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

FSIS DIRECTIVE	5100.1 Revision 2	7/10/08

ENFORCEMENT, INVESTIGATIONS, AND ANALYSIS OFFICER (EIAO) COMPREHENSIVE FOOD SAFETY ASSESSMENT METHODOLOGY

Part I -- General

I. PURPOSE

The purpose of this directive is to provide instructions to the EIAOs on the methodology that they are to use when they conduct comprehensive food safety assessments and on how they are to document their findings.

II. CANCELLATION

FSIS Directive 5100.1, Revision 1, Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology, 7/8/08

III. REASON FOR REISSUANCE

FSIS is reissuing this directive to incorporate section IV from Chapter 4 of FSIS Directive 5000.1, Verifying an Establishment's Food Safety System. The added information is in Part IX, Verification Plans. FSIS is adding this work method information to this directive, so that EIAOs will have it in the directive that addresses their activities. This revised directive also includes additional work methods for EIAOs regarding how to make and document recommendations.

IV. REFERENCES

9 CFR 300 to end

V. BACKGROUND

The comprehensive food safety assessment considers all food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment. The EIAO is to assess the design and validity of the hazard analysis, HACCP plan; Sanitation Standard Operating Procedures (Sanitation SOPs), pre-requisite programs,

testing programs, e.g., its generic *E. coli* written procedures; and any other programs that constitute the establishment's HACCP system. The order in which the EIAO assesses these programs does not matter, but the assessment must be comprehensive. An EIAO is to complete the assessment before leaving the establishment, however there is not an established time period for the EIAO to complete the assessment.

Part II -- Comprehensive Food Safety Assessment

I. General

A. The EIAO is to know the microorganisms of concern for each processing category and know the characteristics of these microorganisms. The EIAO should identify and evaluate the factors affecting growth of the microorganisms and assess the statistical validity of the plant's micro sampling plans and monitoring procedures.

B. The EIAO should review the plant's laboratory analytical methods and confirm that they are appropriate for the products and processes. The EIAO should observe the establishment taking product and environmental samples.

C. The EIAO applies critical thinking to analyze and assess findings to determine the adequacy of the establishment's food safety systems.

D. After the EIAO has assessed the systems individually, he or she determines whether the findings from one system correlate to the findings from another, such as whether there is information from sanitation records indicating that there were sanitation problems on a ready-to-eat (RTE) line on the day that the establishment collected a sample of RTE product that tested positive for *L. monocytogenes*.

E. When the assessment is complete, the EIAO should apply critical thinking to assess whether, given the standards established in the applicable statute or regulation, a solid basis exists for taking an enforcement action, if applicable.

F. When the EIAO has completed the food safety assessment in the establishment, he or she documents an Agency position. The EIAO's report is e-mailed to the District Office (DO) and the Front-line Supervisor.

II. Reasons for Conducting Comprehensive Food Safety Assessments

A. EIAOs may visit a plant to conduct a comprehensive food safety assessment for various reasons, such as:

- Positive laboratory findings
- To determine whether a plant has reassessed its HACCP plan or evaluated its Sanitation SOPs
- Foodborne illness outbreaks, recalls, or consumer complaints
- Randomly selected by district office officials.

Regardless of the reason for the food safety assessment, the EIAO should assess all of the food safety systems in operation in that establishment.

III. Preparation for EIAO Establishment Visits

A. When an EIAO is preparing to conduct a comprehensive food safety assessment, he or she should:

1. Provide the establishment 1-2 weeks advance notice of the visit when possible;

2. Provide the Front-line Supervisor and Inspector-in-Charge (IIC) 1-2 weeks advance notification of the plant visit when possible;

3. Review 6 - 8 months of FSIS data prior to visiting the establishment. The EIAO should review all relevant data and determine whether there are patterns or trends that should be investigated when visiting the establishment. The types of data that should be reviewed are:

- PBIS data
- Consumer complaints
- Plant compliance history
- Enforcement data
- Laboratory results

4. Review, if necessary, relevant policy issuances (Federal Register Notices, Directives, Notices) that pertain to the processes associated with the establishment.

B. When the food safety assessment is complete, the EIAO should assess the significance of the pre-visit data in light of the overall assessment outcome.

IV. Arriving at Establishment

A. When the EIAO arrives at the establishment he/she should meet with FSIS personnel and conduct an entrance meeting with FSIS personnel and establishment officials. Some of the topics that should be discussed during the entrance meeting are:

1. an explanation of a comprehensive food safety assessment and how it differs from the day-to-day verification that is done by in-plant inspection program personnel;

2. the purpose of the comprehensive food safety assessment;

3. that the role of the EIAO is not to resolve disputes between the establishment and in-plant inspection program personnel;

4. that if the assessment results in an NOIE or suspension, the EIAO will work with in-plant inspection program personnel to develop a verification plan.

Part III -- Assessing the Sanitation System

I. EIAO Assessment of the Sanitation SOPs

A. The EIAO systemically looks at the establishment's Sanitation SOPs. The EIAO will focus on the design of the Sanitation SOPs. The EIAO should review the Sanitation SOPs and pre-operational and operational sanitation records for at least the past 60-days and answer questions such as:

1. Are the Sanitation SOPs designed to include all procedures necessary to prevent direct contamination or adulteration of product?

2. If the establishment is doing microbiological testing as part of the Sanitation SOPs, is the design of the procedure appropriate for the organism?

3. If the establishment has an extended cleanup written in the Sanitation SOPs, does the design of the procedure support extended cleanup?

4. If the establishment does microbiological testing to verify the extended cleanup procedure, are the procedures designed to find the organisms of concern?

5. If the establishment produces RTE products, are the Sanitation SOPs designed to prevent cross-contamination from raw to RTE products?

6. If the establishment produces RTE products and includes environmental testing in the Sanitation SOPs, are the procedures designed to increase testing when significant construction occurs?

7. If there is construction going on in the establishment, have the Sanitation SOPs been designed to identify problems that may emerge as a result of the construction (sanitary conditions, product contamination)?

8. If environmental testing is included as part of the Sanitation SOPs, are the corrective actions designed to meet the corrective action requirements of section 416.15?

9. If the establishment produces RTE products, are the Sanitation SOPs designed to prevent post lethality contamination from personal hygiene, product handling practices, equipment maintenance?

II. EIAO Assessment of Sanitation Performance Standards (SPS)

A. The SPS regulations do not require establishments to maintain records associated with the SPS requirements. Because there is no design requirement for these regulations, the EIAOs do not focus on these regulatory requirements directly. However, during an EIAO's initial data assessment, he or she should review and consider non-compliance records (NRs) issued under 06D01. Also, if an establishment is consistently failing the *Salmonella* performance standards, the EIAO might be asked to assess whether the establishment is complying with the SPS. In performing this assessment, the EIAO should be aware of any problems in complying with the SPS that could be having an impact on food safety. For example, if the EIAO found that the employee hygiene and product handling practices were not meeting the regulatory requirements, this failure could be having a direct impact on an establishment's ability to meet the *Salmonella* performance standards. SPS can also have an impact on the HACCP system. For example, if the establishment is reusing water and has not considered the impact of the reuse water on the product, the EIAO may not be able to determine that the product is not adulterated.

B. The EIAO should consider the findings related to the sanitation programs in context with all of the other food safety systems at the establishment.

Part IV -- Review of the HACCP System

I. EIAOs Assessment of the Hazard Analysis and HACCP Plan

A. EIAOs should start the review of the HACCP system, using their scientific knowledge and professional expertise, by verifying the design of the hazard analysis. Some questions the EIAO may seek answers for when reviewing the hazard analysis are:

1. Are all of the steps in the process included in the flow chart and hazard analysis?

2. Are the activities occurring at each of the steps accurately reflected in the hazard analysis?

3. Has the establishment considered food safety hazards that can occur before, during, and after entry of product into the establishment?

4. Has the establishment considered the appropriate hazards for the products produced?

5. Have the specific microbial, chemical, and physical hazards been identified that are prevalent to the specific products or process categories?

6. Are there any other hazards that would seem to be relevant that the establishment has not considered?

7. Are the establishment's determinations about hazards that are reasonably likely to occur based on relevant historical data, scientific information, or technical information about the process and a clear understanding of the regulatory standard?

8. Does the hazard analysis consider all of the controls in place in the establishment?

9. Has the establishment validated the controls that it has put in place? Has validation been accomplished by repeated testing of the adequacy of the CCPs and critical limits, and review of records, to ensure that the hazard is prevented, eliminated, or reduced to acceptable levels?

10. Are any of the ingredients likely to present microbial, chemical, or physical hazards?

11. Does the product contain reworked product that might have different microbial, chemical, or physical characteristics than the original ingredients?

12. Does the product permit survival or multiplication of pathogens before or during preparation?

13. Is the product subject to recontamination after the lethality step?

14. What is the normal microbial content of the product under proper storage conditions?

15. Under what circumstances will the normal microbial content of the product change?

16. Does the layout of the facility provide an adequate separation of raw materials from RTE product?

17. Will the equipment provide the time/temperature controls necessary for safe product?

18. Does the method of packaging affect the multiplication of microbial pathogens or the formation of toxins?

19. Can the sanitation practices that are employed affect the safety of the product that is being prepared?

20. If water is reused, does the design of the hazard analysis consider the impact the reuse has on the product or process?

21. What is the likelihood that the product will be stored at an appropriate temperature?

22. Is the product intended for consumption by a population with increased susceptibility to illness?

23. Will the preventive measures associated with each hazard prevent, eliminate, or reduce to an acceptable level the hazards the establishment identified in the hazard analysis?

II. EIAOs Assessment of Prerequisite Programs

A. Prerequisite Programs

1. Prerequisite programs are conditions and practices that provide the basic environmental and operating conditions that are necessary for the production of safe and wholesome food. The programs provide a foundation for the development and implementation of an effective HACCP system. They frequently function across product lines and are often managed as facility-wide programs rather than being process or product specific.

2. In the hazard analysis (9 CFR 417.2), an establishment may determine that a hazard is unlikely to occur because of the on-going execution of a prerequisite program. This is different from determining that a hazard is reasonably likely to occur in the process in the absence of controls that prevent, eliminate, or reduce to an acceptable level the hazard (i.e., the need for critical control points (9 CFR 417.2).

3. An EIAO should be aware that prerequisite programs can not be used as the direct means to control a hazard. Deviations from compliance with a prerequisite program usually would not create a food safety concern or necessitate action on the product, whereas deviations from the controls in a HACCP plan cause food safety concerns and generally require action on the affected product. This is a key difference and can aid in distinguishing whether a prerequisite program is being used appropriately or whether critical control points are necessary.

B. Determining the adequacy of the design of a prerequisite program

1. To make a determination as to whether a prerequisite program is appropriately supporting decisions made in the hazard analysis, or whether the program is being inappropriately used to control a hazard, EIAOs should seek answers to questions similar to the following:

a. If the criteria in the prerequisite program are not met, are there questions concerning the safety of the product?

b. If the criteria listed in the prerequisite program are not met, does the establishment implement corrective actions that meet the requirements of 9 CFR 417.3?

c. Is the only support for the use of the prerequisite program historical information showing that the prerequisite program is the primary means of control to eliminate, prevent, or limit to an acceptable level the hazard from occurring?

d. If the answers to such questions are yes, then it is probable that the prerequisite programs are being used to directly control the hazard. EIAOs are to discuss such findings with the establishment and are to inform the establishment that it needs to reassess its HACCP plan to reconsider the use of the programs and to properly address the hazards. The failure of the establishment to do such may result in FSIS issuing an NOIE.

C. Determining the adequate design for the execution of prerequisite programs

1. Because prerequisite programs form the basis of decisions in the hazard analysis, an EIAO is to review the features of the prerequisite program, including any supporting documents that the establishment has for the criteria in the program. If a prerequisite program is found to be ineffective or is not being executed as designed and there are no resulting food safety concerns, an establishment would need to reassess its hazard analysis, 9 CFR 417.4, to determine whether the prerequisite program is continuing to support decisions made in the hazard analysis.

2. An EIAO is to review data reflecting how the program has operated over a recent period of time and consider whether it seems to be successful. The EIAO should find that the records continue to support the decision that the hazard is not reasonably likely to occur because of the use of the prerequisite program.

3. For example, if an establishment is producing raw ground beef products and has a prerequisite program based on compliance with purchase specifications, the EIAO should review the records associated with such a prerequisite program to verify that the documentation supports the decision made in the hazard analysis that *E. coli* O157:H7 is not reasonably likely to occur.

4. For example, if the establishment is producing RTE products and has included product or environmental testing in a prerequisite program, the EIAO should review the prerequisite program to verify that it is science-based. The EIAO will assess the establishment's total system to verify that the establishment has designed its testing procedures so that if indicator organisms or *L. monocytogenes* are detected, the establishment has procedures in place to effectively address their presence. The EIAO will review written procedures, assess decisionmaking documents for rationale, and review laboratory results.

III. EIAOs Assessment of Validation

A. EIAOs should start the review of validation of the HACCP system, using their scientific knowledge and professional expertise, by verifying that the establishment has validated the HACCP plan's adequacy in controlling the food safety hazards identified during the hazard analysis and that the HACCP plan is effectively implemented. When verifying the validation requirement, the EIAO should request the hazard analysis, HACCP plan and supporting documentation for the controls in place. Some questions the EIAO may seek answers for when verifying that the HACCP system is validated are:

1. Has the establishment identified hazards and specified controls are in place controlling these hazards?

2. Does the establishment have information to support controlling food safety hazards?

3. Does the establishment have information to support that the controls are adequate for controlling the specific identified food safety hazards?

4. Does the establishment have data to demonstrate that the parameters of the supporting documents can be attained in that specific establishment?

5. If the establishment has implemented corrective measures to ensure appropriate disposition of product, does the establishment have data to support that the measures are valid to ensure food safety?

6. When changes occur in the operation that impact food safety, does the establishment have data to support any changes or decisions made in the HACCP system?

7. Does the establishment have data to demonstrate that the system has been implemented as designed and is effective in controlling the identified food safety hazards?

8. If the establishment is using Agency documents as validation data, are the documents being used as intended?

IV. EIAOs Assessment of the Monitoring Requirements

A. EIAOs will perform data collection and analysis to verify that the design of the establishment's monitoring procedures, and the frequency with which it performs those procedures, are adequate to demonstrate process control. The EIAO should review a minimum of 60 days of monitoring records to assess the following questions about the establishment's monitoring procedures and frequencies. More records can be reviewed anytime the EIAO determines that he or she needs to determine regulatory compliance:

1. Are the monitoring frequencies in the HACCP plan continuous?

2. Would it be feasible to have continuous monitoring frequencies?

3. If the monitoring frequencies are not continuous, are they adequate to demonstrate process control, e.g., statistically based, historically supported?

4. Is the basis for discontinuous monitoring frequencies documented and appropriate for the HACCP process being verified?

5. Does the establishment review monitoring records to detect trends that can be corrected before there is loss of control? If so, the EIAO should request to review these records.

V. EIAOs Assessment of the Verification Requirements

A. While the CSI focuses on how an establishment is performing the verification activities outlined in its HACCP plan, EIAOs will determine whether an establishment's on-going verification activities comply with regulatory requirements by focusing on the design of these verification activities. Consideration of design features should be based on a review of all the verification procedures associated with a single HACCP plan.

B. The EIAO should review records that cover a minimum of 60 days of activity. The EIAO should carefully review verification records associated with CCPs. The EIAO should review documents used to justify the selection of these procedures and the frequency of their performance and then consider the following analytic questions:

1. Are the verification procedures in the HACCP plan adequately designed for the establishment to determine whether the HACCP system is functioning as intended?

2. What do records reveal about performance at the CCPs?

3. Have there been deviations from critical limits?

4. If there were several deviations from critical limits, was there a reassessment and a new critical limit established? If not, does the establishment have documentation to support this decision?

5. If there were any deviations from critical limits at the CCP, was the establishment effective in correcting the deviations?

6. What do the records show about the results of verification?

7. Is the HACCP plan designed to include product testing as a verification procedure?

a. If product testing is a verification procedure listed in the HACCP plan, is this testing program science-based?

b. Is the frequency and methodology of the testing supported in the science-based program? For example, is there a rationale for when product sampling is triggered based on the results of food contact surface or environmental testing for an indicator organism; a rationale for sample size; a rational for swab area size, along with a rationale for whether composite sampling on a daily or weekly basis is used; a rationale for product action based on indicator and pathogen testing results; or a rationale for hold-and-test provisions if a food contact surface is positive for an indicator organism or pathogen?

c. Is the testing procedure designed in a manner to detect the organism of concern?

VI. EIAOs Assessment of the Recordkeeping Requirements

A. The EIAO will assemble the establishment's HACCP records, as specified in 9 CFR 417.5(a)(3), that cover a defined recent period of time. The EIAO should also conduct an assessment of the scientific, regulatory, technical, or other supporting documentation. During the assessment of the records the EIAO will seek answers to the following types of questions:

1. Do the decisionmaking documents support the selection and development of the CCPs and critical limits?

2. Do the supporting documents support both the monitoring and verification procedures selected and the frequency of those procedures?

3. Do the decisionmaking documents support the decisions made in the hazard analysis?

4. Does the establishment have documents to support the disposition of affected products?

5. Do the documents support the decisions made during reassessment?

6. If scientific documents are used to support decisions made, has the establishment demonstrated applicability to their in-plant environment?

VII. EIAOs Assessment of the Corrective Action Requirements

A. EIAOs should select records from at least 60 days of activity to verify the establishment's corrective actions. EIAOs should focus the assessment on the design of the corrective actions. EIAOs will select a variety of types of critical limits, of corrective actions planned when a deviation occurs, and of recent records of critical limits, deviations from critical limits, and the corrective actions.

B. The EIAO should seek answers to the following type questions when verifying the corrective action requirement:

1. Were the corrective actions taken in response to a deviation from a critical limit designed to identify and eliminate the cause of the deviation or were the corrective actions taken in response to a deviation from a critical limit designed to lessen the rate of deviations from a critical limit?

2. Were the corrective actions taken in response to a deviation from a critical limit designed to ensure that the CCP is under control?

3. Were the corrective actions taken in response to a deviation from a critical limit

designed to ensure that no adulterated product enters commerce?

4. Were the corrective actions taken in response to an unforeseen hazard designed to prevent adulterated product from entering commerce?

5. Were all design aspects of the food safety system considered when the determination was made whether the unforeseen hazard should be incorporated into the HACCP plan?

VIII. EIAOs Assessment of the Reassessment Requirements

A. The EIAO should review a minimum of 60 days records to determine whether there were situations that occurred that should have triggered a reassessment of the hazard analysis or HACCP plan.

B. If reassessment has occurred, the EIAO should review the determinations the establishment made based on the reassessment and consider the following:

1. Did the establishment change its HACCP plan?

2. What was the basis for its decision?

3. Does it have decisionmaking documents to support making the change, or to support not making a change, as appropriate?

4. If a change was made, has the establishment validated the change?

5. Does it have supporting documents for the critical limit, the monitoring frequency?

6. For example, if the establishment produces raw beef products and conducted a reassessment considering the relevant scientific data, the EIAO should ask the following questions:

a. If the establishment is producing trimmings for ground beef and tests the trimmings for *E. coli* O157:H7, does the establishment conduct a reassessment when a positive result is received?

b. Does the establishment producing the trimmings have documentation (scientific, technical) to support the decisions made during the reassessment that the controls in place are adequate to control *E. coli* O157:H7?

c. Has the establishment validated the modified HACCP plan by repeatedly testing the adequacy of the CCP, critical limits, monitoring, verification, recordkeeping procedures, and corrective actions set forth in the HACCP plan?

d. If the HACCP plan was modified to include microbiological sampling as a verification activity on the effectiveness of interventions, is the sampling program statistically valid?

e. If the establishment did not modify its hazard analysis or HACCP plan as a result of the reassessment, does the establishment have documents to support this decision?

7. If the establishment receives raw beef for grinding and conducted a reassessment using the relevant scientific data, the EIAO should seek answers to the following type questions:

a. Does the receiving establishment have purchase specifications requiring all suppliers that determined *E. coli* O157:H7 to be a hazard reasonably likely to occur to have one or more CCPs that are validated to eliminate or to reduce *E. coli* O157:H7 below detectable levels, and that verify that these specifications are met?

b. If the establishment considered *E. coli* O157:H7 as a hazard likely to occur in the grinding process, are the CCPs designed to control the pathogen?

c. If the establishment decided that *E. coli* O157:H7 is not a hazard likely to occur because this pathogen is addressed in prerequisite programs, does the establishment maintain documents setting out the procedures of the prerequisite program and related records as part of the decisionmaking documents?

8. If the establishment is producing RTE products, the EIAO should review the control measures included in the HACCP plans, Sanitation SOPs, or prerequisite programs. The EIAO will review the written procedures, assess decisionmaking documents for completeness and rationale, and review laboratory results. The EIAO should seek answers to the following type questions:

a. Has the establishment designed a written science-based program as part of the HACCP plan, Sanitation SOPs, or prerequisite program?

b. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment have in place procedures to effectively address their presence?

c. If the establishment has testing procedures in place for indicator organisms or *L. monocytogenes*, does the establishment increase its monitoring or verification sampling when significant construction occurs*?*

d*.* If the establishment is using an anti-microbial agent in the product in the final packaging to prevent *L. monocytogenes* growth, does the establishment have data to validate that it is effective against *L. monocytogenes?*

e*.* If the establishment has a post-lethality treatment applied, does the establishment have data to validate it is effective against *L. monocytogenes?*

PART V -- Assessment of Establishment's Generic *E. coli* Process

A. The EIAOs should assemble and review the following information:

1. The results of verification procedures conducted by the CSIs.

2. The establishment's written generic *E. coli* procedures.

3. The establishment's justification for an alternative sampling frequency, if applicable.

4. Laboratory information or assurances about methodology.

5. Records of recent test results.

B. The EIAO may also verify elements of sampling procedures by observing establishment employees performing them, if practicable. The EIAO should analyze this information and determine whether there is compliance with 9 CFR 310.25(a) (1) – (4) or 381.94(a)(1) – (4).

The EIAOs should collect test data results covering at least 60 days.

C. The EIAO should review these data against the evaluation criteria, which may be m/M values or values established by statistical process control. If any of the criteria are not met, the EIAO is to conduct further data collection and analysis to determine whether the Agency needs to take other action to ensure that all applicable provisions of the law are met.

D. If the EIAO observes that the evaluation criteria are not met routinely, the testing records should be compared with records of fecal NRs or deviations from the zero tolerance critical limit for the same time period. If the Agency was sampling and testing for *Salmonella* during the 60-day period, the EIAO should seek those results. If by chance the establishment's product was sampled and tested for *E. coli* O157:H7 or implicated in a recall during the same 60-day period, the EIAO should seek those results as well.

E. The EIAO is to assess available data and make any descriptive associations that are apparent from the data. If the EIAO believes that an actual statistical analysis is needed, he or she should contact the District Office.

F. Whether the data sets show significant correlations or not, if there were NRs for fecal contamination or deviations from fecal critical limits, shortly before or during the 60-day period, the EIAO should seek the corrective action records for each such instance and verify that the corrective actions taken meet regulatory requirements.

G. The EIAO may want to discuss the generic *E. coli* testing results that do not meet the criteria with establishment officials, to see if they have any views about what might have caused those results, and about what they may have done to improve the situation.

PART VI – Communication and Exit Meeting

I. On-going Communication

During the assessment process, EIAO are to provide frequent updates to the DDM as well as remain in communication with the IIC and Front-line Supervisor. EIAOs are to inform the Deputy District Manager, Front-line Supervisor, and IIC of findings and any

recommendations being made. The Deputy District Manager may indicate a need for additional information, or may provide additional resources.

II. Exit Meeting

A. Before holding an exit meeting with the establishment, EIAOs may need to meet with the inspection program personnel, including the IIC and Front-line Supervisor. The EIAO is to discuss any design flaws or execution problems at this meeting.

B. the plant management should be present at the exit meeting. Although it is strongly encouraged that the IIC and the Front-line Supervisor also attend the exit conference, the exit conference should not be inordinately delayed to provide for their attendance.

C. The EIAO is to discuss the findings with the establishment and advise of establishment management of any enforcement action that the District Manager will be issuing. Generally, the EIAO is to provide a copy of any enforcement action during the exit conference, or no later than 24 hours following the end of the exit conference. He or she is to answer any questions the establishment may have.

D. The EIAO is to work with small and very small plants to meet the Agency's obligation related to the Small Business Regulatory Enforcement and Fairness Act (SBREFA). (See http://www.fsis.usda.gov/Regulations_&_Policies/Policies_on_Regulatory_Decisions/index.asp#contacts) Also, during the exit meeting, the EIAO should advise the establishment of where they can obtain information and assistance in making improvements to its food safety system and assuring regulatory compliance is met.

PART VII – Completing FSIS Form 5000-8, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems Report

A. EIAOs complete FSIS Form 5000-8 or 5000-8A (for *E. coli* O157:H7 reassessments). EIAOs can find these electronic forms in the Public Folders/All Public Folders/Agency Issuances/Forms/5000 Series. The EIAO can access these forms and save them to a disk, or can open and complete the Form and save the information as a file.

B. Apart from the data assessment completed before the plant visit, EIAOs are to only include the facts gathered during the plant visit, and they are to document these facts in a manner that will allow anyone reading the report to understand the observations that were made.

I. Completing the First Portion of FSIS Form 5000-8

The first portion of the Form should be completed with the appropriate information in the blocks provided (i.e., establishment number, dates of the establishment visit, name and address of establishment, name of EIAO, district, circuit visited, and reason for visit).

II. Completing the Second Portion of FSIS Form 5000-8

A. The second portion of the form should include the following:

1. A summary of the data assessment that was completed before visiting the establishment (e.g., the type of data analyzed and a brief summary of the analysis of the data).

2. A description of the food safety noncompliance records (NRs) issued to the plant in the last 6-9 months.

3. A listing of any enforcement actions taken against the establishment during the 6-9 months.

a. What food safety issues were involved in the enforcement action?

b. Were pathogens of public health significance involved?

c. What measures did the establishment implement to address the issues?

d. Were the establishment's measures effective?

4. A summary analysis of NRs.

a. Were NRs written in the last 6-9 months?

b. What noncompliances were identified?

c. Were there repetitive NRs for the same noncompliance?

d. Were the establishment's preventive measures adopted in response to the NRs effective?

e. What do the data from FSIS testing reveal?

f. Are there positive results or trends?

g. Are there relationships or other findings documented on NRs and positive test results?

h. How did the establishment respond to the positive results?

III. Completing the Recommendation Section of FSIS Form 5000-8

A. In the third portion of the Form, EIAOs provide findings and recommendations. EIAOs are to include:

1. Recommendation (Check all that apply)

a. No action needed

b. Reassessment letter

c. NRs written by in-plant inspection team

d. Notice of Intended Enforcement Action (NOIE) (9 CFR 500.4)

e. Withholding or suspension without an NOIE (9 CFR 500.3)

2. A recommendation is required whenever a report is complete, even if the facts do not support an enforcement action.

3. A brief summary of why recommendation was made.

IV. Completing the Narrative Section of FSIS Form 5000-8

The narrative section of the Form should include:

1. A summary of the entrance meeting

2. Findings of the comprehensive food safety assessment including the establishment's strategy in its hazard analysis to address pathogens.

9. An analysis of the scientific and technical issues related to regulatory noncompliances

10. An analysis of the public health issues

5. A description of any regulatory noncompliances

6. A summary of any discussions with the establishment regarding noncompliances observed during the assessment

7. An analysis of any statutory violations, including the type of adulteration at issue.

8. A description of the exit meeting, e.g., who attended and the issues that were discussed.

V. Distribution of FSIS Form 5000-8

After EIAOs complete the Form, they are to e-mail it to the DM and the Front-line Supervisor. The DM will file the report in a District Public Folder.

Part VIII – Documenting Recommendations

I. No further action

When EIAOs conduct a food safety assessment (FSA), they are responsible for documenting the facts as they exist in the establishment at the time of the assessment. When the FSA is completed, the EIAO has the responsibility to make a recommendation based on the documented facts. One recommendation might be that no further action is required. For that recommendation, the documentation in the FSA report needs to support that the establishment was complying with the regulatory requirements during the visit.

II. Reassesment Letter

During the FSA, the EIAO may find a situation where he or she needs additional information before determining whether a non-compliance exist (e.g., the establishment needs to clarify how it has supported a determination made in its hazard analysis). In such cases, the EIAO is to make the in-plant inspection team aware of the situation. The EIAO is to draft and issue the letter to the establishment. The letter is to request the necessary information that will assist the EIAO in determining whether there is non-compliance, typically regarding the design of the establishment program.

NOTE: Such letters can stand alone or accompany non-compliance records or an NOIE.

III. Recommending that inspection team issue non-compliance records

A. Another recommendation that the EIAO may make is for the in-plant inspection team to write noncompliance records. For example, an EIAO finds that the establishment has failed to identify a step in the flow chart as required by the regulations, but the situation does not pose an immediate health risk. In this instance, the EIAO is to document in the FSA the noncompliance in a manner that makes it clear what regulatory requirement the establishment has failed to meet, and that he or she requested the in-plant inspection team to issue an NR. The EIAO is to recommend the issuance of a NR only if the noncompliances will not be used to support the issuance of an NOIE. NOIEs can only reference previous NRs that relate to the cause for the NOIE. If an EIAO recommends the issuance of NRs, he or she should notify the Front-line Supervisor.

B. If an EIAO finds non-compliance and plans to use the non-compliances as support for an NOIE, he or she should only reference the noncompliances in the report and should not have the inspection team issue NRs. However, it may be necessary for the inspection team to take an appropriate regulatory control action. The EIAO is to explain in the FSA the need for regulatory control actions.

IV. Recommending that the District Office issue an NOIE

A. For an EIAO to recommend that the District Office issue an NOIE, he or she

needs to have support in his or her report that conditions in the establishment, or the actions of the establishment, meet the situations as set out in 9 CFR 500.4, and that such conditions may lead to the adulteration of product or the creation of insanitary conditions that could cause product to become adulterated.

B. To support such a finding, an EIAO is to compile information (e.g., referenced NRs, noncompliance findings during the assessment, documented trend of noncompliance) and analyze it with care and good judgment. An EIAO is to only include NRs related to cause for the issuance of the NOIE. An EIAO is not to reference non-related NRs in the NOIE.

C. In addition, when issuing the NOIE the EIAO is to use their findings to clearly set out and explain how the establishment's noncompliances led to the condition. The EIAO needs to base his or her determination to issue the NOIE on one of the provisions or a combination of the provisions from 9 CFR 500.4.

V. Withholding or suspension without an NOIE (9 CFR 500.3)

A. If the establishment is shipping or producing adulterated product, operating without a HACCP plan, treating animals in an egregious inhumane manner, or engaging in any other type of noncompliance that supports taking a withholding or suspension action without prior notification (9 CFR 500.3), the first obligation of FSIS is to stop the wrongful practice.

B. The EIAO is to work with the in-plant inspection team to take appropriate regulatory control action, notify establishment officials of the withholding or suspension without an NOIE, and document the basis for the action in the Notice of Suspension.

C. The EIAO is to correlate, as necessary, with the in-plant inspection team, the Front-line Supervsior, and the District Officer to document the facts of the situation.

D. Under these situations, the EIAO may complete the FSA later during the enforcement process.

Part IX – Verification Plans

I. Verification Plan Design

A. A verification plan (VP) is to be developed by the EIAO in conjunction with the in-plant inspection team when the District Manager decides to defer enforcement following the issuance of a NOIE or to hold a suspension in abeyance following the suspension of the assignment of inspection personnel. The VP provides a systematic means for inspection program personnel to verify that an establishment is effectively implementing the corrective measures that were proffered to FSIS. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO is to work with the in-plant inspection team, including the Frontline Supervisor, in the development of the VP.

B. The VP is to:

1. describe the verification activities that will be performed by inspection personnel based on the establishment's corrective measures.

2. list the inspection system procedure (ISP) codes associated with each verification activity that will be carried out by the inspection team.

3. list the regulatory provisions associated with each verification activity.

4. be developed so that the verification activities identified in the VP are performed by in-plant inspection program personnel as part of scheduled and unscheduled PBIS procedures.

C. The EIAO has primary responsibility for communicating and discussing the final verification plan to the IIC. The Front-line Supervisor, and appropriate district office personnel, should also participate in the discussion. If a new IIC is assigned to the facility at any time during the deferral or abeyance period (e.g., due to a scheduled rotation), the EIAO and Front-line Supervisor should ensure that the IIC understands how to implement the verification plan.

II. Verification of Establishment's Corrective Measures

A. On at least a bi-weekly basis, the in-plant team is to report via e-mail to the Front Line Supervisor, and the District Office, the results of the activities it has conducted under the VP.

B. The in-plant inspection team has the flexibility to increase the frequency of the verification activities based on its findings, and should notify the Front-line Supervisor if they do so. The in-plant team, through the Front-line Supervisor, may request that the EIAO conduct a follow-up visit to an establishment that has had an enforcement action deferred or is under a suspension action that is held in abeyance to determine the overall effectiveness of the establishment's corrective measures.

C. The EIAO is to revisit an establishment operating under a verification plan at 30, 60, and 90-day intervals as long as the verification plan is in place. The EIAO should assess the adequacy of the plant's corrective and preventive actions that resulted in the deferral or abeyance and should provide a recommendation to the District Office as to the appropriate next steps. Recommendations made by the EIAO could include continuing to hold the action in abeyance, close the action, or to initiate further enforcement in the event that the establishment's corrective and preventive actions are found not to be effective.

D. When the in-plant inspection team believes it appropriate that a deferral or abeyance action be closed, the in-plant team may request that an EIAO visit the establishment to review the effectiveness of the corrective and preventive measures implemented by the establishment. When such requests are made and throughout the course of the EIAO visit, the in-plant inspection team should continue with their daily verification responsibilities.

Assistant Administrator
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