Results of Checklist and Reassessment of Control for *Escherichia coli* O157:H7 in Beef Operations

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ACRONYMS AND ABBREVIATIONS

AMR	advanced meat recovery
AOAC	Association of Official Analytical Chemists
APC	aerobic plate count
ASC	acidified sodium chlorite
CCP	critical control point
CFR	*Code of Federal Regulations*
COA	certificate of analysis
CY	calendar year
DAIG	Data Analysis and Integration Group
E. coli	*Escherichia coli*
EIAO	Enforcement, Investigations, and Analysis Officer
FR	*Federal Register*
FLS	Front Line Supervisors
FSA	Food Safety Assessment
FSIS	Food Safety and Inspection Service
GMP	good manufacturing practice
HACCP	Hazard Analysis and Critical Control Points
IIC	inspector in charge
LFTB	lean finely textured beef
OFO	Office of Field Operations
OIA	Office of International Affairs
OPEER	Office of Program Evaluation, Enforcement, and Review
OPHS	Office of Public Health Services
OPPED	Office of Policy, Program, and Employee Development
OPPD	Office of Policy and Program Development
PBIS	performance based inspection system
PDBFT	partially defatted beef fatty tissue
PDCB	partially defatted chopped beef
PEIS	Program Evaluation and Improvement Staff
RTE	ready-to-eat
SBA	Small Business Administration
SSOPs	sanitation standard operating procedures
USDA	United States Department of Agriculture

EXECUTIVE SUMMARY

The Food Safety and Inspection Service (FSIS) issued Notice 65-07 as a result of a number of significant developments involving *Escherichia coli* O157:H7 (*E. coli* O157:H7) in beef products that occurred in 2007. These developments included an adverse trend in percent positive rate of *E. coli* O157:H7 in FSIS verification testing; an unusual number of positive samples in a short span of time; an increased number of recalls associated with *E. coli* O157:H7, including those specifically initiated as a consequence of human illness; and repetitive implication of certain source materials used in production of ground beef in positives or recalls. In response, FSIS issued Notice 65-07 instructing FSIS inspection personnel to notify establishments of these trends and collect information about any reassessment of Hazard Analysis and Critical Control Points (HACCP) plans the establishment conducted and changes they made (the Reassessment). The Notice also instructed FSIS inspection personnel to complete a checklist to collect information about the practices at several types of raw beef operations (the Checklist).

FSIS received 2,002 Reassessment responses and 2,323 Checklist responses, representing a greater than 90 percent response rate. Response rates to individual questions were generally about 95 percent, and represent a high completion rate. Response results were collected and assessed for data quality prior to analysis. The results presented are descriptive summaries of the 5 Reassessment questions and 118 Checklist questions. For each question, the number and percentage of responses are provided. Assessments of the text responses are also provided.

As the Reassessment showed, 96 percent of establishments reassessed their HACCP plan(s) as a result of the Notice. The results also showed that half of establishments made changes to their HACCP plan(s), sanitation standard operating procedures [SOP(s)], and/or other prerequisite programs in response to their reassessments. The reasons for changing or not changing these plans were varied and are discussed in the body of the report.

Responses to the Checklist indicated that Slaughter operations (03J) were more likely to consider *E. coli* O157:H7 as a hazard likely to occur (93 percent) than either Raw product – ground establishments (35 percent) or Raw product – not ground establishments (34 percent). Responses also indicated that testing for *E. coli* O157:H7 is performed by 59 percent of 03B Raw product – ground establishments, 39 percent of 03C Raw product – not ground establishments, and 46 percent of 03J Slaughter establishments.

Volume data showed that “Fabrication of Primal/Sub-primal Cuts” and “Trim Fabrication Production” represented the two largest production categories in terms of monthly production volume. “Fabrication of Primal/Sub-primal Cuts” and “Grinding boneless manufacturing trimmings or other raw ground beef components” represented the two product categories produced by the largest number of establishments.

Responses to the Checklist also indicated that most establishments use between one and three third-party suppliers. Between 43 percent (Patty Forming operations) and 76 percent (Beef Grinding operations) of establishments have purchase specifications for these suppliers. Interventions, such as an organic acid rinse, were a commonly referenced purchase specification made of suppliers, but were infrequently employed by the establishments themselves. About 5 percent to 15 percent of establishments, depending on the operation, applied interventions themselves.

While the use of interventions was low for establishments, the use of testing for *E. coli* O157:H7 was higher. The testing rates ranged from 15 percent to 50 percent, depending on the operation type. The Checklist data indicated that about one-quarter to one-third of establishments test for indicator organisms such as coliform, generic *e. coli*, aerobic plate count (APC), etc.

Other Checklist results showed that 93 percent to 99 percent of establishments clean and sanitize daily. Generally, 80 percent to 85 percent of establishments have documented temperature monitoring procedures (exceptions were Slaughter establishments at 65 percent and Beef Trim Fabrication establishments at 26 percent). The use of imported source materials is non-existent or intermittent for most operations, but Beef Grinding and Patty Forming operations were more likely to use these imported materials on a daily basis. Seventeen percent of Enhanced Product establishments and 32 percent of Mechanical Tenderization establishments created bench trim that is not part of a robust testing program and that could be used as a raw ground beef component. Additional findings are detailed in the Summary at the end of this report.

The results of this Reassessment and Checklist provide a profile of operations at raw beef product manufacturers and will help inform the Agency on policy issues. Work continues to be done that integrates the findings from this Notice with other Agency data sources to better understand establishment practices in other contexts. The Agency is looking at how establishment practices relate to *E. coli* O157:H7 positive test results and recalls, how the current sampling programs reflect use of bench trim and other source materials, and how practices might vary by establishment size or production volume. These results will help inform the Agency and further the goals of reducing the incidence of *E. coli* O157:H7 and protecting public health.

1. INTRODUCTION

The Food Safety and Inspection Service (FSIS) issued Notice 65-07, "Notice of Reassessment for *Escherichia coli* O157:H7 Control and Completion of Checklist for All Beef Operations," on October 12, 2007. The Notice was issued as a result of a number of significant developments involving *Escherichia coli* O157:H7 (*E. coli* O157:H7) in beef products that occurred in 2007. As further described in the Background section below, this included an adverse trend in percent positive rate of *E. coli* O157:H7 in FSIS verification testing; an unusual number of positive samples in a short span of time; an increased number of recalls associated with *E. coli* O157:H7, including those specifically initiated as a consequence of human illness; and repetitive implication of certain source materials used in production of ground beef in positives or recalls.

These developments raised questions about the adequacy of the interventions and controls that beef operations are employing to address this pathogen. Because these developments happened over a short period of time, FSIS was also concerned establishments may not have been fully aware of the extent of the problems evidenced by these developments. As a result, establishments may not have considered the implications of these developments for their Hazard Analysis and Critical Control Points (HACCP) systems.

The FSIS deemed it essential for inspection program personnel to meet with regulated establishments to review the developments involving *E. coli* O157:H7 in beef products, and to advise the establishments that, in accordance with 9 *Code of Federal Regulations* (CFR) 417.4(a)(3), these developments constitute changes that could affect the establishments' hazard analysis or cause the establishments to alter their HACCP plans As such, Notice 65-07 (Attachment 1) instructed FSIS inspection personnel to discuss with industry the need to reassess HACCP Plans, Sanitation Standard Operating Procedures (SSOPs), and any other prerequisite programs and plans. Inspection program personnel informed establishment management that 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. Through Attachment 3 (the Reassessment) of Notice 65-07, FSIS inspection personnel collected and documented information on whether establishments had reassessed and modified any of those plans.

FSIS needed information on best practice measures for raw beef establishments which, while not required, the Agency considers to be essential to controlling *E. coli* O157:H7. In addition, the Agency is also interested in known control measures and activities employed by beef operations that may affect the level of control employed by the establishments. Notice 65-07 instructed FSIS inspection personnel, through Attachment 5 (the Checklist), to collect and provide the Agency with information on beef establishments, including information on control measures that establishments use during production of raw ground beef products to prevent, reduce, or eliminate *E. coli* O157:H7 in the final product.

For purposes of the Notice, beef operations were considered to be official establishments that:

- Grind trim or other raw ground beef components
- Fabricate trim or other raw ground beef components
- Slaughter cattle
- Regrind coarse ground beef
- Form beef patties
- Enhance (tumbling; massaging; or injecting, such as with marinades) raw beef components
- Mechanically tenderize raw beef products
- Conduct some combination of these operations

As detailed in Chapters 4 and 5, Reassessment questions (Attachment 3) were completed by inspection personnel at 2,002 establishments, and Checklist questionnaires (Attachment 5) were completed by inspection personnel at 2,323 establishments.

Responses to Attachment 3 and 5 of Notice 65-07 are presented in this report, along with descriptive statistics and summaries of the results. In accordance with its Standard Operating Procedures for Data Collection and Analysis (July 2007), FSIS developed a data analysis plan to guide how results of the Reassessment and the responses to the Checklist were analyzed. The results of the analyses presented in this report will be used to inform Agency policies and develop future initiatives to prevent future *E. coli* O157:H7 spikes.

Background

The FSIS has issued two *Federal Register* (FR) Notices since 2002, specifically mandating the reassessment of HACCP plans related to *E. coli* O157:H7 control measures. In October 2002, FSIS issued an FR Notice that outlined adulteration considerations regarding intact and nonintact 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 an 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 was an increased number of positives in Agency sampling for *E. coli* O157:H7, compared to the preceding 3 years, a couple of outbreaks attributed to this pathogen and beef products, and a number of large recalls. This situation required a broad reassessment of how beef operations and FSIS are assessing this pathogen. Details on these developments are provided in Attachment 2, "Developments That Support That There Is a Need for Establishments to Reassess Their HACCP Systems."

2. DATA COLLECTION DESIGN AND IMPLEMENTATION

In June 2007, Food Safety and Inspection Service (FSIS) identified an increased number of *Escherichia coli* (*E. coli*) O157:H7 positive tests in beef, as well as an increase in the number of recalls and illnesses caused by this pathogen in the past year. Shortly thereafter (October 2007), the Agency developed and implemented Notice 65-07, Reassessment for *E. coli* O157:H7 Control and Completion of a Checklist for All Beef Operations, to collect relevant information on the control measures that establishments used during production of raw beef products to prevent, reduce, or eliminate *E. coli* O157:H7 in the final product. The Notice is provided as Attachment A, and the distributed version of the Checklist (Attachment 5 of the Notice) is provided as Attachment B to this report.

2.1 Development of Hazard Analysis and Critical Control Points Reassessment, Attachment 3

Attachment 3 of FSIS Notice 65-07 was developed in order to provide a mechanism for FSIS inspection personnel to capture the actions taken by raw beef establishments in response to new information about *E. coli* O157:H7 that emerged throughout calendar year (CY) 2007. FSIS made the determination that establishments should reassess their HACCP plans, as required by 9 *Code of Federal Regulations* (CFR) 417.4(a)(3), whenever changes occur that might affect the adequacy of an establishment's HACCP plan. In addition, this information will provide a means to prioritize which establishments should be scheduled for a food safety assessment. Those establishments that chose not to reassess their HACCP plans likely will be scheduled sooner than establishments that made changes to their plans.

Attachment 3 was designed by the FSIS Office of Policy and Program Development (OPPD). The information captured in Attachment 3 is intended to provide insight into how the raw beef industry views the needed level of control for *E. coli* O157:H7 and what changes, if any, this industry has made as a consequence of new information. The content of Attachment 3 was tailored after the format of the questions asked in response to a prior reassessment directed by FSIS for raw beef operations (67 FR 62325, October 7, 2002). The Reassessment conducted in 2002 had no mechanism in place to readily capture the actions taken in response to it, whereas the design of Attachment 3 allows for this information to be documented. The information obtained via Attachment 3 was not available from any other data source and there was no duplication of information collection efforts. Attachment 3 was intended to be completed by FSIS inspection personnel instead of other food safety procedures.

Attachment 3 was directed to Inspectors-In-Charge in all raw beef operations as described above. Attachment 3 was intended to be transmitted and completed electronically, where feasible, and via hard copy in those rare situations in which electronic processing was not available.

Attachment 3 instructed FSIS program personnel to meet with the establishments to advise them that these developments constituted changes that could affect the establishments' hazard analyses or cause them to alter their HACCP plans. Accordingly, inspection program personnel were to advise establishments to reassess their HACCP plans. Inspection program personnel were then to document and submit to FSIS Headquarters each establishment's response, i.e. whether or not it reassessed its HACCP or other control plans, what it determined, and whether it changed its plans. Attachment 3 was intended to be completed and submitted to OPPD by November 2, 2007.

Attachment 3 contains a total of five questions. Four of the questions asked about the reassessment actions by the establishment, and one question asked about the amount of time it took to complete Attachment 3. Attachment 3 had both open-ended and dichotomous-type questions. The open-ended questions allowed the responder to provide a description of an establishment's actions relative to the Reassessment.

2.2 Development of *E. coli* Checklist, Attachment 5

Attachment 5 of FSIS Notice 65-07 was developed to collect information on the control measures used by official establishments that slaughter and process beef products to prevent, reduce, or eliminate *E. coli* O157:H7 during beef slaughter and processing. It was also developed to collect information on the controls that establishments used for the purpose of informing the Agency's development of some of the risk factors for the risk-based verification sampling program for *E. coli* O157:H7 in beef products. The risk ranking of the establishments as determined from the risk factors, helps determine the frequency of sampling by FSIS. Due to the increase in the *E. coli* O157:H7 positives and recalls in the CY 2007 high prevalence season, the checklist was expanded so that the Agency could also use the information for the following purposes: (1) to identify those beef operations that are not employing certain interrelated practices that FSIS has identified as directly contributing to the control of this pathogen; (2) to capture production practices used by the establishments to control *E. coli* O157:H7, and to identify vulnerabilities in the design of the establishments' food safety system; and (3) to help prioritize whether and when a food safety assessment should be conducted at the establishment. Information gathered provides an overview of the level of effectiveness of the food safety system controls for this pathogen.

A subgroup was formed from a larger FSIS *E. coli* O157:H7 Working Group to develop the checklist questions. The subgroup included participants from OPPD, the Office of Public Health Science (OPHS), Office of Field Operations (OFO), Office of Program Evaluation, Enforcement and Review (OPEER), and Office of International Affairs (OIA). The team looked into other similar Agency questionnaires that were either under development or being used, to avoid unnecessary duplication of information collection. FSIS Notice 65-07 was distributed electronically. The team worked with the Survey Coordination Initiative Group of the Program Evaluation and Improvement Staff (PEIS) within OPEER for the electronic distribution and the administration of the survey.

The initial draft version of the Checklist included sections on beef slaughter, fabrication of beef trim, and beef grinding. Sections on regrinding coarse grind and formation of beef patties were added later. Due to the increase in the *E. coli* O157:H7 positives and recalls in the 2007 high prevalence season, the checklist was again expanded to include questions on: mechanical tenderization of beef and enhancement (marinating and injection) of; the establishment's general raw beef food safety system; and the establishment's production volume of different types of beef products. The draft questionnaire was reviewed and commented by the team members as well as subject matter experts before it went through the clearance process. After the clearance it was converted to an electronic format by PEIS. A draft of the Checklist was included in the October 2007 FSIS Notice 65-07.

The Data Analysis and Statistical Support Staff (now Policy Analysis Division), OPPD, provided the beef slaughter and processing establishment numbers and the name and email addresses of inspectors in charge (IICs) for the electronic distribution of the survey. The questions were answered by the Office of Field Operations (OFO) Field Program Personnel at these beef slaughter and processing establishments.

The questionnaire, in the form of a checklist, was targeted at beef operations that slaughter cattle, fabricate beef trim, grind beef, regrind coarse ground beef, form beef patties, mechanically tenderize beef, and enhance beef (e.g., by injection). The checklist included questions answerable by checking "yes," "no," or "don't know," or by selecting from multiple answers provided, and some open-ended questions.

The checklist asked questions about the validated interventions used by the establishments to control *E. coli* O157:H7, verification sampling for *E. coli* O157:H7 and the testing method used, testing for microbial indicator organisms, frequency of testing, number of source materials, basis for sorting lots, sanitation controls, purchase specifications, use of other raw ground beef components (such as cheek meat, head meat, low temperature rendered products, etc.), volume of production, and use of imported products, among others. For example, 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 being essential to controlling *E. coli* O157:H7. The definitions of best practices for HACCP Processing Categories "03B Raw Product – Ground," "03C Raw Product – Not Ground," and "03J Slaughter," are included in Attachment B. The remainder of the checklist asked about slaughter and processing practices employed by beef operations that could affect the level of control achieved by the establishments.

2.3 Implementation of Notice 65-07 and Data Collection

Within 1 week of receipt of the Notice, FSIS inspection personnel at all beef operations were to meet with an establishment management official to discuss the Notice and inform them of the need to reassess their HACCP plans. Management was instructed that the Reassessment should be conducted by October 26, 2007.

At a subsequent meeting, personnel were to ascertain whether and how the establishment reassessed and completed the questions in Attachment 3 to FSIS Notice 65-07. The completed Reassessment was to be submitted in printed or electronic form no later than November 2, 2007, to the Front-line Supervisor, District Analyst in the District Office, and PAD/OPPD.

The distribution of the Checklist was conducted in a manner that maximized questionnaire distribution and collection of responses, eliminated any duplication of information collection, reduced complexity of submission procedure for respondents, and decreased total information collection time for the Agency. FSIS Program Evaluation and Improvement Staff (PEIS) distributed the Checklist using *Perseus Survey Solutions* software. *Perseus* allowed PEIS to distribute invitations to complete the Checklist via an email that contained a link to the online Checklist. Perseus also collected the Checklist results, exported them to various electronic formats (delimited text, SPSS, and Excel), and helped manage reminders for nonresponders.

The first distribution of the Checklist consisted of forms prepopulated with the selected establishment name. Shortly after this initial distribution, PEIS made available to the Districts an "open" version of the Checklist, which they could distribute via email to any inspection program personnel at establishments who were accidentally missed in the first distribution. The "open" Checklist allowed inspection program personnel to enter data for those establishments who were not initially identified. This resulted in greater coverage of the establishments subject to the Notice. However, because the distribution of the "open" Checklist was not controlled by *Perseus*, the number of "open" Checklists that were distributed is not known. This is discussed in more detail in Chapter 3.

Respondents to the Checklist were, for the most part, Inspectors-in-Charge (IICs) at establishments that slaughter cattle and/or produce non-intact beef products or components of non-intact beef products. In some cases other inspection personnel (relief inspectors, Enforcement Investigations and Analysis Officers [EIAOs] and Front Line Supervisors [FLSs]) completed the Checklist.

PEIS emailed invitations to complete the Checklist to approximately 2,500 IICs on October 25 and 26, 2007. PEIS identified these IICs by using plant profile data in the Performance-Based Inspection System (PBIS) and, with the help of OPPD staff in Omaha, NE, by conferring with the Districts on all the establishments subject to inspection under FSIS Notice 65-07.

Before filling out the Notice 65-07 Checklist (Attachment 5), FSIS inspection personnel were instructed to review the attachment questions to determine whether they had any questions. After reviewing the Checklist and having any questions answered, personnel were to complete training provided to them on a CD. The training was designed to increase understanding of the purpose of the Notice and to minimize errors in completing the attachment. The training and a test for comprehension were also uploaded to AgLearn, USDA's online training system.

Before inspection program personnel submitted the online checklist to the Policy Analysis Division, Office of Policy, Program, and Employee Development (PAD/OPPED), they were to share a copy with a management official at the establishment. The management official was to be given the opportunity to correct any response for which a change could be substantiated. Also, FLSs were instructed to check that inspection personnel accurately completed the attachments. If the FLSs had concerns or changes to the checklist, it could be modified and re-submitted to PAD/OPPED. The Checklist was to be completed and submitted by November 30, 2007.

Around 12/19/2007, PEIS closed the collection of responses to Checklist by disallowing data entry, and calculated the response rate. It was apparent from the nonresponse rate and communications with the Districts that Checklist data were not collected from all establishments subject to the Notice. In an effort to identify and ultimately to reduce non-responses, PEIS and District Offices identified establishments for which Checklist data still needed to be collected. PEIS also received data from the FSIS Data Analysis and Integration Group (DAIG) regarding the Checklists that were incomplete and would need to be redistributed. Using this information, the Checklist was redistributed to this smaller group around February 25, 2008. PEIS did not circulate an open Checklist during this second distribution. This second wave of collection was closed on March 18, 2008.

PEIS combined the results from the two waves of Checklist data collection and submitted them to DAIG for analysis. Throughout these distributions, PEIS and DAIG identified duplicate submissions for establishments and discarded all but the most recent collection for the final results.

3. ANALYSIS PROCEDURE

3.1 Response Rates

Checklist return rates were calculated to measure the effectiveness of the Checklist distribution and to assess whether non-response bias might influence the results. Checklist return rates are an approximation. Over time, some establishments may cease production of raw beef products, whereas other establishments may begin or resume production. Therefore, the number of eligible establishments varies from month to month. Attachments 3 and 5 of Notice 65-07 were distributed over a 5-month period. As of March 21, 2008, the end of the response collection period, 2,347 establishments in Performance Based Inspection System (PBIS) were eligible for inspection under the Notice.

To compute the overall response rate, the following formula was used[1,2]:

$$RR = \frac{C}{C + NR + NC + U}, \text{ where}$$

RR = Response rate
C = Number of completed or partially completed cases
NR = Number of non-response cases
NC = Number of non-contacted inspectors for the establishments known to be eligible
U = Number of establishments of unknown eligibility and that did not respond

The Notice was intended to be distributed to all inspectors who inspect eligible establishments. Thus, the number of non-contacted inspectors and the number of establishments of unknown eligibility were assumed to be zero.

FSIS received Reassessment (Attachment 3) results from inspectors for 2,002 beef establishments. Therefore, the overall response rate for Attachment 3 of Notice 65-07 was:

$RR = [2,002 / (2,002 + 345 + 0 + 0)] * 100 \approx 85.3$ percent

FSIS received unique Checklist (Attachment 5) results from inspectors for 2,323 establishments producing beef products and potentially subject to inspection under Notice 65-07. The overall response rate for Attachment 5 of Notice 65-07 was:

$RR = [2,323/(2,323 + 24 + 0 + 0)] * 100 \approx 98.9$ percent

The number of establishments that change eligibility is considered to be small and would not mislead the determination of either overall or per-question response rates. FSIS is confident that Checklist responses have been received for more than 90 percent of establishments producing beef products between November 2007 and March 2008. The response rates are considered high enough that non-response bias is not a concern. The response rates are also considered sufficient to allow FSIS to understand the practices of various classes of raw beef operations.

[1] The American Association for Public Opinion Research. 2008. *Standard Definitions*: *Final Dispositions of Case Codes and Outcome Rates for Surveys*. 5th edition. Lenexa, Kansas: AAPOR.
[2] Council of American Survey Research Organizations. 1982. *Special Report: On the Definition of Response Rates*. Port Jefferson, New York: CASRO.

Question response rates for the Checklist were also calculated in order to assess completion rates and identify problematic questions. As mentioned earlier, the Checklist was divided into 11 major classes. Numbers of eligible respondents for the question classes varied, and appropriate denominators were used to calculate response rates according to the question classes. The response rates to questions in each of the 11 major classes, and time spent completing the Checklist, are summarized in **Tables 3.1** to **3.12**.

Table 3.1. Establishment Information

Question Number	Response Rate
EstabInformation	100%
Q. EstabInformation2	99%
Q. EstabInformation3	100%
Q. MGMTOFF1	100%
Q. MGMTOFF2	100%

Table 3.2. A-Raw Beef Food Safety System

Question Number	Response Rate
Q. FBFSS1	99%
Q. FBFSS2	98%
Q. FBFSS3	100%
Q. FBFSS4	99%
Q. FBFSS5	99%
Q. FBFSS6	100%
Q. FBFSS7	99%
Q. FBFSS8	100%
Q. FBFSS9	100%
Q. FBFSS10	99%
Q. FBFSS11	99%
Q. FBFSS12	100%

Table 3.3. B-Product Production and Volume

Question Number	Response Rate
Q. PPV1	88%
Q. PPV2	88%
Q. PPV3	83%
Q. PPV4	85%
Q. PPV5	86%

Table 3.4. C-Establishment Category

Question Number	Response Rate
Q. EstabCategory	87%

Table 3.5. D-Beef Grinding

Question Number	Response Rate
Q. BGShift	99%
Q. BeefGrind1	99%
Q. BeefGrind2	99%
Q. BeefGrind3	99%
Q. BeefGrind3a	99%
Q. BeefGrind4	99%
Q. BeefGrind5	100%
Q. BeefGrind6	50%
Q. BeefGrind7	99%
Q. BeefGrind8	99%
Q. BeefGrind9	100%
Q. BeefGrind10	97%
Q. BeefGrind11	99%
Q. BeefGrind12	100%
Q. BeefGrind13	99%
Q. BeefGrind14	100%
Q. BeefGrind15	99%
Q. BeefGrind16	99%

Table 3.6. E-Beef Trim Fabrication

Question Number	Response Rate
Q. BTFShift	96%
Q. BeefTrimFab1	96%
Q. BeefTrimFab2	96%
Q. BeefTrimFab3	85%
Q. BeefTrimFab4	96%
Q. BeefTrimFab5	96%
Q. BeefTrimFab6	96%

Table 3.7. F-Beef Slaughter

Question Number	Response Rate
Q. BSShift	98%
Q. BeefSlaughter1	99%
Q. BeefSlaughter2	99%
Q. BeefSlaughter3	99%
Q. BeefSlaughter4	99%
Q. BeefSlaughter5	99%
Q. BeefSlaughter6	100%

Table 3.8. G-Regrind Coarse Ground

Question Number	Response Rate
Q. RCGShift	97%
Q. RCG1	96%
Q. RCG2	98%
Q. RCG3	98%
Q. RCG3a	98%
Q. RCG4	97%
Q. RCG5	98%
Q. RCG6	44%
Q. RCG7	97%
Q. RCG8	97%
Q. RCG9	98%
Q. RCG10	98%
Q. RCG11	98%
Q. RCG12	98%
Q. RCG13	98%
Q. RCG14	98%

Table 3.9. H-Patty Forming

Question Number	Response Rate
Q. PFShift	99%
Q. PatForm1	94%
Q. PatForm2	98%
Q. PatForm3	99%
Q. PatForm4	100%
Q. PatForm5	100%
Q. PatForm6	32%
Q. PatForm7	99%
Q. PatForm8	99%
Q. PatForm9	100%
Q. PatForm10	99%
Q. PatForm11	99%
Q. PatForm12	99%
Q. PatForm13	99%

Table 3.10. I-Enhanced Product (marinated and injected)

Question Number	Response Rate
Q. EPShift	99%
Q. EP1	99%
Q. EP2	99%
Q. EP3	100%
Q. EP4	99%
Q. EP5	74%
Q. EP6	99%
Q. EP7	99%
Q. EP8	100%
Q. EP9	99%
Q. EP10	100%
Q. EP11	99%
Q. EP12	100%
Q. EP13	99%
Q. EP14	99%
Q. EP15	99%

Table 3.11. J-Mechanical Tenderizing

Question Number	Response Rate
Q. MTShift	99%
Q. MT0	99%
Q. MT1	99%
Q. MT2	99%
Q. MT3	99%
Q. MT4	99%
Q. MT5	68%
Q. MT6	98%
Q. MT7	99%
Q. MT8	99%
Q. MT9	99%
Q. MT10	99%
Q. MT11	99%
Q. MT12	99%
Q. MT13	98%
Q. MT14	99%
Q. MT15	98%

Table 3.12. Time Spent Completing Checklist

Question Number	Response Rate
Q. Time	64%

Response rates for most questions in Attachment 5 were greater than 95 percent with the following exceptions: Questions Q. EstabCategory (87 percent), Q. BeefGrind6 (50 percent), Q. BeefTrimFab3 (86 percent), Q. RCG6 (44 percent), Q. PatForm1 (94 percent), Q. PatForm6 (32 percent), Q. EP5 (74 percent), Q. MT5 (68 percent), Q. Time (64 percent). The response rates and possibility of non-response biases of these questions are further discussed in the following section.

3.2 Non-response Bias

Five questions had response rates below 70 percent (Q. BeefGrind6, Q. RCG6, Q. PatForm6, Q. EP5, and Q. MT5). An assessment of these questions determined they were fundamentally the same question for different beef product types: *What laboratory method does the establishment or its designee use to test the product for E. coli O157:H7?* These questions were closely related to the question immediately preceding them: *Does the establishment or its designee specifically conduct on-going verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?* (see Q. BeefGrind5, Q. RCG5, Q. PatForm5, Q. EP4, and Q. MT4). The second question about the laboratory method used did not apply to respondents who indicated on the first question that the establishment did not conduct testing. The question did not allow for a "Not applicable" type of response. Under this circumstance, respondents often did not select any response. Thus, these low response rates are a result of the practices of the establishments and are not considered a consequence of non-response bias.

It is not known why the response rate for the Q. Time is only 64 percent. One possibility is that inspectors were not instructed beforehand to track their time spent completing the Checklist, and the Checklist did not have to be completed all at once. This, combined with the relatively large number of questions and their complexity, may have resulted in respondents being unable to account for their time spent completing the Checklist.

A statistically sufficient sample size for a population size of 2,323 and a 95 percent confidence level ($\alpha = 0.05$) with 5 percent of error margin is 330. Responses to the 'Time' question numbered 1,476 out of 2,323; a sufficient number of responses to analyze this question at a 95 percent confidence level under the assumption that there was no non-response bias. The time to complete the Checklist is further analyzed in the following section.

3.3 Data Quality Measures

Data quality measures allow an assessment of whether the data collected and the results of the analyses can scientifically support national level decisionmakers for better control of Escherichia coli (*E. coli*) O157:H7 contamination in U.S. raw beef establishments.

As indicated in the previous sections, Checklist responses have been received for more than 90 percent of eligible establishments. Most questions were answered with a greater than 95 percent response rate. The high response rate and high completion rate are two measures of the quality of data collected for Attachment 5 of Notice 65-07.

The time inspectors spent to answer each question was also evaluated as a measure of data quality. Unusually short completion times may identify Checklists of questionable data integrity. The time spent by inspectors per question was calculated by dividing the total time that took an inspector to complete Checklist (Q. Time) by the number of the questions answered. Some of the questions, such as production volume questions (Q. PPV 1, 2, and 4), had more items to answer than other questions. The complexity of each question was not factored into this analysis.

Figure 3.1 shows a box plot for average time spent by inspectors to answer each question of the Checklist. The "+" in the boxes shows average time spent in that particular operation category, which was about 3.87 minutes per question for all operations. In general, questions for slaughter operation took longer to answer than others. As shown in the box plot, there were a relatively large number of inspectors who spent more time (represented by the circles above each box) than the usual time range (represented by the whiskers above each box). There were no lower outliers that represent responders who took less time than usual. The upper outliers may represent FSIS inspectors who were cautious in answering questions and took time to conduct necessary background research on the establishment's practices. Some responses to the Time question indicated that some inspectors may have included time spent researching establishment practices. FSIS believes that the time information reflects a good and consistent effort on the part of inspectors to accurately complete the Checklist.

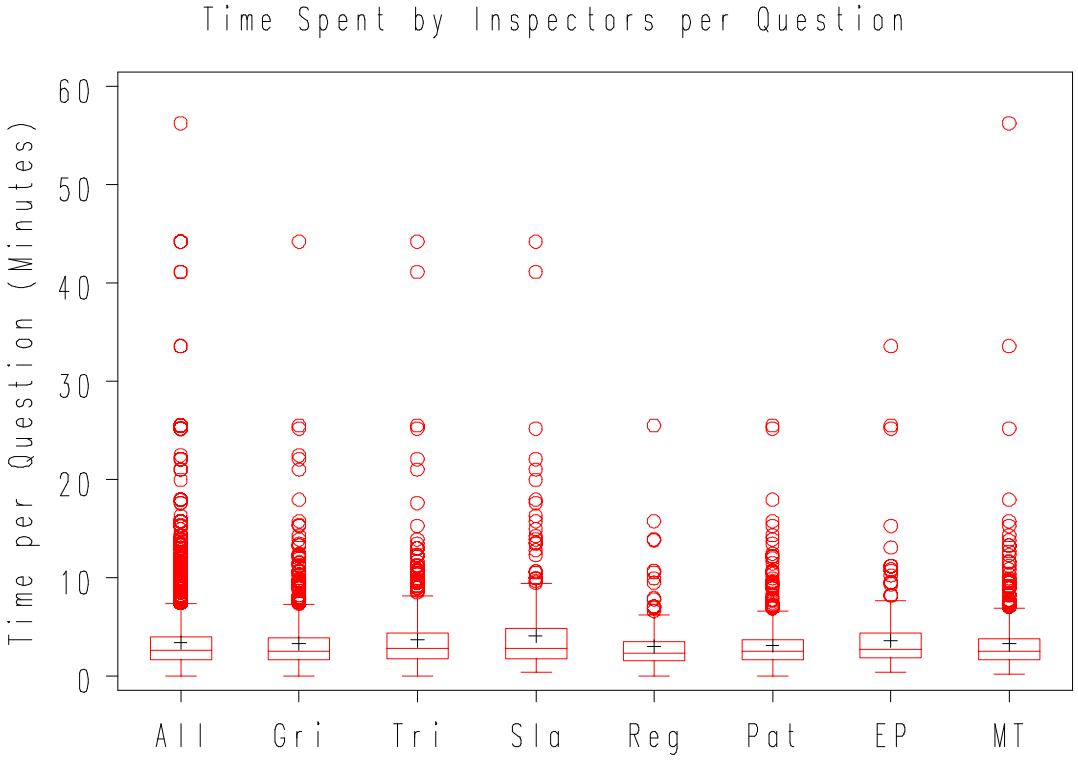

Figure 3.1. Box Plot of Average Time Spent by Inspectors to Answer Checklist Questions

3.4 Data Cleaning

The Checklist response data required some data cleaning before analysis could be performed. An examination for any possible errors in data entry was performed, including searching for duplicate Checklist responses, illogical responses, invalid character and numeric values, and other problematic data entries.

Some cases were identified where duplicate Checklist responses for the same establishment were collected. Some of the duplication was due to the "open" Checklist distribution. The open Checklist didn't allow results to be updated for individual establishments and, so, some establishments submitted multiple Checklists. In addition, the two waves of Checklist submission and response collection contributed to duplicate responses. After the first data collection was closed in December 2007, about 10 percent of collected data were considered to be incomplete. As a result, a second wave of data collection was conducted in February 2008, which included establishments with incomplete responses from the first wave. For duplicate Checklist responses, the latest response was used.

Some cases of illogical responses were also identified. In some Checklist responses, the responder indicated that the establishment did not perform a particular operation, but then proceeded to answer the questions for that operation type. These responses were not considered valid and were excluded from the analysis.

Invalid numeric or character data were identified, such as misspellings or typos, alphanumeric responses to questions where only numeric responses were expected, and missing values. Invalid values were cleaned where appropriate. For example, units of measure were removed from volume and time response (e.g., "1,000 lbs" was cleaned to be "1,000"). Some data transformation was necessary for time values. For example, "once a week" was transformed to "4" for a question that asked "how many times per month" something occurred. Narrative responses were referred to at times when additional background information was necessary to transform data.

The majority of questions required little, if any, cleaning. The questions requiring the most cleaning were the Product Production Volume (PPV) questions and the Time Spent Completing the Checklist question.

3.5 Data Analysis

Checklist questions consisted of single-choice, multiple-choice, or free text questions. Descriptive analyses were conducted for the responses to 118 questions. Each answer choice for a question was considered an independent factor. An open-ended question regarding monthly production volume (PPV2) was also analyzed. For several questions, the response "Other, please specify:" was an option. The specified responses were free text fields that allowed for any type of response. Specified responses were qualitatively discussed, along with any identified trends.

Histograms and descriptive statistics for categorical data were used to describe the responses to most questions. Box plots and descriptive statistics for continuous data were used for the Production Volume and Time questions. Monthly production volumes were computed by multiplying "Daily Volume Produced" and "Days Per Month this Amount of Product Produced" from the Q. PPV2 question, and were presented for each beef product type (e.g., head meat, cheek meat, etc.). Checklist questions PPV1, PPV3, PPV4, and PPV5 were excluded because of data quality or interpretation issues, or they were supplementary narrations. Percentages were calculated as the number of responses divided by the number of eligible responders.

The number of eligible responders varied depending on the types of raw beef operations conducted at the establishment. There were seven operation types subject to questions from the Checklist. Some questions were answered for all Checklist responses. Other questions were answered only if the establishment conducted the particular type of operation. The number of eligible responders for each operation category is discussed in more detail in Chapter 5.

The majority of Checklist questions were asked for specific beef operation categories. Several of these were essentially the same question asked for each operation type. These common questions covered topics such as shift, interventions, and testing for *E. coli* O157:H7. Common questions were identified and summarized to allow for comparison across the different operations. The analysis of common questions is further described in Chapter 5.

Selected Checklist results were cross-referenced with other available datasets to provide a more detailed understanding of the establishment's status. The beef operation categories of the establishments in the checklist were cross-referenced with HACCP sizes from the PBIS database to allow for analysis of Checklist responses by HACCP size category. Also, monthly production volumes were compared with HACCP sizes and HACCP processing category.

4. RESULTS OF ATTACHMENT 3

4.1 Results and Discussion

As discussed in Chapter 2, Attachment 3 was intended to capture information on actions taken by raw beef establishments after reassessment of their control practices for Escherichia coli (*E. coli*) O157:H7. These actions included reassessment, and changes to their HACCP plans, Sanitation Standard Operating Procedures (SSOP), or other prerequisite programs as a result of the reassessment.

4.2 HACCP Size Profile

The 2,002 establishments are made up of different size establishments. These sizes are categorized into "Large," "Small," and "Very Small," according to criteria established by FSIS and the Small Business Administration (SBA). SBA class sizes, referred to as "HACCP" classes, are based primarily on the number of employees at an establishment. Large establishments are those having 500 or more employees. Small establishments are those having between 10 and 500 employees. Very Small establishments are those having fewer than 10 employees or less than $2.5 million in annual sales. FSIS maintains information about the HACCP size of individual establishments. This information was combined with the reassessment data in order to profile the establishments represented. **Table 4.1** summarizes the 2,002 reassessment establishments according to HACCP class.

Table 4.1. HACCP Processing Categories

	Number	Percent
Large	53	3
Small	766	38
Very Small	1,178	59
N/A	5	0

As indicated in the above table, about 3 percent (53) establishments are Large, 38 percent (766) are Small, and 59 percent (1,178) are Very Small. The majority of the establishments profiled by this reassessment are Very Small establishments. This distribution of establishment sizes may assist in understanding the types of establishments characterized by each Checklist question. HACCP class is determined by the number of establishment employees and is not entirely reflective of the volume produced by the establishment. For a further discussion of establishment production volumes as they relate to HACCP size, see Chapter 5.

Five establishments are identified as Not Applicable. HACCP class was not a question on the Checklist. This information was collected from other FSIS data sources and used to profile the establishments. The HACCP class of an establishment changes over time to reflect their current status. Establishments that fall under the Not Applicable category may no longer be operating and, therefore, do not have current HACCP class information.

Reassessment Results

FSIS inspectors were asked to answer questions about the establishment's HACCP plan reassessment for all 2,002 establishments. **Tables 4.2** through **4.6** provide tabulations (Number of Establishments and Percentage) of the five *E. coli* reassessment questions related to food safety systems. Inspectors who completed the reassessment were able to select only one response and provide a text response. For

questions 1 through 4, the text responses[3] were categorized to identify general reasons for the selected response.

The first reassessment question asked whether the establishment reassessed its HACCP plan(s).

Table 4.2. HACCP Reassessment

Q1: Did the establishment reassess its HACCP plan(s) based on the developments as set out in Section III above?	**Number**	**Percent**
No	77	4
Yes	1,925	96

As indicated in Table 4.2, 96.2 percent (1,925) of establishments reassessed their HACCP plans based on the developments as set out in Section III of Notice 65-07. Four percent (77) of establishments did not reassess their HACCP plan. The reasons provided for why the establishments did not reassess their HACCP plan for control practices for *E. coli* O157:H7 were further analyzed.

Of the 77 responses that indicated that establishments did not reassess their HACCP plans, 75 provided reasons. Seventeen of the establishments indicated that they do not process raw beef products, or that they decided to stop processing raw beef products. In addition, two establishments indicated that they are no longer in business. Combined, these 19 establishments did not have or need HACCP plans for raw beef products, as set out in Notice 65-07. Of the remaining 56 establishments, 31 said that they did not need to reassess their plans for the control of *E. coli* O157:H7 because they said that they have had no positive results in their testing for this pathogen. Moreover, 25 establishments indicated that they were still thinking about reassessing, but were not sure what to do at the time of the survey.

The second reassessment question asked whether the establishment changed its HACCP plan(s) as a result of the reassessment.

Table 4.3. Changes to HACCP Plan(s)

Q2: Did the establishment change its HACCP plan(s) as a result of the reassessment?	**Number**	**Percent**
No	1,349	67
Yes	653	33

As indicated in Table 4.3, 33 percent (653) of establishments changed their HACCP plan(s) as a result of the reassessment, whereas 67 percent (1,349) of establishments did not change their HACCP plan(s). The rationales for these actions were further analyzed.

For the 653 establishments that indicated that they changed their HACCP plan(s) after reassessment, nearly all establishments gave more than one reason. The 653 responses provided a total of 5,722 reasons for the changes in their HACCP plan(s). The calculated average is about 9 (5,722/653) reasons per establishment that changed their HACCP plan(s) after reassessment. This average is skewed to the right because some responders submitted several paragraphs or pages of changes that were made after reassessment. Other responders submitted only a few sentences.

Based on further analysis of the various reasons provided for why HACCP plan(s) were changed, increased testing of table or bench beef trim (5 percent) and increased frequency of random sampling and

[3] The text responses of filers were classified into categories by key word searches, using the text analysis services of Microsoft™ SQL Server 2005.

testing for *E. coli* O157:H7 of other beef products (7 percent) represented about 12 percent of the total actions.

In addition, of the total new actions taken (in descending order by percent), establishments:

- educated or trained employees (about 8 percent);
- separated beef plans from other plans (about 8 percent);
- added beef sirloin flap meat and other meats to the HACCP program (about 8 percent);
- dropped beef program and are no longer making any beef products (about 6 percent);
- added raw material product requirements for boneless beef intended for grinding (see ISO document JPU-009-SC) (about 6 percent);
- changed product descriptions to be more precise in the intended usage (about 6 percent);
- updated raw-not ground corned beef plan hazard analysis on receiving meat to reflect more specific purchase specifications (about 5 percent);
- modified the order of processing steps in the manufacturing of raw beef-not ground product, or added a step in the hazard analysis for the testing of cuts of beef (about 4 percent);
- added or modified one or more Critical Control Point (CCP)s (about 3 percent);
- required suppliers to have approved HACCP programs (about 3 percent);
- requested certificates of analysis (COA) from beef suppliers (about 3 percent);
- added or updated letters of guarantee from suppliers (about 2 percent);
- included a more frequent verification of the product received from approved suppliers (about 2 percent);
- included head meat as its own category of “domestic frozen” (about 2 percent);
- added steam vacuum treatment (about 2 percent);
- changed lactic acid application from CP to CCP, or implemented a second lactic/acetic acid spray prior to boning SOP, or raised the lower minimum limit on lactic acid from 1 to 2 percent (about 2 percent);
- eliminated the production of raw enhanced product (about 2 percent);
- changed procedures so that trim will only be added to the last production lot of the day, and the lot will be held pending results of *E-coli* testing (about 2 percent);
- changed the raw-not ground plan by removing the tenderizing of raw intact meat, or phased out mechanical tenderization, as well as needle injection (about 1 percent);
- lowered temperature in further processing department (about 1 percent);
- changed procedures so that product is intended for sale to FSIS-inspected facilities where it will eventually be cooked under an HACCP plan (about 1 percent);
- added requirements that all boxes of ground beef will have code date as the day of manufacturing before freezing (about 1 percent);
- modified raw material purchase specifications to include a requirement for a robust *E. coli* testing method (about 1 percent);
- required to keep *E. coli* 0157:H 7 testing records longer (about 1 percent);

- changed zero tolerance audit to a shorter time period (about 0.4 percent);
- placed warning label on master cases of product mechanically tenderized (cook to 140 degrees °F) (about 0.4 percent);
- implemented the American Meat Institute "Best Practices for Pathogen Control for Tenderizing Operations of Whole Muscle Cuts" (about 0.3 percent);
- changed procedures to no longer uses table or bench beef trim in ground beef (about 0.2 percent);
- added that meat storage will be at 40 degrees °F or less (about 0.2 percent); and
- changed "others" (about 0.5 percent).

The "others" category included infrequent responses, such as reviewing the scientific literature or technical reports.

For the 1,349 establishments that indicated that they did not change their HACCP plans after reassessment, many establishments gave more than 1 reason for making no changes to their HACCP plans. The 1,349 responses provided a total of 3,819 reasons. The calculated average is about 3 (3,819/1,349) reasons per establishment that did not change their HACCP plans after reassessment.

The reasons given for no action to change the HACCP plans were as follows (in descending order by percent); the establishment:

- had not produced ground beef or had purchase specifications in place for all incoming beef product to come from facilities that have interventions in place (about 21 percent);
- had changed their prerequisite program (about 16 percent);
- had already made recent changes in SSOP (about 14 percent);
- had an effective use of antimicrobials (about 14 percent);
- had a sufficient plan, based on testing results (about 12 percent);
- had ground beef products used for further processing (about 9 percent);
- had never had a positive sample for *E. coli* O157:H7 (about 5 percent);
- were satisfied with their purchase specifications for all incoming meat used in their grinding operation (about 5 percent);
- produced fully cooked beef products (about 2 percent); and
- had other reasons (about 1 percent).

The "other" category included infrequent responses, such as unsure what changes need to be made.

The third reassessment question asked whether the establishment changed its SSOP(s) as a result of the reassessment.

Table 4.4. Changes to SSOP(s)

Q3: Did the establishment change its SSOP(s) as a result of the reassessment?	**Number**	**Percent**
No	1,708	85
Yes	294	15

As indicated in Table 4.4, 15 percent (294) of establishments changed their SSOP(s) as a result of the reassessment, whereas 85 percent (1,708) of establishments did not change their SSOP(s). The rationale for these actions were further analyzed.

For the 294 establishments that indicated that they changed their SSOP(s) after reassessment, many establishments gave more than 1 reason for making changes. The 294 responses provided a total of 854 reasons for the changes in their SSOP(s). The calculated average is about 3 (854/294) reasons per establishment that did change their SSOP(s) after reassessment.

Of the new actions taken as a result of changing their SSOP(s) (in descending order by percent), establishments:

- enhanced hand washing sanitation actions (about 32 percent);
- enhanced programs for sanitation of equipment (about 21 percent);
- enhanced foot/boot washing sanitation actions (about 11 percent);
- incorporated a written sanitary procedure for raw beef operations (about 11 percent);
- increased pre-wash soak time for the injection needles used for tenderization process (about 11 percent);
- added a second operational checklist for the shift to ensure equipment is clean and to maintain sanitary conditions (about 10 percent);
- had other reasons (about 4 percent).

For the 1,708 establishments that indicated that they did not change their SSOP(s) after reassessment, many establishments gave only 1 reason for making no changes. The 1,708 responses provided a total of 1,763 reasons for not changing in their SSOP(s). The calculated average is about 1 (1,763/1,708) reason per establishment that did not change their SSOP(s) after reassessment.

About 26 percent of the "no action was taken" responses were because "all the requirements are currently met by the existing program." About 34 percent did not change their SSOP(s) because *E. coli* O157:H7 control is not addressed in the SSOP(s). Moreover, 27 percent indicated that no action was taken because "the establishment has trained employees on hygiene and sanitation practices."

In addition, other less frequent reasons included (in descending order by percent), the establishment:

- had no beef product contact surfaces in operation (about 3 percent);
- was satisfied that the current use of sanitizers in the sanitization of the facility is efficient to the best of its ability (about 2 percent);
- had no slaughtering process and control for *E. coli* O157:H7 is covered in the beef purchasing specifications (about 3 percent);
- took no action because of a recent Food Safety Assessment (FSA) and extensive changes, the establishment has a plan that is sufficient (about 2 percent);

- had beef production that is low volume and only made a few times a year (about 2 percent); and
- other reasons (about 1 percent).

The "other" category included infrequent responses, such as unsure what changes need to be made.

The fourth reassessment question asked whether the establishment changed its other prerequisite programs as a result of the reassessment.

Table 4.5. Changes to Other Prerequisite Programs

Q4: Did the establishment change its other prerequisite programs as a result of the reassessment?	**Number**	**Percent**
No	1,302	65
Yes	700	35

As indicated in Table 4.5, 35 percent (700) of establishments changed their other prerequisite programs as a result of the reassessment, whereas 65 percent (1,302) of establishments did not change their other prerequisite programs. The rationales for these actions were further analyzed.

For the 700 establishments that indicated that they changed their other prerequisite programs after reassessment, many establishments gave more than 1 reason for making changes. The 700 responses provided a total of 2,427 reasons for the changes in their other prerequisite programs. The calculated average is about 3 (2,427/700) reasons per establishment that did change their other prerequisite programs after reassessment.

About 21 percent of the responses were for new sampling plans and protocols for testing. About 18 percent were for an increased frequency of sampling and testing. About 18 percent of the responses said beef suppliers had been requested to provide updated letters of guarantees.

In addition, other actions taken by the establishments included (in descending order by percent):

- adding more robust sampling of raw beef materials that they are using for grinding (about 10 percent);
- requesting beef suppliers' COA for purchased beef products (about 8 percent);
- adding GMP for room temperature monitoring (about 8 percent);
- adding grinding GMP records to include source of all beef trimmings and cuts generated for grinding (about 7 percent);
- increasing the frequency of taking cooler/freezer temperatures and product temperature (about 7 percent);
- implementing a training program that was documented (about 1 percent); and
- other actions (about 1 percent).

For the 1,302 establishments that indicated that they did not change their other prerequisite programs after reassessment, many establishments gave more than 1 reason for making changes. The 1,302 responses provided a total of 2,177 reasons for the changes in their other prerequisite programs. The calculated average is about 2 (2,177/1,302) reasons per establishment who did change their other prerequisite programs after reassessment.

Establishments took no action because (in descending order by percent) the establishment:

- had a sufficient plan, based on testing results (about 22 percent);
- had no other prerequisite program that was affected (about 22 percent);
- had a Beef Purchase Specification Program in place to handle any boxed beef received from outside vendors (about 15 percent);
- had reconfirmed the letters of guarantee from beef suppliers for the intervention steps at the establishment of origin (about 10 percent);
- had only boxed beef and no swinging beef received at this establishment (about 8 percent);
- had never had a positive sample for *E. coli* O157:H7 (about 8 percent);
- had verification methods to ensure the continued effectiveness of its purchasing specifications (about 8 percent);
- had purchasing specifications (about 6 percent);
- produced fully cooked beef products (about 1 percent); or
- had other reason (about 1 percent).

The "other" category included reasons infrequent responses, such as unsure what changes need to be made.

The fifth Reassessment question asked how much time the inspector took to complete the Reassessment.

An analysis of the responses to this question indicated that the average time to complete these five Reassessment questions was about 70 minutes. The range of time was from about 2 minutes to several hours.

Overall Changes to Practices

Based on a combined analysis of reassessment questions 2 through 4, the number of total establishments that changed at least one of their HACCP Plans, SSOP, or other prerequisite program as a result of the reassessment was determined.

Table 4.6. Changes to Any Program

Did the establishment change any of its HACCP Plans, Sanitation SOPs, or other prerequisite programs as a result of the reassessment?	**Number**	**Percent**
"No" to Q2, Q3, and Q4	952	48
"Yes" to any of Q2, Q3, or Q4	1,050	52

As indicated in Table 4.6, 52 percent (1,050) of establishments changed at least one of their HACCP Plan(s), SSOP(s), or other prerequisite programs, as a result of the reassessment.

Summary

Selected findings about changes to HACCP plans, SSOPs, and other prerequisite programs, as indicated from reassessment responses, are summarized below.

- Ninety-six percent (1,925) of establishments reassessed their HACCP plans.

- Fifty-two percent (1,050) of establishments changed 1 or more of their HACCP plans, SSOPs, or other prerequisite programs.
- About 6 percent of establishments dropped their beef program or are no longer making any beef products.
- The most frequent change was to other prerequisite programs (35 percent overall), followed by changes to HACCP plans (33 percent overall), and SSOPs (15 percent overall).
- A combined 49 percent of responses about establishments who changed their other prerequisite programs indicated they made changes to sampling and testing programs (21 percent for new sampling plans and protocols for testing, 18 percent for an increased frequency of sampling and testing, and 10 percent for more robust sampling of raw beef materials that they are using for grinding).
- A combined 26 percent of responses about establishments who changed their other prerequisite programs indicated they made changes to supplier requirements (18 percent for beef suppliers to provide updated letters of guarantees, and 8 percent for suppliers' COA for purchased beef products).
- A combined 83 percent of responses about establishments who did not change their other prerequisite programs indicated they did not make changes because the programs were either sufficient (22 percent) or not affected (22 percent), or they had sufficient purchase specifications (21 percent), letters of guarantee (10 percent), or other verification methods (8 percent).
- A combined 12 percent of responses about establishments who changed their HACCP plans indicated they made changes to testing for *E. coli* O157:H7 (7 percent for more testing programs for *E. coli* O157:H7 of raw beef products and 5 percent for increased testing frequency of beef products).
- A combined 77 percent of responses about establishments who did not change their HACCP plans indicated they did not make changes because purchase specifications were in place (21 percent), prerequisite programs were changed (16 percent), SSOPs were changed (14 percent), or they had sufficient interventions (14 percent) or testing (12 percent).
- A combined 64 percent of responses about establishments who changed their SSOPs indicated they made changes to hand or foot sanitation (43 percent) or equipment sanitation (21 percent).
- A combined 87 percent of responses about establishments who did not change their HACCP plans indicated they did not make changes because their SSOP did not address *E. coli* O157:H7 (34 percent), employees had been sufficiently trained (27 percent), or all program requirements were met (26 percent).

5. RESULTS OF ATTACHMENT 5

5.1 HACCP Sizes of Checklist Establishments

The 2,323 establishments that provided information for Attachment 5 are different sizes. They are categorized into "Large," "Small," and "Very Small," according to criteria established by FSIS and the Small Business Administration[4] (SBA). SBA class sizes are based primarily on the number of employees at an establishment. Large establishments are those having 500 or more employees. Small establishments are those having between 10 and 500 employees. Very Small establishments are those having fewer than 10 employees or less than $2.5 million in annual sales. FSIS maintains information about the SBA class size of individual establishments. This information was combined with the Checklist data in order to profile the establishments represented by the Checklist data. **Figure 5.1.1** summarizes the numbers of Checklist establishments according to SBA class.

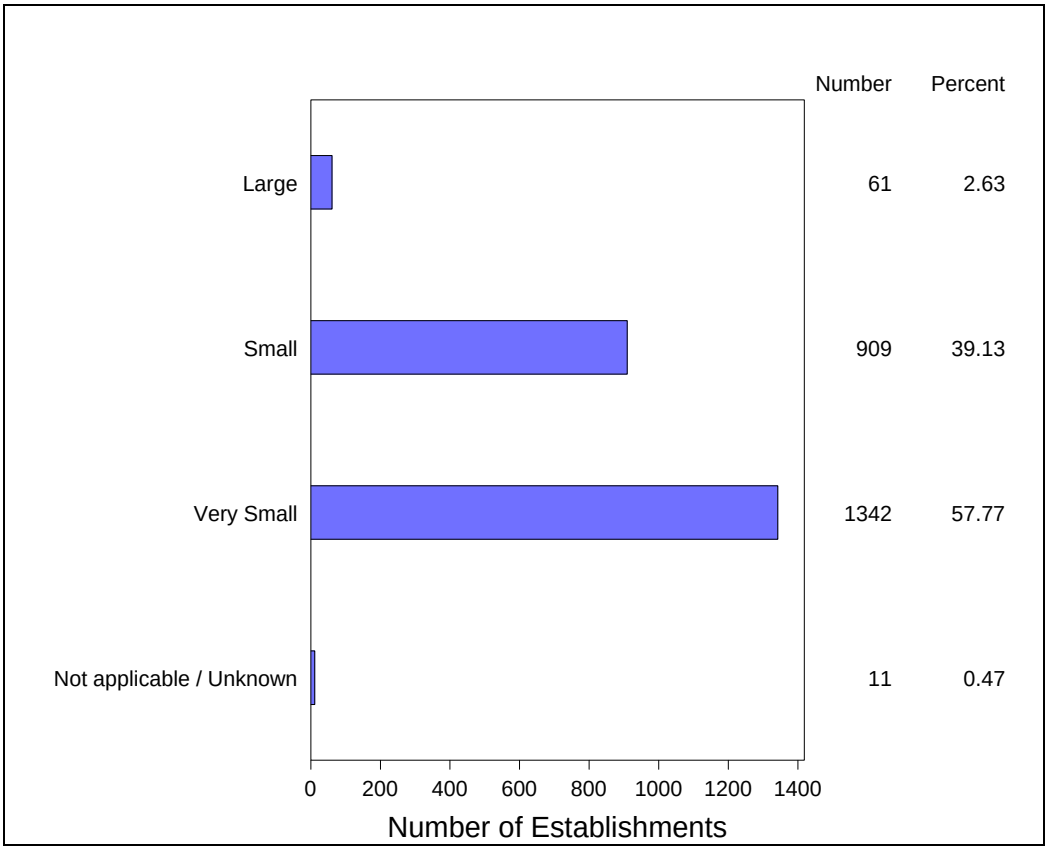

Figure 5.1.1. Checklist Establishments by SBA Class

As indicated in Figure 5.1.1, about 3 percent (61) establishments are Large, 39 percent (909) are Small, and 58 percent (1,342) are Very Small. The majority of the establishments profiled by the Checklist are Very Small establishments. This distribution of establishment sizes may be important in understanding the types of establishments characterized by each Checklist question. It should be noted that SBA class is determined by the number of establishment employees and is not reflective of the volume produced by the

[4] "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) System, Final Rule." *Federal Register* 61:144 (25 July 1996) p. 38806.

establishment. For a further discussion of establishment production volumes, see Section 5.3 of this chapter.

Eleven establishments are identified as Not applicable or Unknown. As discussed earlier, SBA class was not a question on the Checklist. This information was collected from other FSIS data sources and used to profile these establishments.

5.2 Food Safety System Questions

Raw Beef Food Safety Systems

The FSIS inspectors were asked to answer questions about the food safety systems for all 2,323 establishments.

Tables 5.2.1 through **5.2.12** provide tabulations (number of establishments and percentage) of responses to 12 Checklist questions related to food safety systems. For most questions, inspectors who completed the Checklist were able to select only one response. In some cases, more than one response was permitted. In these cases, the total number of responses to a question is more than the number of establishments represented and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end of the question. The number and percent in the "No response" category refer to Checklists where no response to a specific question was given.

The first Checklist question about food safety systems asked about the HACCP processing categories for which the establishment had a hazard analysis.

Table 5.2.1. HACCP Processing Categories

FBFSS1: For which raw beef HACCP processing categories does the establishment have a hazard analysis? (check all that apply).	**Number**	**Percent**
03J Slaughter	591	25
03C Raw product - not ground	1,849	80
03B Raw product - ground	1,520	65
No response	15	1

As indicated in Table 5.2.1, 25 percent (591) of establishments have a 03J (Slaughter) process, 80 percent (1,849) of establishments have a 03C (raw product – not ground) process, and 65 percent (1,520) have a 03B (raw product – ground) process.

For each of the three processing categories identified in Table 5.2.1, specific food safety questions were asked. Questions FBFSS2 through FBFSS4 asked about the practices of the 591 03J establishments. Best practices for 03J establishments are defined as the implementation of a validated decontamination intervention, controlled through a CCP, to eliminate, prevent, or reduce *E. coli* O157:H7 to a nondetectable level.

The Checklist asked about the identification of *E. coli* O157:H7 as a hazard for 03J establishments.

Table 5.2.2. *E. coli* O157:H7 Hazard for 03J Establishments

FBFSS2: Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely or not likely to occur in the 03J slaughter HACCP processing category?	**Number**	**Percent**
Likely to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a nondetectable level (best practice)	547	93
Not likely to occur	29	5
Don't know	4	1
No response	11	2

As indicated in Table 5.2.2, 93 percent (547) of establishments identified *E. coli* O157:H7 as a hazard reasonably likely to occur and had a CCP to prevent, eliminate, or reduce the pathogen to nondetectable levels. Five percent (29) of establishments did not identify *E. coli* O157:H7 as a hazard likely to occur.

The Checklist also asked about testing of beef carcasses for *E. coli* O157:H7.

Table 5.2.3. Beef Carcass Testing for 03J Establishments

FBFSS3: Does the establishment test beef carcasses for *E. coli* O157:H7?	**Number**	**Percent**
No	319	54
Yes, the establishment conducts robust testing of at least 1 in 300 carcasses	51	9
Other, please specify:	219	37
Don't know	0	0
No response	2	0

As indicated in Table 5.2.3, 54 percent (319) of 03J establishments did not test beef carcasses for *E. coli* O157:H7. Nine percent (51) of establishments followed the FSIS best practices of conducting robust testing of at least 1 in 300 carcasses. Thirty-seven percent (219) of 03J establishments perform testing at a different standard. A review of specified responses identified a variety of actions. Some establishments tested every carcass, whereas, others tested 1 in more than 4,000 carcasses. Other responses were in the form of frequency rather than numbers of carcasses. Some establishments tested once per shift, whereas, others tested annually. Since these responses did not indicate the number of slaughters in the timeframe, the number of carcasses tested cannot be determined. Some establishments tested for generic *E. coli*. In some responses, positive tests for generic *E. coli* would trigger a test for *E. coli* O157:H7.

Checklist question FBFSS4 asked about third-party audits of the establishment's 03J controls.

Table 5.2.4. Third-Party Audit Controls for 03J Establishments

FBFSS4: Does the establishment have a third-party audit its controls for its 03J controls?	**Number**	**Percent**
No	506	86
Yes, for every supplier and itself at least once annually	57	10
Yes, but at another frequency	22	4
Don't know	2	0
No response	4	1

As indicated in Table 5.2.4, 86 percent (506) of 03J establishments did not have third-party audits of its controls. Ten percent (57) of establishments had audits of itself and every supplier at least annually. Four percent (22) of establishments had audits at a different frequency. A review of the specified other frequencies identified establishments who audited themselves, but not their suppliers. Some establishments specified more frequent audits than annually. Other establishments had audits at the customer's request.

Questions FBFSS5 through FBFSS8 asked about the practices of the 1,849 03C establishments. Best practices for 03C establishments are defined as: (1) the use of source materials from an 03J process that employed slaughter best practice; (2) the use of ongoing verification testing of source materials from all suppliers, at least quarterly using robust testing methods; and (3) the use of ongoing verification testing of all finished product that is, or will be, used as non-intact raw beef using robust testing methodology.

Checklist question FBFSS5 asked whether 03C establishments identified *E. coli* O157:H7 as a hazard likely to occur and whether they had controls to require that source materials be processed under FSIS best practices.

Table 5.2.5. *E. coli* O157:H7 Hazard for 03C Establishments

FBFSS5: Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely or not likely to occur in the 03C Raw–Not Ground HACCP processing category?	**Number**	**Percent**
Likely to occur with a CCP to prevent, eliminate, or reduce *E. coli* to a nondetectable level, along with controls that require incoming raw beef source materials to have been processed under 03J slaughter best practices and, if applicable, 03C raw--not ground best practices	236	13
Likely to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a nondetectable level, but with controls other than best practices, please specify:	380	21
Not likely to occur because the establishment has a purchase specification, as part of its written sanitation standard operating procedures or other prerequisite program, that requires incoming raw beef source materials to have been processed under 03J slaughter best practices and, if applicable, 03C raw-not ground best practices	667	36
Not likely to occur for other reasons, please specify:	546	30
Don't know	10	1
No response	10	1

As indicated in Table 5.2.5, 13 percent (236) of 03C establishments did identify *E. coli* O157:H7 as a hazard, had a CCP to prevent, eliminate or reduce *E. coli* O157:H7, and had controls requiring suppliers to have used slaughter best practices and/or raw – not ground best practices. Twenty-one percent (380) of establishments did identify *E. coli* O157:H7 as a hazard likely to occur, but had controls other than best practices. A review of the specified other controls identified temperature controls in about three quarters of the responses. Less frequent responses included establishments who did not use suppliers (i.e., all source materials are from in-house) and the use of letters of guarantee.

Thirty-six percent (667) of 03C establishments did not identify *E. coli* O157:H7 as a hazard likely to occur because the establishment relies on purchase specifications requiring the incoming source materials to be processed using best practices. Thirty percent (546) of establishments did not identify *E. coli* O157:H7 as a hazard likely to occur for other reasons. A review of the specified other responses indicated that the most common practice was to have purchase specifications or letters of guarantee that required suppliers to conduct interventions.

The Checklist also asked about testing of source materials by 03C establishments.

Table 5.2.6. Testing of Source Materials for 03C Establishments

FBFSS6: Does the establishment or its designee test source materials used in the 03C Raw–Not Ground HACCP process?	**Number**	**Percent**
No, the establishment tests no source materials	1,339	72
The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods	83	4
The establishment tests source materials using a different frequency and/or method, please specify:	413	22
Don’t know	6	0
No response	8	0

As indicated in Table 5.2.6, 72 percent (1,339) of 03C establishments did not test source materials. Four percent (83) of establishments tested source materials at least quarterly using robust testing methods. Twenty-two percent (413) of establishments tested source materials using a different method or frequency. A review of the specified other methods/frequencies indicates that establishments tested source materials anywhere from daily or by lot to annually. The most common frequency was monthly to quarterly. For those establishments that tested quarterly, some did not test all suppliers or did not use robust testing methods. Other responses did not indicate how the establishment who tested quarterly differed from the Checklist best practice response.

The Checklist also asked about testing of finished product by 03C establishments.

Table 5.2.7. Testing of Finished Product for 03C Establishments

FBFSS7: Does the establishment or its designee test finished 03C product that is or will be used to make non-intact product?	**Number**	**Percent**
No, the establishment tests no finished product	1,405	76
The establishment tests all production lots of such finished product using a robust testing method	76	4
The establishment tests such finished product using a different frequency and/or method, please specify:	348	19
Don't know	9	0
No response	11	1

As indicated in Table 5.2.7, 76 percent (1,405) of 03C establishments did not test the finished product. Four percent (76) of establishments tested all lots of finished product using a robust testing method. Nineteen percent (348) of establishments tested finished product using a different frequency and/or method. A review of specified other responses indicates that establishments tested finished product anywhere from daily to annually. The most common frequency was in the monthly to quarterly range. For those establishments that tested quarterly, some did not test all suppliers or did not use robust testing methods. Other responses did not indicate how the establishment who tested quarterly differed from the Checklist best practice response.

The Checklist also asked about third-party audit controls for 03C establishments.

Table 5.2.8. Third-Party Audit Controls for 03C Establishments

FBFSS8: Does the establishment have a third-party audit its controls for its 03C product and the controls of all its raw beef suppliers?	**Number**	**Percent**
No	1,586	86
Yes, for every supplier and itself at least once annually	182	10
Yes, but at another frequency, please specify:	68	4
Don't know	8	0
No response	5	0

As indicated in Table 5.2.8, 86 percent (1,586) of 03C establishments did not have a third-party audit its controls or the controls of their suppliers. Ten percent (182) of establishments did have a third-party audit itself and its suppliers at least annually. Four percent (68) of establishments had audits at a different frequency. A review of the specified other frequencies identified establishments who had audits of themselves, but not their suppliers. Some establishments audited suppliers, but not themselves. Some responses specified that audits occurred as frequently as monthly or as infrequently as every 2 years. Some specified responses indicated that establishments did not audit all suppliers or audited just North American suppliers. A few establishments audited only at the customer's request.

Questions FBFSS9 through FBFSS12 asked about the practices of the 1,520 03B establishments.

Table 5.2.9. *E. coli* O157:H7 Hazard for 03B Establishments

FBFSS9: Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably likely or not likely to occur in the 03B Raw Product–ground HACCP processing category	**Number**	**Percent**
Likely to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a nondetectable level, along with controls that require raw beef source materials to have been processed under 03J slaughter best practices, 03C beef best practices and, if applicable, 03B beef best practices	181	12
Likely to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a nondetectable level, but with controls other than best practices, please specify:	348	23
Not likely to occur because the establishment has a written purchase specification, as part of its written Sanitation SOP or other prerequisite program, that require raw beef source materials to have been processed under 03J slaughter best practices, 03C beef best practices and, if applicable, 03B beef best practices	529	35
Not likely to occur for other reasons, please specify:	445	29
Don't know	10	1
No response	7	0

As indicated in Table 5.2.9, 12 percent (181) of 03B establishments did identify *E. coli* O157:H7 as a hazard, had a CCP to prevent eliminate or reduce *E. coli* O157:H7, and had controls requiring suppliers to have used slaughter (03J), raw – not ground (03C), and/or raw – ground (03B) best practices. Twenty-three percent (348) of establishments did identify *E. coli* O157:H7 as a hazard likely to occur, but had controls other than best practices. A review of the specified other controls identified temperature controls in about two-thirds of the responses. Less frequent responses included establishments who relied on certificates of analysis or letters of guarantee from suppliers.

Thirty-five percent (529) of 03B establishments did not identify *E. coli* O157:H7 as a hazard likely to occur because the establishment relies on purchase specifications requiring the incoming source materials to be processed using best practices. Twenty-nine percent (445) of establishments did not identify *E. coli* O157:H7 as a hazard likely to occur for other reasons. A review of the specified other responses indicated that the most common practice was to have purchase specifications or letters of guarantee from suppliers.

The Checklist also asked about testing of source materials by 03B establishments.

As indicated in Table 5.2.10, 67 percent (1,024) of 03B establishments did not test source materials. Six percent (86) of establishments tested source materials at least quarterly, using robust testing methods and more frequent testing during high prevalence season months. Twenty-six percent (395) of establishments tested source materials using a different method or frequency. A review of the specified other methods/frequencies indicates that establishments tested source materials anywhere from hourly to annually. The most common frequency was monthly to quarterly. For those establishments that tested quarterly, some did not test all suppliers or did not use robust testing methods. Other responses did not indicate how the establishment who tested quarterly differed from the Checklist best practice response.

The Checklist also asked about testing of finished product by 03B establishments.

Table 5.2.10. Testing of Source Materials for 03B Establishments

FBFSS10: Does the establishment or its designee specifically conduct ongoing verification testing of source materials received from each supplier at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?	**Number**	**Percent**
No, the establishment does not test source materials	1,024	67
Yes, for every supplier, including in-house generated source materials, without exception	86	6
The establishment tests source materials using a different frequency and/or method, please specify:	395	26
Don't know	2	0
No response	13	1

Table 5.2.11. Testing of Finished Product for 03B Establishments

FBFSS11: Does the establishment or its designee specifically conduct ongoing verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?	**Number**	**Percent**
No, the establishment does not test finished product	829	55
Yes	83	5
The establishment tests finished product using a different frequency and/or method, please specify:	595	39
Don't know	2	0
No response	11	1

As indicated in Table 5.2.11, 55 percent (829) of 03B establishments did not test the finished product. Five percent (83) of establishments tested all lots of finished product, at least monthly, using a robust testing method. Thirty-nine percent (595) of establishments tested finished product using a different frequency and/or method. A review of specified other responses indicates that establishments tested finished product anywhere from every 30 minutes to annually. The most common frequency was in the monthly to quarterly range. For those establishments that tested quarterly, some did not test all suppliers or did not use robust testing methods. Other responses did not indicate how the establishment who tested quarterly differed from the Checklist best practice response.

The Checklist also asked about third-party audit controls for 03B establishments.

Table 5.2.12. Third-party Audit Controls for 03B Establishments

FBFSS12: Does the establishment have a third-party audit its controls for its 03B products and the controls of all its raw beef suppliers	**Number**	**Percent**
No	1,319	87
Yes, for every supplier and itself at least once annually	139	9
Yes, but at another frequency, please specify:	52	3
Don't know	5	0
No response	5	0

As indicated in Table 5.2.12, 87 percent (1,319) of 03B establishments did not have a third-party audit its controls or the controls of their suppliers. Nine percent (139) of establishments did have a third-party audit itself and its suppliers at least annually. Three percent (52) of establishments had audits at a different frequency. A review of the specified other frequencies identified establishments who had audits of themselves, but not their suppliers. Some establishments audited suppliers, but not themselves. Some responses specified that audits occurred as frequently as monthly or as infrequently as every 2 years. Some specified responses indicated that establishments did not audit all suppliers or audited just North American suppliers. A few establishments audited only at the customer's request.

Summary

Selected findings about raw beef food safety systems as indicated from Checklist responses are summarized below.

- Ninety-three percent (547) of 03J establishments, 13 percent (236) of 03C establishments, and 12 percent (181) of 03B establishments identify *E. coli* O157:H7 as a hazard and use respective "best practices" as defined in the Checklist (Tables 5.2.2, 5.2.5, and 5.2.9).
- Fifty-four percent of 03J establishments did not test beef carcasses (Table 5.2.3).
- Eighty-six percent (506) of 03J establishments, 86 percent (1,586) of 03C establishments, and 87 percent (1,319) of 03B establishments do not have third party audits of their controls (Tables 5.2.4, 5.2.8, and 5.2.12).
- Based on a combined analysis of Checklist questions FBFSS6 and FBFSS7, 61 percent (1,132) of 03C establishments test neither source materials nor finished product for *E. coli* O157:H7 (Tables 5.2.6 and 5.2.7).
- Based on a combined analysis of Checklist questions FBFSS10 and FBFSS11, 41 percent (629) of 03B establishments test neither source materials nor finished product for *E. coli* O157:H7 (Tables 5.2.10 and 5.2.11).

5.3 Product Production and Volume Questions

The Checklist asked several questions to assess production volume.

Checklist Question PPV2 was analyzed to determine monthly production volume of each of 18 product types. To determine monthly production volume, the daily production volume for a given product type was multiplied by the number of days the establishment produced that product type.

As described earlier, these data required a significant amount of cleaning. After data cleaning, valid data were used from 2,253 of 2,323 Checklist responses. Results are reported as the number of establishments producing each product type and the monthly volume (in 100,000 pounds). More than one product type can be produced by an establishment. In such cases, the production volume of each product type is reported and the establishment is counted for each product type. Since establishments can be represented in multiple product type categories, the total number of establishments represented in the tables and figures is greater than the 2,253 Checklist responses.

Total Monthly Production Volume

As reported by the Checklist responses to question PPV2, the total production volume of the 18 categories of raw beef products is 2,083,000,000 pounds per month. Some of the product types are used in subsequent operations. For example, fabrication of primal/sub-primal cuts may be used in mechanical tenderizing or enhanced product operations to produce other raw beef products. Therefore, the total volume produced as measured by the Checklist responses should not be considered an estimate of the total monthly commercial product produced.

As indicated in **Figure 5.3.1**, the monthly total production volume varies by HACCP size. The Large establishments generally produce the greatest amount of product per establishment, followed by the Small establishments and then the Very Small establishments. Although the production volume trend is consistent with HACCP size, there are clear exceptions. Some Large establishments produce as little as 1,000 to 10,000 pounds per month. This is less than most Small establishments and about half of the Very Small establishments. Some of the Small establishments produce in the range of 10 million to 100 million pounds per month. This is comparable to many of the Large establishments. The overlap of the whiskers (i.e., the lines extending from each box) and outliers (i.e., the points beyond the whiskers) from Figure 5.3.1 indicates that, while HACCP size may be a rough estimator of monthly production volume, there is a high degree of overlap.

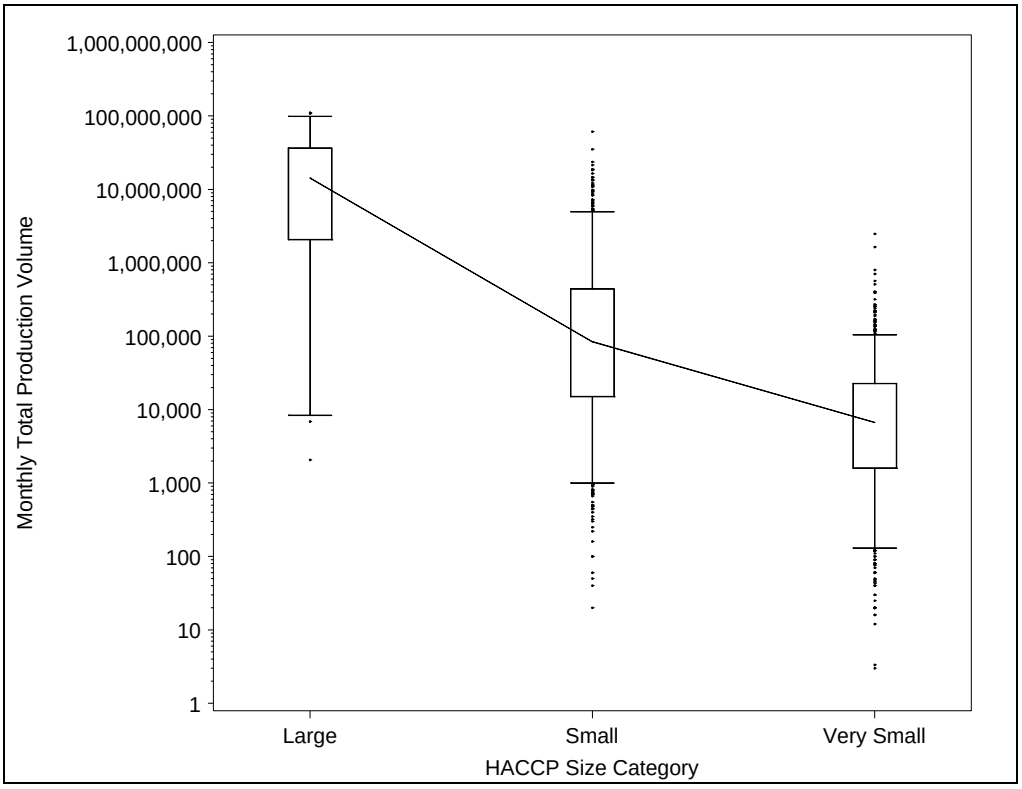

Figure 5.3.1. Monthly Production Volume by HACCP Size

Monthly Production Volume by Category

Checklist question PPV2 asked about production of 18 types of beef products. The total monthly production volume discussed earlier is based on the sum of the 18 types. The following section summarizes the monthly production volumes of each of the raw beef production types.

As indicated in **Table 5.3.1,** the greatest number of establishments (1,094) produced "Grinding boneless manufacturing trimmings or other raw ground beef components." "Fabrication of primal/sub-primal cuts" is produced by 949 establishments.

Table 5.3.1. Monthly Production Volume (Number of Establishments and Amount Produced)

Product Type	Number of Establishments	Monthly Volume (in 100,000 pounds)
Head meat	120	54
Cheek meat	205	88
Weasand meat	45	9
Heart meat	287	95
Advanced meat recovery (AMR) product	15	28
Low temperature rendered lean finely textured beef	10	443
Partially defatted beef fatty tissue	3	34
Partially defatted chopped beef	14	31
Fabrication of primal/sub-primal cuts	949	7,723
Trim fabrication production	755	5,813
Mechanical blade tenderizing	601	283
Mechanical needle tenderizing	273	222
Mechanical tenderizing by pounding	25	3
Fabricated steak	668	327
Enhanced product (tumbled, massaged, or injected with solutions [e.g., marinade])	372	554
Regrind coarse ground product	208	149
Grinding boneless manufacturing trimmings or other raw ground beef components	1,094	2,925
Formed patties	799	2,048

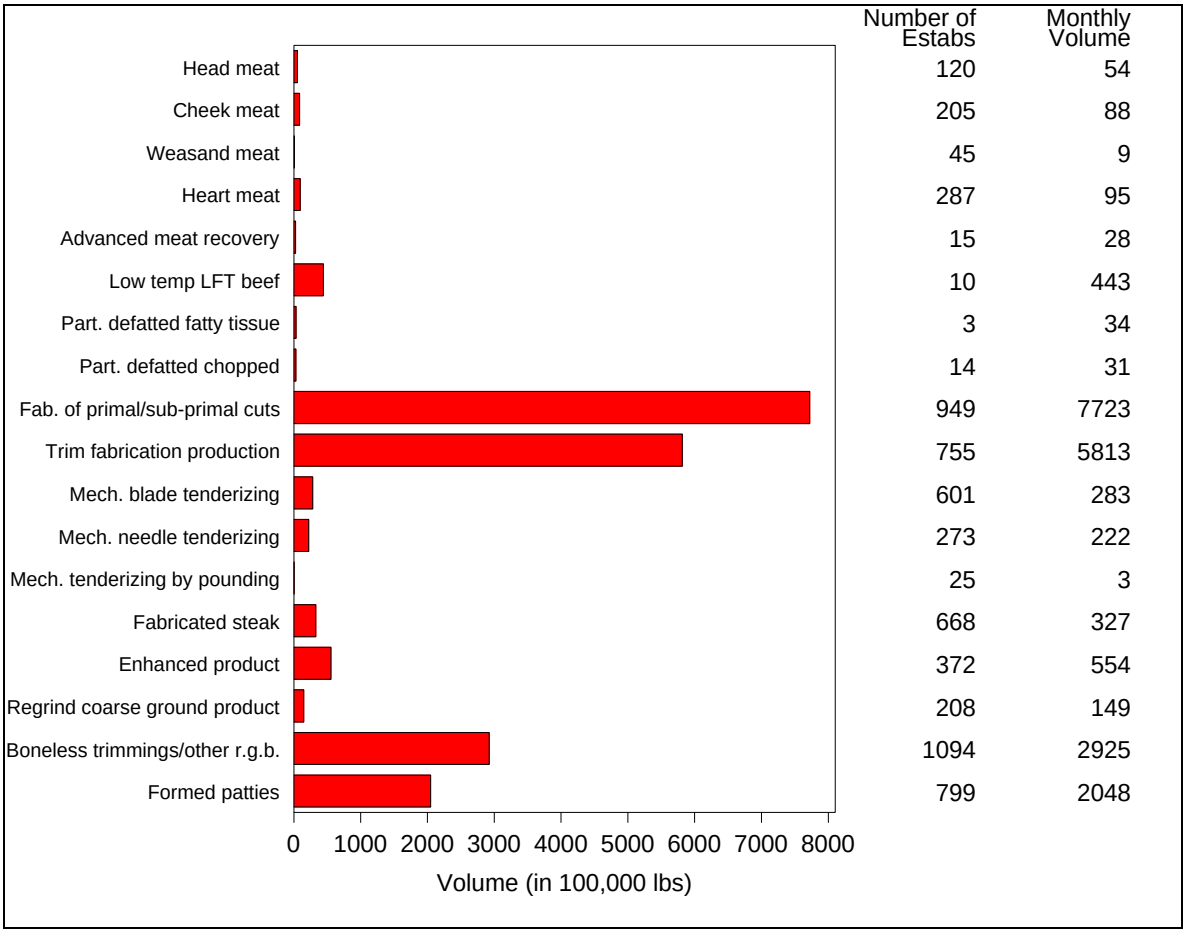

Figure 5.3.2. Monthly Production Volume (in 100,000 pounds)

The product type with the greatest volume produced is "Fabrication of primal/sub-primal cuts" (772.3 million pounds per month). The product type with the second largest monthly production volume is "Trim fabrication production" (581.3 million pounds per month).

Trim fabrication production differs from boneless manufacturing trimmings based on the source material. Boneless manufacturing trimmings are produced from the carcass during the fabrication process and are created from the materials left after primal/sub-primal cuts have been removed from the carcass. Trim fabrication also is produced at the fabrication step, but is created from the preparation of the primal/sub-primal cuts themselves. Trim fabrication production is sometimes referred to as bench trim.

Summary

Selected findings about monthly production volume as indicated from Checklist responses to question PPV2 are summarized below:

- HACCP size is a general, but not a strong indicator of total monthly production volume.
- The four categories with the greatest production volume are: Fabrication of primal/sub-primal cuts (772.3 million pounds per month); trim fabrication production (581.3 million pounds per month); grinding boneless manufacturing trimmings and other raw ground beef components (292.5 million pounds per month); and formed patties (204.8 million pounds per month).

5.4 Establishment Category Questions

The Checklist question, EstabCategory, asked about the types of beef operations conducted at the establishment.

An establishment could conduct more than one beef operation, and thus more than one selection could be made for this question. Therefore, the total number of operations selected in response to this question is greater than the number of Checklists returned. The percentages also add up to more than 100 percent for the same reason.

As indicated in **Table 5.4.1**, the majority of establishments (1,375; 59 percent) conducted the operation, "Grinding trim and other raw ground beef components." The Checklist questions related to beef grinding operations were asked for 1,375 establishments. The next most common operation conducted was "Trim and other raw ground beef component fabrication" (1,008; 43 percent). The Checklist questions related to trim fabrication were asked for 1,008 establishments. The "Patty forming" operation was the third most selected operation (952; 41 percent). The Checklist questions related to patty forming were asked for 952 establishments. "Mechanical tenderization" was the fourth most selected operation (850; 37 percent) and the Checklist questions related to mechanical tenderization were asked for 850 establishments. The fifth most selected operation type was "Slaughter" (587; 25 percent) and the Checklist questions related to slaughter were asked for 587 establishments. The sixth most commonly selected operation was "Enhanced product (marinated or injected)" (472; 20 percent) and the Checklist questions related to enhanced products were asked for 472 establishments. The least common operation conducted was "Regrind coarse ground" (281; 12 percent). The Checklist questions related to regrinding were asked of 281 establishments. Thirteen percent (297) of establishments either did not conduct any of these specific beef operations or did not record responses to this question. Checklist questions related to specific beef operations were not asked for these 297 establishments. **Figure 5.4.1** illustrates the numbers of establishments that conducted each of the seven beef operations subject to this Checklist.

Table 5.4.1. Beef Operation Categories

EstabCategory: Please select the specific beef operations conducted at your establishment from the list below (check all that apply).	**Number**	**Percent**
Grinding trim and other raw ground beef components	1,375	59
Trim and other raw ground beef component fabrication	1,008	43
Slaughter	587	25
Regrind coarse ground	281	12
Patty forming	952	41
Enhanced product (marinated or injected)	472	20
Mechanical tenderization	850	37
No response	297	13

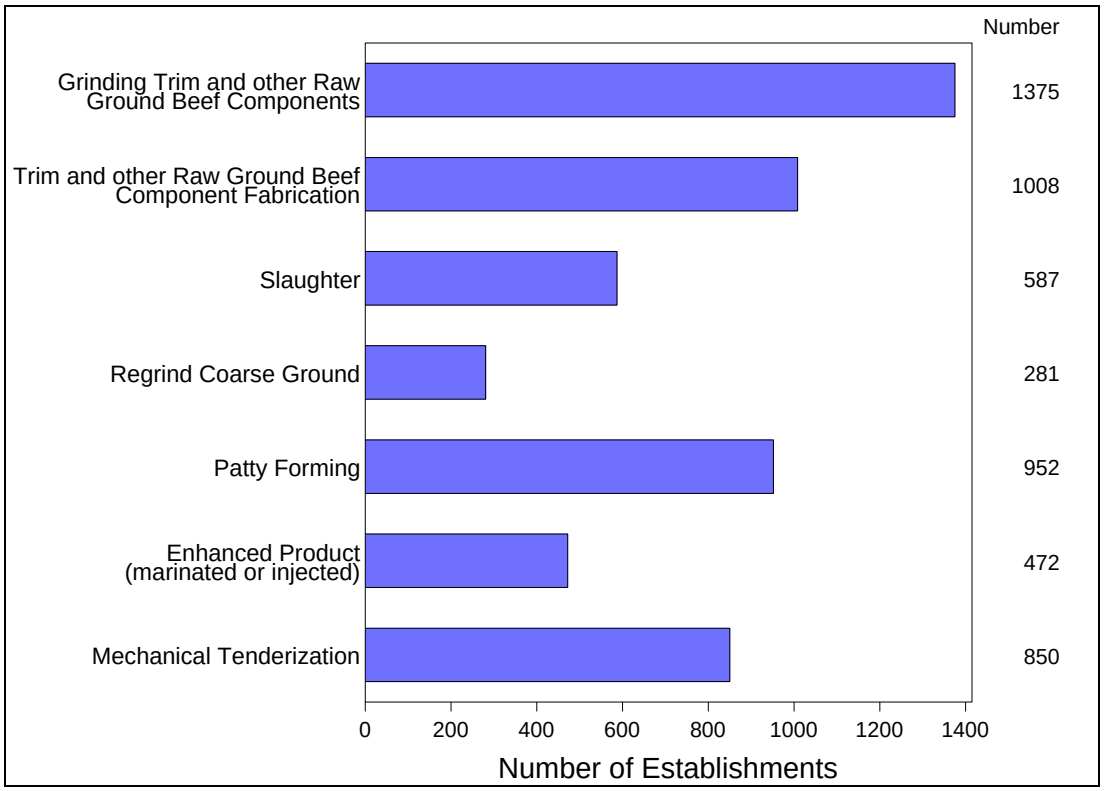

Figure 5.4.1. Beef Operation Categories

5.4.1 Grinding Trim and Other Raw Ground Beef Components

As indicated in Table 5.4.1, 1,375 Checklist responses (out of 2,323) indicated that the establishment had a beef grinding operation.

Tables 5.4.2 through **5.4.19** provide tabulations (number of establishments and percentage) of 18 *E. coli* Checklist questions specific for establishments with beef grinding operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question is more than 1,375, and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end of the question. The number and percent in the "No Response" category refer to Checklists where no response to a specific question was selected.

The first beef grinding operation question asked whether an establishment operated one or two beef grinding shifts.

As indicated in Table 5.4.2, 98 percent (1,353) of establishments with beef grinding operations ground beef during shift 1, and 8 percent (107) of establishments ground beef during a second shift.

The Checklist asked whether establishments had purchase specifications requiring suppliers to apply various intervention methods and/or testing for *E. coli* O157:H7.

Table 5.4.2. Shifts for Beef Grinding Operations

BGShift: Please select each shift(s) of operation this establishment grinds beef (check all that apply)?	**Number**	**Percent**
Shift 1	1,353	98
Shift 2	107	8
No response	17	1

Table 5.4.3. Purchase Specifications for Supplier Testing and/or Interventions

BeefGrind1: Does the establishment have purchase specifications requiring that suppliers conduct any of the following? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)	**Number**	**Percent**
No	328	24
Validated intervention methods during slaughter	739	54
Validated intervention methods during fabrication	256	19
Testing of carcasses for *E. coli* O157:H7	290	21
Testing of trim for *E. coli* O157:H7	322	23
Testing of other raw ground beef components for *E. coli* O157:H7	221	16
Other, please specify	264	19
Don't know	8	1
No response	12	1

As indicated in Table 5.4.3, 24 percent (328) of establishments did not have purchase specifications for suppliers, 1 percent (8) responded "Don't know," and 1 percent (12) did not have a response to the question. The remaining 74 percent (1,027) of establishments had one or more types of purchase specifications. The most common purchase specification required suppliers to have validated intervention methods during slaughter. This was required by 54 percent (739) of establishments. Validated intervention methods during fabrication were required by 19 percent (256) of establishments. In terms of testing for *E. coli* O157:H7, 21 percent (290) of establishments tested carcasses, 23 percent (322) tested trim, and 16 percent (221) tested other raw ground beef components. The most common explanations for selecting "Other, please specify" (N=264, 19 percent) were that the establishment only used their own slaughter product or they had letters of guarantee.

Checklist question BeefGrind2 asked about documentation that establishments had, other than purchase specifications, which showed that suppliers applied validated intervention methods and/or testing for *E. coli* O157:H7.

Table 5.4.4. Other Documentation of Supplier Testing and/or Interventions

BeefGrind2: Does the establishment have documentation other than purchase specifications showing that suppliers apply any of the following (check all that apply)?	**Number**	**Percent**
No	614	45
Validated intervention methods during slaughter	444	32
Validated intervention methods during fabrication	164	12
Testing of carcasses for *E. coli* O157:H7	237	17
Testing of trim for *E. coli* O157:H7	304	22
Testing of other raw ground beef components for *E. coli* O157:H7	212	15
Other, please specify	257	19
Don't know	4	0
No response	9	1

As indicated in Table 5.4.4, 45 percent (614) did not have other documentation for suppliers, another <1 percent (N=4) responded "Don't know," and 1 percent (9) did not respond to question BeefGrind2. The other 748 (54 percent) had documentation showing that intervention methods and/or testing were applied. Documentation of validated intervention methods during slaughter was the most common response (N=444, 32 percent). Validated intervention methods during fabrication were required by 12 percent (164) of establishments. In terms of testing for *E. coli* O157:H7, 17 percent (237) of establishments used suppliers that tested carcasses, 22 percent (304) used suppliers that tested trim, and 15 percent (212) used suppliers that tested other raw ground beef components.

Checklist questions BeefGrind3 and BeefGrind3a asked about validated interventions applied by establishments. BeefGrind3 asked about interventions applied to trim or other ground beef components, and BeefGrind3a asked about interventions applied to ground product.

Table 5.4.5. Use of Validated Interventions on Components

BeefGrind3: Does the establishment apply any validated intervention on trim or other ground beef components (check all that apply)?	**Number**	**Percent**
No Intervention	1,259	92
Organic acid	30	2
Acidified sodium chlorite	15	1
Acidified calcium sulfate	2	0
Irradiation	0	0
Gaseous ammonia	0	0
Other, please specify	78	6
Don't know	1	0
No response	10	1

Table 5.4.6. Use of Validated Interventions on Product

BeefGrind3a: Does the establishment apply any validated intervention on the ground product (check all that apply)?	**Number**	**Percent**
No Intervention	1,296	94
Organic acid	3	0
Acidified sodium chlorite	8	1
Acidified calcium sulfate	2	0
Irradiation	2	0
Gaseous ammonia	0	0
Other, please specify	68	5
Don't know	2	0
No response	9	1

As indicated in Tables 5.4.5 and 5.4.6, 92 percent (1,259) of establishments did not apply interventions on the trim or other ground beef components and 94 percent (1,296) did not apply interventions on the ground product. The most common intervention selected was "Other, please specify" for both questions (N=78 [6 percent] for BeefGrind3 and N=68 [5 percent] for BeefGrind3a). When asked to specify other interventions, temperature control was most frequently noted. It should be noted that temperature controls are not considered a validated intervention method. The specified "Other" responses indicated that some of these may be better classified as "No intervention." For the purposes of this report, no reclassification of responses was made.

The Checklist also asked about verification testing of source materials.

Table 5.4.7. Verification Testing of Source Materials

BeefGrind4: Does the establishment or its designee specifically conduct ongoing verification testing of source materials (e.g., trim, head meat, weasand meat) at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?	**Number**	**Percent**
No, the establishment does not test source materials	918	67
Yes, for every supplier, including in-house generated source materials, without exception	83	6
The establishment test source materials using a different frequency and/or method, please specify:	359	26
Don't know	3	0
No response	12	1

As indicated in Table 5.4.7, verification testing conducted on source materials varied widely. Sixty-seven percent (918) of establishments did not test source materials. Six percent (83) of establishments conducted testing using the same frequency and/or method as stated in the Checklist question. Twenty-six percent (359) of establishments used a frequency or method other than what was specified in the Checklist question. When asked to specify other methods and/or frequencies used, the frequency of

testing reported varied widely from hourly to annually. There was little indication from the specified responses that testing was being performed more frequently in high prevalence season months. Some establishments also randomly selected suppliers for testing rather than testing the more frequent suppliers at a higher rate. The methods for randomly selecting suppliers for testing were not described in the specified responses.

The Checklist also asked about verification testing of finished product.

Table 5.4.8. Verification Testing of Finished Product

BeefGrind5: Does the establishment or its designee specifically conduct ongoing verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?	**Number**	**Percent**
No, the establishment does not test finished product	691	50
Yes	69	5
The establishment tests finished product using a different frequency and/or method, please specify:	609	44
Don't know	1	0
No response	5	0

As indicated in Table 5.4.8, verification testing conducted on finished product varied widely. Fifty percent (691) of establishments did not test finished product. Five percent (69) of establishments test using the same frequency and/or method as stated in the question. Forty-four percent (609) of establishments used a frequency or method other than what was specified in the Checklist question. When asked to specify the other methods and/or frequencies used, the frequency of testing varied widely from hourly to annually. There was little indication from the specified responses that testing is being performed more frequently in high prevalence season months.

Based on a tabulation of combined responses to both questions, 526 (38 percent) of establishments did not conduct testing on either the source materials or the finished product.

The Checklist asked about laboratory methods used for testing for *E. coli* O157:H7.

Table 5.4.9. Laboratory Methods for Testing for *E. coli* O157:H7

BeefGrind6: What laboratory method does the establishment or its designee use to test ground beef or finished product for *E. coli* O157:H7?	**Number**	**Percent**
FSIS Method	205	15
Other, please specify	414	30
Don't know	65	5
No response	691	50

As indicated in Table 5.4.9, 15 percent (205) of establishments used the FSIS Method for testing ground beef or finished product for *E. coli* O157:H7. Thirty percent (414) used a method other than the FSIS Method. When asked to specify other methods used, about half indicated various Association of Official Analytical Chemists (AOAC) methods were used. Other responses did not indicate the specific method,

but did indicate that a third-party testing lab performed the testing. The nonresponse rate for this question was 50 percent (691), higher than for any of the other beef grinding operation questions. Please refer to Chapter 4.1 for a discussion of nonresponse rates.

The Checklist asked about how source materials were grouped.

Table 5.4.10. Grouping of Source Materials

BeefGrind7: How does the establishment group source materials into lots for grinding (check all that apply)?	**Number**	**Percent**
Based on groupings of tested, combo bins/boxes/other units	135	10
Based on combo bins/boxes/other units from one supplier	322	23
Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conduct robust testing	178	13
All combo bins/units received in 1 day	209	15
Other, please specify:	617	45
Don't know	50	4
No response	15	1

Based on responses to the Checklist, establishments grouped source materials into lots for grinding using a variety of criteria. Most often (N=617, 45 percent), those criteria were different from the options in the Checklist. When asked to specify other methods, some establishments used source material according to age, with the oldest material used first, and some establishments randomly selected material for grouping or selected material based on availability. Some establishments did not group materials, but treated each lot of source material separately. Of the possible responses listed in the Checklist question, the most common response (N=322, 23 percent) was to group source materials based on combo bins/boxes/other units from one supplier.

The Checklist also asked about how many suppliers of trim or other raw ground beef components were used in the last 30 days.

Table 5.4.11. Descriptive Statistics for Beef Grinding Operations

BeefGrind8: Approximately how many suppliers of trim or other raw ground beef components has the establishment used in the last 30 days?	**Number**	**Percent**
Only from its own slaughter plant	231	17
1, from other slaughter plant	177	13
2-3	559	41
4-6	244	18
More than 6	123	9
Don't know	27	2
No response	14	1

Of the 1,375 beef grinding operations, 17 percent (231) of establishments only used raw ground beef components from their own slaughter plant (see Table 5.4.11). Of the establishments that used outside

suppliers for their components, 41 percent (559) used two to three suppliers. Nine percent (126) of establishments used more than 6 suppliers.

The Checklist asked about 11 potential raw ground beef components used by grinding operations.

Table 5.4.12. Components Used in Beef Grinding Operations

BeefGrind9: Does the establishment use any of the following raw ground beef components in producing ground beef products (check all that apply)?	**Number**	**Percent**
Boneless manufacturing trimmings	858	62
Trim fabrication from fabricated primal/sub-primal cuts	872	63
Trim fabrication from mechanically tenderized or enhanced primal/sub-primal cuts	158	11
Primal/sub-primal cuts not intended for use as boneless manufacturing trimmings (e.g., other than a 2-piece chuck not specifically intended for grinding)	419	30
Head meat	57	4
Cheek meat	51	4
Weasand meat	15	1
AMR (Advanced Meat Recovery products)	21	2
Low temperature rendered LFTB (lean finely textured beef)	83	6
Low temperature rendered PDCB (partially defatted chopped beef)	26	2
Low temperature rendered PDBFT (partially defatted beef fatty tissue)	5	0
Other, please specify	182	13
None of the above	30	2
Don’t know	2	0
No response	5	0

The greatest number (N=872, 63 percent) of establishments used trim fabrication from fabricated primal/sub-primal cuts, followed closely by boneless manufacturing trimmings (N=858, 62 percent). Another source from primal/sub-primal cuts, “Primal/sub-primal cuts not intended for use as boneless manufacturing trimmings,” was used by 30 percent (419) of establishments. A third source from primal/sub-primal cuts, “Trim fabrication from mechanically tenderized or enhanced primal/sub-primal cuts,” was used by 11 percent (158) of establishments. Further analysis of the 3 primal/sub-primal cuts sources combined identified 75 percent (1,030) of establishments who used 1 or more of these components.

Other than “boneless manufacturing trimmings” and the sources related to “Primal/sub-primal cuts,” the next most common response was “Other, please specify” with 13 percent (182) of responses. Specified other responses included 52 related to “chuck,” including predominantly 2-piece chuck (including some

specifically intended for grinding). Twenty-seven responses specified beef heart, and 25 specified coarse or fine ground beef. Other categories were selected at a lesser frequency.

The components, "Head meat," "Cheek meat," and "Weasand meat" are obtained from the slaughter process. These three components were used by 1 percent (15) to 4 percent (57) of operations. Based on an analysis of these three components together, 7 percent (100) of establishments used any of the head, cheek, or weasand meat components.

Components produced after the slaughter process include "Advanced meat recovery" (AMR), "Low temperature rendered lean finely textured beef," "Low temperature rendered partially defatted chopped beef," and "Low temperature rendered partially defatted beef fatty tissue." These four components were used by 2 percent (21), 6 percent (83), 2 percent (26), and less than 1 percent (5) of establishments. Based on an analysis of these four components combined, 7 percent (100) of establishments used one or more of the advanced meat recovery or low temperature rendered components.

Figure 5.4.2 illustrates the number of establishments using the raw ground beef components summarized in Table 5.4.12.

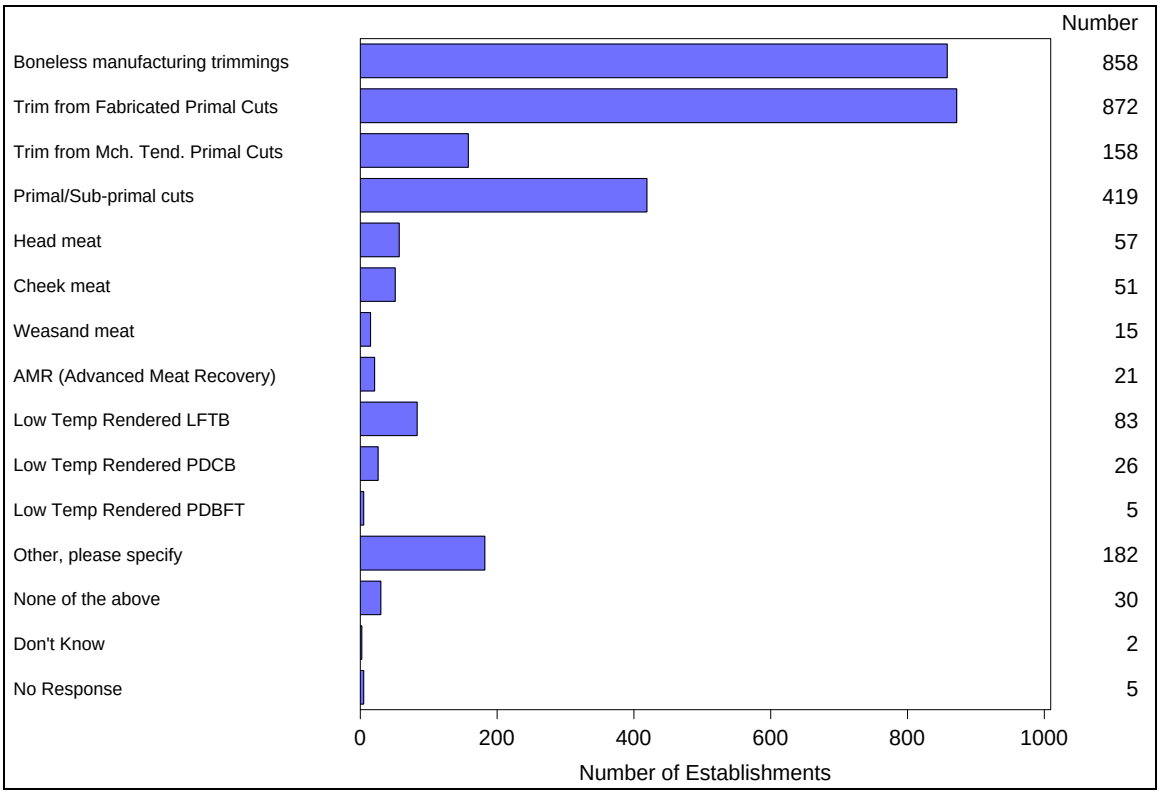

Figure 5.4.2. Components Used in Beef Grinding Operations

The Checklist further asked about documented interventions in any of the components listed in Table 5.4.12.

As summarized in Table 5.4.13, 25 percent (349) of establishments had documented use of any intervention method for addressing *E. coli* O157:H7.

The Checklist also asked about the use of imported materials by beef grinding operations. Question BeefGrind11 (see Table 5.4.14) asked specifically about ground beef.

Table 5.4.13. Documented Interventions for Addressing *E. coli* O157:H7

BeefGrind10: Does the establishment have documented use of any intervention method for addressing *E. coli* O157:H7 contamination in any of the trim or other raw ground beef components listed in number 9?	**Number**	**Percent**
Yes	349	25
No	984	72
Don't know	6	0
No response	36	3

Table 5.4.14. Use of Imported Ground Beef

BeefGrind11: Does the establishment knowingly use imported coarse or finely ground beef to produce ground beef products?	**Number**	**Percent**
No	1,334	97
Every production day	3	0
Weekly	5	0
Monthly	1	0
Intermittently	13	1
Other, please specify:	6	0
Don't know	5	0
No response	8	1

Ninety-seven percent (1,334) of establishments did not use imported coarse or finely ground beef to produce ground beef products. Of those establishments that did use imported ground beef, the most common frequency (N=13, 1 percent) was intermittently.

Question BeefGrind12 (Table 5.4.15) asked specifically about imported trim and other components (other than ground beef).

As summarized in Table 5.4.15, 72 percent (988) of establishments did not use imported trim and other component materials (other than imported coarse or finely ground beef). Of those establishments that did import these components, 13 percent (184) imported daily, 4 percent (58) imported weekly, and 1 percent (11) imported monthly. Another 7 percent (102) imported intermittently.

Table 5.4.15. Descriptive Statistics for Beef Grinding Operations

BeefGrind12: Does the establishment knowingly use imported trim or other raw ground beef components other than coarse or finely ground beef to produce ground beef products?	**Number**	**Percent**
No	988	72
Every production day	184	13
Weekly	58	4
Monthly	11	1
Intermittently	102	7
Other, please specify:	23	2
Don't know	3	0
No response	6	0

The Checklist also asked about documentation of temperature controls at various steps in the process.

Table 5.4.16 Documented Monitoring or Verification of Temperature Controls

BeefGrind13: Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40º F or below at any of these processing steps? (check all that apply)	**Number**	**Percent**
No	262	19
Receipt of source materials	557	41
Grinding	560	41
Storage	792	58
Distribution	232	17
Other, please specify:	312	23
Don't know	0	0
No response	9	1

As indicated in Table 5.4.16, 19 percent (262) of establishments did not have documented monitoring or verification procedures to demonstrate that product was maintained at 40° F at any step in the process. Of the establishments that did have documented monitoring or verification procedures, the most common step in the process was storage (N=792, 58 percent). The receipt of source materials step (N=557, 41 percent) and the grinding step (N=560, 41 percent) were also frequent steps for monitoring or verification. Twenty-three percent (312) of establishments responded "Other, please specify." A review of the responses to the "Other" category indicated that alternate temperature requirements were used. Temperature requirements varied from 30° F to 55° F, but the most common temperature requirements ranged from 40° F to 45° F. Other process steps were also mentioned. Packaging was most commonly mentioned as a step where monitoring or verification was performed. Also mentioned was the use of alarm systems for temperature monitoring.

Checklist question BeefGrind14 asked about cleaning and sanitizing of equipment.

Table 5.4.17. Cleaning and Sanitizing of Equipment and Processing Areas

BeefGrind14: How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas? (check all that apply)	**Number**	**Percent**
After grinding trim or other raw ground beef components from each supplier	37	3
After grinding trim or other raw ground beef components from a group of suppliers	21	2
After a sample is collected for *E. coli* O157:H7 testing	421	31
After each shift	177	13
Daily after production	1,288	94
Less than daily (extended clean-up)	6	0
Other, please specify	78	6
Don't know	0	0
No response	6	0

As indicated in Table 5.4.17, 94 percent (1,288) of establishments cleaned and sanitized the equipment and processing areas daily after production. The next most common responses were cleaning and sanitizing after a sample was collected for *E. coli* O157:H7 testing (N=421, 31 percent) and after each shift (N=177, 13 percent). Further analysis was done to compare the responses to this question to the BGShift question. Question BGShift (see Table 5.4.2) indicated that 107 establishments ground beef during a second shift. Of these 107, all of them cleaned and sanitized daily, but only 2 cleaned and sanitized after every shift.

Only 3 percent (37) of establishments conducted cleaning and sanitizing after grinding trim or other raw ground beef components from each supplier. This implies that product from multiple suppliers was processed between cleaning and sanitizing. The grinding of components from multiple suppliers between cleaning and sanitization may result in larger recalls than is potentially necessary because a positive *E. coli* O157:H7 test cannot be linked to a single supplier.

Checklist question BeefGrind15 asked where establishments tested for microbial indicator organisms.

Table 5.4.18. Testing for Microbial Indicator Organisms

BeefGrind15: Does the establishment test product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliforms, APC, Enterobacteriaceae) (check all that apply)?	**Number**	**Percent**
No	955	69
Beef trim or other raw ground beef components	137	10
Ground beef product	237	17
Grinding equipment	238	17
Processing area	224	16
Other, please specify	111	8
Don't know	3	0
No response	7	1

As indicated in Table 5.4.18, 69 percent (995) of establishments did not test for indicator organisms. Of those establishments that did, three responses were most commonly selected for testing. These were the ground beef product (N=237, 17 percent), the grinding equipment (N=238, 17 percent), and the processing area (N=224, 16 percent). Eight percent (111) of establishments tested other areas. Based on additional analysis of this question, 6 percent (81) of establishments tested all 4 Checklist question options (components, product, equipment, and processing area).

A review of the other areas described identified environmental areas, food contact areas, and employees (e.g., hands), and equipment (e.g., gloves, aprons, etc.) as the most common responses.

The Checklist also asked about the use of carryover or rework by grinding operations where the carryover or rework was not specifically accounted for in a robust testing program.

Table 5.4.19. Use of Carryover or Rework Not Accounted for in a Testing Program

BeefGrind16: Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program (check all that apply)?	**Number**	**Percent**
Yes	219	16
No	1,127	82
Don't know	11	1
No response	18	1

As indicated in Table 5.4.19, carryover or rework which was not specifically accounted for in a robust testing program was used by 16 percent (219) of establishments. Interpretation of responses to this question should be made with caution. It is possible that Checklist responders may have answered either "Yes" or "No" to confirm the use of rework not accounted for in a testing program. The "Yes" response could mean that the establishment did use rework in the manner described. The "No" response could mean "No, the establishment did not account for its rework in a testing program." These interpretations mean that either response could indicate the use of rework that was not accounted for in a testing program.

Summary

Selected findings about beef grinding operations as indicated from Checklist responses are summarized below:

- Twenty-four percent (328) of establishments did not have purchase specifications for suppliers requiring testing or validated intervention methods (see Table 5.4.3).
- Further analysis of supplier questions indicates that the number of establishments that did not have either purchase specifications or documentation is actually 9 percent overall. Based on a combined analysis of questions BeefGrind1 and BeefGrind2, 12 percent (164) of establishments did not have purchase specifications and did not have other documentation from suppliers. Furthermore, of these 164 establishments, 45 (27 percent) responded to question BeefGrind8 that only product from their own slaughter plant was used. Based on this combined analysis, the number of establishments that: (a) used product from other suppliers; (b) did not have purchase specifications about testing and intervention for suppliers; and (c) did not have other documentation showing that suppliers tested or applied interventions was 119, or 9 percent overall (see Tables 5.4.3, 5.4.4, and 5.4.11).
- Relatively few establishments conducted validated interventions on either source material or product (see Tables 5.4.5 and 5.4.6).
- Approximately two-thirds of establishments were not conducting ongoing verification testing of source materials, and only 6 percent were using FSIS "best practices" as outlined in Attachment 5 of Notice 65-07 (see Table 5.4.7).
- Approximately half of the establishments were not conducting ongoing verification testing of their finished product, and only 5 percent were using FSIS "best practices" (see Table 5.4.8).
- Seventy-five percent of the establishments were using bench trim from primal/sub-primal cuts (see Table 5.4.12).
- Three percent of the establishments were cleaning and sanitizing after processing components from each supplier (see Table 5.4.17).

5.4.2 Trim and Other Raw Ground Beef Component Fabrication

As indicated in Table 5.4.1, 1,008 Checklist responses (out of 2,323) indicated that the establishment had a trim fabrication operation.

Tables 5.4.20 through **5.4.26** provide tabulations (number of establishments and percentage) of seven *E. coli* Checklist questions specific to establishments with trim fabrication operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question was more than 1,008, and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first trim fabrication operation question asked whether an establishment operated one or two fabrication shifts.

Table 5.4.20. Shifts for Trim Fabrication Operations

BTFShift: During which shift(s) of operation does this establishment fabricate trim?(check all that apply)	**Number**	**Percent**
Shift 1	965	96
Shift 2	74	7
No response	39	4

As indicated in Table 5.4.20, 96 percent (965) of establishments with trim fabrication operations fabricated trim during shift 1 and 7 percent (74) of establishments fabricated trim during a second shift.

The Checklist asked about the use of cross-contamination controls.

Table 5.4.21. Cross-contamination Controls for Trim Fabrication Operations

BeefTrimFab1: Does the establishment use one or more of the following cross-contamination controls (check all that apply)?	**Number**	**Percent**
Sanitation of knives and sharpening steels	785	78
Formulate trim and other raw ground beef components from a sole supplier into the creation of individual production lot	249	25
Formulate production lots that contain only source materials treated to reduce *E. coli* O157:H7 to a nondetectable level (e.g., gaseous ammonia, irradiation)	70	7
None of the above	125	12
Other, please specify:	126	13
Don't know	2	0
No response	37	4

As indicated in Table 5.4.21, 78 percent (785) of establishments sanitized knives and sharpening steels to control cross-contamination. The second most common response (N=249, 25 percent) was "Formulate trim and other raw ground beef components from a sole supplier into the creation of individual production lots."

Upon closer inspection of responses to this question, 4 of the "None of the above" responses also selected "Other, please specify." This leaves 121 (12 percent) that did not apply some kind of cross-contamination control.

The Checklist also asked about production lot formulation.

As indicated in Table 5.4.22, the most common response (N=427, 42 percent) was "Formulate trim and other raw ground beef components from multiple suppliers into the creation of individual production lots." Another 39 percent (390) did not formulate production lots.

Upon closer inspection of responses to this question, 15 of the "None of the above" responses also selected "Other, please specify." These establishments are considered to have applied some kind of production lot formulation. This leaves 375 (37 percent) that did not formulate production lots.

Another Checklist question asked about temperature controls for trim fabrication operations.

Table 5.4.22. Production Lot Formulation for Trim Fabrication Operations

BeefTrimFab2: Does the establishment use one or more of the following methods (check all that apply)?	**Number**	**Percent**
Formulate trim and other raw ground beef components from multiple suppliers into the creation of individual production lots	427	42
Formulate production lots that contain combinations of source materials treated to reduce *E. coli* O157:H7 and source materials not treated to reduce *E. coli* O157:H7	44	4
None of the above	390	39
Other, please specify:	160	16
Don't know	9	1
No response	39	4

Table 5.4.23. Temperature Control Procedures for Trim Fabrication Operations

BeefTrimFab3: Does the establishment have documented monitoring and verification procedures of the carcass surface temperature being maintained below 45º F within 24 hours of slaughter?	**Number**	**Percent**
Yes	261	26
No	561	56
Don't know	39	4
No response	147	15

As shown in Table 5.4.23, 26 percent (261) of establishments had documented monitoring and verification procedures. Fifty-six percent (561) of establishments did not have these procedures. As indicated in the discussion about temperature controls for beef grinding operations (see Table 5.4.16), several responses identified alarm systems as "Other" controls. The trim fabrication question did not allow other responses. It is possible that a proportion of the "No" responses had alarm systems in place.

The Checklist also asked about the application of validated intervention methods on the trim and other raw ground beef components.

As indicated in Table 5.4.24, 85 percent (854) of establishments did not apply any validated intervention methods. The second most common response was "Other, please specify" (N=88, 9 percent). Nearly half of the specified other responses mentioned temperature controls as the method used by the establishment. As discussed earlier in the section for beef grinding operations, temperature controls are not considered a validated intervention method.

The Checklist also asked about testing of production lots.

Table 5.4.24. Intervention Methods for Trim Fabrication Operations

BeefTrimFab4: Does the establishment apply any validated intervention method identified as a CCP in the HACCP plan on the trim and other raw ground beef components (check all that apply)?	**Number**	**Percent**
No	854	85
Organic acid	38	4
Acidified sodium chlorite	13	1
Acidified calcium sulfate	1	0
Irradiation	0	0
Gaseous ammonia	4	0
Other, please specify	88	9
Don't know	1	0
No response	40	4

Table 5.4.25. Testing of Production Lots for Trim Fabrication Operations

BeefTrimFab5: Does the establishment or its designee test any production lots of trim and other raw ground beef components for *E. coli* O157:H7?	**Number**	**Percent**
No	604	60
The establishment tests all production lots of such product using a robust testing method	81	8
The establishment tests such product using a different frequency and/or method, please specify:	283	28
Test purge from one or more combo bins/boxes/other units per lot (lot as defined by the establishment)	1	0
Don't know	1	0
No response	38	4

As indicated in Table 5.4.25, 60 percent (604) of establishments did not test any production lots of trim or other raw ground beef components. Twenty-eight percent (283) tested at a different frequency or using a different method. A review of specified other methods and/or frequencies identified a wide range of responses. Testing frequency varied from daily to quarterly. Some establishments tested only certain materials, such as trim intended for grinding, but not all materials.

The Checklist also asked about the production of "specially handled beef manufacturing trimmings."

Table 5.4.26. Descriptive Statistics for Trim Fabrication Operations

BeefTrimFab6: Does the establishment produce "specially 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? (Note: "Specially Handled Beef Manufacturing Trimmings" are sub-primal that have undergone an antimicrobial treatment for *E. coli* O157:H7 as part of an HACCP plan, are trimmed to meet a specific lean to fat ratio, are cut into slices, are sampled for *E. coli* O157:H7 through the establishment's verification testing program, and are sealed in bags for direct sale to a retail facility, which is expected to grind the contents of the bags without mixing in other beef manufacturing trimmings.)	**Number**	**Percent**
Yes	12	1
No	952	94
Don't know	5	0
No response	39	4

Ninety-four percent (952) of establishments did not produce "specially handled beef manufacturing trimmings" for direct sale. Interpretation of this question should take into consideration the fact that "Yes" responses would indicate establishment that had produced trimmings that: (a) had undergone an antimicrobial treatment; (b) had been trimmed to meet a specific lean-to-fat ratio; (c) were cut into slices; and (d) were tested for *E. coli* O157:H7. Establishments that were not performing all of these steps may be represented by the "No" response.

Summary

Selected findings about trim fabrication operations, as indicated from Checklist responses, are summarized below.

- Twelve percent (121, see discussion) did not apply some kind of cross-contamination control (see Table 5.4.21).
- Only 4 percent (44) of establishments combined tested and untested source materials into production lots (see Table 5.4.22).
- More than 50 percent of establishments did not have documented temperature controls (see Table 5.4.23).
- Eight-five percent did not apply validated intervention methods to the trim or other raw ground beef components (see Table 5.4.24).
- Sixty percent did not have production lots tested for *E. coli* O157:H7 (see Table 5.4.25).

5.4.3 Slaughter

As indicated in Table 5.4.1, 587 Checklist responses (out of 2,323) indicated that the establishment had a slaughter operation.

Tables 5.4.27 through **5.4.33** provide tabulations (number of establishments and percentage) of seven *E. coli* Checklist questions specific for establishments with slaughter operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question is more than 587 and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The

number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first slaughter operation question asked whether an establishment slaughtered beef during a first and/or second shift.

Table 5.4.27. Shifts for Slaughter Operations

BSShift: During which shift(s) of operation does this establishment slaughter beef (check all that apply)?	**Number**	**Percent**
Shift 1	578	98
Shift 2	14	2
No response	9	2

As indicated in Table 5.4.27, 98 percent (578) of establishments slaughtered beef during a first shift. Two percent (14) of establishments slaughtered beef during a second shift.

The Checklist also asked about decontamination procedures applied prior to hide removal.

Table 5.4.28. Decontamination Procedures for Slaughter Operations

BeefSlaughter1: Does the establishment apply any of the following decontamination procedures to the live or slaughtered cattle prior to hide removal (check all that apply)?	**Number**	**Percent**
No	472	80
Pre-slaughter animal wash	53	9
Pre-slaughter head wash	17	3
Post-slaughter dehairing	5	1
Pre-dehiding carcass wash	53	9
Other, please specify	19	3
Don't know	0	0
No response	6	1

As indicated in Table 5.4.28, 80 percent (472) of establishments with a slaughter operation did not apply decontamination procedures prior to hide removal. Among establishments that did apply decontamination procedures, the two most common procedures were a "Pre-slaughter animal wash" (N=53, 9 percent) and a "Pre-dehiding carcass wash" (N=53, 9 percent). For those establishments who specified other procedures (N=19, 3 percent), one common response was that only certain areas were washed (e.g., head, feet, or the incision area). Another common response was that washing was performed only under certain conditions, such as if the animal defecated during slaughter or if excessive amounts of debris were on the animal.

The Checklist also asked about the application of full-carcass intervention procedures after hide removal.

Table 5.4.29. Full-carcass Interventions After Hide Removal for Slaughter Operations

BeefSlaughter2: Does the establishment apply any of the following full-carcass intervention procedures after hide removal (check all that apply)?	**Number**	**Percent**
No	27	5
Pre-evisceration organic acid rinse	44	7
Pre-evisceration hot water wash	31	5
Pre-evisceration steam vacuum	41	7
Pre-chill organic acid rinse	407	69
Pre-chill hot water wash	224	38
Pre-chill steam treatment	24	4
Pre-chill steam vacuum	44	7
Other, please specify	91	16
Don't know	0	0
No response	3	1

As indicated in Table 5.4.29, 5 percent (27) of establishments did not apply full-carcass intervention procedures after hide removal. The other 95 percent of establishments applied some form of intervention procedure. The most common intervention procedure (N=407, 69 percent) was a pre-chill organic rinse. The second most common intervention procedure (N=224, 38 percent) was a pre-chill hot water wash. The other specified procedures were used by 7 percent or fewer establishments. The response, "Others, please specify," was selected 16 percent (91) of the time. About one-third of specified "Other" responses frequently included various types of acid washes (lactic acid, citric acid, organic acid, etc.) that would be generally classified as organic acid rinses. Five specified "Other" responses indicated that the organic acid rinse was applied post-chill.

The Checklist also asked about employee training at slaughter establishments.

Table 5.4.30. Employee Training for Slaughter Operations

BeefSlaughter3: Does the establishment have documentation of employee training in any of the following areas of the slaughter operation (check all that apply)?	**Number**	**Percent**
No	406	69
Proper hide removal	126	21
Proper carcass dressing procedures	132	22
Proper carcass evisceration procedures	123	21
Proper application of carcass intervention procedures	133	23
Adequate sanitation of knives and sharpening steels	144	25
Don't know	19	3
No response	3	1

As indicated in Table 5.4.30, 69 percent (406) of establishments did not have documentation of employee training in any of the areas listed. Another 3 percent (19) responded "Don't Know" and 1 percent (3) did not respond to the question. The remaining 27 percent (159) had documentation of one or more of the specified areas. The five specified areas were all selected at generally the same rate (21 percent to 25 percent). Further analysis of this question identified 113 establishments who had documented employee training in all five specified areas. These 113 establishments represent 71 percent of the 159 establishments who had documentation in one or more areas.

The Checklist also asked about testing carcasses for *E. coli* O157:H7.

Table 5.4.31. Carcass Testing for *E. coli* O157:H7 for Slaughter Operations

BeefSlaughter4: Does the establishment or its designee test carcasses for *E. coli* O157:H7 using robust testing methods (swabbing or the N-60 excision method) on individual carcasses?	**Number**	**Percent**
No	386	66
Yes, the establishment conducts robust testing of at least 1 in 300 carcasses	47	8
Other, please specify:	149	25
Don't know	0	0
No response	5	1

Sixty-six percent (386) of establishments did not test carcasses for *E. coli* O157:H7 using robust testing methods. Of the establishments that did test, 8 percent (47) conducted testing of at least 1 in 300 carcasses, and 25 percent (149) conducted testing by another method. A review of the other specified responses indicates that in about a third of the responses a swab test was commonly used, but in a non-robust manner or at a different frequency. Other frequencies included daily to annually or were based on a different number of carcasses per test.

The Checklist also asked about testing for indicator organisms other than the regulatory generic *E. coli* test requirement.

Seventy-nine percent (465) of establishments with slaughter operations did not test for indicator organisms (see Table 5.4.32). The most commonly selected testing response (N=96, 16 percent) was to test the carcass after an intervention method had been applied. Testing the carcass before intervention was done by 9 percent (52) of establishments. Equipment was tested by 7 percent (42) of establishments.

The Checklist also asked slaughter operations about documentation of temperature monitoring and verification.

Table 5.4.32. Indicator Organism Testing for Slaughter Operations

BeefSlaughter5: Does the establishment or its designee 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*, coliform, APC, Enterobacteriaceae) to determine process control (check all that apply)?	**Number**	**Percent**
No	465	79
Carcass before intervention method	52	9
Carcass after intervention method	96	16
Equipment	42	7
Other, please specify	32	5
Don't know	1	0
No response	6	1

Table 5.4.33. Temperature Monitoring and Verification for Slaughter Operations

BeefSlaughter6: Does the establishment have documented monitoring and verification procedures of the carcass surface temperature being maintained below 45º F within 24 hours of slaughter?	**Number**	**Percent**
Yes	381	65
No	203	35
Don't know	1	0
No response	2	0

As indicated in Table 5.4.33, 65 percent (381) of establishments documented monitoring and verification procedures indicating that the carcass surface temperature was being maintained below 45° F within 24 hours of slaughter. Thirty-five percent (203) of establishments responded "No."

Summary

Selected findings about slaughter operations, as indicated from Checklist responses are summarized below:

- Eighty percent of establishments with slaughter operations did not apply decontamination procedures (see Table 5.4.28).
- Ninety-five percent of establishments did apply a full-carcass intervention procedure after hide removal. The two most common procedures were a pre-chill organic acid rinse and a pre-chill hot water wash (see Table 5.4.29).
- Sixty-nine percent of establishments did not have documentation of employee training. Of those establishments that do, 71 percent had training documentation for all five specified steps (see Table 5.4.30).
- Two-thirds of establishments did not test carcasses for *E. coli* O157:H7 (see Table 5.4.31).

- Seventy-nine percent of establishments did not test for indicator organisms other than generic *E. coli* (see Table 5.4.32).

5.4.4 Regrind Coarse Ground

As shown in Table 5.4.1, 281 Checklist responses (out of 2,323) indicated that the establishment had a regrind coarse ground operation.

Tables 5.4.34 through **5.4.49** provide tabulations (number of establishments and percentage) of 16 *E. coli* Checklist questions specific to establishments with regrind coarse ground operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question is more than 281 and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first regrind coarse ground operation question asked whether an establishment performed regrinding during a first and/or second shift.

Table 5.4.34. Shifts for Regrind Coarse Ground Operations

RCGShift: During which shift(s) of operation does this establishment regrind coarse ground beef (check all that apply)?	**Number**	**Percent**
Shift 1	272	97
Shift 2	13	5
No response	8	3

As indicated in Table 5.4.34, 97 percent (272) of establishments regrind coarse ground beef during a first shift. Five percent (13) of establishments regrind coarse ground beef during a second shift.

The Checklist also asked about purchase specifications that required suppliers to conduct testing or interventions as a CCP in an HACCP plan.

Table 5.4.35. Purchase Specifications for Regrind Coarse Ground Operations

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? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)?	**Number**	**Percent**
No	106	38
Validated intervention methods prior to coarse grinding	98	35
Validated intervention methods during coarse grinding	27	10
Robust Testing of coarse grind for *E. coli* O157:H7	36	13
Other, please specify	69	25
Don't know	1	0
No response	11	4

As indicated in Table 5.4.35, 38 percent (106) of establishments did not have purchase specifications of suppliers. The most common purchase specification, "Validated intervention methods prior to coarse grinding," was selected by 35 percent (98) of establishments. The second most common purchase specification response (N=69, 25 percent), was "Other, please specify." A review of other specified answers indicates a variety of responses. Letters of guarantee or certificates of analysis were cited as other types of purchase specifications. Some specified responses indicated that the establishment was requiring interventions or testing, but the testing was not considered "robust," or they were allowing the supplier to select the method.

The Checklist also asked about documentation, other than purchase specifications, showing that the supplier applied some form of testing or intervention.

Table 5.4.36. Other Supplier Documentation for Regrind Coarse Ground Operations

RCG2: Does the establishment have documentation other than purchase specifications showing that suppliers apply any of the following (check all that apply)?	**Number**	**Percent**
No	170	60
Validated intervention methods prior to coarse grind	55	20
Validated intervention methods during coarse grind	16	6
Robust Testing of coarse ground for *E. coli* O157:H7	31	11
Other, please specify	49	17
Don't know	5	2
No response	6	2

Sixty percent (170) of establishments did not have other documentation showing that suppliers applied testing or interventions. The most commonly selected method for which establishments had documentation is "Validated intervention methods prior to coarse grind" (N=55, 20 percent). The second most commonly selected method was "Other, please specify" (N=49, 17 percent). Specified other responses were similar to the specified other responses to Checklist question RCG1 (see Table 5.4.35).

The Checklist also asked about validated interventions applied to the coarse ground source material.

As indicated in Table 5.4.37, 94 percent of establishments were not applying any intervention to the coarse ground source material. Four percent (10) of establishments were applying an intervention other than the ones specified in the question. Six of those 10 establishments specified temperature controls as the intervention used. As discussed earlier, temperature controls are not considered a validated intervention.

The Checklist also asked about validated interventions on the finished product.

Table 5.4.37. Validated Interventions of Source Materials for Regrind Coarse Ground Operations

RCG3: Does the establishment apply any validated intervention on the coarse ground (check all that apply)?	**Number**	**Percent**
No intervention	263	94
Organic acid	1	0
Acidified sodium chlorite	2	1
Acidified calcium sulfate	0	0
Irradiation	0	0
Gaseous ammonia	0	0
Others, please specify	10	4
Don't know	0	0
No response	6	2

Table 5.4.38. Validated Interventions of Finished Product for Regrind Coarse Ground Operations

RCG3a: Does the establishment apply any validated intervention on the finished ground product (check all that apply)?	**Number**	**Percent**
No intervention	267	95
Organic acid	0	0
Acidified sodium chlorite	0	0
Acidified calcium sulfate	1	0
Irradiation	0	0
Gaseous ammonia	0	0
Others, please specify	9	3
Don't know	0	0
No response	5	2

Ninety-five percent (267) of establishments did not apply interventions to the finished ground product (see Table 5.4.38). Three percent (9) specified other interventions than the ones specified by the Checklist question. As in the responses to Checklist question RCG3, the most common specified other response was temperature controls, which are not considered a validated intervention.

The Checklist also asked whether establishments specifically conducted on-going verification testing of source materials, at least quarterly, using robust testing methodology, and with more frequent testing in high prevalence season months and for more frequent suppliers.

Table 5.4.39. Testing of Source Materials for Regrind Coarse Ground Operations

RCG4: Does the establishment or its designee specifically conduct ongoing verification testing of source materials (coarse ground) at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?	**Number**	**Percent**
No, the establishment does not test source materials	203	72
Yes, for every supplier, including in-house generated source materials, without exception	15	5
The establishment tests source materials using a different frequency and/or method, please specify:	53	19
Don't know	2	1
No response	8	3

As shown in Table 5.4.39, 72 percent (203) of establishments did not test source materials. Five percent (15) of establishments tested according to the criteria specified in the Checklist question. Nineteen percent (53) tested according to different criteria. A review of specified other criteria indicates that the greatest difference was in frequency of testing. Other specified testing frequencies varied from monthly to annually.

Establishments with regrind coarse ground operations were also asked about testing.

Table 5.4.40: Testing of Finished Product for Regrind Coarse Ground Operations

RCG5: Does the establishment or its designee specifically conduct ongoing verification testing of all production lots of finished product at least monthly, using robust testing methodology, and with proportionally more frequent testing in high prevalence season months?	**Number**	**Percent**
No, the establishment does not test finished product	148	53
Yes	9	3
The establishment tests finished product using a different frequency and/or method, please specify:	117	42
Don't know	1	0
No response	6	2

As indicated in Table 5.4.40, 53 percent (148) of establishments did not test finished product. Three percent (9) tested finished product according to the criteria specified in the Checklist question. Forty-two percent (117) tested according to different criteria. A review of those specified other criteria indicated that the frequency of testing varied from daily to annually. There is no indication that testing was more frequent in high prevalence season months.

Based on a tabulation of combined responses to both questions about testing, 43 percent (122) of establishments did not conduct testing on either the source materials or the finished product.

The Checklist also asked about the method used for testing finished product.

Table 5.4.41. Method of Testing Finished Product for Regrind Coarse Ground Operations

RCG6: What laboratory does the establishment or its designee use to test coarse ground beef or finished product for *E. coli* O157:H7?	**Number**	**Percent**
FSIS Method	34	12
Other, please specify	82	29
Don't know	9	3
No response	156	56

As indicated in Table 5.4.41, this question was not answered for 56 percent (156) of the Checklists. The nonresponse rate to this question is related to the results shown in Table 5.4.40. In Table 5.4.40, 148 establishments did not test finished product, another 2 percent (6) did not answer that question, and less than 1 percent (1) did not know the answer to that question, for a total of 155 who did not select a testing frequency. These 155 establishments are not expected to answer this question about the method used to conduct that testing.

Twelve percent (34) of establishments used the FSIS Method for testing, and 29 percent (82) used another method. A review of specified other responses identified more than one-third who identified various AOAC methods. Other responses identified specific testing labs that were used.

The Checklist also asked how establishments grouped product into lots.

Table 5.4.42. Grouping of Product into Lots for Regrind Coarse Ground Operations

RCG7: How does the establishment group products into lots for grinding (check all that apply)?	**Number**	**Percent**
Based on groupings of tested combo bins/boxes/other units	19	7
Based on combo bins/boxes/other units from one supplier	78	28
Based on combo bins/boxes/other units from suppliers using validated intervention methods	50	18
All combo bins/units received in 1 day	37	13
Other, please specify:	106	38
Don't know	11	4
No response	9	3

As indicated in Table 5.4.42, the most common response (N=106, 38 percent) was to group products according to a method not specifically listed in the Checklist question. A review of these responses indicates a variety of grouping methods including only using in-house material, and grouping material based on availability or age (i.e., first-in, first-out).

The second most common response selected (N=78, 28 percent) was based on combo bins/boxes/other units from one supplier. The least common method was to group based on tested units (N=19, 7 percent).

The Checklist also asked the number of suppliers of coarse ground beef that were used.

Table 5.4.43. Suppliers for Regrind Coarse Ground Operations

RCG8: Approximately how many suppliers of coarse ground beef has the establishment used in the 30 days?	**Number**	**Percent**
Only from its own grinding plant	21	7
1, from other grinding plant	92	33
2-3	117	42
4-6	29	10
More than 6	5	2
Don't know	9	3
No response	8	3

Seven percent (21) of establishments only used coarse ground beef from their own grinding plant (see Table 5.4.43). Thirty-three percent (92) of establishments used only 1 supplier. The most common response (N=117, 42 percent) was to use 2 to 3 suppliers. Ten percent (29) of establishments used 4 to 6 suppliers, and 2 percent (5) used more than 6 suppliers.

The Checklist also asked about the use of imported coarse ground beef.

Table 5.4.44. Use of Imported Coarse Ground Beef for Regrind Coarse Ground Operations

RCG9: Does the establishment knowingly use imported coarse ground beef to produce ground beef?	**Number**	**Percent**
No	267	95
Every production day	1	0
Weekly	0	0
Monthly	0	0
Intermittently	7	2
Other, please specify:	1	0
Don't know	0	0
No response	5	2

As indicated in Table 5.4.44, 95 percent (267) of establishments did not knowingly use imported coarse ground beef. Of the total 9 establishments that did import coarse ground beef, 7 (2 percent overall) imported intermittently.

The Checklist also asked about the import of trim or other raw ground beef components for use in a regrind coarse ground operation.

Table 5.4.45. Use of Imported Trim or Other Raw Ground Beef Components for Regrind Coarse Ground Operations

RCG10: Does the establishment knowingly use imported trim or other raw ground beef components to produce ground beef products?	**Number**	**Percent**
No	211	75
Every production day	18	6
Weekly	12	4
Monthly	4	1
Intermittently	28	10
Other, please specify:	3	1
Don't know	0	0
No response	5	2

Seventy-five percent (211) of regrinding establishments did not use imported trim or other raw ground beef components to produce ground beef products. Among establishments that did use imported trim and other raw ground beef components, the most common frequency of use (N=28, 10 percent) was intermittently.

The Checklist also asked whether establishments had documented monitoring or verification procedures to demonstrate that product is maintained at 40° F or below at various processing steps.

Table 5.4.46. Documented Temperature Controls for Regrind Coarse Ground Operations

RCG11: Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40º F or below at any of these processing steps (check all that apply)?	**Number**	**Percent**
No	37	13
Receipt of source materials	124	44
Grinding	127	45
Storage	191	68
Distribution	55	20
Other, please specify:	53	19
Don't know	0	0
No response	5	2

As indicated in Table 5.4.46, 13 percent (37) of regrinding establishments did not have documented monitoring or verification procedures. The most common step where documented procedures existed was at the storage step (N=191, 68 percent). The next most common steps for documented procedures were "Grinding" (N=127, 45 percent) and "Receipt of source materials" (N=124, 44 percent).

The Checklist also asked how often establishments conducted complete cleaning and sanitizing of equipment and processing areas.

Table 5.4.47. Cleaning and Sanitizing for Regrind Coarse Ground Operations

RCG12: How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas (check all that apply)?	**Number**	**Percent**
After grinding coarse grind from a supplier	14	5
After grinding coarse grind from a group of suppliers	1	0
After a sample is collected for *E. coli* O157:H7 testing	111	40
After each shift	43	15
Daily after production	260	93
Less than daily (extended clean-up)	1	0
Other, please specify:	14	5
Don't know	0	0
No response	5	2

Ninety-three percent (260) of establishments cleaned and sanitized daily after production (see Table 5.4.47). Forty-percent (111) of establishments cleaned and sanitized after collecting a sample for *E. coli* O157:H7 testing. The third most selected response, "After each shift," was selected by 15 percent (43) of establishments.

Only 5 percent (14) of establishments conducted cleaning and sanitizing after grinding coarse grind from each supplier. This implies that product from multiple suppliers was processed between cleaning and sanitizing. The grinding of components from multiple suppliers between cleaning and sanitization may result in larger recalls than is potentially necessary because a positive *E. coli* O157:H7 test cannot be linked to a single supplier.

The Checklist also asked about testing of microbial indicator organisms.

Table 5.4.48. Testing for Microbial Indicator Organisms for Regrind Coarse Ground Operations

RCG13: Does the establishment or its designee test product or food contact, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliform, APC, Enterobacteriaceae) (check all that apply)?	**Number**	**Percent**
No	193	69
Ground beef product	46	16
Grinding equipment or other food contact equipment	51	18
Processing area	47	17
Other, please specify	14	5
Don't know	1	0
No response	5	2

As indicated in Table 5.4.48, 69 percent (193) of establishments did not test product or food contact, equipment, or processing areas for microbial indicator organisms. Eighteen percent (51) tested grinding

equipment, 17 percent (47) tested the processing area, and 16 percent (46) tested ground beef product. Based on further analysis of this question, 9 percent (24) of establishments tested all three options (product, equipment, and processing area).

The Checklist asked regrind establishments about the use of carryover or rework in their operations.

Table 5.4.49. Use of Carryover or Rework for Regrind Coarse Ground Operations

RCG14: Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program?	**Number**	**Percent**
Yes	42	15
No	230	82
Don't know	2	1
No response	7	2

As indicated in Table 5.4.49, 82 percent (230) did not use rework or carryover, and 15 percent (42) of establishments did. Interpretation of this question should be made with caution. It is possible that Checklist responders may have answered either "Yes" or "No" to confirm the use of rework not accounted for in a testing program. The "Yes" response could mean that the establishment used rework in the manner described. The "No" response could mean "No, the establishment did not account for its rework in a testing program." These interpretations mean that either response could indicate the use of rework not accounted for in a testing program.

Summary

Selected findings about beef grinding operations, as indicated from Checklist responses, are summarized below:

- Thirty-eight percent (106) of establishments did not have purchase specifications for suppliers requiring testing or validated intervention methods (see Table 5.4.35).
- Relatively few establishments conducted validated interventions on either source material or product (see Tables 5.4.37 and 5.4.38).
- Approximately three-quarters of establishments were not conducting ongoing verification testing of source materials, and only 5 percent were using FSIS "best practices" as outlined in Attachment 5 of Notice 65-07 (see Table 5.4.39).
- Approximately half of the establishments were not conducting ongoing verification testing of their finished product, and only 3 percent were using FSIS "best practices" (see Table 5.4.40).
- Five percent of the establishments were cleaning and sanitizing after processing components from each supplier (see Table 5.4.47).

5.4.5 Patty Forming

As indicated in Table 5.4.1, 952 Checklist responses (out of 2,323) indicated that the establishment had a patty forming operation.

Tables 5.4.50 through **5.4.63** provide tabulations (number of establishments and percentage) of 14 *E. coli* Checklist questions specific to establishments with patty forming operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the

total number of responses to a question is more than 952 and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first Checklist question for patty forming operations asked whether an establishment performed patty forming during a first and/or second shift.

Table 5.4.50. Shifts for Patty Forming Operations

PFShift: For which shift(s) of operation does this establishment form patties (check all that apply)?	**Number**	**Percent**
Shift 1	940	99
Shift 2	87	9
No response	9	1

As indicated in Table 5.4.50, 99 percent (940) of establishments with patty forming operations formed patties during the first shift and 9 percent (87) of establishments formed patties during a second shift.

The Checklist asked whether establishments had purchase specifications requiring suppliers to apply various intervention methods and/or testing for *E. coli* O157:H7.

Table 5.4.51. Purchase Specifications for Patty Forming Operations

PatForm1: 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? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)	**Number**	**Percent**
No	504	53
Validated intervention methods prior to grinding	153	16
Validated intervention methods during grinding	38	4
Testing of ground beef for *E. coli* O157:H7	80	8
Other, please specify	246	26
Don't know	13	1
No response	59	6

As indicated in Table 5.4.51, 53 percent (504) of establishments did not have purchase specifications for suppliers, 1 percent (13) responded "Don't know," and 6 percent (59) did not respond to the question. The remaining 40 percent (376) of establishments had 1 or more types of purchase specifications. The most common purchase specification response (N=246, 26 percent) was "Other, please specify." A review of these specified other responses identified establishments that did not purchase pre-coarse ground product. Some purchased only trim for their operations. Other establishments used their own in-house generated source materials. Some establishments had letters of guarantee from their suppliers.

Checklist question PatForm2 asked about documentation, other than purchase specifications.

Table 5.4.52. Other Documentation of Supplier Practices for Patty Forming Operations

PatForm2: Does the establishment have documentation other than purchase specifications showing that suppliers conduct any of the following (check all that apply)?	**Number**	**Percent**
No	564	59
Validated intervention methods prior to grinding	125	13
Validated intervention methods during grinding	28	3
Testing of ground beef for *E. coli* O157:H7	106	11
Other, please specify	220	23
Don't know	9	1
No response	23	2

As indicated in Table 5.4.52, 59 percent (564) did not have other documentation for suppliers, another 1 percent (9) responded "Don't know," and 2 percent (23) did not respond to question PatForm2. The other 37 percent (356) had documentation showing that intervention methods and/or testing were applied. The most common documentation response (N=220, 23 percent) was "Other, please specify." Specified responses were similar to those from question PatForm1 (see Table 5.4.51). Thirteen percent (125) of establishments had validated intervention methods during grinding. In terms of testing for *E. coli* O157:H7, 11 percent (106) of establishments had documentation that suppliers tested source materials.

Checklist questions PatForm3 asked about validated interventions that establishments apply on the ground product.

Table 5.4.53. Validated Interventions on Product for Patty Forming Operations

PatForm3: Does the establishment conduct any validated intervention on the ground product (check all that apply)?	**Number**	**Percent**
No intervention	894	94
Organic acid	3	0
Acidified sodium chlorite	6	1
Acidified calcium sulfate	0	0
Irradiation	2	0
Gaseous ammonia	0	0
Other, please specify	51	5
Don't know	0	0
No response	8	1

As indicated in Table 5.4.53, 94 percent (894) of establishments did not apply validated interventions on ground product. The most common intervention selected was "Other, please specify" (N=51, 5 percent). When asked to specify other interventions, temperature controls were most frequently noted. As discussed in earlier sections, temperature controls are not considered a validated intervention method.

The Checklist also asked about verification testing of source materials prior to patty forming.

Table 5.4.54. Testing of Source Materials for Patty Forming Operations

PatForm4: Does the establishment or its designee specifically conduct ongoing verification testing of source materials prior to patty forming, at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?	**Number**	**Percent**
No, the establishment does not test source materials	614	64
Yes, for every supplier, including in-house generated source materials without exception	61	6
The establishment test source materials using a different frequency and/or method, please specify:	272	29
Don't know	2	0
No response	3	0

As indicated in Table 5.4.54, 64 percent (614) of establishments did not test source materials. Six percent (61) of establishments conducted testing using the same frequency and/or method as stated in the Checklist question. Twenty-nine percent (272) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify other methods and/or frequencies used, the frequency of testing reported varied from daily to annually. A few specified other responses indicated more frequent testing during high prevalence season months, but the majority did not. Some establishments also randomly selected suppliers for testing rather than testing the more frequent suppliers at a higher rate.

The Checklist also asked about verification testing of finished product.

Table 5.4.55. Testing of Finished Patties for Patty Forming Operations

PatForm5: Does the establishment or its designee specifically conduct ongoing verification testing of all production lots of finished patties at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?	**Number**	**Percent**
No, the establishment does not test finished product	639	67
Yes	39	4
The establishment tests finished product using a different frequency and/or method, please specify:	268	28
Don't know	2	0
No response	4	0

As indicated in Table 5.4.55, 67 percent (639) of establishments with patty forming operations did not test finished product. Four percent (39) of establishments tested using the same frequency and/or method stated in the Checklist question. Twenty-eight percent (268) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify the other methods and/or frequencies used, the frequency of testing varied from daily to annually.

Based on a tabulation of combined responses to both questions, 48 percent (456) of establishments with patty forming operations did not conduct testing on either the source materials or the finished product.

The Checklist asked about laboratory methods used for testing for *E. coli* O157:H7.

Table 5.4.56. Method of Testing for Patty Forming Operations

PatForm6: What laboratory does the establishment or its designee use to test patties for *E. coli* O157:H7?	**Number**	**Percent**
FSIS Method	86	9
Other, please specify	192	20
Don't know	29	3
No response	645	68

As indicated in Table 5.4.56, 9 percent (86) of establishments used the FSIS Method for testing ground beef or finished product for *E. coli* O157:H7. Twenty percent (192) used a method other than the FSIS Method. When asked to specify other methods used, about one-third identified various AOAC methods. Other responses did not indicate the specific method, but did indicate that a third-party lab was performing the testing. The nonresponse rate for this question (N=645, 68 percent) was expected. As indicated in Checklist question PatForm5 (see Table 5.4.55), 639 establishments did not test their finished patty product. These establishments would not be expected to identify a testing method in this question. Please refer to Chapter 4.1 for more discussion about nonresponse rates.

The Checklist also asked how source materials were grouped.

Table 5.4.57. Grouping of Source Materials into Lots for Patty Forming Operations

PatForm7: How does the establishment group source materials into lots for patty forming (check all that apply)?	**Number**	**Percent**
Based on groupings of tested combo bins/boxes/other units	115	12
Based on combo bins/boxes/other units from one supplier	219	23
Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing	121	13
All combo bins/units received in one day	146	15
Other, please specify:	430	45
Don't know	30	3
No response	8	1

Based on responses to the Checklist, establishments grouped source materials into lots for grinding using a variety of criteria. Most often (N=430, 45 percent), that criteria was different from the responses specified in the Checklist question (see Table 5.4.57). When asked to specify other methods, the most common response was that daily production was grouped into lots. Another common response was to group materials from multiple suppliers. Some establishments used source material according to age, with the oldest material used first, and some establishments grouped according to customer needs. In some cases, the customer was also the supplier. Of the possible responses listed in the Checklist question, the most common response (N=219, 23 percent) was to group source materials based on combo bins/boxes/other units from one supplier.

The Checklist also asked how many suppliers of ground beef components were used in the last 30 days.

Table 5.4.58. Suppliers for Patty Forming Operations

PatForm8: Approximately how many suppliers of ground beef has the establishment used in the last 30 days?	**Number**	**Percent**
Only from its own grinding plant	437	46
1, from other grinding plant	87	9
2-3	239	25
4-6	106	11
More than 6	52	5
Don't know	18	2
No response	13	1

Of the 952 patty forming operations, 46 percent (437) of establishments only used raw ground beef components from their own slaughter plant (see Table 5.4.58). Of the establishments that used outside suppliers for their components, 25 percent (239) used two to three suppliers. Five percent (52) of establishments used more than 6 suppliers.

The Checklist also asked the use of imported materials by patty forming operations.

Table 5.4.59. Imported Beef Usage for Patty Forming Operations

PatForm9: Does the establishment knowingly use imported raw beef for the production of patties?	**Number**	**Percent**
No	634	67
Every production day	167	18
Weekly	43	5
Monthly	4	0
Intermittently	90	9
Other, please specify:	9	1
Don't know	2	0
No response	3	0

As indicated in Table 5.4.59, 67 percent (634) of establishments did not use imported raw beef to produce patty products. Of those establishments that did use imported beef, the most common frequency (N=167, 18 percent) was "Every production day."

The Checklist also asked about documentation of temperature controls at various steps in the process.

Table 5.4.60. Temperature Monitoring for Patty Forming Operations

PatForm10: Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40º F or below at any of these processing steps (check all that apply)?	**Number**	**Percent**
No	189	20
Receipt of source materials	409	43
Patty Forming	321	34
Storage	562	59
Distribution	175	18
Other, please specify:	218	23
Don't know	1	0
No response	5	1

As indicated in Table 5.4.60, 20 percent (189) of establishments did not have documented monitoring or verification procedures to demonstrate that product was maintained at 40° F at any step in the process. Of the establishments that did have documented monitoring or verification procedures, the most common step in the process was storage (N=562, 59 percent). The receipt of source materials (N=409, 43 percent) and patty forming (N=321, 34 percent) were also frequent steps for monitoring or verification. Twenty-three percent (218) establishments responded "Other, please specify." A review of the responses to the "Other" category indicated that alternate temperature requirements were used. The most common temperature requirements ranged from 40° F to 45° F. Other process steps were also mentioned. Packaging was most commonly mentioned as a step where monitoring or verification was performed.

Checklist question PatForm11 asked about cleaning and sanitizing of equipment.

Table 5.4.61. Cleaning and Sanitizing for Patty Forming Operations

PatForm11: How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas (check all that apply)?	**Number**	**Percent**
After patty forming from each supplier	29	3
After patty forming from a group of suppliers	11	1
After a sample is collected for *E. coli* O157:H7 testing	229	24
Daily after production	939	99
Less than daily (extended clean-up)	7	1
Other, please specify:	44	5
Don't know	0	0
No response	5	1

As indicated in Table 5.4.61, 99 percent (939) of establishments cleaned and sanitized the equipment and processing areas daily after production. The next most common response was to clean and sanitize after a sample was collected for *E. coli* O157:H7 testing (N=229, 24 percent).

Only 3 percent (37) of establishments conducted cleaning and sanitizing after patty forming from each supplier. This implies that product from multiple suppliers was processed between cleaning and sanitizing. Patty forming using components from multiple suppliers between cleaning and sanitization may result in larger recalls than is potentially necessary because a positive *E. coli* O157:H7 test cannot be linked to a single supplier.

Checklist question PatForm12 asked if establishments tested for microbial indicator organisms.

Table 5.4.62. Testing for Microbial Indicator Organisms for Patty Forming Operations

PatForm12: Does the establishment or its designee test product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliform, APC, Enterobacteriaceae) (check all that apply)?	**Number**	**Percent**
No	647	68
Ground beef product	154	16
Ground beef patties	118	12
Food-contact equipment	194	20
Other, please specify	82	9
Don't know	2	0
No response	6	1

As indicated in Table 5.4.62, 68 percent (647) of establishments did not test for indicator organisms. Of those establishments that did, 20 percent (194) tested food contact equipment, 16 percent (154) tested ground beef product, and 12 percent (118) tested ground beef patties.

Nine percent (82) of establishments tested other areas, with the processing area being the most common response. Environmental areas, nonfood contact areas, and employees (e.g., hands) and equipment (e.g., gloves, aprons, etc.) were also mentioned.

Based on additional analysis of this question, 7 percent (67) of establishments tested all four Checklist question options (product, patties, and equipment).

The Checklist also asked about the use of carryover or rework by patty forming operations.

Table 5.4.63. Use of Carryover or Rework for Patty Forming Operations

PatForm13: Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program?	**Number**	**Percent**
Yes	154	16
No	774	81
Don't know	15	2
No response	9	1

As indicated in Table 5.4.63, carryover or rework which was not specifically accounted for in a robust testing program was used by 16 percent (154) of establishments. Interpretation of responses to this question should be made with caution. It is possible that Checklist responders may have answered either

"Yes" or "No" to confirm the use of rework not accounted for in a testing program. The "Yes" response could mean that the establishment did use rework in the manner described. The "No" response could mean "No, the establishment did not account for its rework in a testing program." These interpretations mean that either response could indicate the use of rework not accounted for in a testing program.

Summary

Selected findings about patty forming operations, as indicated from Checklist responses, are summarized below:

- Fifty-three percent (504) of establishments did not have purchase specifications for suppliers requiring testing or validated intervention methods, and 59 percent (564) did not have documentation other than purchase specifications (see Tables 5.4.51 and 5.4.52).
- Further analysis of supplier questions indicates that the number of establishments that did not have either purchase specifications or documentation is actually 19 percent overall. Based on a combined analysis of questions PatForm1 and PatForm2, 39 percent (367) of establishments did not have purchase specifications and did not have other documentation from suppliers. Furthermore, of these 367 establishments, 190 (52 percent of 367) responded on question PatForm8 that only product from their own slaughter plant was used. Based on this combined analysis, the number of establishments that: (a) used product from other suppliers; (b) did not have purchase specifications about testing and intervention for suppliers; and (c) did not have other documentation showing that suppliers tested or applied interventions is 177, or 19 percent overall (see Tables 5.4.51, 5.4.52 and 5.4.58).
- Relatively few establishments conducted validated interventions on ground product (see Table 5.4.53).
- Approximately two-thirds of establishments were not conducting ongoing verification testing of source materials and only 6 percent were using FSIS "best practices" as outlined in Attachment 5 of Notice 65-07 (see Table 5.4.54).
- Approximately two-thirds of establishments were not conducting ongoing verification testing of their finished product, and only 4 percent were using FSIS "best practices" (see Table 5.4.55).
- Three percent of establishments were cleaning and sanitizing after processing components from each supplier (see Table 5.4.61).

5.4.6 Enhanced Product (marinated or injected)

As shown in Table 5.4.1, 472 Checklist responses (out of 2,323) indicated that the establishment had an enhanced product operation.

Tables 5.4.64 through **5.4.79** provide tabulations (number of establishments and percentage) of 16 *E. coli* Checklist questions specific to establishments with enhanced product operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question is more than 472 and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first Checklist question for enhanced product operations asked whether an establishment enhanced product during a first and/or second shift.

Table 5.4.64. Shifts for Enhanced Product Operations

EPShift: During which shift(s) of operation does this establishment enhance product (check all that apply)?	**Number**	**Percent**
Shift 1	465	99
Shift 2	71	15
No response	3	1

As indicated in Table 5.4.64, 99 percent (465) of establishments enhanced product during the first shift and 9 percent (87) enhanced product during a second shift.

The Checklist asked whether establishments had purchase specifications requiring suppliers to apply various intervention methods and/or testing for *E. coli* O157:H7.

Table 5.4.65. Purchase Specifications for Enhanced Product Operations

EP1: Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the source materials (check all that apply)?	**Number**	**Percent**
No intervention	225	48
Organic acid	41	9
Acidified sodium	7	1
Acidified calcium	3	1
Irradiation	1	0
Gaseous ammonia	2	0
Other, please specify:	230	49
Don’t know	5	1
No response	7	1

As indicated in Table 5.4.65, 48 percent (225) of establishments did not have purchase specifications for suppliers, 1 percent (5) responded “Don’t know,” and 1 percent (7) did not respond to the question. The remaining 50 percent (235) of establishments had one or more types of purchase specifications. The most common purchase specification response (N=230, 49 percent) was “Other, please specify.” A review of these specified other responses identified, as the most common response, that establishments had purchase specifications requiring interventions. These specifications were either general in that the supplier could select the intervention, or the intervention was not part of a CCP. Some establishments only used in-house materials or fully cooked their product. Some establishments have letters of guarantee from their suppliers rather than purchase specifications.

Checklist question EP2 asked about validated interventions that establishments apply on the pre-enhanced product as a CCP.

Table 5.4.66. Interventions for Enhanced Product Operations

EP2: Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-enhanced product (check all that apply)?	**Number**	**Percent**
No intervention	404	86
Organic acid	5	1
Acidified sodium	3	1
Acidified calcium	0	0
Irradiation	0	0
Gaseous ammonia	0	0
Other, please specify:	65	14
Don't know	4	1
No response	6	1

As indicated in Table 5.4.66, 86 percent (404) of establishments did not apply interventions on the pre-enhanced product. The most common intervention selected was "Other, please specify" (N=65, 14 percent). When asked to specify other interventions, temperature controls were most frequently noted. As discussed in earlier sections, temperature controls are not considered a validated intervention method. Also mentioned were letters of guarantee or certificates of analysis from suppliers and the use of acidified sodium chlorite (ASC) and lactic acid. Reclassifying the ASC responses as Acidified sodium and lactic acid responses as Organic acid would not change the results to any meaningful degree.

The Checklist also asked about testing of source materials prior to enhancing product.

Table 5.4.67. Testing of Source Materials for Enhanced Product Operations

EP3: Does the establishment or its designee test source materials for *E. coli* O157:H7 prior to enhancing the product?	**Number**	**Percent**
No, the establishment tests no source materials	352	75
The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods	15	3
The establishment tests source materials using a different frequency and/or method, please specify:	101	21
Don't know	2	0
No response	2	0

As indicated in Table 5.4.67, 75 percent (352) of establishments did not test source materials. Three percent (15) of establishments conducted testing using the same frequency and/or method as stated in the Checklist question. Twenty-one percent (101) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify other methods and/or frequencies used, the frequency of testing reported varied from every lot or shipment to annually. A few specified other responses indicated more frequent testing during high prevalence season months, but the majority did not. Some establishments also randomly selected suppliers for testing, rather than testing the more frequent suppliers at a higher rate.

The Checklist also asked about testing of finished product for *E. coli* O157:H7.

Table 5.4.68. Testing of Finished Product for Enhanced Product Operations

EP4: Does the establishment or its designee test the finished enhanced product for *E. coli* O157:H7?	**Number**	**Percent**
No, the establishment tests no finished product	372	79
The establishment tests all production lots of finished product using a robust testing method	5	1
The establishment tests finished product using a different frequency and/or method, please specify:	87	18
Don't know	4	1
No response	4	1

As indicated in Table 5.4.68, 79 percent (372) of establishments with enhanced product operations did not test finished enhanced product. One percent (5) of establishments tested using the same frequency and/or method specified in the Checklist question. Eighteen percent (87) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify the other methods and/or frequencies used, the frequency of testing varied from a sample per production line per shift to annually. The most common frequency tended to be monthly to quarterly.

Based on a tabulation of combined responses to both questions (EP3 and EP4), 63 percent (298) of establishments with enhanced product operations did not conduct testing on either the source materials or the finished enhanced product.

The Checklist asked about laboratory methods used to test product for *E. coli* O157:H7.

Table 5.4.69. Testing Laboratory for Enhanced Product Operations

EP5: What laboratory does the establishment or its designee use to test product for *E. coli* O157:H7?	**Number**	**Percent**
FSIS Method	50	11
Other, please specify:	250	53
Don't know	47	10
No response	125	26

As indicated in Table 5.4.69, 11 percent (50) of establishments used the FSIS Method for testing ground beef or finished product for *E. coli* O157:H7. Fifty-three percent (250) used a method other than the FSIS Method. When asked to specify other methods used, about one-third of the establishments indicated that no testing was done. About one-quarter identified specific labs used. The nonresponse rate for this question (N=125, 26 percent) was somewhat unexpected. As indicated in Checklist question EP4 (see Table 5.4.68), 372 establishments did not test their enhanced product. These establishments would not be expected to identify a testing method in this question. In fact, 210 of the 372 nontesters responded that the establishment used the FSIS Method or some other method. It is not clearly understood why there are responses to this question when no product testing was being performed. Please refer to Chapter 4.1 for more discussion about nonresponse rates.

The Checklist also asked how source materials were grouped.

Table 5.4.70. Grouping of Source Materials into Lots for Enhanced Product Operations

EP6: How does the establishment group source materials into lots for enhancement (check all that apply)?	**Number**	**Percent**
Based on groupings of tested combo bins/boxes/other units	25	5
Based on combo bins/boxes/other units from one supplier	160	34
Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing	54	11
All combo bins/boxes/other units received in 1 day	80	17
Other, please specify:	165	35
Don't know	12	3
No response	6	1

Based on responses to the Checklist, establishments grouped source materials into lots for grinding using a variety of criteria. Most often (N=165, 35 percent), that criteria was different from the responses specified in the Checklist question (see Table 5.4.70). When asked to specify other methods, the most common response was that daily production was grouped into lots. Another common response was to group materials from multiple suppliers. Some establishments used source material according to age, with the oldest material used first, and some establishments grouped according to customer needs. Other establishments only used suppliers that had applied interventions.

Of the possible responses listed in the Checklist question, the most common response (N=160, 34 percent) was to group source materials based on combo bins/boxes/other units from one supplier.

The Checklist also asked how many suppliers of ground beef components were used in the last 30 days.

Table 5.4.71. Suppliers for Enhanced Product Operations

EP7: Approximately how many suppliers has the establishment used in the last 30 days?	**Number**	**Percent**
Only from its own slaughter/fabrication/grinding plant	21	4
1, from other slaughter/fabrication/grinding plant	101	21
2-3	185	39
4-6	76	16
More than 6	72	15
Don't know	11	2
No response	6	1

Of the 472 enhanced product operations, 4 percent (21) of establishments only used raw ground beef components from their own slaughter plant (see Table 5.4.71). Of the establishments that used outside suppliers for their components, 39 percent (185) used two to three suppliers. Another 21 percent (101) of establishments only used one supplier. Fifteen percent (72) of establishments used more than 6 suppliers.

The Checklist also asked about the use of imported materials by enhanced product operations.

Table 5.4.72. Imported Product Use for Enhanced Product Operations

EP8: Does the establishment knowingly use imported product for producing enhanced product?	**Number**	**Percent**
No	367	78
Every production day	21	4
Weekly	15	3
Monthly	6	1
Intermittently	51	11
Other, please specify:	7	1
Don't know	3	1
No response	2	0

As indicated in Table 5.4.72, 78 percent (367) of establishments did not use imported raw beef to produce enhanced products. Of those establishments that did use imported beef, the most common frequency (N=51, 11 percent) was "Intermittently."

The Checklist also asked about documentation of temperature controls at various steps in the process.

Table 5.4.73. Temperature Monitoring for Enhanced Product Operations

EP9: Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40º F or below at any of these process steps (check all that apply)?	**Number**	**Percent**
No	103	22
Receipt of source materials	231	49
Mechanical tenderization process	91	19
Storage	262	56
Distribution	111	24
Other, please specify:	129	27
Don't know	2	0
No response	3	1

As indicated in Table 5.4.73, 22 percent (103) of establishments did not have documented monitoring or verification procedures to demonstrate that product was maintained at 40° F at any step in the process. Of the establishments that did have documented monitoring or verification procedures, the most common step in the process was storage (N=262, 56 percent). The receipt of source materials (N=231, 49 percent) was the second most frequent step where establishments had monitoring or verification. Twenty-seven percent (129) establishments responded "Other, please specify." A review of the responses to the "Other" category indicated that alternate temperature requirements were common. More than half of the specified responses indicated that establishments had temperature requirements ranging from 40° F to 45° F. Other process steps were also mentioned. Packaging was commonly mentioned as a step where monitoring or verification was performed.

Checklist question EP10 asked about cleaning and sanitizing of equipment.

Table 5.4.74. Cleaning and Sanitizing for Enhanced Product Operations

EP10: How often does the establishment conduct complete cleaning and sanitizing of equipment (check all that apply)?	**Number**	**Percent**
After application of enhancing operations from each supplier	12	3
After application of enhancing operations from a group of suppliers	10	2
After a sample is collected for *E. coli* O157:H7	24	5
After each shift	49	10
Daily after production	441	93
Less than daily (extended clean-up)	2	0
Other, please specify:	27	6
Don't know	1	0
No response	2	0

As indicated in Table 5.4.74, 93 percent (441) of establishments cleaned and sanitized the equipment and processing areas daily after production. The next most common response was to clean and sanitize after each shift (N=49, 10 percent).

Only 3 percent (12) of establishments cleaned and sanitized after enhancement from each supplier. This implies that product from multiple suppliers was processed between cleaning and sanitizing. Enhancing product using components from multiple suppliers between cleaning and sanitization may result in larger recalls than is potentially necessary because a positive *E. coli* O157:H7 test cannot be linked to a single source.

Checklist question EP11 asked if establishments tested for microbial indicator organisms.

Table 5.4.75. Testing for Microbial Indicator Organisms for Enhanced Product Operations

EP11: Does the establishment or its designee test the product or food-contact equipment or solution (e.g., marinade) for microbial indicator organisms (e.g., generic *E. coli*, coliform, APC, Enterobacteriaceae) (check all that apply)?	**Number**	**Percent**
No	296	63
Enhanced product	48	10
Enhancing equipment	137	29
Solution (e.g., marinade)	20	4
Other, please specify:	50	11
Don't know	1	0
No response	3	1

As indicated in Table 5.4.75, 63 percent (296) of establishments did not test for indicator organisms. Of those establishments that did, 29 percent (137) tested enhancing equipment, 10 percent (48) tested the enhanced product, and 4 percent (20) tested the solution.

Eleven percent (50) of establishments tested other areas. A review of the other areas described identified the processing area as a common response. Environmental areas and nonfood contact areas were also mentioned.

Based on additional analysis of this question, 3 percent (13) of establishments tested all three Checklist question options (product, equipment, and solution).

The Checklist also asked about the creation of bench trim from the enhancement operation.

Table 5.4.76. Bench Trim from Enhanced Product Operations

EP12: Does the establishment create bench trim from the primal/sub-primal cuts undergoing enhancement that could be used as a raw beef component that is not specifically accounted for in a robust testing program?	**Number**	**Percent**
Yes	79	17
No	349	74
Don't know	1	0
Not applicable	41	9
No response	2	0

As indicated in Table 5.4.76, 74 percent (349) of establishments did not create bench trim that could be used as a raw beef component and was not part of a robust testing program. Interpretation of this group should be made with caution. These 349 could include establishments that: a) did not produce bench trim at all, b) produced bench trim, but did not use it as a raw beef component, or c) produced bench trim and used that trim as a raw beef component and accounted for it in a robust testing program. Seventeen percent (79) of establishments created bench trim that could be used as a raw beef component, but did not include it in a testing program.

The Checklist also asked about whether, and how often, an establishment tested its bench trim.

As indicated in Table 5.4.77, 39 percent (185) of establishments did not test bench trim. Another 33 percent (157) responded that the question was not applicable, and 15 percent (70) diverted bench trim to cooking or another non-raw beef product use. A total of 53 (11 percent) establishments performed some kind of testing: 2 percent (9) tested all production lots, and 9 percent (44) used a different frequency and/or method. A review of the other specified responses indicated that frequency was the main difference. The frequencies of testing ranged from daily to annually, with most responses being monthly to quarterly.

Checklist question EP14 asked whether establishments labeled enhanced product to inform purchasers that the product was enhanced.

Table 5.4.77. Testing of Bench Trim from Enhanced Product Operations

EP13: Does the establishment or its designee test all bench trim from the primal/sub-primal cuts undergoing enhancement for *E. coli* O157:H7 (check all that apply)?	**Number**	**Percent**
No, the establishment tests no bench trim	185	39
The establishment tests all production lots of bench trim using a robust testing method	9	2
The establishment tests bench trim using a different frequency and/or method, please specify:	44	9
Divert bench trim to cooking or other non-raw beef product use	70	15
Don't know	2	0
Not applicable	157	33
No response	5	1

Table 5.4.78. Product Labeling for Enhanced Product Operations

EP14: Does the establishment choose to provide labeling on the enhanced product to inform purchasers that the product is enhanced (i.e., non-intact)?	**Number**	**Percent**
Yes, specify labeling:	329	70
No	126	27
Don't know	11	2
No response	6	1

As indicated in Table 5.4.78, 27 percent (126) of establishments did not provide labeling to inform purchasers that the product was enhanced. Enhanced product operations are required by FSIS policy to provide labeling identifying the product as enhanced.[5,6] The number of establishments that did not identify their product as enhanced was considered high. It may be that the inspectors interpreted the question literally and were responding to whether the product was "non-intact." Some methods of producing enhanced product pierce the surface of the meat, such as the use of injection needles. These methods would render the product as "non-intact." Other methods do not pierce the meat. With these methods, the product may be considered intact, but still enhanced with a marinade or other solution. If the question was interpreted to be asking whether the enhanced product was non-intact, then the "No" responses may represent some proportion of enhanced product that is considered intact. It is also possible that establishments are failing to identify their product according to FSIS policy. The specific cause of this high rate is not known.

According to FSIS expectations, whenever an uncooked cured red meat product is injected, massaged, tumbled, etc., with a flavoring or seasoning solution, the product name must be qualified with a statement indicating that the addition of a solution has taken place (e.g., "Containing 6% of a Solution," "Injected with up to 12% of a Flavoring Solution"). The qualifier must appear contiguous to the product name

[5] FSIS Food Standards and Labeling Policy Book, August 2005.
[6] FSIS Policy Memo 066C.

whenever it appears on the label. The ingredients of the solution may accompany the qualifier or appear in locations prescribed for ingredient statements.

Seventy percent (329) of establishments provided labeling identifying the product as enhanced. A review of the specified labeling indicated that information about the addition of solution was most commonly indicated. Other less common labeling practices were to list ingredients or to specify that seasoning or marinade was added.

The Checklist also asked how establishments were labeling solutions for enhanced products.

Table 5.4.79. Solution Labeling for Enhanced Product Operations

EP15: How is the enhancement solution labeled regarding name and ingredients?	**Number**	**Percent**
Not applicable	34	7
Name(s), please specify:	270	57
Ingredient(s), please specify:	384	81
Don't know	13	3
No response	4	1

As indicated in Table 5.4.79, 81 percent (384) of establishments labeled the enhancement solution with ingredients. A review of the specified ingredients labeling indicated that a variety of ingredients were used. Solutions commonly included the percentage (e.g., "Contains X% solution of . . . "). Fifty-seven percent (270) of establishments labeled the enhancement solution with a name. A review of the specified names identified a variety of responses. Some specified the product name, and some specified more generic names, including references to "X% of solution added."

Summary

Selected findings about enhanced product operations, as indicated from Checklist responses are summarized below:

- Forty-eight percent (225) of establishments did not have purchase specifications for suppliers requiring testing or validated intervention methods (see Table 5.4.65).
- Relatively few establishments conducted validated interventions on enhanced product (see Table 5.4.66).
- Approximately three-quarters of establishments were not conducting ongoing verification testing of source materials, and only 3 percent were using FSIS "best practices" as outlined in Attachment 5 of Notice 65-07 (see Table 5.4.67).
- Approximately three-quarters of establishments were not conducting ongoing verification testing of their finished product, and only 1 percent were using FSIS "best practices" (see Table 5.4.68).
- Three percent of establishments were cleaning and sanitizing after enhancing components from each supplier (see Table 5.4.74).
- Seventeen percent of establishments were creating bench trim that could be used as a raw beef component and was not accounted for in a testing program.
- According to Checklist responses, a high percentage (27 percent) of enhanced product establishments did not appear to be labeling their product as enhanced.

5.4.7 Mechanical Tenderizing

As indicated in Table 5.4.1, 850 Checklist responses (out of 2,323) indicated that the establishment had a mechanical tenderizing operation.

Tables 5.4.80 through **5.4.96** provide tabulations (number of establishments and percentage) of 17 *E. coli* Checklist questions specific to establishments with mechanical tenderizing operations. For most questions, inspectors who completed the Checklist were able to select more than one response. In these cases, the total number of responses to a question is more than 850, and the percentage adds up to more than 100 percent. These questions typically have the "(check all that apply)" statement at the end. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first Checklist question for mechanical tenderizing operations asked whether an establishment tenderized product during a first and/or second shift.

Table 5.4.80. Shifts for Mechanical Tenderizing Operations

MTShift: During which shift(s) of operation does the establishment mechanically tenderize beef (check all that apply)?	**Number**	**Percent**
Shift 1	839	99
Shift 2	64	8
No response	8	1

As indicated in Table 5.4.80, 99 percent (839) of establishments mechanically tenderized product during the first shift, and 8 percent (64) mechanically tenderized product during a second shift.

The Checklist asked about the types of tenderizing methods used by establishments.

Table 5.4.81. Types of Tenderizing for Mechanical Tenderizing Operations

MT0: Please select the mechanical tenderizing operations that you perform at your establishment (check all that apply)?	**Number**	**Percent**
Mechanical blade tenderizing	713	84
Mechanical needle tenderizing	312	37
Mechanical tenderizing by pounding	30	4
Other, please specify:	16	2
No response	7	1

As indicated in Table 5.4.81, 84 percent (713) of establishments used mechanical blade tenderizing. The second most commonly selected response (N=312, 37 percent) was mechanical needle tenderizing. Four percent (30) of establishments performed mechanical tenderizing by pounding.

The Checklist asked whether establishments had purchase specifications requiring suppliers to apply various intervention methods and/or testing for *E. coli* O157:H7.

Table 5.4.82. Purchase Specifications for Mechanical Tenderizing Operations

MT1: Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the source materials (check all that apply)?	**Number**	**Percent**
No intervention	452	53
Organic acid	67	8
Acidified sodium chlorite	17	2
Acidified calcium sulfate	10	1
Irradiation	1	0
Gaseous ammonia	2	0
Other, please specify:	351	41
Don't know	13	2
No response	12	1

As indicated in Table 5.4.82, 53 percent (452) of establishments did not have purchase specifications for suppliers, 2 percent (13) responded "Don't know," and 1 percent (12) did not responded to this question. The remaining 44 percent (373) of establishments had one or more types of purchase specifications. The most common purchase specification response (N=351, 41 percent) was "Other, please specify." A review of these specified other responses identified, as the most common response, that establishments had purchase specifications requiring one or more unspecified interventions. These specifications were general, so that the supplier could select the intervention. Some establishments only used in-house materials or fully cooked their product. Some establishments had letters of guarantee from their suppliers, rather than purchase specifications.

Checklist question MT2 asked about validated interventions that establishments apply on the pre-tenderized product as a CCP.

Table 5.4.83. Interventions for Mechanical Tenderizing Operations

MT2: Does the establishment conduct any of the following as a CCP in the HACCP plan prior to mechanically tenderizing product (check all that apply)?	**Number**	**Percent**
No intervention	748	88
Organic acid	19	2
Acidified sodium	3	0
Acidified calcium	3	0
Irradiation	0	0
Gaseous ammonia	0	0
Other, please specify:	87	10
Don't know	0	0
No response	7	1

As indicated in Table 5.4.83, 88 percent (748) of establishments did not apply interventions prior to mechanically tenderizing the product. The most common intervention selected was "Other, please specify" (N=87, 10 percent). When asked to specify other interventions, temperature controls were most frequently noted. As discussed in earlier sections, temperature controls are not considered a valid intervention method. Also mentioned as specified other responses were the use of ASC and lactic acid. Reclassifying the ASC responses as Acidified sodium and lactic acid responses as Organic acid did not change the results to any meaningful degree.

The Checklist also asked about testing of source materials prior to mechanically tenderizing the product.

Table 5.4.84. Testing of Source Materials for Mechanical Tenderizing Operations

MT3: Does the establishment or its designee test source materials for *E. coli* O157:H7 prior to mechanical tenderization?	**Number**	**Percent**
No, the establishment tests no source materials	707	83
The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods	26	3
The establishment tests source materials using a different frequency and/or method, please specify:	107	13
Don't know	0	0
No response	10	1

As indicated in Table 5.4.84, 83 percent (707) of establishments did not test source materials. Three percent (26) of establishments conducted testing using the same frequency and/or method stated in the Checklist question. Thirteen percent (107) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify other methods and/or frequencies used, the frequency of testing reported varied from every lot or shipment to annually. The most common frequency tended to be monthly to quarterly. A few specified other responses indicated more frequent testing during high prevalence season months, but the majority did not. Some also indicated more frequent testing for new suppliers. Other establishments also randomly selected suppliers for testing rather than testing the more frequent suppliers at a higher rate.

The Checklist also asked about testing of finished product for *E. coli* O157:H7.

Table 5.4.85. Testing of Finished Product for Mechanical Tenderizing Operations

MT4: Does the establishment or its designee test the finished tenderized product for *E. coli* O157:H7 (check all that apply)?	**Number**	**Percent**
No, the establishment tests no finished product	694	82
The establishment tests all production lots of such finished product using a robust testing method	12	1
The establishment tests such finished product using a different frequency and/or method, please specify:	135	16
Don't know	1	0
No response	8	1

As indicated in Table 5.4.85, 82 percent (694) of establishments with mechanically tenderized product operations did not test finished tenderized product. One percent (12) of establishments tested using the

same frequency and/or method specified in the Checklist question. Sixteen percent (135) of establishments used a frequency or method other than that specified in the Checklist question. When asked to specify the other methods and/or frequencies used, the frequency of testing varied from a sample per lot to annually. The most common frequency tended to be monthly or quarterly.

Based on a tabulation of combined responses to both questions (MT3 and MT4), 72 percent (611) of establishments with mechanically tenderized product operations did not conduct testing on either the source materials or the finished tenderized product.

The Checklist asked about laboratory methods used to test product for *E. coli* O157:H7.

Table 5.4.86. Laboratory for Testing for Mechanical Tenderizing Operations

MT5: What laboratory does the establishment or its designee use to test product for *E. coli* O157:H7?	**Number**	**Percent**
FSIS method	95	11
Other, please specify:	385	45
Don't know	97	11
No response	273	32

As indicated in Table 5.4.86, 11 percent (95) of establishments used the FSIS Method for testing ground beef or finished product for *E. coli* O157:H7. Forty-five percent (385) used a method other than the FSIS Method. When asked to specify other methods used, about one-half of the establishments indicated that no testing was done. About one-quarter identified specific labs used including in-house testing labs. The nonresponse rate for this question was 32 percent (N=273). As indicated earlier, 611 establishments did not test source materials for tenderized product. Based on further analysis of these 611 establishments, 254 had no response to this question, 34 used the FSIS Method, 77 did not know, and 246 indicated "Other." Please refer to Chapter 4.1 for more discussion about nonresponse rates.

The Checklist also asked how source materials were grouped.

Table 5.4.87. Grouping of Source Materials for Mechanical Tenderizing Operations

MT6: How does the establishment group source materials into lots for mechanical tenderization (check all that apply)?	**Number**	**Percent**
Based on groupings of tested combo bins/boxes/other units	45	5
Based on combo bins/boxes/other units from one supplier	186	22
Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing	84	10
All combo bins/boxes/other units received in 1 day	135	16
Other, please specify:	385	45
Don't know	45	5
No response	17	2

Based on responses to the Checklist, establishments grouped source materials into lots for grinding using a variety of criteria. Most often (N=385, 45 percent), that criteria was different from the responses specified to the Checklist question (see Table 5.4.87). When asked to specify other methods, the most

common response was that daily production was grouped into lots. This is viewed as distinct from the Checklist response, "All combo bins/boxes/other units received in one day." Establishments may have received combo bins/boxes/other units over several days and then processed that material on a single day. Another common response was to group materials from multiple suppliers. Some establishments used source material according to age with the oldest material used first, and some establishments grouped according to customer needs. Other establishments only used suppliers that had applied interventions. Establishments also grouped materials based on customer needs or purchase requirements.

Of the possible responses listed in the Checklist question, the most common response (N=186, 22 percent) was to group source materials based on combo bins/boxes/other units from one supplier.

The Checklist also asked how many suppliers of ground beef components were used in the last 30 days.

Table 5.4.88. Suppliers for Mechanical Tenderizing Operations

MT7: Approximately how many suppliers has the establishment used in the last 30 days?	**Number**	**Percent**
Only from its own slaughter/fabrication plant	153	18
1, from other slaughter plant	87	10
2-3	339	40
4-6	137	16
More than 6	111	13
Don't know	14	2
No response	9	1

Of the 850 mechanically tenderized product operations, 18 percent (153) of establishments only used components from their own slaughter plant (see Table 5.4.88). Of the establishments that used outside suppliers for their components, 40 percent (339) used two to three suppliers. Another 10 percent (87) of establishments only used one supplier. Thirteen percent (111) of establishments used more than 6 suppliers.

The Checklist also asked about the use of imported materials by mechanical tenderizing operations.

Table 5.4.89. Imported Product Use for Mechanical Tenderizing Operations

MT8: Does the establishment knowingly use imported product for producing mechanically-tenderized product?	**Number**	**Percent**
No	708	83
Every production day	29	3
Weekly	21	2
Monthly	5	1
Intermittently	66	8
Other, please specify:	9	1
Don't know	4	0
No response	8	1

As indicated in Table 5.4.89, 83 percent (708) of establishments did not use imported product to produce mechanically tenderized products. Of those establishments that did use imported materials, the most common frequency (N=66, 8 percent) was "Intermittently."

The Checklist also asked about documentation of temperature controls at various steps in the process.

Table 5.4.90. Temperature Monitoring Documentation for Mechanical Tenderizing Operations

MT9: Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40º F or below at any of these process steps (check all that apply)?	**Number**	**Percent**
No	179	21
Receipt of source materials	347	41
Mechanical tenderization process	208	24
Storage	489	58
Distribution	152	18
Other, please specify:	202	24
Don't know	1	0
No response	10	1

As indicated in Table 5.4.90, 21 percent (179) of establishments did not have documented monitoring or verification procedures to demonstrate that product was maintained at 40° F at any step in the process. Of the establishments that did have documented monitoring or verification procedures, the most common step in the process was storage (N=489, 58 percent). The receipt of source materials step (N=347, 41 percent) was the second most frequent step where establishments to used monitoring or verification. Twenty-four percent (202) establishments responded, "Other, please specify." A review of the responses to the "Other" category indicated that alternate temperature requirements were common. More than half of the specified responses indicated that establishments had temperature requirements ranging from 40° F to 45° F. Other process steps were also mentioned. Packaging was commonly mentioned as an alternate step where monitoring or verification was performed.

Checklist question MT10 asked about cleaning and sanitizing of equipment.

As indicated in Table 5.4.91, 94 percent (797) of establishments cleaned and sanitized the equipment and processing areas daily after production. The next most common response was cleaning and sanitizing after a sample was collected for *E. coli* O157:H7 (N=102, 12 percent) followed closely by cleaning and sanitizing after each shift (N=100, 12 percent).

Only 3 percent (12) of establishments conducted cleaning and sanitizing after mechanical tenderization from each supplier. This implies that product from multiple suppliers was processed between cleaning and sanitizing. Mechanically tenderizing product using components from multiple suppliers between cleaning and sanitization may result in larger recalls than is potentially necessary because a positive *E. coli* O157:H7 test cannot be linked to a single source.

Checklist question MT11 asked if establishments tested for microbial indicator organisms.

Table 5.4.91. Cleaning and Sanitizing for Mechanical Tenderizing Operations

MT10: How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas (check all that apply)?	**Number**	**Percent**
After mechanical tenderization from each supplier	21	2
After mechanical tenderization from a group of suppliers	10	1
After a sample is collected for *E. coli* O157:H7	102	12
After each shift	100	12
Daily after production	797	94
Less than daily (extended clean-up)	3	0
Other, please specify:	37	4
Don't know	0	0
No response	8	1

Table 5.4.92. Testing for Microbial Indicator Organisms for Mechanical Tenderizing Operations

MT11: Does the establishment or its designee test the product or the food-contact surfaces of equipment for microbial indicator organisms (e.g., generic *E. coli*, coliform, APC, Enterobacteriaceae) (check all that apply)?	**Number**	**Percent**
No	622	73
Mechanical tenderize product	61	7
Mechanical tenderization equipment food-contact surfaces	151	18
Processing area	141	17
Other, please specify:	46	5
Don't know	0	0
No response	8	1

As indicated in Table 5.4.92, 73 percent (622) of establishments did not test for indicator organisms. Of those establishments that did, 18 percent (151) tested equipment food-contact surfaces, 17 percent (141) tested the processing area, and 7 percent (61) tested the mechanically tenderized product.

Five percent (46) of establishments tested other areas. A review of the other areas described identified frequency of testing as a variable. Some establishments tested multiple areas daily, while others tested annually. Some establishments tested different areas at different frequencies (e.g., product was tested biweekly and environment annually). Environmental areas and nonfood contact areas were also mentioned.

Based on additional analysis of this question, 4 percent (34) of establishments tested all three Checklist question options (product, surfaces, and processing area).

The Checklist also asked about the creation of bench trim from the mechanical tenderization operation.

Table 5.4.93. Bench Trim Creation for Mechanical Tenderizing Operations

MT12: Does the establishment create bench trim from primal/sub-primal cuts undergoing mechanical tenderization that could be used as a raw ground beef component that is not specifically accounted for in a robust testing program?	**Number**	**Percent**
Yes	269	32
No	559	66
Don't know	11	1
No response	11	1

As indicated in Table 5.4.93, 66 percent (559) of establishments did not create bench trim that could be used as a raw beef component and was not part of a robust testing program. Interpretation of this group should be made with caution. The 559 could include establishments that: (a) did not produce bench trim at all; (b) produced bench trim, but did not use it as a raw beef component; or (c) produced bench trim and used that trim as a raw beef component, and also accounted for it in a robust testing program. Thirty-two percent (269) of establishments created bench trim that could be used as a raw beef component, but did not include it in a testing program.

The Checklist also asked about whether, and how often, an establishment tested its bench trim.

Table 5.4.94. Bench Trim Testing for Mechanical Tenderizing Operations

MT13: Does the establishment or its designee test all bench trim from the primal/sub-primal cuts undergoing mechanical tenderization for *E. coli* O157:H7?	**Number**	**Percent**
No, the establishment tests no bench trim	498	59
The establishment tests all production lots of bench trim using a robust testing method	19	2
The establishment tests bench trim using a different frequency and/or method, please specify:	71	8
Divert bench trim to cooking or other non-raw beef product use	97	11
Don't know	0	0
Not applicable	149	18
No response	16	2

As indicated in Table 5.4.94, 59 percent (498) of establishments did not test bench trim. Another 18 percent (149) responded that the question was not applicable, and 11 percent (97) diverted bench trim to cooking or another non-raw beef product use. A total of 90 establishments performed some kind of testing: 2 percent (19) tested all production lots, and 8 percent (71) used a different frequency and/or method. A review of the other specified responses indicated that frequency was the main difference. The frequency of testing ranged from daily to annually, with most responses being monthly or quarterly.

Checklist question MT14 asked whether establishments labeled product to inform purchasers that the product was mechanically tenderized.

Table 5.4.95. Labeling of Product for Mechanical Tenderizing Operations

MT14: Does the establishment choose to provide labeling on the mechanically tenderize product to inform purchasers that the product is mechanically tenderized (i.e., non-intact)?	**Number**	**Percent**
Yes, specify labeling:	199	23
No	632	74
Don't know	8	1
No response	11	1

As indicated in Table 5.4.95, 74 percent (632) of establishments did not provide labeling to inform purchasers that the product was enhanced. Twenty-three percent (199) of establishments provided labeling identifying the product as enhanced. A review of the specified labeling indicated that the majority of establishments identified their product as "cubed." Cubed beef generally consists of tenderization whereby the piercing is evident. Other forms of tenderization may result in product whereby the piercing is not evident. In both cases, the product is considered non-intact as a result of the piercing process. Some establishments also included the word "Tenderized" on the label. A few establishments identified the specific type of tenderization (e.g., needle, pounding, etc.).

The Checklist also asked establishments how many passes were used for tenderizing products.

Table 5.4.96. Tenderizing Passes for Mechanical Tenderizing Operations

MT15: Approximately how many times does an individual product pass through the mechanical tenderization process?	**Number**	**Percent**
1	214	25
2-3	505	59
4-6	87	10
More than 6	15	2
Don't know	9	1
No response	20	2

As indicated in Table 5.4.96, 25 percent (214) of establishments passed product through the mechanical tenderization process once. The most common practice (N=505, 59 percent) was to use two to three passes. Ten percent (87) of establishments used four to six passes, and 2 percent (15) of establishments used more than six passes.

Summary

Selected findings about mechanical tenderizing operations, as indicated from Checklist responses, are summarized below:

- Fifty-three percent (452) of establishments did not have purchase specifications for suppliers requiring intervention methods (see Table 5.4.82).
- Less than 15 percent of establishments conducted validated interventions on mechanically tenderized product (see Table 5.4.83).

- More than 80 percent of establishments did not conduct ongoing verification testing of source materials, and only 3 percent used FSIS "best practices" as outlined in Attachment 5 of Notice 65-07 (see Table 5.4.84).
- More than 80 percent of establishments did not conduct ongoing verification testing of their finished product, and only 1 percent used FSIS "best practices" (see Table 5.4.85).
- Two percent of establishments cleaned and sanitized after mechanically tenderizing components from each supplier (see Table 5.4.91).
- Thirty-two percent of establishments were creating bench trim that could be used as a raw beef component and was not specifically accounted for in a robust testing program.

5.5 Common Category Questions

Section 5.4 of this chapter presented results from the Checklist according to raw beef operation type. Each operation type was asked a specific set of questions. A review of those questions identified several that were "common" across the operations. The responses from different operation types are summarized here for each common question. Due to variations in wording or response options, the common questions represent generalized versions of the questions asked in the Checklist. The responses have also been generalized to accommodate the variations in Checklist question design.

Tables 5.5.1 through **5.5.19** provide tabulations (percentage of establishments and number) of 19 common questions which represent generalized versions of the *E. coli* Checklist questions. For most questions, inspectors who completed the Checklist were able to select more than one response. In those cases, the total number of responses to a question is more than the number of establishments for each operation type, and the percentages add up to more than 100 percent. The actual Checklist questions to which these common responses refer are noted in the discussion for each table. Some common questions did not apply to all seven operation types. In those cases, the columns for operation types for which the common question did not apply were left blank. The number and percent in the "No response" category refer to Checklists where no response to a specific question was selected.

The first common question asks whether an establishment operated one or two shifts to produce their respective product. This common question was derived from Checklist questions BGShift, BTFShift, BSShift, RCGShift, PFShift, EPShift, and MTShift.

Table 5.5.1. Shift Responses by Operation Type

During which shift(s) of operation does this establishment produce its designated product?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Shift 1	98% (1,353)	96% (965)	98% (578)	97% (272)	99% (940)	99% (465)	99% (839)
Shift 2	8% (107)	7% (74)	2% (14)	5% (13)	9% (87)	15% (71)	8% (64)
No response	1% (17)	4% (39)	2% (9)	3% (8)	1% (9)	1% (3)	1% (8)

As indicated in Table 5.5.1, the 7 operation types produced their product during a first shift more than 96 percent of the time. The percentages of establishments that produced their product during a second shift varied from 2 percent (Slaughter) to 15 percent (Enhanced Product).

The next common question asks whether establishments had purchase specifications requiring that suppliers conduct a CCP on the source materials. This common question was derived from Checklist questions BeefGrind1, RCG1, PatForm1, EP1, and MT1. Due to variations in Checklist question design, the responses were reclassified into more general "Yes" / "No" categories.

Table 5.5.2. Purchase Specifications by Operation Type

Does the establishment have purchase specifications requiring that suppliers conduct a CCP in the HACCP plan on the source materials?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	24% (328)			38% (106)	53% (504)	48% (225)	53% (452)
Yes	76% (1,051)			59% (167)	43% (413)	52% (246)	46% (391)
Don't know	1% (8)			0% (1)	1% (13)	1% (5)	2% (13)
No response	1% (12)			4% (11)	6% (59)	1% (7)	1% (12)

As indicated in Table 5.5.2, Beef Grinding operations were most likely to have purchase specifications (76 percent). Establishments from the other operation types required purchase specifications 43 to 59 percent of the time.

The next common question asks whether establishments had documentation other than purchase specifications requiring that suppliers conduct either interventions or testing. This common question was derived from Checklist questions BeefGrind2, RCG2, and PatForm2. Due to variations in Checklist question design, the responses were reclassified into more general categories.

As indicated in Table 5.5.3, the Beef Grinding operation was more likely to have other documentation about validated intervention methods (33 percent versus 20 percent for Regrind Coarse Ground and 14 percent for Patty Forming) and source material testing (33 percent versus 11 percent for Regrind Coarse Ground, and 11 percent for Patty Forming).

The next common question asks about the types of interventions applied by establishments on source materials. This question was derived from Checklist questions BeefGrind3, BeefTrimFab4, RCG3, PatForm3, EP2, and MT2.

Table 5.5.3. Other Supplier Documentation by Operation Type

Does the establishment have documentation other than purchase specifications showing that suppliers conduct any of the following?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	45% (614)			60% (170)	59% (564)		
Validated intervention methods	33% (460)			20% (57)	14% (130)		
Testing of source material for *E. coli* O157:H7	33% (448)			11% (31)	11% (106)		
Other	19% (257)			17% (49)	23% (220)		
Don't know	0% (4)			2% (5)	1% (9)		
No response	1% (9)			2% (6)	2% (23)		

Table 5.5.4. Interventions on Source Materials by Operation Type

Does the establishment apply any validated intervention, including as a CCP in the HACCP plan, on source material?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No intervention	92% (1,259)	85% (854)		94% (263)	94% (894)	86% (404)	88% (748)
Organic acid	2% (30)	4% (38)		0% (1)	0% (3)	1% (5)	2% (19)
Acidified sodium chlorite	1% (15)	1% (13)		1% (2)	1% (6)	1% (3)	0% (3)
Acidified calcium sulfate	0% (2)	0% (1)		0% (0)	0% (0)	0% (0)	0% (3)
Irradiation	0% (0)	0% (0)		0% (0)	0% (2)	0% (0)	0% (0)
Gaseous ammonia	0% (0)	0% (4)		0% (0)	0% (0)	0% (0)	0% (0)
Other	6% (78)	9% (88)		4% (10)	5% (51)	14% (65)	10% (87)
Don’t know	0% (1)	0% (1)		0% (0)	0% (0)	1% (4)	0% (0)
No response	1% (10)	4% (40)		2% (6)	1% (8)	1% (6)	1% (7)

For the 6 operation types for which this question was asked, the percentage of establishments who did not apply any interventions ranged from 85 percent (Beef Trim Fabrication) to 94 percent (Regrind Coarse Ground and Patty Forming). Of the establishments that did apply interventions, the most common response for all six operation types was “Other”. As was discussed in the operation specific sections of this report (see Section 5.4 of this chapter), temperature controls was a common response for all categories. Also discussed earlier was the fact that temperature controls were not considered an intervention and may reflect a misinterpretation of the question or of appropriate responses.

The next common question asks about the types of interventions applied by establishments on finished product. This question was derived from Checklist questions BeefGrind3a, and RCG3a.

Table 5.5.5. Interventions on Finished Product by Operation Type

Does the establishment apply any validated intervention on the finished ground product?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No intervention	94% (1,296)			95% (267)			
Organic acid	0% (3)			0% (0)			
Acidified sodium chlorite	1% (8)			0% (0)			
Acidified calcium sulfate	0% (2)			0% (1)			
Irradiation	0% (2)			0% (0)			
Gaseous ammonia	0% (0)			0% (0)			
Other	5% (68)			3% (9)			
Don’t know	0% (2)			0% (0)			
No response	1% (9)			2% (5)			

As indicated in Table 5.5.5, 94 percent of Beef Grinding establishments and 95 percent of Regrind Coarse Ground establishments did not apply validated interventions to the finished product. The most common intervention applied was “Other,” and tended to be temperature controls. The subject of temperature control as an invalid intervention response was discussed earlier.

The next common question asks about testing of source materials by establishments. This question was derived from Checklist questions BeefGrind4, BeefTrimFab5, RCG4, PatForm4, EP3, and MT3. Due to variations in Checklist question design, the responses were reclassified into more general categories.

Table 5.5.6. Testing of Source Materials by Operation Type

Does the establishment test source materials?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	67% (918)	60% (604)		72% (203)	64% (614)	75% (352)	83% (707)
Yes, according to question criteria	6% (83)	8% (81)		5% (15)	6% (61)	3% (15)	3% (26)
Yes, using different methodology/frequency	26% (359)	28% (284)		19% (53)	29% (272)	21% (101)	13% (107)
Don't know	0% (3)	0% (1)		1% (2)	0% (2)	0% (2)	0% (0)
No response	1% (12)	4% (38)		3% (8)	0% (3)	0% (2)	1% (10)

As indicated in Table 5.5.6, the percentage of establishments that did not test source materials was highest (83 percent) for Mechanical Tenderization establishments and lowest for Beef Trim Fabrication (60 percent). Of the establishments that did test source materials, they were more likely to use a different frequency or methodology than to test according to the criteria specified in the original question.

Based on an overall review of the specified other methodologies and/or frequencies, establishments generally tested monthly to quarterly, although a few establishments were found to test daily, and some were found to test annually. When asked, there was little indication among specified other frequencies that establishments were testing more often during high prevalence season months or more often for the more frequent suppliers.

The next common question asks about testing of finished product by establishments. This question was derived from Checklist questions BeefGrind5, RCG5, PatForm5, EP4, and MT4. Due to variations in Checklist question design, the responses were reclassified into more general categories.

As indicated in Table 5.5.7, the percentage of establishments that did not test source materials was highest (82 percent) for Mechanical Tenderization establishments and lowest (50 percent) for Beef Grinding. Of the establishments that did test source materials, they were more likely to use a different frequency or methodology than to test according to the criteria specified in the original question.

Based on an overall review of the specified other methodologies and/or frequencies, establishments generally tested monthly to quarterly, although a few establishments were found to test daily, and some were found to test annually. When asked, there was little indication among specified other frequencies that establishments were testing more often during high prevalence season months or more often for the more frequent suppliers.

The next common question asks about testing for indicator organisms by establishments. This question was derived from Checklist questions BeefGrind15, BeefSlaughter5, RCG13, PatForm12, EP11, and MT11. Due to variations in Checklist question design, the responses were reclassified into more general categories.

Table 5.5.7. Testing of Finished Product by Operation Type

Does the establishment or its designee test the finished product?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	50% (691)			53% (148)	67% (639)	79% (372)	82% (694)
Yes, according to question criteria	5% (69)			3% (9)	4% (39)	1% (5)	1% (12)
Yes, using different methodology/frequency	44% (609)			42% (117)	28% (268)	18% (87)	16% (135)
Don't know	0% (1)			0% (1)	0% (2)	1% (4)	0% (1)
No response	0% (5)			2% (6)	0% (4)	1% (4)	1% (8)

Table 5.5.8. Testing for Indicator Organisms by Operation Type

Does the establishment or its designee test product, equipment, or processing area for microbial indicator organisms (e.g., generic *E. coli*, coliform, APC, Enterobacteriaceae)?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	69% (955)		79% (465)	69% (193)	68% (647)	63% (296)	73% (622)
Components / Product	19% (266)		17% (99)	16% (46)	19% (184)	10% (48)	7% (61)
Equipment / Area	18% (254)		7% (42)	19% (53)	20% (194)	29% (137)	21% (176)
Other	8% (111)		5% (32)	5% (14)	9% (82)	14% (67)	5% (46)
Don't know	0% (3)		0% (1)	0% (1)	0% (2)	0% (1)	0% (0)
No response	1% (7)		1% (6)	2% (5)	1% (6)	1% (3)	1% (8)

As indicated in Table 5.5.8, the percentage of establishments that did not test for indicator organisms was highest (79 percent) for Slaughter establishments and lowest (63 percent) for Enhanced Product. Of the establishments that did test for indicator organisms, 3 operations generally tested "Components / Product" at a rate comparable to "Equipment/Area" (19 percent versus 18 percent for Beef Grinding, 16 percent versus 19 percent for Regrind Coarse Ground, and 19 percent versus 20 percent for Patty Forming). More Slaughter establishments tended to test "Components/Product" (17 percent) than "Equipment/Area" (7 percent). More Enhanced Product and Mechanical Tenderization establishments tended to test

"Equipment/Area" (29 percent and 21 percent, respectively) than "Components/Product" (10 percent and 7 percent, respectively).

The next common question asks about testing for indicator organisms by establishments. This question was derived from Checklist questions BeefGrind6, RCG6, PatForm6, EP5, and MT5.

Table 5.5.9. Testing Laboratory by Operation Type

What laboratory does the establishment or its designee use to test its finished product for *E. coli* O157:H7?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
FSIS method	15% (205)			12% (34)	9% (86)	11% (50)	11% (95)
Other	30% (414)			29% (82)	20% (192)	53% (250)	45% (385)
Don't know	5% (65)			3% (9)	3% (29)	10% (47)	11% (97)
No response	50% (691)			56% (156)	68% (645)	26% (125)	32% (273)

As indicated in Table 5.5.9, the nonresponse rates are higher for this question than for other questions. For the Beef Grinding, Regrind Coarse Grind, and Patty Forming establishments, the nonresponse rates closely reflect the finished product nontesting rates indicated in Table 5.5.7 and, to a lesser extent, the source material testing rates indicated in Table 5.5.6. It is expected that establishments who were not testing finished product or source materials would not utilize a testing laboratory or method.

For the Enhanced Product and Mechanical Tenderization establishments, the nonresponse rates of 26 percent and 32 percent, respectively, are much lower than the nontesting rates from Tables 5.5.7 (79 percent and 82 percent, respectively) and 5.5.6 (75 percent and 83 percent, respectively). It is not known why establishments who did not test source materials or finished product would have a testing laboratory or method.

The next common question asks about temperature monitoring or verification by establishments. This question was derived from Checklist questions BeefGrind13, BeefTrimFab3, BeefSlaughter6, RCG11, PatForm10, EP9, and MT9.

Table 5.5.10. Temperature Monitoring or Verification by Operation Type

Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at proper temperatures?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Yes	82% (1,129)	26% (261)	65% (381)	85% (240)	82% (777)	80% (376)	80% (678)
No	19% (262)	56% (561)	35% (203)	13% (37)	20% (189)	22% (103)	21% (179)
Don't know	0% (0)	4% (39)	0% (1)	0% (0)	0% (1)	0% (2)	0% (1)
No Response	1% (9)	15% (147)	0% (2)	2% (5)	1% (5)	1% (3)	1% (10)

As indicated in Table 5.5.10, the percentage of establishments that had documented monitoring or verification procedures varied somewhat between operation types. Five of the operation types, Beef Grinding, Regrind Coarse Ground, Patty Forming, Enhanced Product, and Mechanical Tenderization, had documented procedures for more than 80 percent of establishments.

Slaughter establishments had documented procedures for 65 percent of establishments. It is believed that the lack of documented procedures for slaughter establishments may be higher (35 percent) because of the nature of this operation. Slaughter operations do not typically chill the carcasses until the end of the slaughter process. Therefore, much of the process is performed under ambient temperature conditions.

Beef Trim Fabrication had documented procedures for 26 percent of establishments. As with Slaughter, the rate of establishments without documented temperature control procedures may be due to the nature of the process. Beef Trim Fabrication usually involves handling the product for only short periods of time. The product may be taken out of storage, fabricated, and returned to storage in a short enough timeframe to allow for ambient temperatures during the processing. The nonresponse rate for Beef Trim Fabrication was somewhat higher than for the other operation types. It is not known why the nonresponse rate would be higher for this operation type.

The next common question asks about the frequency of cleaning and sanitizing of equipment and processing areas by establishments. This question was derived from Checklist questions BeefGrind14, RCG12, PatForm11, EP10, and MT10.

Table 5.5.11. Cleaning and Sanitizing by Operation Type

How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
After processing from 1 supplier	3% (37)			5% (14)	3% (29)	3% (12)	2% (21)
After processing from a group of suppliers	2% (21)			0% (1)	1% (11)	2% (10)	1% (10)
After a sample is collected for *E. coli* O157:H7	31% (421)			40% (111)	24% (229)	5% (24)	12% (102)
After each shift	13% (177)			15% (43)		10% (49)	12% (100)
Daily after production	94% (1,288)			93% (260)	99% (939)	93% (441)	94% (797)
Less than daily (extended clean-up)	0% (6)			0% (1)	1% (7)	0% (2)	0% (3)
Other	6% (78)			5% (14)	5% (44)	6% (27)	4% (37)
Don't know	0% (0)			0% (0)	0% (0)	0% (1)	0% (0)
No response	0% (6)			2% (5)	1% (5)	0% (2)	1% (8)

As indicated in Table 5.5.11, the most common response was "Daily after production," which is practiced by 93 to 99 percent of establishments. For 3 operations, the next most common response was, "After a sample is collected for *E. coli* O157:H7" (31 percent for Beef Grinding, 40 percent for Regrind Coarse Ground, and 24 percent for Patty Forming). For Mechanical Tenderizing operations, 12 percent of establishments cleaned and sanitized after a sample was collected and 12 percent cleaned and sanitized after each shift. For Enhanced Product, "After each shift" was the second most frequent response (10 percent) while cleaning and sanitizing after a sample was collected was third (5 percent).

The percentage of establishments that cleaned and sanitized after each shift is higher than the number of establishments that produce their respective product during a second shift (see Table 5.5.1). This indicates that responses to "After each shift" may be equivalent to "Daily after production" if the establishment operated a single shift only.

The next common question asks about the number of suppliers used by establishments. This question was derived from Checklist questions BeefGrind8, RCG8, PatForm8, EP7, and MT7.

Table 5.5.12. Number of Suppliers by Operation Type

Approximately how many suppliers has the establishment used in the last 30 days?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Only from its own plant	17% (231)			7% (21)	46% (437)	4% (21)	18% (153)
1, from another plant	13% (177)			33% (92)	9% (87)	21% (101)	10% (87)
2-3	41% (559)			42% (117)	25% (239)	39% (185)	40% (339)
4-6	18% (244)			10% (29)	11% (106)	16% (76)	16% (137)
More than 6	9% (123)			2% (5)	5% (52)	15% (72)	13% (111)
Don't know	2% (27)			3% (9)	2% (18)	2% (11)	2% (14)
No response	1% (14)			3% (8)	1% (13)	1% (6)	1% (9)

As indicated in Table 5.5.12, for 4 of the operation types, the most common number of suppliers was "2-3" (41 percent for Beef Grinding, 42 percent for Regrind Coarse Ground, 39 percent for Enhanced Product, and 40 percent for Mechanical Tenderization). For the Patty Forming operations, 46 percent of establishments used source materials from only their own plant. The Enhanced Product and Mechanical Tenderization operations had the highest rates of establishments that used more than 6 suppliers (15 percent and 13 percent, respectively).

The next common question asks about how establishments group source materials into lots for processing. This question was derived from Checklist questions BeefGrind7, BeefTrimFab2, RCG7, PatForm7, EP6, and MT6.

Table 5.5.13. Grouping of Source Materials by Operation Type

How does the establishment group source materials into lots for processing?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Supplier based	23% (322)	42% (427)		28% (78)	23% (219)	34% (160)	22% (186)
Testing/Intervention based	21% (283)	4% (44)		23% (64)	22% (214)	16% (75)	14% (121)
Time based	15% (209)			13% (37)	15% (146)	17% (80)	16% (135)
Other	45% (617)	16% (160)		38% (106)	45% (430)	35% (165)	45% (385)
Don't know	4% (50)	1% (9)		4% (11)	3% (30)	3% (12)	5% (45)
None		39% (390)					
No response	1% (15)	4% (39)		3% (9)	1% (8)	1% (6)	2% (17)

As indicated in Table 5.5.13, responses to this common question varied by operation type. For three operations, the most common response was "Other" (45 percent for Beef Grinding, 38 percent for Regrind Coarse Ground, and 45 percent for Patty Forming). The second and third most frequently selected response for these three operations, "Supplier based" and "Testing/Intervention based," were similar to each other in frequency.

For two other operation types, Enhanced Product and Mechanical Tenderization, the "Other" response was also the most common response (35 percent and 45 percent, respectively), and "Supplier based" was the second most common (34 percent and 22 percent, respectively). The "Time based" response was the third most frequent response (17 percent and 16 percent, respectively), although only slightly higher than the "Testing/Intervention based" response.

For Beef Trim Fabrication operations, the most common response was "Supplier based" methods (42 percent), followed by "None" (39 percent) and "Other" (16 percent). Checklist question BeefTrimFab2 was the only question that allowed a "None" response. For the remaining four operation types, "Other" was the most common response, followed by "Supplier based."

The next common question asks about the use of imported source materials by establishments. This question was derived from Checklist questions BeefGrind12, RCG10, PatForm9, EP8, and MT8.

Table 5.5.14. Use of Imported Source Materials by Operation Type

Does the establishment knowingly use imported source material (including raw beef, trim or other raw ground beef components, or another product) for producing its product?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	72% (988)			75% (211)	67% (634)	78% (367)	83% (708)
Every production day	13% (184)			6% (18)	18% (167)	4% (21)	3% (29)
Weekly	4% (58)			4% (12)	5% (43)	3% (15)	2% (21)
Monthly	1% (11)			1% (4)	0% (4)	1% (6)	1% (5)
Intermittently	7% (102)			10% (28)	9% (90)	11% (51)	8% (66)
Other	2% (23)			1% (3)	1% (9)	1% (7)	1% (9)
Don’t know	0% (3)			0% (0)	0% (2)	1% (3)	0% (4)
No response	0% (6)			2% (5)	0% (3)	0% (2)	1% (8)

As indicated in Table 5.5.14, 72 percent of Beef Grinding, 75 percent of Regrind Coarse Ground, 67 percent of Patty Forming, 78 percent of Enhanced Product, and 83 percent of Mechanical Tenderization operations did not knowingly use imported source materials. For Beef Grinding and Patty Forming establishments that did use imported source materials, the most common response was “Every production day” (13 percent and 18 percent, respectively), followed by “Intermittently” (7 percent and 9 percent, respectively).

The converse was seen for Regrind Coarse Ground, Enhanced Product, and Mechanical Tenderization operations that did use imported materials. For these 3 operations “Intermittently” was the most common frequency (10 percent, 11 percent, and 8 percent, respectively) followed by “Every production day” (6 percent, 4 percent, and 3 percent, respectively).

The Beef Grinding and Regrind Coarse Ground operations were also asked, as a separate Checklist question, whether they imported raw ground beef for their operations (see Checklist questions BeefGrind11 and RCG9). The responses to these questions are summarized and discussed in the following common question.

The next common question asks about the use of imported raw ground beef by establishments. This question was derived from Checklist questions BeefGrind11 and RCG9. The specific question for BeefGrind11 asked whether the establishment used imported coarse or finely ground beef, while the specific question for RCG9 asked whether the establishment used imported coarse ground beef.

Table 5.5.15. Use of Imported Trim or Other Raw Ground Beef Components by Operation Type

Does the establishment knowingly use imported ground beef for producing its product?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No	97% (1,334)			95% (267)			
Every production day	0% (3)			0% (1)			
Weekly	0% (5)			0% (0)			
Monthly	0% (1)			0% (0)			
Intermittently	1% (13)			2% (7)			
Other	0% (6)			0% (1)			
Don't know	0% (5)			0% (0)			
No response	1% (8)			2% (5)			

As indicated in Table 5.5.15, 97 percent of Beef Grinding and 95 percent of Regrind Coarse Ground operations did not knowingly import ground beef to produce ground beef products. For the establishments that did use imported ground beef, the most common response was "Intermittently" (1 percent and 2 percent, respectively).

The next common question asks about the use of carryover or rework by establishments. This question was derived from Checklist questions BeefGrind16, RCG14, and PatForm13.

As indicated in Table 5.5.16, 81 to 82 percent of establishments from each operation type did not use carryover or rework. Fifteen to 16 percent did use carryover or rework.

The next common question asks about the creation of bench trim from primal/sub-primal cuts by establishments. This question was derived from Checklist questions EP12 and MT12.

Table 5.5.16. Use of Carryover or Rework by Operation Type

Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Yes	16% (219)			15% (42)	16% (154)		
No	82% (1,127)			82% (230)	81% (774)		
Don't know	1% (11)			1% (2)	2% (15)		
No response	1% (18)			2% (7)	1% (9)		

Table 5.5.17. Creation of Bench Trim from Primal/Sub-primal Cuts by Operation Type

Does the establishment create bench trim from primal/sub-primal cuts that could be used as a raw ground beef component that is not specifically accounted for in a robust testing program?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Yes						17% (79)	32% (269)
No						83% (390)	66% (559)
Don't know						0% (1)	1% (11)
No response						0% (2)	1% (11)

As indicated in Table 5.5.17, 83 percent of establishments with Enhanced Product operations did not create bench trim and 17 percent did. For Mechanical Tenderization operations, 66 percent did not and 32 percent did create bench trim that could be used as a raw ground beef component.

The next common question asks whether establishments test all bench trim for *E. coli* O157:H7. This question was derived from Checklist questions EP13 and MT13.

Table 5.5.18. Testing of Bench Trim from Primal/Sub-primal Cuts by Operation Type

Does the establishment or its designee test all bench trim from the primal/sub-primal cuts for *E. coli* O157:H7?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
No, the establishment tests no bench trim						39% (185)	59% (498)
The establishment tests all production lots of bench trim using a robust testing method						2% (9)	2% (19)
The establishment tests bench trim using a different frequency and/or method, please specify:						9% (44)	8% (71)
Divert bench trim to cooking or other non-raw beef product use						15% (70)	11% (97)
Don't know						0% (2)	0% (0)
Not applicable						33% (157)	18% (149)
No response						1% (5)	2% (16)

As indicated in Table 5.5.18, 39 percent of Enhanced Product operations did not test bench trim. Fifteen percent diverted bench trim to cooking and therefore likely did not test. Two percent of Enhanced Product operations tested all lots of bench trim using a robust testing method, and 9 percent tested at a different frequency or used a different method. Thirty-three percent of responses indicated "Not applicable." It is likely that these establishments were not producing bench trim.

For Mechanical Tenderization operations, 59 percent did not test bench trim, and 11 percent diverted bench trim to cooked or other non-raw beef product. Two percent tested all lots of bench trim using a robust testing method, and 8 percent tested at a different frequency or used a different method. Eighteen percent of responses for these Mechanical Tenderization establishments indicated "Not applicable."

The next common question asks whether establishments provide labeling on the product to inform purchasers that the product is non-intact. This question was derived from Checklist questions EP14 and MT14. Due to variations in Checklist question design, the responses were reclassified into more general categories.

Table 5.5.19. Product Labeling by Operation Type

Does the establishment provide labeling on the product to inform purchasers that the product is non-intact?							
Response	Beef Grinding	Beef Trim Fabrication	Slaughter	Regrind Coarse Ground	Patty Forming	Enhanced Product	Mechanical Tenderization
Yes						70% (329)	23% (199)
No						27% (126)	74% (632)
Don't know						2% (11)	1% (8)
No response						1% (6)	1% (11)

As indicated in Table 5.5.19, 70 percent of Enhanced Product operations did provide labeling and 27 percent did not. In contrast, 23 percent of Mechanical Tenderization operations provided labeling, while 74 percent did not. Overall, the numbers reflect the differences in labeling requirements for the two operations. FSIS has policy statements regarding the labeling of enhanced products, while no such policy statements are currently issued for mechanically tenderized products.[7,8] The 27 percent of Enhanced Product responders who indicated "No" may have done so because of a literal interpretation of the "non-intact" reference in the questions. For enhanced products, the meat may be considered intact or non-intact, depending on the method used. Mechanically tenderized and enhanced products are considered non-intact if they have been injected or pierced, therefore potentially transferring contaminants such as *E. coli* O157:H7 to the center of the product. Enhanced and mechanically tenderized products can appear intact when in fact they are not.

Summary

Selected findings about the comparison of responses across operation types for related Checklist questions are summarized below:

- For many questions, the responses across operation types are consistent, indicating similar practices across multiple raw beef operation categories (see Tables 5.5.1, 5.5.4, 5.5.5, 5.5.6, 5.5.7, 5.5.11, 5.5.14, 5.5.15, and 5.5.16).
- Beef Grinding establishments are more likely to have purchase specifications or documentation other than purchase specifications than other operation types (see Tables 5.5.2 and 5.5.3).
- More than 60 percent of establishments did not test source materials and more than 50 percent did not test finished product for *E. coli* O157:H7 (see Tables 5.5.6 and 5.5.7).
- Beef Trim Fabrication and Slaughter operations had a higher rate of operations without documented temperature monitoring procedures. This may be related to the nature of their operations (see Table 5.5.10).
- Beef Grinding and Patty Forming operations were the most likely to use imported source materials every production day (see Table 5.5.14).

[7] FSIS Food Standards and Labeling Policy Book, August 2005.
[8] FSIS Policy Memo 066C.

- Enhanced Product establishments were likely to provide labeling informing purchasers that the product was enhanced, while Mechanical Tenderization operations were unlikely to do so (see Table 5.5.19).

6. SUMMARY

In summary, Notice 65-07 implemented a reassessment and Checklist that provided a broad characterization of the current practices at raw beef establishments. FSIS inspectors completed 5 questions as part of the reassessment and, depending on the types of raw beef operations, as many as 119 questions on the Checklist. This characterization covered areas ranging from response to a HACCP reassessment, adherence to FSIS "best practices," supplier requirements, intervention programs, testing programs, handling of source materials, handling of finished products, training, cleaning and sanitizing, temperature controls, lot definition, and product labeling.

Several types of raw beef operations were characterized by the Reassessment and Checklist. The reassessment (Attachment 3 of Notice 65-07) provided data on 2,002 establishments, representing an estimated 90 percent of qualifying establishments. The two waves of the Checklist (Attachment 5 of Notice 65-07) resulted in data from 2,323 establishments, representing an estimated 99 percent of qualifying establishments. These establishments spanned all three categories of HACCP sizes,[9] with approximately 3 percent being Large establishments, approximately 38 percent being Small establishments, and approximately 58 percent being Very Small establishments. This distribution of sizes closely reflects the distribution of federally inspected raw beef establishment sizes.

Results from the reassessment indicated that nearly all establishments (96 percent) reassessed their HACCP plan in response to Section III of Notice 65-07. Based on this Reassessment, about 52 percent identified changes needed in to their HACCP plans, SSOPs, or other prerequisite programs. Prerequisite programs and HACCP plans were the two programs with the most frequent changes.

The most common prerequisite program changes were to sampling and testing programs. These changes included implementing new programs, increasing the testing frequency, and/or increasing the robustness of the programs.

A wide variety of changes were made to HACCP plans. Based on an analysis of the described changes, more than 30 categories of changes to HACCP plans were identified. The most common changes included educating or training employees, separating beef plans from other plans, and adding meat components to the HACCP plan; each represented about 8 percent of the responses. Two categories of testing frequency combined, increased testing of table or bench beef trim and increased frequency of random sampling and testing for Escherichia coli (*E. coli*) O157:H7 of other beef products, represented about 12 percent of the responses.

Responses indicated that the least common changes were changes to SSOPs. Responses also indicated that establishments that did not change SSOPs determined that their employees were adequately trained and that all the requirements were currently met by the existing program. About 15 percent of establishments did make changes to their SSOPs, the majority (64 percent) of which were to procedures for sanitizing hands, feet, and equipment.

Results from Product Production Volume Question #No. 2 of the Checklist identified several high volume products. According to the number of establishments, more establishments (1,094) are producing "Grinding boneless manufacturing trimmings or other raw ground beef components" than any other product, followed by 949 establishments producing "Fabrication of primal/sub-primal cuts," 799 establishments producing "Formed patties," and 755 establishments producing "Trim fabrication production." According to the volume of product, more "Fabrication of primal/sub-primal cuts" is

[9] "Pathogen Reduction; Hazard Analysis and Critical Control Point (HACCP) System, Final Rule" *Federal Register* 61:144 (July 25, 1996 p. 38806)

produced (772.3 million pounds per month) than any other product, followed by "Trim fabrication production" (581.3 million pounds per month), "Grinding boneless manufacturing trimmings or other raw ground beef components" (292.5 million pounds per month), and "Formed patties" (204.8 million pounds per month).

FSIS defined "best practices" in the Checklist for "03B – Raw product, ground," "03C – Raw product, not ground", and "03J – Slaughter." The 03J, or Slaughter, establishments were very likely (93 percent) to identify *E. coli* O157:H7 as a hazard likely to occur. Despite this high identification rate, only 54 percent of 03J establishments tested beef carcasses for *E. coli* O157:H7.

The 03B and 03C establishments were notably less likely to identify *E. coli* O157:H7 as a hazard likely to occur (12 percent and 13 percent, respectively). Furthermore, 41 percent of 03B establishments and 61 percent of 03C establishments tested neither source materials nor finished product.

Testing by establishments or their designees is used to identify contaminated product and prevent it from entering commerce. Testing alone cannot ensure that each pound of raw beef product produced is free of *E. coli* O157:H7. Other practices include the use of interventions, cleaning and sanitizing of equipment, temperature controls, and other practices. All of these practices contribute to a process that minimizes the risk of contamination. These practices may be implemented in different ways depending on the type of raw beef operation conducted. A significant portion of the Checklist addressed these practices for each of seven raw beef operation types: "Grinding Trim and other Raw Ground Beef Components," "Trim and other Raw Ground Beef Component Fabrication," "Slaughter," "Regrind Coarse Ground," "Patty Forming," "Enhanced Product (marinated or injected)," and "Mechanical Tenderization." Of the 2,323 establishments represented by the Checklist data, these operation types were conducted by between 12 percent and 59 percent of establishments. The least frequent operation type was "Regrind Coarse Ground" (12 percent). The most frequent operation types were "Grinding Trim and other Raw Ground Beef Components" (59 percent) and "Trim and other Raw Ground Beef Component Fabrication" (43 percent).

Most establishments rely on suppliers to obtain source materials for their operations. About 80 percent to 90 percent of Beef Grinding, Regrind Coarse Ground, Enhanced Product, and Mechanical Tenderization operations have used one or more third party suppliers in the past 30 days. For Patty Forming operations, about 50 percent of establishments rely on third party suppliers.

A typical practice is for establishments to have purchase specifications or other documentation requiring suppliers to conduct interventions or testing. For Beef Grinding establishments, 76 percent had purchase specifications requiring suppliers to conduct a CCP on source materials. Intervention during slaughter were the most common requirement (54 percent of Beef Grinding establishments), but testing and other requirements were required by 16 percent to 23 percent of establishments. Other raw beef operations were less likely to have purchase specifications for suppliers. Regrind Coarse Ground, Patty Forming, Enhanced Product, and Mechanical Tenderization operations had purchase specifications 43 percent to 59 percent of the time. Generally, interventions tended to be the most common specification. Other types of supplier documentation often cited in responses about purchase specification were letters of guarantee, which appears to be a frequent requirement of operations, and certificates of analysis (COA). No specific question addressed the subjects of letters of guarantee or COAs. This qualitative finding was based on a combination of specified "Other" responses to supplier related questions from Attachment 5. Documentation other than purchase specifications were less common, but still employed by 35 percent to 55 percent of Beef Grinding, Regrind Coarse Ground, and Patty Forming operations.

How establishments group source materials into lots can be a factor in limiting the scope of affected product resulting from an *E. coli* O157:H7 contamination. Grouping materials into lots based on the supplier provides more specific traceability. Other practices for grouping source materials into lots

include grouping by day of production and grouping materials that have been tested for *E. coli* O157:H7 or had interventions applied. Beef Trim Fabrication operations had the highest rate of supplier-based grouping practices (42 percent). The other operations, Beef Grinding, Regrind Coarse Ground, Enhanced Product, and Mechanical Tenderization, were most likely to use a grouping method other than the ones described above. Commonly cited other methods included "first in, first out," where the oldest source materials are used first; random grouping, and grouping according to daily production of finished product (as opposed to daily receipt of source materials).

In addition to practices by suppliers, the Checklist also collected data about practices concerning testing and interventions at the establishments. Testing for the presence of *E. coli* O157:H7 and interventions to minimize or eliminate *E. coli* O157:H7 can typically be applied to either the source materials or the finished product.

Interventions are applied to reduce or eliminate the presence of *E. coli* O157:H7 in raw beef products. Checklist response data indicate that interventions were infrequently used by establishments. Depending on the operation type, only about 6 percent to 15 percent of establishments applied interventions to their source materials. For those that did, the most common intervention specified was the use of temperature controls. "Temperature controls," as a response to questions about interventions, is generally considered an invalid response and may represent a misunderstanding of intervention procedures. Interventions are practices that prevent, reduce, or eliminate the presence of *E. coli* O157:H7 on the source material or product. Temperature controls can be used to slow or stop the growth of *E. coli* O157:H7, but temperature alone cannot reduce or eliminate *E. coli* O157:H7 contamination. Therefore, the rates for establishments that did not apply any interventions to source materials (85 percent to 94 percent) may be an underestimation of the true rates. The use of interventions on finished product was only asked of Beef Grinding and Regrind Coarse Ground operations. Here again, the use of interventions is about 5 percent or less.

Testing by establishments or their designees is used to identify contaminated product and prevent it from entering commerce. Checklist response data indicates that testing is more frequently employed by processing establishments than interventions, but is still a minority practice. The highest rate of testing, about 40 percent, was seen in the Beef Trim Fabrication operations. The lowest rate, about 17 percent, was seen in the Mechanical Tenderization operations. Depending on the operation type, only 3 percent to 8 percent of establishments performed testing according to criteria specified in the Checklist question. Those criteria generally included testing quarterly, using robust methodology, testing more frequently during high prevalence season months, and testing more frequently for the more frequent suppliers. Of the establishments that performed testing, but did not test at the same frequency or with the same methodology as specified in the question, the differences tended to be related to the frequency of testing. The most common frequency of testing tended to be monthly or quarterly, but relatively few establishments in this category changed their testing rates during the high prevalence season months or for more frequent suppliers. It should be noted that some establishments test as often as hourly or daily, whereas others test as infrequently as annually. The actual frequency of testing was not directly asked in the Checklist. These findings were based on a qualitative assessment of specified responses about other testing frequencies.

Testing of finished product was done at rates similar to those for source materials for Patty Forming, Enhanced Product, and Mechanical Tenderization operations. Generally, about 17 percent to 33 percent of establishments from these operation classes tested their finished product. Beef Grinding and Regrind Coarse Ground tested their finished product somewhat more frequently than their source materials. About 50 percent of Beef Grinding establishments and about 45 percent of Regrind Coarse Ground establishments tested finished product. As with testing of source materials, the frequency of testing tended to be monthly to quarterly typically did not change according to the season or for different

suppliers. Again, based upon a qualitative assessment of written responses to Checklist questions, testing frequency varied from daily to annually.

In addition to testing for *E. coli* O157:H7, the Checklist also asked about testing for indicator organisms. About 20 percent to 36 percent of establishments test for indicator organisms. Testing of equipment and/or the processing area was about as frequent as testing source materials and/or product for the Beef Grinding, Regrind Coarse Ground, and Patty Forming operations. For Slaughter operations, testing of the product was more common. For Enhanced Product and Mechanical Tenderization operations, testing of processing areas was more common.

Other practices, such as cleaning and sanitizing and temperature controls, can control the growth or spread of *E. coli* O157:H7 in an establishment. For Beef Grinding, Regrind Coarse Ground, Patty Forming, Enhanced Product, and Mechanical Tenderization operations, about 80 percent to 85 percent of establishments had documented temperature monitoring procedures. The rates were lower for Slaughter operations, where about 65 percent of establishments had documented procedures for temperature monitoring. As discussed in Chapter 5, much of the slaughter process is performed at ambient temperature, which might account for the decreased rate. Beef Trim Fabrication operations had the lowest rate of documented monitoring procedures (26 percent). One possible explanation for this lower rate may be that Trim Fabrication operations tend to quickly process their materials and return them to storage. The time that product is out of storage may be short enough that temperature monitoring is less important.

Complete cleaning and sanitizing of equipment and processing areas is commonly performed by establishments. The most common frequency for cleaning and sanitizing is daily after production. Depending on the operation type, between 93 percent and 99 percent of establishments clean and sanitize daily after production. Between 10 percent and 15 percent of establishments also indicated that they clean and sanitize after each shift. Some of these establishments indicated that they only produce their raw beef product during one shift. Twenty-four to 40 percent of Beef Grinding, Regrind Coarse Ground and Patty Forming operations also indicated that they clean and sanitize equipment after a sample is taken for *E. coli* O157:H7 testing.

The Checklist also collected data about the types of source materials used, such as specific components like bench trim, imported source materials, and carryover or rework. Some establishments knowingly import source materials from other countries in order to produce their product. The percentages of establishments that knowingly imported source materials ranged from 16 percent for Mechanical Tenderization operations to 33 percent for Patty Forming operations. Beef Grinding and Patty Forming operations tended to use imported source materials every production day while Regrind Coarse Ground, Enhanced Product, and Mechanical Tenderization operations tended to use imported source materials only intermittently. Beef Grinding and Regrind Coarse Ground operations were also asked whether they specifically imported coarse or finely ground beef for their operations. Relatively few establishments, 3 percent to 5 percent, imported this kind of source material. The use of carryover or rework by Beef Grinding, Regrind Coarse Ground, or Patty Forming operations was employed by 15 percent to 16 percent of establishments. Seventeen percent of Enhanced Product and 32 percent of Mechanical Tenderization establishments created bench trim that could be used as a raw ground beef component and not specifically tested for in a robust testing program.

Product labeling can be an important tool for consumers to understand the product they are purchasing, both in terms of its ingredients and proper cooking. The Checklist collected data about the labeling practices of Enhanced Product and Mechanical Tenderization operations. Seventy percent of Enhanced Product establishments provide labeling to inform purchasers that the product is non-intact. The rate is much lower for Mechanical Tenderization operations (23 percent). The rate for Enhanced Product

operations is lower than expected. It is FSIS policy[10,11] that enhanced product operations provide labeling to indicate the addition of a solution. It is not known why the "Yes" response rate is only 70 percent for Enhanced Product establishments. One possibility is that Checklist responders interpreted "non-intact" literally and responded "No" if the enhanced product was intact. The same labeling policy does not currently exist for Mechanical Tenderization operations.

[10] FSIS Food Standards and Labeling Policy Book, August 2005.
[11] FSIS Policy Memo 066C.

7. NEXT STEPS

The results from the Notice 65-07 Reassessment and Checklist provide insight into the practices of several types of raw beef operations. This report provides a summary of response rates for each of the questions and a discussion of the findings. Several areas have been identified where Checklist response data can be integrated with other Agency data to help provide a better understanding of *E. coli* O157:H7 occurrence in raw beef products.

According to the Attachment #3 Reassessment responses, 52 percent of establishments made changes to one or more HACCP plans, SSOPs, or other prerequisite programs in response to events in 2007 that included an increase in the FSIS percent positive rate in raw ground beef. The Agency believes that these changes should result in an increase in effective control for *E. coli* O157:H7 and a decrease in the FSIS percent positive rate.

FSIS will continue to use the Attachment #5 Checklist data, in combination with 2008 *E. coli* O157:H7 sampling test results, to evaluate any changes to the percent positive rate and how they might relate to practices characterized by the Checklist. It is the Agency's intention to re-issue the Checklist on a recurring basis in the future, starting in late Fall 2008.

The Checklist responses indicated lack of consistency in the design of sampling programs designed to verify the on-going effectiveness of food safety systems. Consequently, FSIS has prepared a sampling compliance guideline focused on beef manufacturing trimmings. This guidance is intended to provide establishments with insight into the limitations of N60 testing. In addition, this guidance will provide guidance on how to discern when the number of positive results for *E. coli* O157:H7 is indicative of a system that is inadequately controlled.

The results of the Checklist indicate that bench trim is likely a significant source material used by a majority of grinding establishments. Importantly, bench trim is not currently included as a tested material for *E. coli* O157:H7 in an existing FSIS sampling program. Although ground beef sampled by FSIS contains bench trim, it is the intention of FSIS to initiate a new sampling program for bench trim prior to grinding.

The Agency is evaluating how the Checklist responses relate to the occurrence of *E. coli* O157:H7 positives and recalls. FSIS is analyzing these data in concert with other Agency information to assess practices at establishments with *E. coli* O157:H7 positives and recalls. FSIS will focus on the food safety assessments (FSAs) performed in these establishments following the positives and recalls, and on the controls in place in those establishments prior to and after the FSA. This information will help inform the Agency about more or less common practices at these establishments.

Although not a food safety issue, the Agency will issue a policy instruction to FSIS inspection program personnel to ensure that enhanced beef products are properly labeled. According to the Checklist responses, 27 percent of responses indicated that such product was not properly labeled.

The Agency is interested in how the Checklist responses differ by establishment HACCP size. FSIS is evaluating responses to selected Checklist questions according to HACCP size and production volume size to better understand which practices are more common among larger or smaller establishments.

In conclusion, the Checklist data provided a level of detail about federally inspected establishments not previously available to FSIS or the public. FSIS, specifically OPPD, will continue to review the findings of the Checklist and develop additional risk mitigation actions beyond those identified in this report. These results will help inform raw beef product manufacturers, consumers, and FSIS about common practices of several types of raw beef establishments. These results will also help inform the Agency's policy development to reduce the incidence of *E. coli* O157:H7 and reach it's goal of improved public health.

8. REFERENCES

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APPENDIX A: NOTICE 65-07

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,

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 the 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.

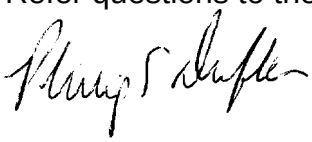
9. After completing the *E. coli* O157:H7 Checklist, inspection program personnel are to maintain a copy of it in the official government file and provide a copy to the establishment management.

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.

Attachment 3

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?

Attachment 5

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

A-ESTABLISHMENT INFORMATION

EstabInformation. 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 "*specially 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

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 form 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

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

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

PatFomr8. 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

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

APPENDIX B: ATTACHMENT 5 CHECKLIST FINAL DRAFT

United States Department of Agriculture
Food Safety and Inspection Service

OFFICE OF POLICY, PROGRAM AND EMPLOYEE DEVELOPMENT

FSIS is collecting information on the control measures that establishments use during production of raw beef products to prevent, reduce, or eliminate *E. coli* O157:H7 in the final product. The Agency will use the information for determining targeted approaches for the risk-based verification testing program of *E. coli* O157:H7 in raw beef final products, and for prioritizing the scheduling of food safety assessments.

Please complete this survey for each establishment at which you are the IIC and that 1) grinds trim or other raw ground beef components; 2) fabricates trim or other raw ground beef components; 3) slaughters cattle; 4) regrinds coarse ground beef; 5) forms beef patties; 6) "Enhances" (marinates or injects) raw beef products; 7) mechanically tenderizes raw beef products; or 8) conducts some combination of these operations.

S. **ESTABLISHMENT INFORMATION**

Q. EstabInformation
Please provide us with the following information before you continue. Please enter the date and establishment number in the following formats (dd/mm/yyyy) and (00000 M).

Today's Date _____

Your Name _____

Q. EstabInformation2
Are you the IIC at establishment _____?

- ❍ Yes
- ❍ No

Q. EstabInformation3
Has this establishment engaged in the production of raw beef products (cattle slaughter or production of 03C or 03B beef) in the last 6 months?

- ❍ Yes
- ❍ No

Q. MGMTOFF1
Has a management official at the establishment reviewed the Checklist responses?

- ❍ Yes
- ❍ No

Q. MGMTOFF2
Has the Frontline Supervisor reviewed the Checklist responses?

- ❍ Yes
- ❍ No

S. **A-RAW BEEF FOOD SAFETY SYSTEM —** The purpose of this section of the Checklist is to determine which establishments that produce raw beef products are engaging in *best practices* to prevent the adulteration of non-intact raw beef products by *E. coli* O157:H7. The best practices are interrelated and cumulative, i.e. best practices at grinding or at the production of some other non-intact finished products are directly tied to the steps taken at slaughter, as well as during further processing. The information you collect about which practices the establishment uses to eliminate, prevent, or reduce *E. coli* O157:H7 to a non-detectable level will be used by FSIS to schedule testing and other verification activities. As you answer the questions in this section of the Checklist, you will need to refer to the definitions of best practices, as well as the definition of "robust testing."

Best Practices for Slaughter (03J) -- The implementation of a validated decontamination intervention, controlled through a CCP, to eliminate, prevent, or reduce *E. coli* O157:H7 to a non-detectable level.

Best Practices for Raw Not Ground (03C) -- The use of source materials from an 03J process that implemented best practices, along with: 1) the ongoing verification testing of source materials from all suppliers, at least quarterly, and using robust testing methods; and 2) the on-going verification testing of all finished product that is or will be used as non-intact raw beef, using robust testing methodology.

Best Practices for Raw Product-Ground (03B) -- The use of source materials from 03J and 03C processes that implemented best practices, along with: 1) the ongoing verification testing of source materials from all suppliers, at least quarterly, and using robust testing methods and with proportionally more frequent testing in high prevalence season months; and 2) the on-going verification testing of all finished product, at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months. If the 03B process uses source materials from another 03B process (e.g. if an establishment regrinds coarse ground beef), all 03B processes involved would need to apply best practices.

Robust Testing means that the following features are part of the establishment's 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 up to 5 combo bins/boxes/other units -- 12 very thin slices of exterior surface materials from each combo bin//box/other unit): each slice should be approximately 1/8" thick, 4.0 inches in length, and 2.0 inches wide. The composite sample should weigh at least 2 pounds and consist of at least 60 slices places together in an aseptic package); a 375 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method. (For additional information on N-60 training, see FSIS Notice 18-07 and its associated training).

- 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 combo bin/box/other unit); at least a 325 gram sample is enriched and analyzed using a method at least as sensitive and specific as the FSIS method.

- In slaughter operations (pre-chill), an establishment might swab carcasses as the method of sampling. Robust testing in this case would mean that entire sides, whereby 4000 cm^2 per side, are swabbed and analyzed using a method at least as sensitive and specific as the FSIS method (see T. M Authur *et al*. 2004. *E. coli* O157 Prevalence and Enumeration of Aerobic Bacteria, *Enterobacteriaceae*, and *Escherichia coli* O157 at Various Steps in Commercial Beef Processing Plants. JFP 67(4): 658-665).

Q. FBFSS1
For which raw beef HACCP processing categories does the establishment have a hazard analysis? (check all that apply).

- ❑ 03J Slaughter
- ❑ 03C Raw product - not ground
- ❑ 03B Raw product - ground

Q. FBFSS2
Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably **likely** or **not likely** to occur in the 03J slaughter HACCP processing category?

- ❍ **Likely** to occur with a CCP to prevent, eliminate, or reduce to *E. coli* O157:H7 a non-detectable level(best practice)
- ❍ **Not likely** to occur
- ❍ Don't Know

Q. FBFSS3
Does the establishment test beef carcasses for *E. coli* O157:H7?

- ❍ No
- ❍ Yes, the establishment conducts robust testing of at least one in 300 carcasses
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. FBFSS4
Does the establishment have a third -party audit its controls for its 03J controls?

- ❍ No
- ❍ Yes, for every supplier and itself at least once annually
- ❍ Yes, but at another frequency, please specify: _____
- ❍ Don't Know

Q. FBFSS5
Does the establishment specifically identify *E. coli O*157:H7 as a hazard reasonably **likely** or **not likely** to occur in the 03C Raw--Not Ground HACCP processing category?

- ❍ **Likely** to occur with a CCP to prevent, eliminate, or reduce *E. coli* to a non-detectable level, along with controls that require incoming raw beef source materials to have been processed under 03J slaughter best practices and, if applicable, 03C raw--not ground best practices
- ❍ **Likely** to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a non-detectable level, but with controls other than best practices, please specify:_____
- ❍ **Not likely** to occur because the establishment has a purchase specification, as part of its written Sanitation SOP or other prerequisite program, that requires incoming raw beef source materials to have been processed under 03J slaughter best practices and, if applicable, 03C raw--not ground best practices
- ❍ **Not likely** to occur for other reasons, please specify:_____
- ❍ Don't Know

Q. FBFSS6
Does the establishment or its designee test source materials used in the 03C Raw--Not Ground HACCP process?

- ❍ No, the establishment tests no source materials
- ❍ The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods
- ❍ The establishment tests source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. FBFSS7
Does the establishment or its designee test finished 03C product that is or will be used to make non-intact product?

- ❍ No, the establishment tests no finished product
- ❍ The establishment tests *all* production lots of such finished product using a robust testing method
- ❍ The establishment test such finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. FBFSS8
Does the establishment have a third-party audit its controls for its 03C product and the controls of all its raw beef suppliers?

- ❍ No
- ❍ Yes, for every supplier and itself at least once annually
- ❍ Yes, but at another frequency, please specify: _____
- ❍ Don't Know

Q. FBFSS9
Does the establishment specifically identify *E. coli* O157:H7 as a hazard reasonably **likely** or **not likely** to occur in the 03B Raw Product--ground HACCP processing category?

- ❍ **Likely** to occur with a CCP to prevent, eliminate, or reduce *E. coli* O157:H7 to a non-detectable level, along with controls that require raw beef source materials to have been processed under 03J slaughter best practices, 03C beef best practices and, if applicable, 03B beef best practices
- ❍ **Likely** to occur with a CCP to prevent, eliminate, or reduce E. coli O157:H7 to a non-detectable level, but with controls other than best practices, please specify:_____
- ❍ **Not likely** to occur because the establishment has a written purchase specification, as part of its written Sanitation SOP or other prerequisite program, that require raw beef source materials to have been processed under 03J slaughter best practices, 03C beef best practices and, if applicable, 03B beef best practices
- ❍ **Not likely** to occur for other reasons, please specify:_____
- ❍ Don't Know

Q. FBFSS10
Does the establishment or its designee specifically conduct on-going verification testing of source materials received from each supplier at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?

- ❍ No, the establishment does not test source materials
- ❍ Yes, for every supplier, including in-house generated source materials, without exception
- ❍ The establishment tests source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. FBFSS11
Does the establishment or its designee specifically conduct on-going verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?

- ❍ No, the establishment does not test finished product
- ❍ Yes
- ❍ The establishment tests finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. FBFSS12
Does the establishment have a third-party audit its controls for its 03B products and the controls of all its raw beef suppliers?

- ❍ No
- ❍ Yes, for every supplier and itself at least once annually
- ❍ Yes, but at another frequency, please specify:_____
- ❍ Don't Know

S. **B-PRODUCT PRODUCTION AND VOLUME**

Q. PPV1
What is the volume of production of each type of product produced? (Note: Obtain the poundage for the ***3 most recent*** production lots of each type of product produced and record the three figures separately (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 on file with the Checklist in the government office). **Please enter poundage in Numeric form, not written form, and round up to the nearest 10 pounds.**

	Lot 1	Lot 2	Lot 3
	lbs.	lbs.	lbs.
Head meat			
Cheek meat			
Weasand meat			
Heart meat			
Advanced meat recovery (AMR) product			

	Lot 1	Lot 2	Lot 3
	lbs.	lbs.	lbs.
Low temperature rendered lean finely textured beef			
Partially defatted beef fatty tissue			
Partially defatted chopped beef			
Fabrication of primal/sub-primal cuts			
Trim Fabrication production			
Mechanical blade tenderizing			
Mechanical needle tenderizing			
Mechanical tenderizing by pounding			
Fabricated steak			
Enhanced product (tumbled, massaged, or injected with solutions (e.g. marinade))			
Regrind coarse ground product			
Grinding boneless manufacturing trimmings or other raw ground beef components			
Formed patties			

Q. PPV2 What is the ***estimated*** volume of production of each type of product produced in a ***day*** for the shift you are working today? What is the **estimated** number of days in a month that the establishment produces this amount? (note: Make note of how the estimates were derived, identifying the assumptions you made in coming up with this figure in question PPV3 below. Also keep a copy of the calculation on file with this Checklist in the government office). **Please enter poundage in Numeric form, not written form, and round up to the nearest 10 pounds.**

	Shifts		Daily Volume Produced	Days Per Month this Amount of Product Produced
	1	2	DVP	Days
Head meat	☐	☐		
Cheek meat	☐	☐		
Weasand meat	☐	☐		
Heart meat	☐	☐		
Advanced meat recovery (AMR) product	☐	☐		
Low temperature rendered lean finely	☐	☐		

	Shifts		Daily Volume Produced	Days Per Month this Amount of Product Produced
	1	2	DVP	Days
textured beef				
Partially defatted beef fatty tissue	☐	☐		
Partially defatted chopped beef	☐	☐		
Fabrication of primal/sub-primal cuts	☐	☐		
Trim Fabrication production	☐	☐		
Mechanical blade tenderizing	☐	☐		
Mechanical needle tenderizing	☐	☐		
Mechanical tenderizing by pounding	☐	☐		
Fabricated steak	☐	☐		
Enhanced product (tumbled, massaged, or injected with solutions (e.g. marinade))	☐	☐		
Regrind coarse ground product	☐	☐		
Grinding boneless manufacturing trimmings or other raw ground beef components	☐	☐		
Formed patties	☐	☐		

Q. PPV3

Explain how you calculated the estimates above, in response to question PPV2, for each type of product.

_____

_____

_____

Q. PPV4
How many shipments did the establishment ship on the day of observation? And, how representative is this number of shipments?

Product	Number of Shipments	How representative is this number of shipments?		
	# of shipments	The typical number of shipments each day during 6 months out of the year	The typical number of shipments each day during more than 6 months out of the year	The typical number shipments each day during fewer than 6 months out of a year
Head meat		☐	☐	☐
Cheek meat		☐	☐	☐
Weasand meat		☐	☐	☐
Heart meat		☐	☐	☐
Advanced meat recovery (AMR) product		☐	☐	☐
Low temperature rendered lean finely textured beef		☐	☐	☐
Partially defatted beef fatty tissue		☐	☐	☐
Partially defatted chopped beef		☐	☐	☐
Fabrication of primal/sub-primal cuts		☐	☐	☐
Trim Fabrication production		☐	☐	☐
Mechanical blade tenderizing		☐	☐	☐
Mechanical needle tenderizing		☐	☐	☐
Mechanical tenderizing by pounding		☐	☐	☐
Fabricated steak		☐	☐	☐
Enhanced product (tumbled, massaged, or injected with solutions (e.g. marinade))		☐	☐	☐
Regrind coarse ground product		☐	☐	☐

Product	Number of Shipments	How representative is this number of shipments?		
	# of shipments	The typical number of shipments each day during 6 months out of the year	The typical number of shipments each day during more than 6 months out of the year	The typical number shipments each day during fewer than 6 months out of a year
Grinding boneless manufacturing trimmings or other raw ground beef components		☐	☐	☐
Formed patties		☐	☐	☐

Q. PPV5
Explain or comment on your answers about shipments in questions PPV4.

_____
_____
_____

S. **C-ESTABLISHMENT CATEGORY**

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

- ❑ Grinding Trim and other Raw Ground Beef Components
- ❑ Trim and other Raw Ground Beef Component Fabrication
- ❑ Slaughter
- ❑ Regrind Coarse Ground
- ❑ Patty Forming
- ❑ Enhanced Product (marinated or injected)
- ❑ Mechanical Tenderization

S. **D-BEEF GRINDING**

Q. BGShift
Please select each shift(s) of operation this establishment grinds beef?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. BeefGrind1
Does the establishment have purchase specifications requiring that suppliers conduct any of the following? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)

- ❑ No
- ❑ Validated intervention methods during slaughter
- ❑ Validated intervention methods during fabrication
- ❑ Testing of carcasses for *E. coli* O157:H7

- ❑ Testing of trim for *E. coli* O157:H7
- ❑ Testing of other raw ground beef components for *E. coli* O157:H7
- ❑ Other, please specify _____
- ❑ Don't Know

Q. BeefGrind2
Does the establishment have documentation other than purchase specifications showing that suppliers apply any of the following?(check all that apply)

- ❑ No
- ❑ Validated intervention methods during slaughter
- ❑ Validated intervention methods during fabrication
- ❑ Testing of carcasses for *E. coli* O157:H7
- ❑ Testing of trim for *E. coli* O157:H7
- ❑ Testing of other raw ground beef components for *E. coli* O157:H7
- ❑ Other, please specify _____
- ❑ Don't Know

Q. BeefGrind3
Does the establishment apply any validated intervention on trim or other ground beef components? (check all that apply)

- ❑ No Intervention
- ❑ Organic acid
- ❑ Acidified sodium chlorite
- ❑ Acidified calcium sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Other, please specify _____
- ❑ Don't Know

Q. BeefGrind3a
Does the establishment apply 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, please specify _____
- ❑ Don't Know

Q. BeefGrind4
Does the establishment or its designee specifically conduct on-going verification testing of source materials (e.g. trim, head meat, weasand meat) at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?

- ❍ No, the establishment does not test source materials
- ❍ Yes, for every supplier, including in-house generated source materials, without exception
- ❍ The establishment test source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. BeefGrind5
Does the establishment or its designee specifically conduct on-going verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?

- ❍ No, the establishment does not test finished product
- ❍ Yes
- ❍ The establishment tests finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. BeefGrind6
What laboratory method does the establishment or its designee use to test ground beef or finished product for *E. coli* O157:H7?

- ❍ FSIS Method
- ❍ Other, please specify _____
- ❍ Don't Know

Q. BeefGrind7
How does the establishment group source materials into lots for grinding? (check all that apply)

- ❑ Based on groupings of tested, combo bins/boxes/other units
- ❑ Based on combo bins/boxes/other units from one supplier
- ❑ Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conduct robust testing
- ❑ All combo bins/units received in one day
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. BeefGrind8
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

Q. BeefGrind9
Does the establishment use any of the following raw ground beef components in producing ground beef products? (check all that apply)

- ❑ Boneless manufacturing trimmings
- ❑ Trim fabrication from fabricated primal/sub-primal cuts
- ❑ Trim fabrication from mechanically tenderize or enhanced primal/sub-primal cuts
- ❑ Primal/sub-primal cuts not intended for use as boneless manufacturing trimmings (e.g., other than a 2-piece chuck not specifically intended for grinding)
- ❑ Head meat
- ❑ Cheek meat
- ❑ Weasand meat
- ❑ AMR (Advanced Meat Recovery products)
- ❑ Low temperature renderedLFTB (lean finely textured beef)

- ❑ Low temperature rendered PDCB (partially defatted chopped beef)
- ❑ Low temperature rendered PDBFT (partially defatted beef fatty tissue)
- ❑ Other, please specify _____
- ❑ None of the above
- ❑ Don't Know

Q. BeefGrind10
Does the establishment have documented use of any intervention method for addressing *E. coli* O157:H7 contamination in any of the trim or other raw ground beef components listed in number 9?

- ❍ Yes
- ❍ No
- ❍ Don't Know

Q. BeefGrind11
Does the establishment knowingly use imported coarse or finely ground beef to produce ground beef products?

- ❍ No
- ❍ Every production day
- ❍ Weekly
- ❍ Monthly
- ❍ Intermittently
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. BeefGrind12
Does the establishment knowingly use imported trim or other raw ground beef components other than coarse or finely ground beef to produce ground beef products?

- ❍ No
- ❍ Every production day
- ❍ Weekly
- ❍ Monthly
- ❍ Intermittently
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. BeefGrind13
Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40^{o} F or below at any of these processing steps? (check all that apply)

- ❑ No
- ❑ Receipt of source materials
- ❑ Grinding
- ❑ Storage
- ❑ Distribution
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. BeefGrind14
How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas? (check all that apply)

- ❑ 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

Q. BeefGrind15
Does the establishment test product, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliforms, APC, Enterobacteriaceae)? (check all that apply)

- ❑ No
- ❑ Beef trim or other raw ground beef components
- ❑ Ground beef product
- ❑ Grinding equipment
- ❑ Processing area
- ❑ Other, please specify _____
- ❑ Don't Know

Q. BeefGrind16
Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program? (check all that apply)

- ❍ Yes
- ❍ No
- ❍ Don't Know

S. **E-BEEF TRIM FABRICATION**

Q. BTFShift
During which shift(s) of operation does this establishment fabricate trim?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. BeefTrimFab1
Does the establishment use one or more of the following cross-contamination controls? (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 production lots that contain only source materials treated to reduce *E. coli* O157:H7 to a non-detectable level (e.g. gaseous ammonia, irradiation)
- ❑ None of the above
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. BeefTrimFab2
Does the establishment use one or more of the following methods? (check all that apply)

- ❑ Formulate trim and other raw ground beef components from multiple suppliers into the creation of individual production lots
- ❑ Formulate production lots that contain combinations of source materials treated to reduce *E. coli O157:H7* and source materials not treated to reduce *E. coli* O157:H7
- ❑ None of the above
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. BeefTrimFab3
Does the establishment have documented monitoring and verification procedures of the carcass surface temperature being maintained below 45º F within 24 hours of slaughter?

- ❍ Yes
- ❍ No
- ❍ Don't Know

Q. BeefTrimFab4
Does the establishment apply any validated intervention method identified as a CCP in the HACCP plan on the trim and other raw ground beef components? (check all that apply)

- ❑ No
- ❑ Organic acid
- ❑ Acidified sodium chlorite
- ❑ Acidified calcium sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Others, please specify _____
- ❑ Don't Know

Q. BeefTrimFab5
Does the establishment or its designee test any production lots of trim and other raw ground beef components for E. *coli* O157:H7?

- ❍ No
- ❍ The establishment tests all production lots of such product using a robust testing method
- ❍ The establishment tests such product using a different frequency and/or method, please specify: _____
- ❍ Test purge from one or more combo bins/boxes/other units per lot (lot as defined by the establishment)
- ❍ Don't Know

Q. BeefTrimFab6
Does the establishment produce "*specially 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? (Note: "*Specially Handled Beef Manufacturing Trimmings" - are sub-primal that have undergone an antimicrobial treatment for E. coli O157:H7 as part of a HACCP plan, are trimmed to meet a specific lean to fat ratio, are cut into slices, are sampled for E. coli O157:H7 through the establishment's verification testing program, and are sealed in bags for direct sale to a retail facility, which is expected to grind the contents of the bags without mixing in other beef manufacturing trimmings.)*

- ❍ Yes
- ❍ No
- ❍ Don't Know

S. **F-BEEF SLAUGHTER**

Q. BSShift
During which shift(s) of operation does this establishment slaughter beef?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. BeefSlaughter1
Does the establishment apply any of the following decontamination procedures to the live or slaughtered cattle **prior** to hide removal? (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

Q. BeefSlaughter2
Does the establishment apply any of the following full-carcass intervention procedures **after** hide removal? (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 hot water wash
- ❑ Pre-chill steam treatment
- ❑ Pre-chill steam vacuum
- ❑ Others, please specify _____
- ❑ Don't Know

Q. BeefSlaughter3
Does the establishment have documentation of employee training in any of the following areas of the slaughter operation? (check all that apply)

- ❑ No
- ❑ Proper hide removal
- ❑ Proper carcass dressing procedures

- ❑ Proper carcass evisceration procedures
- ❑ Proper application of carcass intervention procedures
- ❑ Adequate sanitation of knives and sharpening steels
- ❑ Don't Know

Q. BeefSlaughter4
Does the establishment or its designee test carcasses for *E. coli* O157:H7 using robust testing methods (swabbing or the N-60 excision method) on individual carcasses?

- ❍ No
- ❍ Yes, the establishment conducts robust testing of at least one in 300 carcasses
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. BeefSlaughter5
Does the establishment or its designee 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*, coliform, APC, Enterobacteriaceae) to determine process control? (check all that apply)

- ❑ No
- ❑ Carcass before intervention method
- ❑ Carcass after intervention method
- ❑ Equipment
- ❑ Other, please specify _____
- ❑ Don't know

Q. BeefSlaughter6
Does the establishment have documented monitoring and verification procedures of the carcass surface temperature being maintained below 45º F within 24 hours of slaughter?

- ❍ Yes
- ❍ No
- ❍ Don't Know

S. **G-Regrind Coarse Ground**

Q. RCGShift
During which shift(s) of operation does this establishment regrind coarse ground beef?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. 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? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)

- ❑ No
- ❑ Validated intervention methods prior to coarse grinding
- ❑ Validated intervention methods during coarse grinding
- ❑ Robust Testing of coarse grind for E. *coli* O157:H7
- ❑ Others, please specify _____
- ❑ Don't Know

Q. RCG2
Does the establishment have documentation other than purchase specifications showing that suppliers apply any of the following? (check all that apply)

- ❑ No
- ❑ Validated intervention methods prior to coarse grind
- ❑ Validated intervention methods during coarse grind
- ❑ Robust Testing of coarse ground for E. *coli* O157:H7
- ❑ Other, please specify _____
- ❑ Don't Know

Q. RCG3
Does the establishment apply any validated intervention on the coarse ground? (check all that apply)

- ❑ No Intervention
- ❑ Organic acid
- ❑ Acidified sodium chlorite
- ❑ Acidified calcium sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Others, please specify _____
- ❑ Don't Know

Q. RCG3a
Does the establishment apply any validated intervention on the finished ground product? (check all that apply)

- ❑ No Intervention
- ❑ Organic acid
- ❑ Acidified sodium chlorite
- ❑ Acidified calcium sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Others, please specify _____
- ❑ Don't Know

Q. RCG4
Does the establishment or its designee specifically conduct on-going verification testing of source materials (coarse ground) at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?

- ❍ No, the establishment does not test source materials
- ❍ Yes, for every supplier, including in-house generated source materials, without exception
- ❍ The establishment tests source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. RCG5
Does the establishment or its designee specifically conduct on-going verification testing of all production lots of finished product at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?

- ❍ No, the establishment does not test finished product
- ❍ Yes

❍ The establishment tests finished product using a different frequency and/or method, please specify: _____
❍ Don't Know

Q. RCG6
What laboratory does the establishment or its designee use to test coarse ground beef or finished product for *E. coli* O157:H7?
❍ FSIS Method
❍ Other, please specify _____
❍ Don't Know

Q. RCG7
How does the establishment group products into lots for grinding? (check all that apply)
❑ Based on groupings of tested combo bins/boxes/other units
❑ Based on combo bins/boxes/other units from one supplier
❑ Based on combo bins/boxes/other units from suppliers using validated intervention methods
❑ All combo bins/units received in one day
❑ Others, please specify: _____
❑ Don't Know

Q. RCG8
Approximately how many suppliers of coarse ground beef has the establishment used in the 30 days?
❍ Only from its own grinding plant
❍ 1, from other grinding plant
❍ 2-3
❍ 4-6
❍ More than 6
❍ Don't Know

Q. RCG9
Does the establishment knowingly use imported coarse ground beef to produce ground beef?
❍ No
❍ Every production day
❍ Weekly
❍ Monthly
❍ Intermittently
❍ Other, please specify: _____
❍ Don't Know

Q. RCG10
Does the establishment knowingly use imported trim or other raw ground beef components to produce ground beef products?
❍ No
❍ Every production day
❍ Weekly
❍ Monthly
❍ Intermittently
❍ Other, please specify: _____
❍ Don't Know

Q. RCG11
Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40^{o} F or below at any of these processing steps? (check all that apply)

- ❑ No
- ❑ Receipt of source materials
- ❑ Grinding
- ❑ Storage
- ❑ Distribution
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. RCG12
How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas? (check all that apply)

- ❑ After grinding coarse grind from a supplier
- ❑ After grinding coarse grind 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

Q. RCG13
Does the establishment or its designee test product or food contact, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliform, APC, Enterobacteriaceae)? (check all that apply)

- ❑ No
- ❑ Ground beef product
- ❑ Grinding equipment or other food contact equipment
- ❑ Processing area
- ❑ Other, please specify _____
- ❑ Don't Know

Q. RCG14
Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program?

- ❍ Yes
- ❍ No
- ❍ Don't Know

S. **H-Patty Forming**

Q. PFShift
For which shift(s) of operation does this establishment form patties?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. PatForm1
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? (purchase specification: a set of requirements for source materials established by the buyer and agreed to be met by the supplier before the product is purchased) (check all that apply)

- ❑ No
- ❑ Validated intervention methods prior to grinding
- ❑ Validated intervention methods during grinding
- ❑ Testing of ground beef for *E. coli* O157:H7
- ❑ Others, please specify _____
- ❑ Don't Know

Q. PatForm2
Does the establishment have documentation other than purchase specifications showing that suppliers conduct any of the following? (check all that apply)

- ❑ No
- ❑ Validated intervention methods prior to grinding
- ❑ Validated intervention methods during grinding
- ❑ Testing of ground beef for *E. coli* O157:H7
- ❑ Others, please specify _____
- ❑ Don't Know

Q. PatForm3
Does the establishment conduct any validated intervention on the ground product? (check all that apply)

- ❑ No Intervention
- ❑ Organic acid
- ❑ Acidified sodium chlorite
- ❑ Acidified calcium sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Others, please specify _____
- ❑ Don't Know

Q. PatForm4
Does the establishment or its designee specifically conduct on-going verification testing of source materials prior to patty forming, at least quarterly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months and for the more frequent suppliers?

- ❍ No, the establishment doe snot test source materials
- ❍ Yes, for every supplier, including in-house generated source materials without exception
- ❍ The establishment test source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. PatForm5
Does the establishment or its designee specifically conduct on-going verification testing of all production lots of finished patties at least monthly, using robust testing methodology and with proportionally more frequent testing in high prevalence season months?

- ❍ No, the establishment does not test finished product
- ❍ Yes

- ❍ The establishment tests finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. PatForm6
What laboratory does the establishment or its designee use to test patties for *E. coli* O157:H7?
- ❍ FSIS Method
- ❍ Other, please specify _____
- ❍ Don't Know

Q. PatForm7
How does the establishment group source materials into lots for patty forming?(check all that apply)
- ❑ Based on groupings of tested combo bins/boxes/other units
- ❑ Based on combo bins/boxes/other units from one supplier
- ❑ Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing
- ❑ All combo bins/units received in one day
- ❑ Others, please specify: _____
- ❑ Don't Know

Q. PatForm8
Approximately how many suppliers of ground beef has the establishment used in the last 30 days?
- ❍ Only from its own grinding plant
- ❍ 1, from other grinding plant
- ❍ 2-3
- ❍ 4-6
- ❍ More than 6
- ❍ Don't Know

Q. PatForm9
Does the establishment knowingly use imported raw beef for the production of patties?
- ❍ No
- ❍ Every production day
- ❍ Weekly
- ❍ Monthly
- ❍ Intermittently
- ❍ Others, please specify: _____
- ❍ Don't Know

Q. PatForm10
Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40^{o} F or below at any of these processing steps? (check all that apply)
- ❑ No
- ❑ Receipt of source materials
- ❑ Patty Forming
- ❑ Storage
- ❑ Distribution
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. PatForm11
How often does the establishment conduct complete cleaning and sanitizing of equipment and processing areas? (check all that apply)

- ❑ 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
- ❑ Daily after production
- ❑ Less than daily (extended clean-up)
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. PatForm12
Does the establishment or its designee test product, equipment, or processing area for microbial indicator organisms (e.g. generic *E. coli*, coliform, APC, Enterobacteriaceae)? (check all that apply)

- ❑ No
- ❑ Ground beef product
- ❑ Ground beef patties
- ❑ Food -contact equipment
- ❑ Other, please specify _____
- ❑ Don't Know

Q. PatForm13
Does the establishment use carryover or rework in which the carryover or rework is not specifically accounted for in a robust testing program?

- ❍ Yes
- ❍ No
- ❍ Don't Know

S. **I-ENHANCED PRODUCT (marinated and injected)**

Q. EPShift
During which shift(s) of operation does this establishment enhance product?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. EP1
Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the source materials? (check all that apply)

- ❑ No Intervention
- ❑ Organic Acid
- ❑ Acidified Sodium
- ❑ Acidified Calcium
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. EP2
Does the establishment conduct any of the following as a CCP in the HACCP plan on the pre-enhanced product? (check all that apply)

- ❑ No Intervention
- ❑ Organic Acid
- ❑ Acidified Sodium
- ❑ Acidified Calcium
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Other's, please specify: _____
- ❑ Don't Know

Q. EP3
Does the establishment or its designee test source materials for *E. coli* O157:H7 prior to enhancing the product?

- ❍ No, the establishment tests no source materials
- ❍ The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods
- ❍ The establishment tests source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. EP4
Does the establishment or its designee test the finished enhanced product for *E.coli* O157:H7?

- ❍ No, the establishment tests no finished product
- ❍ The establishment tests all production lots of finished product using a robust testing method
- ❍ The establishment tests finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. EP5
What laboratory does the establishment or its designee use to test product for *E. coli* O157:H7?

- ❍ FSIS Method
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. EP6
How does the establishment group source materials into lots for enhancement?(check all that apply)

- ❑ Based on groupings of tested combo bins/boxes/other units
- ❑ Based on combo bins/boxes/other units from one supplier
- ❑ Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing
- ❑ All combo bins/boxes/other units received in one day
- ❑ Others, please specify: _____
- ❑ Don't Know

Q. EP7
Approximately how many suppliers has the establishment used in the last 30 days?

- ❍ Only from its own slaughter/fabrication/grinding plant
- ❍ 1, from other slaughter/fabrication/grinding plant
- ❍ 2-3
- ❍ 4-6
- ❍ More than 6
- ❍ Don't Know

Q. EP8
Does the establishment knowingly use imported product for producing enhanced product?

- ❍ No
- ❍ Every production day
- ❍ Weekly
- ❍ Monthly
- ❍ Intermittently
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. EP9
Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40^{o} Fahrenheit or below at any of these process steps? (check all that apply)

- ❑ No
- ❑ Receipt of source materials
- ❑ Mechanical tenderization process
- ❑ Storage
- ❑ Distribution
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. EP10
How often does the establishment conduct complete cleaning and sanitizing of equipment? (check all that apply)

- ❑ After application of enhancing operations from each supplier
- ❑ After application of enhancing operations from a group of suppliers
- ❑ After a sample is collected for E. coli O157:H7
- ❑ After each shift
- ❑ Daily after production
- ❑ Less than daily (extended clean-up)
- ❑ Other, please specify:
- ❑ Don't Know

Q. EP11
Does the establishment or its designee test the product or food-contact equipment or solution (e.g., marinade) for microbial indicator organisms (e.g., generic E. coli, coliform, APC, Enterobacteriaceae)? (check all that apply)

- ❑ No
- ❑ Enhanced Product
- ❑ Enhancing Equipment
- ❑ Solution (e.g., marinade)
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. EP12
Does the establishment create bench trim from the primal/sub-primal cuts undergoing enhancement that could be used as a raw beef component that is not specifically accounted for in a robust testing program?

- ❍ Yes
- ❍ No
- ❍ Don't Know
- ❍ Not Applicable

Q. EP13
Does the establishment or its designee test all bench trim from the primal/sub-primal cuts undergoing enhancement for *E. coli* O157:H7? (check all that apply)

- ❍ No, the establishment tests no bench trim
- ❍ The establishment tests all production lots of bench trim using a robust testing method
- ❍ The establishment tests bench trim using a different frequency and/or method, please specify: _____
- ❍ Divert bench trim to cooking or other non-raw beef product use
- ❍ Don't Know
- ❍ Not Applicable

Q. EP14
Does the establishment choose to provide labeling on the enhanced product to inform purchasers that the product is enhanced (i.e., non-intact)?

- ❍ Yes, specify labeling: _____
- ❍ No _____
- ❍ Don't Know

Q. EP15
How is the enhancement solution labeled regarding name and ingredients?

- ❑ Not Applicable
- ❑ Name(s), please specify: _____
- ❑ Ingredient(s), please specify: _____
- ❑ Don't Know

S. **J-MECHANICAL TENDERIZING**

Q. MTShift
During which shift(s) of operation does the establishment mechanically tenderize beef?(check all that apply)

- ❑ Shift 1
- ❑ Shift 2

Q. MT0
Please select the mechanical tenderizing operations that you perform at your establishment? (check all that apply)

- ❑ Mechanical Blade Tenderizing
- ❑ Mechanical Needle Tenderizing
- ❑ Mechanical Tenderizing by Pounding
- ❑ Other, please specify: _____

Q. MT1
Does the establishment have purchase specifications requiring that suppliers conduct any of the following as a CCP in the HACCP plan on the source materials? (check all that apply)

- ❑ No Intervention
- ❑ Organic Acid
- ❑ Acidified Sodium Chlorite
- ❑ Acidified Calcium Sulfate
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. MT2
Does the establishment conduct any of the following as a CCP in the HACCP plan prior to mechanically tenderizing product? (check all that apply)

- ❑ No Intervention
- ❑ Organic Acid
- ❑ Acidified Sodium
- ❑ Acidified Calcium
- ❑ Irradiation
- ❑ Gaseous Ammonia
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. MT3
Does the establishment or its designee test source materials for *E. coli* O157:H7 prior to mechanical tenderization?

- ❍ No, the establishment tests no source materials
- ❍ The establishment tests source materials from all suppliers, at least quarterly, using robust testing methods
- ❍ The establishment tests source materials using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. MT4
Does the establishment or its designee test the finished tenderized product for *E. coli* O157:H7? (check all that apply)

- ❍ No, the establishment tests no finished product
- ❍ The establishment tests all production lots of such finished product using a robust testing method
- ❍ The establishment tests such finished product using a different frequency and/or method, please specify: _____
- ❍ Don't Know

Q. MT5
What laboratory does the establishment or its designee use to test product for *E. coli* O157:H7?

- ❍ FSIS Method
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. MT6
How does the establishment group source materials into lots for mechanical tenderization? (check all that apply)

- ❑ Based on groupings of tested combo bins/boxes/other units
- ❑ Based on combo bins/boxes/other units from one supplier
- ❑ Based on combo bins/boxes/other units from suppliers that only use validated intervention methods and that conducted robust testing
- ❑ All combo bins/boxes/other units received in one day
- ❑ Others, please specify: _____
- ❑ Don't Know

Q. MT7
Approximately how many suppliers has the establishment used in the last 30 days?

- ❍ Only from its own slaughter/fabrication plant
- ❍ 1, from other slaughter plant
- ❍ 2-3
- ❍ 4-6
- ❍ More than 6
- ❍ Don't Know

Q. MT8
Does the establishment knowingly use imported product for producing mechanically-tenderized product?

- ❍ No
- ❍ Every production day
- ❍ Weekly
- ❍ Monthly
- ❍ Intermittently
- ❍ Other, please specify: _____
- ❍ Don't Know

Q. MT9
Does the establishment have documented monitoring or verification procedures to demonstrate that product is maintained at 40^{o} Fahrenheit or below at any of these process steps? (check all that apply)

- ❑ No
- ❑ Receipt of source materials
- ❑ Mechanical tenderization process
- ❑ Storage
- ❑ Distribution
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. MT10
How often does the establishment conduct complete cleaning and sanitzing of equipment and processing areas? (check all that apply)

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

Q. MT11
Does the establishment or its designee test the product or the food-contact surfaces of equipment for microbial indicator organisms (e.g., generic E. coli, coliform, APC, Enterobacteriaceae)? (check all that apply)

- ❑ No
- ❑ Mechanical tenderize product
- ❑ Mechanical tenderization equipment food-contact surfaces
- ❑ Processing area
- ❑ Other, please specify: _____
- ❑ Don't Know

Q. MT12
Does the establishment create bench trim from primal/sub-primal cuts undergoing mechanical tenderization that could be used as a raw ground beef component that is not specifically accounted for in a robust testing program?

- ❍ Yes
- ❍ No
- ❍ Don't Know

Q. MT13
Does the establishment or its designee test all bench trim from the primal/sub-primal cuts undergoing mechanical tenderization for *E. coli* O157:H7?

- ❍ No, the establishment tests no bench trim
- ❍ The establishment tests all production lots of bench trim using a robust testing method
- ❍ The establishment tests bench trim using a different frequency and/or method, please specify: _____
- ❍ Divert bench trim to cooking or other non-raw beef product use
- ❍ Don't Know
- ❍ Not Applicable

Q. MT14
Does the establishment choose to provide labeling on the mechanically tenderize product to inform purchasers that the product is mechanically tenderized (i.e., non-intact)?

- ❍ Yes, specify labeling: _____
- ❍ No
- ❍ Don't Know

Q. MT15
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

Q. Time
Estimate how much time it took you to complete this Checklist, prior to submitting to the establishment management or Frontline Supervisor to review (round up to the nearest hour)

Time to complete Checklist _____