FSIS Notice 65-07

Notice of Reassesment for *E. Coli* O157:H7 Control And Completion of Checklist for all beef operations

- As a public health Agency, FSIS recognizes the Healthy People 2010 food safety objective to lower the number of *E. coli* O157:H7 illnesses.
- FSIS regulation of beef products plays a key role in reaching this goal to ensure improved public health.

- -Healthy People 2010 is a national effort to promote health and disease prevention. Its goals are to increase the quality and years of healthy life.
- -The work of FSIS contributes to reaching the Healthy People 2010 goal of reducing the number of *E. coli* O157:H7 illnesses.
- For example, FSIS tests beef products for *E. coli* O157:H7, and works with establishments to recall product when it tests positive for the pathogen.
- -FSIS also coordinates with the Centers for Disease Control and Prevention (CDC) to monitor illnesses, and to trace human illness back to the source.
- -This training material will help you will understand how your inspection activities at beef operations play a very important role in helping us meet the goals to reduce foodborne illness.



 During the summer of 2007, a number of unfavorable trends emerged causing concern about *E.* coli 0157:H7.

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- -Previously, FSIS issued two Federal Register Notices mandating the reassessment of HACCP plans related to *E. coli* O157:H7 control.
- -In 2002, FSIS called for a mandatory reassessment because of new scientific information that showed an increased prevalence of *E. coli* O157:H7 on live cattle coming to slaughter. This Federal Register Notice discussed the appropriate use of prerequisite programs or purchase specifications.
- -In 2005, FSIS issued another Federal Register Notice due to outbreaks of foodborne illness associated with mechanically tenderized and enhanced products.
- -Over the last few years, the number of recalls and the number of illness outbreaks were going down, and the percent positive in FSIS *E. coli* O157:H7 was getting smaller.
- -But, all of that changed this summer.

o **Unfavorable trends**:

- The percent positive rate for E. coli O157:H7 in FSIS samples of beef products has recently gone up.
- The number of recalls for *E. coli* O157:H7 went up this summer.
- The number of illnesses caused by *E. coli* O157:H7 increased this summer.

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- -FSIS monitors the percentage of raw ground beef analyzed by FSIS that are found to be positive for *E. coli* O157:H7.
- -FSIS has set a goal to keep the positive rate at or below 0.200%.
- -When FSIS started collecting *E. coli* O157:H7 samples in 2002, the percent positive was 0.787% (55 positives out of 6,986 samples).
- -In 2003, the percent positive rate dropped to 0.305%. Since then, there has been a persistent decrease in the percent positive rate, even though the number of samples collected by FSIS increased. FSIS has met its target of 0.200% as well.
- -This summer, there was an increase in the number of FSIS positive samples. This is cause for concern.
- -The number of recalls related to *E. coli* O157:H7 and the number of pounds of product recalled went up in the summer of 2007. This is also cause for concern.
- -The number of human illnesses traced to *E. coli* O157:H7 infections has gone up. The most recent data from 2006 shows that the number of infections was 1.31 infections per 100,000 people, up compared to 1.06 in 2005 and 0.90 in 2004.
- -All of these trends are cause for significant concern.

 Food safety assessments at establishments producing product that tested positive by FSIS for *E.* coli O157:H7 raised questions about the decisions establishments made in the hazard analysis.



- -When there is a positive FSIS sample, an EIAO is sent to the establishment to investigate.
- -The EIAO will compare the establishment's written HACCP plan and the design of the establishment's food safety system with the plan in operation. This includes a review not only of HACCP records, but all food safety system records, including the records associated with prerequisite programs.
- -In plant inspectors also have access to all plant records associated with a plant's food safety system and should include them in verification procedures regularly as instructed in FSIS Directive 5000.2.
- -The food safety assessments showed that establishments with positive sample results are engaging in practices that cause serious concerns. Some of those practices are recognized by both industry and FSIS as risky in terms of allowing *E. coli* O157:H7 to enter commerce.

- The section B of the checklist titled "Raw Beef Food Safety System" deals with the overall design of the control program in place for addressing E. coli O157:H7 in raw been.
- These best practices show how the plant controls *E. coli* O157:H7.

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- -It is recommended (not required) for establishments to consider a list of best practices that are identified in FSIS Notice 65-07.
- -The best practices for plants that produce beef product are interrelated. This means if one of the practices is not followed, the product may be at risk, even if the others are followed, because, to be fully effective, all of the practices must be employed.

- Best Practice example for a beef grinding plant that determined in its Hazard Analysis that E. coli O157 is a hazard not reasonably likely to occur.
 - -The plant's hazard analysis clearly explains the reason why E. coli O157:H7 is not likely to occur.
 - -The reason is that the establishment has a written program as a Sanitation SOP or prerequisite program to control for *E. coli* O157.

- -This best practice is for grinding establishments that determine that *E. coli* O157:H7 is a hazard not reasonably likely to occur in the plant's hazard analysis.
- -The plant made this decision because it has a detailed prerequisite program that it follows regularly.

Best Practice example (continued):

- The prerequisite program requires that:
 - -the supplier has at least 1 validated intervention controlled by a CCP (e.g., applies an antimicrobial that reduces *E. coli* O157)
 - -all trim from all suppliers (including inhouse) is tested using a robust testing method, such as the N-60 method using excision, and stated so on every Certificate Of Analysis.

- -The prerequisite program calls for all beef product suppliers to have at least 1 validated intervention, such as an antimicrobial treatment, that reduces *E. coli* O157:H7.
- -The prerequisite program also calls for all trim, including trim produced by the grinder, to be tested for *E. coli* O157:H7 using a method that is likely to find it. FSIS recommends the N-60 method using excision. Assurance that this testing has been performed is provided by the Certificates of Analysis (COAs).
- -The grinder also tests incoming trim for *E. coli* O157:H7 more frequently during the high prevalence season, from April to October.

Best Practice example (continued):

- o The prerequisite program requires that:
 - -incoming trim is tested by the grinding facility, by supplier, with proportionally greater frequency in high prevalence months than in low prevalence months

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- -The prerequisite program calls for all beef product suppliers to have at least 1 validated intervention, such as an antimicrobial treatment, that reduces *E. coli* O157:H7.
- -The prerequisite program also calls for all trim, including trim produced by the grinder, to be tested for *E. coli* O157:H7 using a method that is likely to find it. FSIS recommends the N-60 method using excision. Assurance that this testing has been performed is provided by the Certificates of Analysis (COAs).
- -The grinder also tests incoming trim for *E. coli* O157:H7 more frequently during the high prevalence season, from April to October.

Best Practice example (continued):

- The prerequisite program requires that:
 - -finished product is tested at least quarterly
 - each supplier is audited annually by a third party

- -The grinder tests finished product for E. coli O157:H7 at least quarterly.
- -The grinder has a third party to conduct an audit of suppliers to make sure that the suppliers are following the specifications in the prerequisite programs.



- These best practices that are shown in section B of the Checklist in FSIS Notice 65-are interrelated
- This means that if an establishment fails to implement one of the best practices, the risk of producing product that is positive for *E. coli* O157:H7 increases, even if other practices are followed.

- -It is recommended (not required) for establishments to consider adopting the best practices that are identified in FSIS Notice 65-07 if they have not done so.
- -The best practices for plants that produce beef product are interrelated. This means if one of the practices is not followed, the product may be at risk, even if the others are followed, because, to be fully effective, all of the practices must be employed.

- Following are scenarios that show examples of practices of concern that may have led to the unfavorable trends related to E. coli O157:H7.
- Keep the section of the set of best practice measures from the checklist titled "Raw Beef Food Safety System" in mind while reviewing the scenarios.
- Remember, while the best practices are not required, the Agency considers them to be essential to controlling *E. coli* O157:H7.

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-Here's a review of some of these practices of concern. It's very important that you understand why these practices cause concern. So, if there is anything you don't understand or something that's not clear, please ask questions of your Front Line Supervisor, District Office, or the Policy Development Division (formerly known as the Technical Service Center).

- Scenario 1 Establishment's failure to ensure effectiveness of prerequisite program
 - -In the hazard analysis, the plant determined *E. coli* O157:H7 was a hazard not reasonably likely to occur because they had a prerequisite program for testing incoming product.
 - -But, the plant failed to follow the prerequisite program to consistently test the incoming product.

- -What is a prerequisite program? Let's do a brief review. You will get more details about prerequisite programs when you review the PowerPoint on Prerequisite Programs.
- In general, prerequisite programs deal with the "good housekeeping" concerns of the establishment, whereas, the HACCP plan focuses on controlling food safety hazards. Inspection personnel are to be aware of all monitoring and food safety testing conducted by the establishment. The plant must provide all documentation including the written program, records and results for all prerequisite programs that support its HACCP system. For example, an establishment may indicate in the hazard analysis that E. coli O157:H7 is a hazard not reasonably likely to occur in the establishment's processing because the establishment has a prerequisite program with purchase specifications addressing E. coli O157:H7. The information regarding this prerequisite program is supporting documentation which must be maintained according to 417.5(a)(1). Without this documentation, FSIS would question the adequacy of the establishment's HACCP system and hazard analysis. FSIS expects the supporting documentation concerning prerequisite programs, other than SSOPs, to include the program's procedures and operational controls in writing. In addition, FSIS expects the documentation to include records that document that the program is effective, and that E. coli O157:H7 is not reasonably likely to occur. Inspectors are required to review testing and prerequisite program records at least once per week according to Directive 5000.2.

Scenario 2 – Establishment's failure to ensure effectiveness of prerequisite program

-In the hazard analysis, the plant determined *E. coli* O157:H7 was a hazard not reasonably likely to occur because they had a prerequisite program for testing finished product.

-But, the plant failed to follow their prerequisite program to consistently test the finished product for *E. coli* O157:H7.

- How would you know if the establishment is following its prerequisite program for testing finished product? When you are performing a HACCP 01 procedure, review testing methods in the establishment's prerequisite plans; then review records to ensure that the tests are performed at the frequency specified in the plan.
- How would you know that the establishment is following the testing procedures for testing finished product according to the prerequisite program? When you are performing a HACCP 01 procedure, review testing methods in the establishment's prerequisite plans; then observe the plant as it conducts its testing. If you have questions about the adequacy of the testing program, contact the District Office.
- -What type of testing method does FSIS recommend for detecting *E. coli* O157:H7? FSIS uses the n-60 method of testing. This is also an industry standard for ensuring food safety. This method is not required, but it is recommended. If you have questions about the adequacy of the testing program, contact the District Office.
- -Why is it important that the establishment follow the prerequisite program? The establishment validated its HACCP system as being effective in preventing, eliminating, or reducing the levels of *E. coli* O157:H7 to the extent possible based on the elements of its HACCP plan, SSOP, and prerequisite program. There is no assurance that the product is safe.

- Scenario 3 Establishment's failure to ensure effectiveness of prerequisite program
 - -In the hazard analysis, the plant determined *E. coli* O157:H7 was a hazard not reasonably likely to occur because the had a prerequisite program that required incoming product to have a Certificate of Analysis (COA) showing the source material had been tested for *E. coli* O157:H7.
 - -But, the plant failed to follow their prerequisite program to consistently require the COAs be submitted for incoming product.

- What is a Certificate of Analysis (COA)? A COA is documentation from a supplying inspected establishment that shows beef products purchased have been tested by the establishment for *E. coli* O157:H7. These certificates typically accompany every shipment of product received by the establishment.
- How is a Certificate of Analysis different from a Letter of Guarantee? A Letter of Guarantee may contain the same information as a Certificate of Analysis documentation that the supplying plant tested the outgoing product for *E. coli* O157:H7 and did not find the pathogen. A Letter of Guarantee may also include information about other interventions taken by the establishment to control *E. coli* O157:H7, such as antimicrobial treatments.
- -Why should we be concerned if a shipment of beef products coming into the establishment fails to include this piece of paper the Certificate of Analysis? The plant is failing to follow its prerequisite program, and that calls into question the effectiveness of the establishment's food safety system. The shipment may NOT have been tested by the supplying establishment, and may contain product that is positive for *E. coli* O157:H7.

- Scenario 4 Establishment's failure to ensure effectiveness of prerequisite program
 In the hazard analysis, the plant determined E. coli O157:H7 was a hazard not reasonably likely to occur because the had a prerequisite program that required incoming product to have a Certificate of Analysis (COAs) showing the source material had been tested for E. coli O157:H7.
 - -But, the establishment failed to ensure that the testing done by the supplying plant for the COAs was adequate to ensure that *E. coli* O157:H7 was non-detectable.

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-Is an establishment required to audit its suppliers to make sure the tests suppliers use effectively detect *E. coli* O157:H7? No. However, a prudent establishment operator will conduct periodic audits, or take other actions, to ensure that the COAs from supplying establishments represent the results of testing that is described in its prerequisite program. Remember that if the prerequisite program fails, there are questions about the receiving establishment's food safety system. So, if a receiving establishment is depending on the supplying establishment to conduct effective *E. coli* O157:H7 testing, but the supplying establishment fails to conduct the testing, or uses an inadequate method of testing, the receiving establishment's food safety system is jeopardized.

- Scenario 5 Establishment's failure to ensure effectiveness of prerequisite program
 In the hazard analysis, the plant determined E. coli O157:H7 was a hazard not reasonably likely to occur because they had a prerequisite program that required incoming product to have a Certificate of Analysis (COAs) showing the source material had been tested for E. coli O157:H7.
 - -But, the establishment failed to ensure that COAs were received for product coming in from foreign countries.

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- This scenario is basically the same as the previous one, except that the supplying establishment was from a foreign country. FSIS has a process to ensure that any country shipping meat, poultry, or egg products to the U.S. has a food safety inspection system that is equivalent to the U.S. inspection system. However, the establishment should follow its prerequisite program for all suppliers, or reassess its HACCP plan to consider the hazards reasonably likely to occur.

- Scenario 6 Hazard not identified in raw ground beef
 - -In the hazard analysis, the establishment determined that *E. coli* O157:H7 was a hazard not reasonably likely to occur in raw ground beef.
 - -But the establishment used "bench trim" (trimmings from roasts and steaks) from boxes of product marked "not intended for grinding."

- -What type of product do you think the boxed "bench trim" product marked "not intended for grinding" was intended for? It was intended for use in cooked product.
- -FSIS *E. coli* O157:H7 testing policies have not focused on testing trim from subprimals such as roasts and steaks. However, FSIS is updating is testing policies to incorporate this type of product.
- -According to the best practices listed in Notice 65-07, should an establishment test its trim? Yes.

- Scenario 7 Hazard not identified in raw ground beef
 - -In the hazard analysis, the establishment determined that *E. coli* O157:H7 was a hazard not reasonably likely to occur in raw ground beef because they received product from another inspected establishment.
 - -But the establishment received "bench trim" (trimmings from roasts and steaks) that was not tested for *E. coli* O157:H7 before it was used in ground product.

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-Is it reasonable to assume that product being shipped to a grinding (receiving) establishment from a slaughter (supplier) establishment with the mark of inspection is free of *E. coli* O157:H7? No. The supplier may not be testing the product for *E. coli* O157:H7 and may not be using interventions to reduce or control for *E. coli* O157:H7. The receiving establishment must actively gather information about the produce it receives and consider it in the hazard analysis.

- Scenario 8 Hazard not identified in raw ground beef
 - -In the hazard analysis, the establishment determined that *E. coli* O157:H7 was a hazard not reasonably likely to occur in raw ground beef.
 - -But the establishment used "bench trim" (trimmings from roasts and steaks) and did not test it for *E. coli* O157: H7 after grinding.

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-Is it appropriate for an establishment to determine that a hazard, such as *E. coli* O157:H7, is not reasonably likely to occur because the establishment does not have a history of product testing positive for *E. coli* O157:H7? No. The Federal Register Notice issued by FSIS in 2002 made it clear that there is information about the prevalence of *E. coli* O157:H7 on cattle coming to slaughter that the establishment must consider in its hazard analysis. The establishment should consider all the steps in its process in its hazard analysis.

- Scenario 9 Hazard not identified in tenderized beef cuts
 - -In the hazard analysis, the establishment determined that *E. coli* O157:H7 was a hazard not reasonably likely to occur in tenderized beef cuts.
 - -But the establishment had no documentation to support this decision.

- -In this scenario, how was *E. coli* O157:H7 introduced into the product? Most likely, *E. coli* O157:H7 was present on the surface of the beef cut. The tenderizing process drove the *E. coli* O157:H7 below the surface of the beef cut. In the absence of any cooking instructions, the consumer or restaurant may not cook the beef cut adequately.
- -What actions does an inspector take when there is no supporting documentation for a decision made in the establishment's hazard analysis? This is noncompliance with 417.5(a)(1). The inspector should write an NR. Without documentation to support the establishment's decision, FSIS would question the adequacy of the establishment's HACCP system and Hazard Analysis.

- Scenario 10 Hazard not identified in tenderized beef cuts
 - -In the hazard analysis, the establishment determined that *E. coli* O157:H7 was a hazard not reasonably likely to occur in tenderized beef cuts.
 - -But the establishment did not test its re-used marinade solution for *E. coli* O157:H7.

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- Why is re-use of marinade solution a concern? Without an appropriate control process, pathogens may build up in the solution and transfer into throughout the muscle of the beef cut, contaminating the cuts with *E. coli* O157:H7. In the absence of any cooking instructions, the consumer or restaurant may not cook the beef cut adequately.

- Scenario 11 Inadequate sanitation
 - -The establishment has no documentation to verify the sanitary conditions of tenderizing equipment, and no measures to ensure product contact surfaces are maintained in a sanitary manner sufficient to prevent contamination of products.

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-What kind of documentation would be adequate to document that the establishment is ensuring that tenderizing equipment is sanitary? Written procedures and records in the establishment's SSOPs, HACCP plan, or prerequisite program for regular cleaning of the tenderizing equipment.

o Scenario 12 - Rework

- -The establishment's written procedures indicated that product from previous day's production will not be used as rework.
- -But, the establishment collected and stored left over beef materials from one production, froze it, and re-used it in another production.

- Rework is sound finished product that is reincorporated into a batch of fresh ingredients prepared to make similar finished product. Establishments also sometimes choose to develop a rework tracking system to reduce the amount of product that would be implicated in a recall. Some establishments include all rework at the end of the production day, or divert it to cooked product processing departments. There have been instances where a product recall was greatly affected by the establishment's ability to track the use of rework. In one example, an establishment recalled a large amount of product due to the presence of *E. coli* O157:H7, found during the investigation of an outbreak of foodborne illness. Review of the establishment's production practices revealed that some of the production lot that was recalled had been used as rework in subsequent days' production.

- Remember the best practices that are shown in section B of the Checklist in FSIS Notice 65-are interrelated.
- These best practices are not required by the regulations, however experience has shown that the best practices are an integral part of a program to control for *E. coli* O157:H7.

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The best practices are interrelated. This means if one of the practices is not followed, the product may be at risk, even if the others are followed, because, to be fully effective, all of the practices must be employed.

- FSIS is responding to these trends by issuing several Notices to inspection personnel increasing its testing programs.
- FSIS is also issuing Notice 65-07 related to reassessment of the HACCP plan for E. coli O157:H7 in beef operations.



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-Before completing the checklist, thoroughly review FSIS Notice 65-07.

 Within 1 week of the publication of Notice 65-07, inspection program personnel at beef operations that slaughter, fabricate, grind, mechanically tenderize, or enhance beef products by tumbling, messaging, or injecting solutions such as marinades must conduct an <u>awareness meeting</u> with establishment officials.

⁻You will be responsible for conducting the awareness meeting with the plant to make plant officials aware of the need for the mandatory reassessment of their HACCP plan.

 During the awareness meeting, inspection program personnel should review this Notice and discuss Attachment 2 with establishment personnel.



- -A good time to have the awareness meeting is when you have your regularly scheduled weekly meeting with establishment management.
- -Share Attachment 2, Developments That Support That There Is A Need For Establishments To Reassess Their HACCP Plans, with the establishment and discuss the trends that took place this summer.
- -Discuss the scenarios that apply to the establishment. For example, if in the hazard analysis, the plant determined *E. coli* O157:H7 was a hazard not reasonably likely to occur because they had a prerequisite program that required incoming product to have a Certificate of Analysis (COAs) showing the source material had been tested for *E. coli* O157:H7, share Scenario 4 with the establishment personnel.

 Inspection program personnel should document in a Memorandum of Interview who was present at this awareness meeting, the date/time of the meeting, what was discussed, and any documents shared with plant management.



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-Follow the instructions in FSIS Notice 65-07 to document the awareness meeting.

- Inspection program personnel are to maintain this memorandum in the official government file, and provide a copy to the establishment management.
- The establishment's mandatory reassessment of its HACCP plan must be conducted by October 26th.

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-The Notice sets a deadline for when the establishment is to have the mandatory reassessment of their HACCP plan completed.

 If inspection program personnel have any concerns related to the establishment's reassessment, they may contact the District Office. The District Office will determine a food safety assessment will be scheduled.

 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.

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-By November 2, 2007, answer and submit the questions in Attachment 3 to Notice 65-07, "Responses to the Reassessment."

 FSIS inspection program personnel must also complete a checklist to record information about the plant's HACCP system.



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Also, complete the checklist in Notice 65-07.

- Section B 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 rest of the checklist describes known control measures and activities employed by beef operations that may affect the level of control employed by the establishment.

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Section B of the checklist lists best practice measures for controlling *E. coli* O157:H7.

- The best practices in Section B of the checklist gives the big picture on how the establishment is controlling *E. coli* O157:H7.
- The best practices for plants that produce beef product are interrelated. This means if one of the practices is not followed, the product may be at risk, even if the others are followed, because, to be fully effective, all of the practices must be employed.
- The rest of the checklist focuses on specific information, such as what product is produced, which procedures to control *E. coli* O157:H7 are in place, and the frequency for the applying the procedures.

- -The best practices in section B of the checklist show how the establishment is controlling for *E. coli* O157:H7 from a broad perspective.
- -The rest of the checklist focuses on specific information that is also important for controlling *E. coli* O157:H7.

- At this time, there are no best practices (BPs) identified in the checklist beyond section B.
- However, as FSIS learns more about the steps establishments are taking to control for *E. coli* O157:H7, more BPs may be identified.

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Over time, FSIS may update the best practices for controlling *E. coli* O157:H7.

 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 of Notice 65-07.
Procedures for products with the lowest risk factor are to be replaced first.

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-Attachment 3 gives you instructions on which procedures not to perform so you will have time to complete the checklist.

Inspection personnel are to share a completed copy of the checklist prior submission with a designated plant management official who will be given 48 hours to review and provide an opportunity to correct any response for which a change can be substantiated.

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-Remember to show the completed checklist to the establishment. They may have some information to share that needs to be considered in completing the checklist. For example, they may be updating their hazard analysis, or they may have new purchase specifications to include in a prerequisite program.

 Inspection program personnel are to save the completed checklist as a Word file and email a copy to the Front Line Supervisor and the District Analyst.

- The checklist will be submitted to the Policy Analysis Division of the FSIS Office of Policy, Program and Employee Development.
- The inspector will also maintain a copy in the government office, provide a copy to plant management and provide a copy to the District Analyst.
- This checklist needs to be completed by November 30, 2007.

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-The information on the checklist is very important. It will be used to develop or modify FSIS policies related to *E. coli* O157:H7.

- The FSIS Office of Policy, Program and Employee Development will use information from the checklist to help in developing risk-based sampling programs for *E. coli* O157:H7
- Based on the information provided in the checklist, the District may send an EIAO to conduct a food safety assessment to review the plant's documentation for its food safety system.

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- Here's an example of a situation that may result in sending an EIAO to conduct a food safety assessment. The checklist information for an establishment shows that the establishment plan includes very few of the best practices. This is cause for concern about the plant's food safety system.

- In the future, FSIS will periodically request that the checklist be updated to reflect any recent changes that the establishment has made to its processes.
- The checklist will help highlight better practices for the industry to consider to better protect public health.



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Completing the checklist will help make sure the establishment is aware of the best practices. Following the best practices will lead to better public health protection.