increased number of recalls associated with *E. coli* O157:H7

1. For CY2007 through October 6, 2007, FSIS already has requested 13 recalls involving about 29 million pounds of product associated with *E. coli* O157:H7. In contrast, there were eight recalls involving less than 200,000 pounds of product associated with *E. coli* O157:H7 for the entire CY2006.

2. FSIS compiled the factors that apparently contributed to the recalls of CY2007. Consistently, these establishments relied upon faulty decisions that did not fully account for the expectations noted by FSIS in either the October 2002 or May 2005 reassessments. The decision that were not sufficiently supported under 9 CFR 417.5, in one or more of the recent recalls, included:

a. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in incoming beef without demonstrating the on-going effectiveness of the prerequisite program upon which this decision was based (e.g., not consistently testing incoming or finished product; not requiring incoming product to be tested using a consistent sampling design among all suppliers; and not demonstrating that the source material or the finished product would meet a standard of non-detectable for *E. coli* O157:H7 through production lot-specific Certificates of Analysis (COAs)).

b. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in raw ground beef even though "bench trim," the boneless manufacturing trimmings generally derived from the sizing of primal/sub-primal cuts (steaks and roasts), was used as a component in the manufacture of raw ground beef; the primal/sub-primal cuts were not handled in the same manner as boneless manufacturing trimmings (i.e., verification of the effective application of antimicrobial treatments was not conducted nor was the primal/sub-primal cut or the bench trim derived from the primal/sub-primal cut tested for *E. coli* O157:H7 using any verification testing protocol before or after grinding).

c. identification of *E. coli* O157:H7 as a hazard not reasonably likely to occur in primal/sub-primal cuts intended for use in a mechanical tenderization process, and neither the primal/sub-primal cuts nor the derived bench trim were handled in a manner designed to ensure that *E. coli* O157:H7 was non-detectable.

D. Increased number of recalls specifically initiated as a consequence of human illness

As of October 6, 2007, of the 13 recalls related to *E. coli* O157:H7 in CY2007, 7 of these were initiated because of their association with human illness. FSIS recognizes the Healthy People 2010 food safety objective for *E. coli* O157:H7 infections (now referred to as shiga toxin-producing *E. coli* O157 or STEC O157 infections) as the public health goal. The 1997 baseline was 2.1 laboratory confirmed cases per 100,000 humans, while the 2010 target is 1.0 case per 100,000 humans. The most current result, represented by CY2006 FoodNet data, is 1.31 infections per 100,000 humans. This is up from 1.06 in 2005 and 0.90 in 2004, which was the only year in which the 2010 target was met. Since 2004, has been an adverse trend above the Healthy People 2010 target despite the FSIS percent positive rate achievements. Now that the CY2007 current percent positive rate is at or above the maximum target percent positive

rate, these apparent upticks are cause for significant concern.

E. Repetitive implication of certain source materials used in the production of ground beef found by FSIS to be positive for *E. coli* O157:H7 or involved in recalls:

1. In March, FSIS began testing boneless manufacturing trimmings. In addition, the Agency began tracking which components used in the production of raw ground beef were included in each production lot of ground beef tested by FSIS and found to be positive for *E. coli* O157:H7. Whenever one of these raw ground beef components was identified as part of the production lot found to be contaminated with *E. coli* O157:H7, FSIS conducted follow-up testing for that specific component, but only on a limited basis. Moreover, in recent recalls involving *E. coli* O157:H7, beef products other than boneless manufacturing trimmings were implicated.

2. Components beyond the traditional boneless manufacturing trimmings include: Two-piece chuck (a primal/sub-primal cut); head meat; cheek meat; weasand meat; heart meat; low temperature rendered beef (also referred to as lean finely textured beef); “specially handled beef” (a product treated with an antimicrobial and designated for grinding at retail via a purchase specification arrangement with the retailer); and meat from advanced meat recovery systems (AMR).

3. Based on this information, FSIS has reason to believe that establishments are not effectively ensuring that *E. coli* O157:H7 is adequately controlled at the slaughter and fabrication operations (i.e., suppliers to grinders). This development is cause for significant concern.

RESPONSES TO THE REASSESSMENT

Inspection program personnel are to answer the following questions as either yes or no and then provide specific and brief information where requested. Inspection program personnel are to obtain answers to these questions by reviewing the establishment's food safety system records.

1. Did the establishment reassess its HACCP plan(s) based on the developments as set out in section III above:

Yes ___ **No** ____

2. Did the establishment change its HACCP plans as a result of the reassessment:

Yes ___ **No** ____

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

3. Did the establishment change its Sanitation SOP(s) as a result of the reassessment.

Yes ___ No ___

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

4. Did the establishment change its other prerequisite programs as a result of the reassessment.

Yes ___ No ___

a. If yes, describe the change.

b. If no, provide the establishment's reason for not making a change.

5. To the best of your ability, estimate how long it took to complete these questions?

E. coli* O157:H7 Checklist*FOR REVIEW PURPOSES ONLY.**

NOTE: This is a draft of the checklist, and there will be differences between it and the final version.

FSIS is collecting information on the control measures for Escherichia coli O157 (E. coli O157:H7) beef operations (i.e., official establishments that slaughter, fabricate, grind, mechanically tenderize, or enhance by tumbling, massaging, or injecting solutions such as marinades) use during the production of raw beef product. The Agency will use the information for a number of purposes, including:

- To identify those beef operations that are not employing certain **INTERRELATED** practices that FSIS has identified as being established as directly contributing to control of this pathogen (designated as “BP” for “best practices” in the section of the checklist titled “B-Raw Beef Food Safety System”). See the compliance guidelines included on the FSIS significant guidance documents web page at:

http://www.fsis.usda.gov/OPPDE/rdad/fsisdirectives/10010_1/ecolio157h7dirguid4-13-04.pdf

While control is certainly possible through use of other measures, because FSIS is not as familiar with other practices that might be employed, it will make review of these other measures by an EIAO a priority;

- To capture production practices used by the establishment to control for E. coli O157:H7, and to identify vulnerabilities in the design of the establishment’s food safety system;
- To help prioritize whether and when a food safety assessment should be conducted at the establishment; and
- To inform the design and development of the Agency’s risk-based verification testing program by ascertaining which establishments to target for more frequent testing.

Before completing the checklist, inspection program personnel should review the training materials on the checklist, particularly as they pertain to the use of prerequisite (purchase specification) programs.

In completing the checklist, please refer to the food safety system on file at the establishment. Complete the checklist for each beef operation establishment. For establishments with multiple shifts in which the production practices differ from one shift to the next, inspection program personnel from each shift should complete the checklist and identify which shift the checklist pertains to.

Periodically, FSIS will ask inspection program to review the responses to the checklist and update the responses, if necessary, to best reflect the production practices employed by the establishment,

Definition: **Robust testing** means that the following features are part of the written program defining how raw beef samples are collected and analyzed:

- For samples capable of excision testing, N-60 represents 375 grams or more of thinly sliced exterior surface tissue (60 slices derived from trim in 5 combo bins/units -- 12 thin slices of exterior surface material from each combo bin/unit); a 375 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method
- For samples not capable of excision testing (e.g., comminuted product), a composite sample is collected representing all units from a specified time period (10-30 minutes for continuous testing; one sample from the entire production lot; grab samples from each /unit); at least a 65 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method

DRAFT

A-ESTABLISHMENT INFORMATION

Establishment information. Please provide the following information. Please enter the establishment information in the following formats: For the date: dd/mm/yyyy; for the establishment number: 00000 M.

Today's date, when the completed checklist is ready to submit: _____

Establishment number: _____

Shift number(s)—mark all that apply if all shifts operate the same: _____

Your name: _____

Was a management official at the establishment provided an opportunity to review the checklist responses:

- Yes
- No
- Don't know

Did the Frontline Supervisor review the checklist responses:

- Yes
- No
- Don't know

To the best of your ability, how long did it take to complete the entire checklist?

B-RAW BEEF FOOD SAFETY SYSTEM

FoodSafetySystem1. What activity does the establishment conduct that may result in product being used as a component in raw ground beef product? Check all that apply.

- Slaughtering
- Fabricating
- Grinding
- Mechanical tenderizing (blade, needle, pounding, pins, other mechanical device to tenderize)
- Enhancing (tumbling, massaging, or injecting solutions such as marinade)
- Other (explain with short description): _____

FoodSafetySystem2. For which raw beef HACCP processing categories does the establishment have a hazard analysis? Check all that apply.

- Slaughter -- (BP) (03J)
- Raw product—ground -- (BP) (03B)
- Raw product—not ground -- (BP) (03C)
- Product with secondary inhibitors—not shelf stable (explain with short description) -- (BP): _____

FoodSafetySystem3. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the slaughter HACCP processing category?

- Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level -- (BP)
- No
- Don't know

FoodSafetySystem4. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the raw product--ground HACCP processing category?

- Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level, and robust testing on finished product -- (BP)
- No
- Don't know

FoodSafetySystem5. Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely to occur in the raw product—not ground HACCP processing category?

- Yes, with a CCP to prevent, eliminate, or reduce to non-detectable level, and robust testing on production lots containing co-mingled finished product (e.g. combo bins of 2-piece chucks), as well as on production lots containing non-co-mingled primal/sub-primal intended for use as non-intact product -- (BP)
- No
- Don't know

FoodSafetySystem6. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the slaughter HACCP processing category?
 Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing
 No
 Don't know

FoodSafetySystem7. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the raw product--ground HACCP processing category?
 Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing – (BP)
 No
 Don't know

FoodSafetySystem8. Does the establishment specifically identify *E. coli* O157:H7 as a hazard **not** reasonably likely to occur in the raw product—not ground HACCP processing category?
 Yes, with a written sanitation SOP or other prerequisite (purchase specification) program that includes robust testing – (BP)
 No
 Don't know

FoodSafetySystem9. Does the establishment specifically require a statement (e.g., Certificate of Analysis) from all supplying establishments identifying that at least one validated intervention was effectively applied as intended and as a CCP in the HACCP plan?
 Yes, for every production lot received, without exception -- (BP)
 No
 Don't know

FoodSafetySystem10. Does the establishment specifically require a statement from the supplying establishment stating that the production lot was tested using a robust testing methodology and found to be negative for *E. coli* O157:H7?
 Yes, for every production lot received from every supplier, including in-house generated source material, without exception -- (BP)
 No
 Don't know

FoodSafetySystem11. Does the establishment specifically conduct on-going verification testing in in-coming product for each supplier at a higher frequency during the high prevalence season (April through September) versus the lower frequency months, and collect no fewer than four tests annually for each supplier?

- Yes -- (BP)
- No
- Don't know

FoodSafetySystem12. Does the establishment specifically conduct on-going verification testing of all finished product at least quarterly (e.g., N-60 or composite testing, as appropriate, with proportionally more frequent testing in the high prevalence season months and for the more frequent suppliers)?

- Yes -- (BP)
- No
- Don't know

FoodSafetySystem13. Does the establishment specifically identify the use of an annual third party audit based on their written program requirements?

- Yes, every supplier at least once annually -- (BP)
- No
- Don't know

C-ESTABLISHMENT CATEGORY

EstabCategory1. Please select the specific beef operations conducted at your establishment from the list below (check all that apply).

- Slaughter
- Head meat production
- Cheek meat production
- Weasand meat production
- Heart meat production
- Advanced meat recovery (AMR) production
- Low temperature rendered lean finely textured beef
- Partially defatted beef fatty tissue
- Partially defatted chopped beef
- Fabrication of primal/sub-primal cuts
- Bench trim production
- Mechanical blade tenderizing
- Mechanical needle tenderizing
- Mechanical tenderizing by pounding
- Fabricated steak
- Enhancing (tumbling, massaging, or injecting solutions such as marinade)
- Regrind coarse ground product
- Grinding boneless manufacturing trimmings or other raw ground beef components
- Patty forming

EstabCategory2. What is the volume of production of each type of product produced (NOTE: Obtain the poundage for the 3 most recent production lots of this type of product produced and record the three figures separately (e.g., use records from the pre-shipment review to obtain the poundage for each production lot; record the poundage and the specifics about the records that were used so that the poundage figure can be verified later, if asked; keep a copy of the on file with this checklist in the government office).

- | | | | |
|----|----|----|----------------------------------------------------------------|
| 1. | 2. | 3. | Head meat production |
| 1. | 2. | 3. | Cheek meat production |
| 1. | 2. | 3. | Weasand meat production |
| 1. | 2. | 3. | Heart meat production |
| 1. | 2. | 3. | Advanced meat recovery (AMR) production |
| 1. | 2. | 3. | Low temperature rendered lean finely textured beef |
| 1. | 2. | 3. | Partially defatted beef fatty tissue |
| 1. | 2. | 3. | Partially defatted chopped beef |
| 1. | 2. | 3. | Fabrication of primal/sub-primal cuts |
| 1. | 2. | 3. | Bench trim production |
| 1. | 2. | 3. | Mechanical blade tenderizing |
| 1. | 2. | 3. | Mechanical needle tenderizing |
| 1. | 2. | 3. | Mechanical tenderizing by pounding |
| 1. | 2. | 3. | Fabricated steak |
| 1. | 2. | 3. | Enhancing (tumbling, massaging, or injecting solutions such as |

marinade)

1. 2. 3. Regrind coarse ground product

1. 2. 3. Grinding boneless manufacturing trimmings or other raw ground beef components

1. 2. 3. Patty forming

EstabCategory3. What is the *estimated* volume of production of this type of product produced in a *day* for the shift you are reporting on? (NOTE: Make a note of how the estimated volume was derived, identifying the assumptions you made in coming up with this figure; keep a copy of the calculation on file with this checklist in the government office).

____ Slaughter (cattle slaughtered)

____ Head meat production

____ Cheek meat production

____ Weasand meat production

____ Heart meat production

____ Advanced meat recovery (AMR) production

____ Low temperature rendered lean finely textured beef

____ Partially defatted beef fatty tissue

____ Partially defatted chopped beef

____ Fabrication of primal/sub-primal cuts

____ Bench trim production

____ Mechanical blade tenderizing

____ Mechanical needle tenderizing

____ Mechanical tenderizing by pounding

____ Fabricated steak

____ Enhancing (tumbling, massaging, or injecting solutions such as marinade)

____ Regrind coarse ground product

____ Grinding boneless manufacturing trimmings or other raw ground beef components

____ Patty forming

D-BEEF GRINDING

BeefGrind1. If the establishment applies any validated intervention on the ground product, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

BeefGrind2. Does the establishment test source materials for *E. coli* O157:H7 prior to grinding? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60 or comminuted)
- Other than robust testing (please specify): _____
- Don't know

BeefGrind3. Does the establishment test the finished ground beef for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (comminuted)
- Other than robust testing (please specify): _____
- Don't know

BeefGrind4. What method does the establishment's laboratory use to test ground beef or finished product for *E. coli* O157:H7?

- FSIS method
- Other (please specify): _____
- Don't know

BeefGrind5. How does the establishment group source materials into lots for grinding?

- Based on 5 combo bins/units
- Based on combo bins/units from one supplier
- Based on combo bins/units from suppliers that use validated intervention methods
- All combo bins/units received in one day
- Others, please specify: _____
- Don't know

BeefGrind6. Approximately how many suppliers of trim or other raw ground beef components has the establishment used in the last 30 days?

- Only from its own slaughter plant
- 1, from other slaughter plant
- 2-3
- 4-6
- More than 6
- Don't know

BeefGrind7. Does the establishment use any of the following raw ground beef components in producing ground beef products? If yes, check all that apply.

- Boneless manufacturing trimmings
- Bench trim from fabricated primal/sub-primal cuts
- Bench trim from mechanically tenderized or enhanced primal/subprimal cuts
- Primal/sub-primal cuts not categorized as boneless manufacturing trimmings (e.g., not specifically intended for grinding)
- Head meat
- Cheek meat
- Weasand meat
- AMR (Advanced meat recovery) product
- Low temperature rendered LFTB (lean finely textured beef)
- Low temperature rendered PDCB (partially defatted chopped beef)
- Low temperature rendered PDBFT (partially defatted beef fatty tissue)
- Others (please specify): _____
- None of the above
- Don't know

BeefGrind8. Does the establishment knowingly use imported coarse or finely ground beef to produce ground beef products? If yes, check all that apply.

- No
- Every production day
- Weekly
- Monthly
- Intermittently
- Others (please specify): _____
- Don't know

BeefGrind9. Does the establishment knowingly use imported raw ground beef components other than coarse or finely ground beef to produce ground beef products? If yes, check all that apply.

- No
- Every production day
- Weekly
- Monthly
- Intermittently
- Others (please specify): _____

Don't know

BeefGrind10. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

- No
- Receipt of source materials
- Grinding
- Storage
- Distribution
- Others (please specify): _____
- Don't know

BeefGrind11. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

- After grinding trim or other raw ground beef components from each supplier
- After grinding trim or other raw ground beef components from a group of suppliers
- After a sample is collected for *E. coli* O157:H7 testing
- After each shift
- Daily after production
- Less than daily (extended clean-up)
- Other (please specify): _____
- Don't know

BeefGrind12. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Beef trim
- Ground beef product
- Grinding equipment
- Processing area
- Other (please specify): _____
- Don't know

BeefGrind13. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?

- Yes
- No
- Don't know

E-BEEF TIM FABRICATION

BeefTrimFab1. Does the establishment use one or more of the following cross-contamination controls? If yes, check all that apply.

- Sanitation of knives and sharpening steels
- Formulate trim and other raw ground beef components from a sole supplier into the creation of individual production lot
- Formulate trim and other raw ground beef components from multiple suppliers into the creation of individual production lots
- Formulate production lots that contains only source material treated to reduce *E. coli* O157:H7 to a non-detectable level (e.g., gaseous ammonia, irradiation)
- Formulate production lots that contain combinations of source material treated to reduce *E. coli* O157:H7 and source materials not treated to reduce *E. coli* O157:H7
- None of the above
- Don't know

BeefTrimFab2. Does the establishment have documented monitoring and verification procedures of the carcass surface temperature maintained below 45 degrees Fahrenheit within 24 hours of slaughter?

- Yes
- No
- Don't know

BeefTrimFab3. Does the establishment apply any validated intervention method, identified in a CCP in the HACCP plan, on the trim and any other raw ground beef component? If yes, check all that apply.

- No
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Gaseous ammonia
- Irradiation
- Other (please specify): _____
- Don't know

BeefTrimFab4. Does the establishment test all trim and other raw ground beef components for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (comminuted)
- Other than robust testing (please specify): _____
- Test purge from one or more combo bins/units
- Don't know

BeefTrimFab5. Does the establishment use mechanical tenderization methods on

intact beef and use any of this material (e.g., rejects) or the bench trim as a component in raw ground beef?

- Yes
- No
- Don't know

BeefTrimFab6. Does the establishment produce “*specialty handled beef manufacturing trimmings*” in this establishment for direct sale and use as ground beef at retail, through a purchase specification arrangement with the retailer?

- Yes
- No
- Don't know

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F-BEEF SLAUGHTER

BeefSlaughter1. Does the establishment apply any of the following decontamination procedures to the live or slaughtered cattle prior to hide removal? If yes, check all that apply.

- No
- Pre-slaughter animal wash
- Pre-slaughter head wash
- Post-slaughter dehairing
- Pre-dehiding carcass wash
- Other (please specify): _____
- Don't know

BeefSlaughter2. Does the establishment apply any of the following full-carcass intervention procedures after hide removal (i.e., not just at limited points on the carcass)? If yes, check all that apply.

- No
- Pre-evisceration organic acid rinse
- Pre-evisceration hot water wash
- Pre-evisceration steam vacuum
- Pre-chill organic acid rinse
- Pre-chill steam treatment
- Pre-chill steam vacuum
- Other (please specify): _____
- Don't know

BeefSlaughter3. Does the establishment have documentation of employee training in any of the following areas of the slaughter operation? If yes, check all that apply.

- No
- Proper hide removal
- Proper evisceration
- Adequate sanitation of knives and sharpening steels
- Other (please specify): _____
- Don't know

BeefSlaughter4. Does the establishment test carcasses for *E. coli* O157:H7 on individual carcasses? If yes, check all that apply.

- Using the N-60 excision method
- Swabbing carcass surfaces
- Other methods, specify _____
- Don't know

BeefSlaughter5. Does the establishment test for indicator organisms on the hide and/or carcass separate and apart from the regulatory generic *E. coli* test requirement (e.g., generic *E. coli*, coliforms, Enterobacteriaceae) to determine process control? If yes, check all that apply.

- No
- Carcass before intervention method
- Carcass after intervention method
- Equipment
- Slaughter area
- Other (please specify): _____
- Don't know

BeefSlaughter6. Does the establishment have documented monitoring and verification procedures of the carcass surface temperature maintained below 45 degrees Fahrenheit within 24 hours of slaughter?

- Yes
- No
- Don't know

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G-REGRIND COARSE GROUND

RCG1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the pre-coarse ground product or the coarse ground product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

RCG2. Does the establishment test source materials for *E. coli* O157:H7 prior to grinding? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60 or comminuted)
- Other than robust testing (please specify): _____
- Don't know

RCG3. Does the establishment test the finished ground beef for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (comminuted)
- Other than robust testing (please specify): _____
- Don't know

RCG4. What method does the establishment's laboratory use to test coarse ground beef or finished product for *E. coli* O157:H7?

- FSIS method
- Other (please specify): _____
- Don't know

RCG5. How does the establishment group source materials into lots for grinding?

- Based on 5 combo bins/units
- Based on combo bins/units from one supplier
- Based on combo bins/units from suppliers that use validated intervention methods
- All combo bins/units received in one day
- Others, please specify: _____
- Don't know

RCG6. Approximately how many suppliers has the establishment used in the last 30 days?

- Only from its own slaughter plant
- 1, from other slaughter plant
- 2-3
- 4-6
- More than 6
- Don't know

RCG7. Does the establishment knowingly use imported coarse ground beef to produce ground beef products? If yes, check all that apply.

- No
- Every production day
- Weekly
- Monthly
- Intermittently
- Others (please specify): _____
- Don't know

RCG8. Does the establishment knowingly use imported raw coarse ground beef components to produce ground beef products? If yes, check all that apply.

- No
- Every production day
- Weekly
- Monthly
- Intermittently
- Others (please specify): _____
- Don't know

RCG9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

- No
- Receipt of source materials
- Grinding
- Storage
- Distribution
- Others (please specify): _____
- Don't know

RCG10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

- After grinding raw ground beef components from each supplier
- After grinding raw ground beef components from a group of suppliers

- After a sample is collected for *E. coli* O157:H7 testing
- After each shift
- Daily after production
- Less than daily (extended clean-up)
- Other (please specify): _____
- Don't know

RCG11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Ground beef product
- Grinding equipment
- Processing area
- Other (please specify): _____
- Don't know

RCG12. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?

- Yes
- No
- Don't know

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H-PATTY FORMING

PatForm1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

PatForm2. Does the establishment test source materials for *E. coli* O157:H7 prior to patty forming? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60 or comminuted)
- Other than robust testing (please specify): _____
- Don't know

PatForm3. Does the establishment test the finished patties for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (comminuted)
- Other than robust testing (please specify): _____
- Don't know

PatForm4. What method does the establishment's laboratory use to test patties for *E. coli* O157:H7?

- FSIS method
- Other (please specify): _____
- Don't know

PatForm5. How does the establishment group source materials into lots for patty forming?

- Based on 5 combo bins/units
- Based on combo bins/units from one supplier
- Based on combo bins/units from suppliers that use validated intervention methods
- All combo bins/units received in one day
- Others, please specify: _____
- Don't know

PatForm6. Approximately how many suppliers has the establishment used in the last 30 days?

- Only from its own slaughter plant
- 1, from other slaughter plant
- 2-3
- 4-6
- More than 6
- Don't know

PatForm7. Does the establishment knowingly use imported product for patties? If yes, check all that apply.

- No
- Every production day
- Weekly
- Monthly
- Intermittently
- Others (please specify): _____
- Don't know

PatForm8. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

- No
- Receipt of source materials
- Patty forming
- Storage
- Distribution
- Others (please specify): _____
- Don't know

PatForm9. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

- After patty forming from each supplier
- After patty forming from a group of suppliers
- After a sample is collected for *E. coli* O157:H7 testing
- After each shift
- Daily after production
- Less than daily (extended clean-up)
- Other (please specify): _____
- Don't know

PatForm10. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Patty product
- Patty forming equipment
- Processing area
- Other (please specify): _____
- Don't know

PatForm11. Does the establishment use carryover or rework in which the carryover or rework is specifically accounted for in a robust testing program?

- Yes
- No
- Don't know

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I-MECHANICAL TENDERIZED

MechTend1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

MechTend2. Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-mechanically tenderized product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

MechTend3. Does the establishment test source materials for *E. coli* O157:H7 prior to mechanical tenderization? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60)
- Other than robust testing (please specify): _____
- Don't know

MechTend4. Does the establishment test the finished tenderized product for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60)
- Other than robust testing (please specify): _____
- Don't know

MechTend5. What method does the establishment's laboratory use to test product for *E. coli* O157:H7?

- FSIS method
- Other (please specify): _____

Don't know

MechTend6. How does the establishment group source materials into lots for mechanical tenderization?

Based on 5 combo bins/units

Based on combo bins/units from one supplier

Based on combo bins/units from suppliers that use validated intervention methods

All combo bins/units received in one day

Others, please specify: _____

Don't know

MechTend7. Approximately how many suppliers has the establishment used in the last 30 days?

Only from its own slaughter plant

1, from other slaughter plant

2-3

4-6

More than 6

Don't know

MechTend8. Does the establishment knowingly use imported product for mechanical tenderization? If yes, check all that apply.

No

Every production day

Weekly

Monthly

Intermittently

Others (please specify): _____

Don't know

MechTend9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

No

Receipt of source materials

Mechanical tenderization process

Storage

Distribution

Others (please specify): _____

Don't know

MechTend10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

After mechanical tenderization from each supplier

- After mechanical tenderization from a group of suppliers
- After a sample is collected for *E. coli* O157:H7 testing
- After each shift
- Daily after production
- Less than daily (extended clean-up)
- Other (please specify): _____
- Don't know

MechTend11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Mechanical tenderized product
- Mechanical tenderization equipment
- Processing area
- Other (please specify): _____
- Don't know

MechTend12. Does the establishment create bench trim in which the bench trim could be used as a raw ground beef component that is specifically accounted for in a robust testing program?

- Yes
- No
- Don't know

MechTend13. Does the establishment provide labeling on the product to inform purchasers that the product is mechanically tenderized (i.e., non-intact)?

- Yes; specify labeling: _____
- No
- Don't know

MechTend14. Approximately how many times does an individual product pass through the mechanical tenderization process?

- 1
- 2-3
- 4-6
- More than 6
- Don't know

J-ENHANCED PRODUCT

EnhProd1. Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the incoming product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

EnhProd2. Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-enhanced product? If yes, check all that apply.

- No intervention
- Organic acid
- Acidified sodium chlorite
- Acidified calcium sulfate
- Irradiation
- Gaseous ammonia
- Other(s), please specify: _____
- Don't know

EnhProd3. Does the establishment test source materials for *E. coli* O157:H7 prior to enhancing the product? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60)
- Other than robust testing (please specify): _____
- Don't know

EnhProd4. Does the establishment test the finished enhanced product for *E. coli* O157:H7? If yes, check all that apply.

- No
- One test per lot (lot as defined by the establishment)
- Robust testing (N-60)
- Other than robust testing (please specify): _____
- Don't know

EnhProd5. What method does the establishment's laboratory use to test product for *E. coli* O157:H7?

- FSIS method
- Other (please specify): _____

Don't know

EnhProd6. How does the establishment group source materials into lots for enhancement?

Based on 5 combo bins/units

Based on combo bins/units from one supplier

Based on combo bins/units from suppliers that use validated intervention methods

All combo bins/units received in one day

Others, please specify: _____

Don't know

EnhProd7. Approximately how many suppliers has the establishment used in the last 30 days?

Only from its own slaughter plant

1, from other slaughter plant

2-3

4-6

More than 6

Don't know

EnhProd8. Does the establishment knowingly use imported product for enhanced product? If yes, check all that apply.

No

Every production day

Weekly

Monthly

Intermittently

Others (please specify): _____

Don't know

EnhProd9. Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40 degrees Fahrenheit or below at any of these process steps? If yes, check all that apply.

No

Receipt of source materials

Enhancement process

Storage

Distribution

Others (please specify): _____

Don't know

EnhProd10. How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?

After enhancement from each supplier

- After enhancement from a group of suppliers
- After a sample is collected for *E. coli* O157:H7 testing
- After each shift
- Daily after production
- Less than daily (extended clean-up)
- Other (please specify): _____
- Don't know

EnhProd11. Does the establishment test the product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae)? If yes, check all that apply.

- No
- Enhanced product
- Enhancement equipment
- Enhancement solution
- Processing area
- Other (please specify): _____
- Don't know

EnhProd12. Does the establishment create bench trim in which the bench trim could be used as a raw ground beef component that is specifically accounted for in a robust testing program?

- Yes
- No
- Don't know

EnhProd13. Does the establishment provide labeling on the product to inform purchasers that the product is enhanced (i.e., non-intact)?

- Yes; specify labeling: _____
- No
- Don't know

EnhProd14. How is the enhancement solution labeled regarding name and ingredients?

- Not applicable
- Name(s), please specify: _____
- Ingredient(s), please specify: _____
- Don't know