# MSA DIRECTIVE	5100.1 Rev. ~~4~~	8/14/15

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

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions on how to document Food Safety Assessments (FSA). The work methodology is designed to focus the FSAs on public health risk and to increase consistency in how EIAOs conduct FSAs. For the purposes of this directive, the term "EIAO" refers to any EIAO trained Meat Safety Assurance or Policy Standards and Quality Assurance Meat Group staff member conducting FSA activities. The term "Central Office" (CO) includes the Policy Standard and Quality Assurance – Meat Group Manager (PSQA Manager) and the Consumer Safety Regulations Officer (CSRO).

II. CANCELLATION

MSA Directive 5100.1, Revision 1

CHAPTER II – FSA

I. FSA METHODOLOGY OVERVIEW

A. The purpose of an FSA is to assess and analyze an establishment's food safety system to verify that the establishment is able to produce safe and wholesome meat or poultry products in accordance with statutory and regulatory requirements.

B. The EIAO is to record findings and to determine whether:

1. The HACCP system is designed to prevent, reduce, or eliminate the hazards identified in the hazard analysis;

2. The establishment's decisions in its hazard analysis are appropriately supported, including by the establishment's validation documents; and

3. The establishment's sampling and testing programs are designed appropriately and performed under validated conditions, and that the establishment reacts appropriately to sampling results.

C. The EIAO is to reach a logical and supportable recommendation that no action is necessary, that the in-plant inspectors are to issue noncompliance records (NRs), that the CO is to issue a Notice of Intended Enforcement (NOIE) with or without NRs~~.~~ The EIAO is to document his or her findings in the final assessment (MSA 20).

D. The EIAO is to focus on documenting vulnerabilities and noncompliance. In particular, he or she is to summarize the findings that bear most directly on the recommendation that he or she is making

with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The EIAO is to use the decision-making analysis to provide an analysis of the background, applicable sample results, and the observations made throughout the FSA to support the recommendation. The EIAO is to provide a recommendation that is supported by statutory and regulatory requirements (e.g. the Acts and 9 CFR). The EIAO is to summarize the analysis in the Summary of reason(s) for recommendation (MSA 20).

E. The EIAO Process Overview and FSA workflow diagrams shown below in Figures 1 and 2 provide a visual depiction of the FSA process, including the performance of FSAs that are part of incidences. The EIAO is to follow the work method flow diagrams shown below as he or she navigates this directive.

Figure 1. EIAO Process Overview

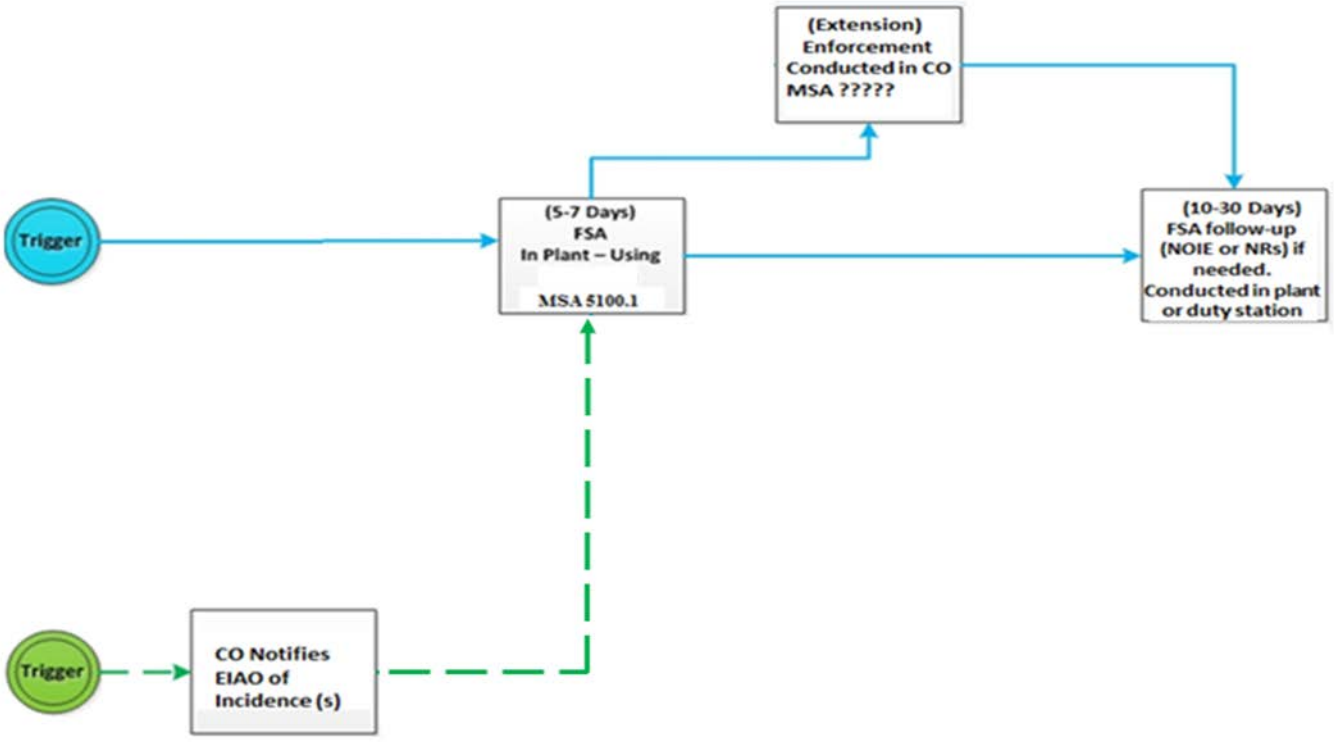
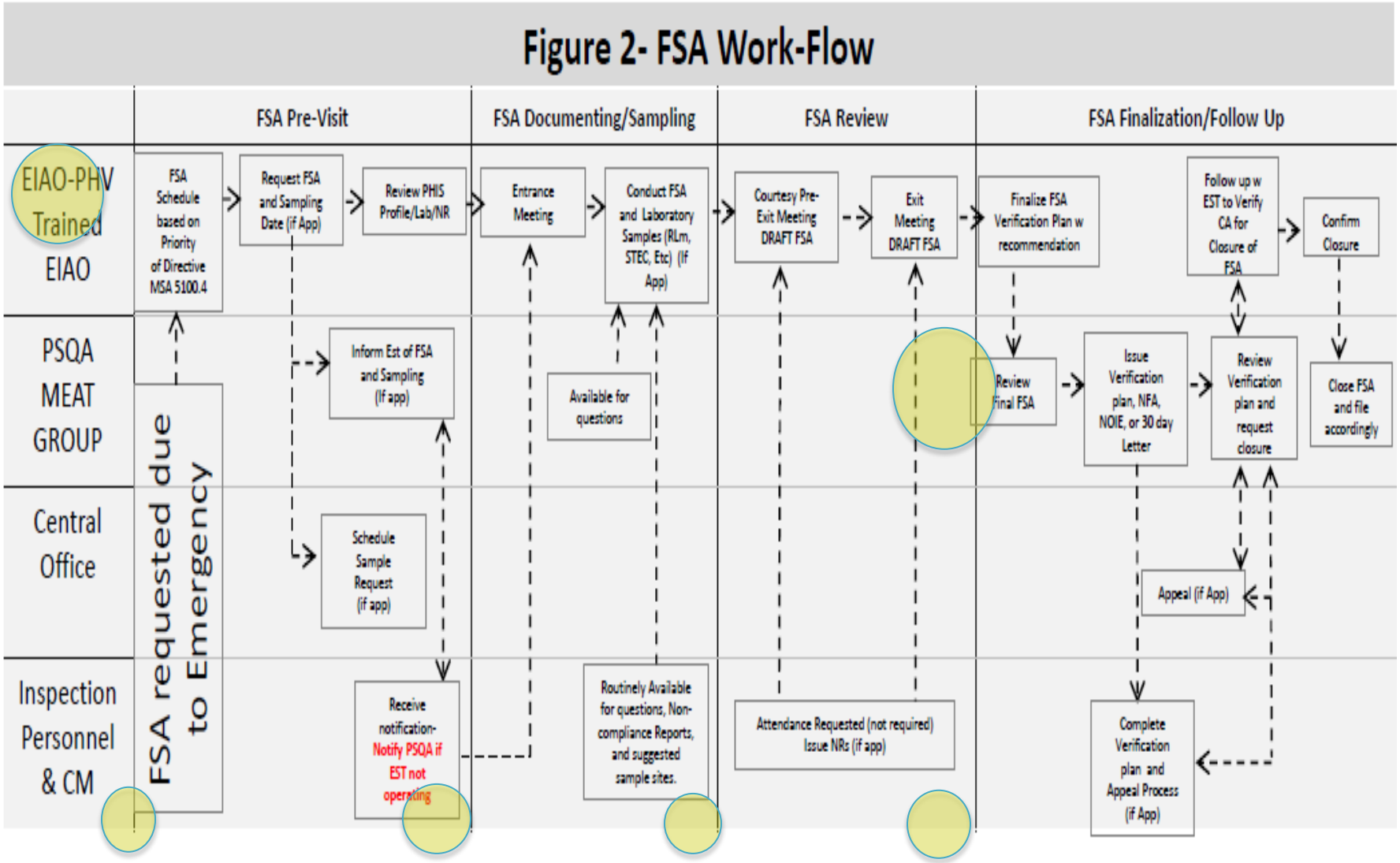


Figure 2. FSA Work-Flow



II. PREPARATION IN ADVANCE OF THE FSA

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

3. 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:

   - PHIS data
   - Enforcement data
   - Laboratory results

4. Review, if necessary, relevant policy issuances (Federal Register Notices, FSIS Directives and Notices, MSA Directives and 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.

C. As part of preparation for the FSA, the EIAO is to determine whether pathogen sampling RLm, Intensified Verification Sampling (IVT), or other sampling is to be performed.

1. If an FSA will include RLm the EIAO is to prioritize sampling before the start of the FSA. RLm sampling can span up to 3 days. The EIAO is to take into account the sampling results when determining the FSA outcome. In some limited circumstances (e.g., there are unanticipated sampling delays or presumptive positives), results may delay the completion of the FSA.

2. The EIAO is to arrive at the establishment the day (day 1) before sampling to perform the walk-through, meet with the establishment management, and stage his or her supplies for sampling. As stated in MSA Directive 10,240.5, the EIAO is able to collect some samples pre-operationally (pre-op) but collect most samples during operations. As is also stated in MSA Directive 10,240.5 sampling may be performed over two days (days 2 and 3) if the establishment takes two days to produce the sampled lot (e.g., slices the product and packages it the next).

3. In identifying sampling sites, the EIAO is to refer to the table of food contact surface sites that have previously tested positive during RLm or IVT sampling. The EIAO is to identify additional sampling sites when meeting with IIC and during the establishment tour.

4. The EIAO is to keep in mind that the sampling may occur before the start of the FSA. However, if he or she observes insanitary conditions or product adulteration at the establishment during the sampling, the EIAO is to immediately inform the IIC.

D. Provide the establishment with at least 1 week notice that RLm sampling will occur, and that an FSA will be performed the week after the RLm sampling.

E. The EIAO is to contact the Sampling Coordinator 2 weeks prior to sampling to schedule with the State Lab and to request the establishment's previous sampling results.

F. Before the EIAO starts the FSA, he or she is to:

1. Communicate with establishment management the types of documentation that need to be made available for review (e.g., last 60-90 production day records for the EIAO to randomly select 13, HACCP plan, sampling program, sampling results). Having the documentation available at the start of the FSA will help the EIAO to accomplish the in-plant portion;

2. Review the laboratory sampling results obtained from the Sampling Coordinator

3. Review available Public Health Information System (PHIS) data to identify the sampling programs being generated by PHIS at the establishment.

CHAPTER III - ESTABLISHMENT ARRIVAL, ENTRANCE MEETING, and ON-GOING COMMUNICATION

I. ACTIVITIES AN EIAO PERFORMS UPON ARRIVAL AT THE ESTABLISHMENT AND DURING THE ENTRANCE MEETING

A. The EIAO is to conduct an entrance meeting that is to be attended by the IIC, establishment management, and the if possible the CM or designee. During the entrance meeting, the EIAO is to explain the reason for the FSA and answer questions about the overall process. The topics that the EIAO are to discuss during the entrance meeting include but are not limited to:

1. What an FSA is, how the scope was determined, and how it differs from the day-to-day verification activities that are performed by IIC;

2. The EIAO's intended typical work schedule during the assessment;

3. That the EIAO may make observations during all shifts and during pre-operational activities;

4. How the EIAO will access the production floor. The EIAO is to inquire whether the establishment has in place any special procedures;

5. Where the EIAO will conduct her or his work. The EIAO is to ask where the establishment stores its records and ask that he or she be given access to examine and copy or scan any records that may be needed to support noncompliance determinations made during the course of the review;

6. That the EIAO will communicate with the in-plant inspection team and establishment management ~~about findings~~ as the assessment progresses;

7. Whom the EIAO is to contact with questions. The plant designates various people for different processes and should identify either a telephone extension, an e-mail address, or some other way to communicate with management personnel to get assistance;

8. When to confer with establishment management in order to meet all intended parties' needs;

9. The possible FSA outcomes;

10. At the conclusion of the FSA, an exit conference will be held with establishment management to discuss in-plant portion of the FSA;

11. The EIAO's contact information so that the establishment may can contact him or her, if necessary.

B. The EIAO is to use the verification plan (MSA 20) to document the entrance conference. The EIAO is to include the date and participants in the documentation of the conference. The EIAO is not to document discussion of the meeting.

II. COMMUNICATING WITH INTERESTED PARTIES DURING AN FSA

A. The EIAO is to communicate with the establishment throughout the course of the assessment and to inform establishment management about any findings of regulatory noncompliance as soon after finding them as possible. The EIAO is to describe to establishment management, in clear terms, the noncompliance and the vulnerabilities that he or she identifies as the assessment progresses. During the course of the assessment, the EIAO is not to predict possible outcomes of the FSA.

B. An establishment's attempt to bring itself into compliance upon being notified of a noncompliance finding during the FSA does not negate the noncompliance finding. The EIAO is to document descriptions of noncompliance in the FSA. IIC is to document noncompliance in NRs. If the EIAO recommends an enforcement action, the EIAO is to document relevant noncompliances in the NOIE.

C. The EIAO is to discuss his or her findings and recommendations with the CO to ensure that all scientific, technical, and policy issues in the EIAO's report have been resolved.

D. The EIAO is to communicate with the IIC and CM throughout the course of the assessment and to describe any noncompliances or vulnerabilities that he or she has identified.

1. The EIAO, the IIC, and the CM are to work collaboratively to ensure that all noncompliances are communicated to establishment management and documented for issuance either during the exit meeting or immediately following. The EIAO is to notify the CM and IIC immediately when a noncompliance that has an immediate

impact on food safety is observed. Noncompliance such as design, support, or recordkeeping issues should be presented at the exit meeting.

2. During the assessment process, the EIAO is to provide frequent updates to the IIC and CM to inform them of the EIAO's findings and of any recommendations that the EIAO is planning to make.

3. The CO may request additional information from the EIAO or may provide additional resources as a result of this communication process.

III. IMPORTANCE OF PROPER COMMUNICATION

A. The EIAO is to carry out his or her duties in a fair, firm, professional, and courteous manner; treat in-plant and establishment personnel with respect; and keep them informed as to his or her actions by maintaining open lines of communication.

B. The EIAO is to request information, not demand it, and to be able to explain to establishment officials MSA's statutory authority under the Texas Adjutant Code (TAC) to examine facilities and to copy records. In the event that the EIAO encounters uncooperativeness or unwillingness of establishment officials to provide information, the EIAO is to communicate with the CO to develop a strategy for gaining access to necessary information.

CHAPTER IV – OVERVIEW OF PERFORMING THE FSA

I. TIME TO COMPLETE FSAs

A. The EIAO is to complete the in-plant portion of the FSA within 5 - 7 production days. "Production days" are the days the establishment is producing the product relevant to the FSA. The FSA may be extended if additional time is necessary to develop the recommendation for an enforcement action (NOIE or suspension).

B. The EIAO is to be present at the establishment making observations throughout the FSA.

C. Once the in-plant portion of an FSA begins, the EIAO is to continue the FSA, except in extenuating circumstances as directed by the CO.

II. GENERAL METHODOLOGY TO USE WHEN CONDUCTING THE FSA

A. The EIAO is to evaluate the HACCP system as a whole. The HACCP system includes the hazard analysis, any supporting documentation including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records. Therefore, the EIAO is to consider all supporting documentation that affects decisions in the hazard analysis when developing a recommendation.

B. The EIAO is to focus on assessing and analyzing the establishment's food safety system as a whole and is not to only verify whether individual regulatory requirements are in compliance. The EIAO is to focus on the vulnerabilities or noncompliances that affect

the food safety system and the establishment's ability to produce safe and wholesome meat or poultry products in accordance with statutory and regulatory requirements.

C. In general, the EIAO is to conduct the assessment by:

1. Direct observation of establishment implementation as described in Chapter V of this directive. At a minimum, the EIAO is to observe the establishment carrying out its HACCP verification procedures, Sanitation standard operating procedures (Sanitation SOPs), and sampling if available if not review records; and

2. Reviewing a random selection of 13 days of records and documentation specific to the HACCP plan targeted (see Chapter V).

D. The EIAO is to use this directive along with the directives and compliance guidelines referenced in Chapter V and any other relevant documents to evaluate the establishment's HACCP system. The EIAO is to be aware that guidance represents best practice recommendations by FSIS/MSA and does not represent requirements that must be met. Establishments may choose to adopt different procedures than those outlined in a guideline, but they would need to support why those procedures are effective.

CHAPTER V - SPECIFIC ACTIVITIES AN EIAO IS TO PERFORM DURING THE FSA

I. INITIAL STEPS

A. The EIAO is to take a tour of the establishment on the first day of the FSA to understand the establishment's process and flow and to strategize for future observations. See Section V of this chapter regarding the types of observations the EIAO is to make during the course of the FSA. As stated above, in an establishment where RLm sampling is performed, the EIAO is to perform the establishment tour before RLm samples are collected.

B. To best use his or her time during the establishment tour and the FSA, the EIAO is to:

1. Prepare for the establishment tour by reviewing the flow chart and HACCP plan immediately on the first day. After review of the flow chart and HACCP plan, the EIAO can formulate a plan to observe critical control points (CCPs), pathogen intervention applications, and possibly sampling;

2. Ask questions of the establishment during the tour in order to ensure he or she has a basic understanding of the establishment's process and flow; and

3. Identify the parts of the establishment where raw and RTE products are produced if performing a FSA at a RTE establishment, as well as how raw and RTE areas are separated (e.g., by time, space, or separation as well as through other means such as different colored uniforms).

C. The EIAO is to start his or her review of the HACCP system, using his or her scientific knowledge, knowledge of Agency issuances, and professional expertise, by verifying the

hazard analysis. The EIAO is to assess whether the establishment has addressed hazards commonly associated with a process (9 CFR 417.5(a)(2)), and whether it can adequately support the decisions it made regarding those hazards (9 CFR 417.5(a)(1)). If there are technical questions about the supporting documentation, the EIAO shall submit questions to the CO as soon as possible to allow time for the CO to research and formulate the response.

D. For each hazard that the establishment has determined is reasonably likely to occur, the EIAO is to verify that the HACCP plan includes one or more CCPs to control it, and that the establishment has adequate documentation to support the design of the CCPs, critical limits, and monitoring and verification procedures as required by 9 CFR 417.5(a)(2).

E. The EIAO is to gather information carefully on prerequisite programs used to support decisions in the establishment's hazard analysis (e.g., to support that potential hazards are not reasonably likely to occur because they are prevented by a prerequisite program) and is to assess whether the prerequisite programs support decisions made in the hazard analysis, and to determine whether there is compliance with 9 CFR 417.5(a)(1) and 9 CFR 417.2(a).

NOTE: Establishments may have unique names for various prerequisite programs without incorporating "prerequisite" in the title. Temperature control programs, allergen control programs, *Listeria* sanitation control programs, and purchase specification programs are some examples.

II. PREREQUISITE PROGRAMS

A. The EIAO is to focus on prerequisite programs designed to support a decision in the hazard analysis because these programs are considered to be part of the HACCP system. Examples of prerequisite programs that may be used to support decisions in the hazard analysis include the Sanitation SOP, written sanitary dressing procedures incorporated into prerequisite programs, and programs related to purchase specifications and antimicrobial interventions. Prerequisite programs provide a foundation for the HACCP plan to operate effectively. In order for the establishment to support its decision that a hazard is not reasonably likely to occur on an ongoing basis it needs to ensure the prerequisite programs are designed and implemented effectively.

B. To verify whether prerequisite programs designed to support a decision in the hazard analysis are designed and implemented effectively, the EIAO is to review the features of the prerequisite program and is to evaluate whether the program meets the following characteristics:

1. The program is written and describes procedures (including the critical operational parameters) that the establishment will implement to show that the hazard is not reasonably likely to occur;

2. The program is designed to prevent the hazard from being likely to occur, and the establishment maintains supporting documentation that the program has been validated (i.e., scientific or technical support and in-plant validation data). See Section VII. of this chapter for a discussion of how to review establishment validation;

3. The establishment maintains records that demonstrate that the program is being implemented as written (i.e., monitoring of the critical operational parameters);

4. The establishment maintains records to demonstrate the program effectively prevents the hazard (i.e., on-going verification of the decision that the hazard is not reasonably likely to occur);

5. The program describes actions that the establishment will take when it fails to implement the program, or when it finds that the program has failed to prevent the hazard (i.e., corrective actions in response to an unforeseen hazard per 9 CFR 417.3(b)); and

6. The EIAO may determine that a prerequisite program is effective at preventing the hazard when the program is not written, provided that the program meets the other characteristics described above. When the other characteristics are not met (e.g., monitoring of the critical operational parameters is not performed), the EIAO may determine that the prerequisite program is ineffective resulting in a hazard being reasonably likely to occur because the hazard is not accounted for in the hazard analysis. Since the prerequisite program is ineffective and not preventing the hazard, there is noncompliance with 9 CFR 417.5(a)(1) and 417.2(a). The establishment would need to reassess its hazard analysis, 9 CFR 417.4, to determine whether any modifications to the hazard analysis are necessary and make those changes to address the hazard. In addition, the HACCP system may be inadequate, 9 CFR 417.6, and result in the EIAO recommending an NOIE be issued by the CO.

III. SANITATION SOPs

The Sanitation SOP is required by regulation (9 CFR 416.12). The EIAO is to analyze and document how problems in complying with Sanitation SOP requirements affect the establishment's ability to support decisions in its hazard analysis or to implement its HACCP plan effectively. The EIAO is to document his or her findings of Sanitation SOP compliance.

IV. REVIEW SAMPLING PROGRAM DESIGN AND RESULT RECORDS

A. If sampling and testing are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), the EIAO is to evaluate the design of the establishment's written sampling procedures and the testing methods used. If the establishment conducts sampling during the course of the FSA, the EIAO is to observe the establishment collecting samples according to its supporting documentation and document any noncompliance.

B. In addition to reviewing the design of the establishment's written procedures and the methods used, the EIAO is to:

1. Review results of the program and analyze the results to identify trends and determine whether the process is in control. The EIAO is to review establishment sampling results from the previous 60-90 days in establishments

2. Review corrective actions taken in response to positive sample results (including re-assessment when required) and evaluate whether the corrective actions were effective and meaningful; and

C. The EIAO is to reference relevant Directives that address verification of establishment sampling and testing including:

1. MSA Directive 10,010.3, *Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim*;

2. MSA Directive 10,240.4, *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program;* and

3. MSA Directive 5000.2, *Review of Establishment Data by Inspection Personnel*.

a. The EIAO is to also reference relevant compliance guidelines that address recommendations for establishment sampling and testing including:

i. *Guidance for the Selection of a Commercial or Private Microbiological Testing Laboratory*;

ii. *FSIS Compliance Guideline: Controlling Listeria monocytogenes in post-lethality exposed Ready-to-eat Meat and Poultry Products;*

iii. *FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry*; and

iv. *FSIS Compliance Guideline for Controlling Salmonella in Market Hogs*.

b. If, after reviewing these documents, the EIAO still has a question regarding the sampling program, he or she is to submit a question through to the CO.

V. DIRECT OBSERVATIONS OF ESTABLISHMENT ACTIVITIES

A. The EIAO is to make observations of the establishment's activities across all shifts. Observations provide valuable information to help the EIAO determine whether the establishment is able to produce safe and wholesome meat or poultry products in accordance with MSA statutory and regulatory requirements. The EIAO is to make the following direct observations:

1. The EIAO's primary role is to verify whether the design and implementation of the establishment's Sanitation SOP is adequate. The purpose of observing implementation is to verify that the establishment conducts the procedures in the Sanitation SOP as written, and that the Sanitation SOP is designed effectively to prevent contamination of food contact surfaces or adulteration of products prior to operations. The EIAO is to spend a limited amount of time observing pre-operational sanitation activities, as inspectors routinely verify that the establishment meets all Sanitation SOP regulatory requirements (monitoring, recordkeeping, maintenance, corrective action). The EIAO is to focus his or her observations to evaluate whether the establishment's pre-operational procedures adequately prevent cross-contamination and the development of insanitary conditions.

2. The EIAO is not to observe IIC perform pre-operational sanitation SOP verification. The EIAO is to observe establishment pre-operational sanitation activities.

3. The EIAO is to observe the establishment's implementation of food safety measures (e.g., CCPs, prerequisite programs, or other programs) that support decisions in the hazard analysis including antimicrobial interventions, lethality treatments, stabilization treatments, and post-lethality treatment/anti-microbial agent or process.

4. During FSAs performed at slaughter establishments, the EIAO is to make direct observations of the slaughter process and sanitary dressing over multiple days, across all shifts, with a focus on the establishment's sanitary dressing procedures and its ability to maintain process control. The EIAO is to assess the sanitary dressing and process controls slaughter establishments employ in its food safety systems, considering the factors and questions presented in MSA Directive 6410.3, *Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Poultry Slaughter Operations,* and MSA Directive 6410.1, *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age.*

5. The EIAO is to make direct observations if establishment is sampling (e.g., Lm sampling for RTE establishments under Alternative 2b and 3, STEC sampling for establishments producing raw non-intact products and components of raw non-intact products, and sampling at poultry slaughter establishments in accordance with the requirements in 9 CFR 381.65(g)) to ensure the establishment is following the procedures in its written program. The EIAO is to also make direct observations of the establishment's in-house laboratory, if applicable.

VI. RECORDS REVIEW

A. During the course of the FSA the EIAO is to review HACCP system components, including intended use, flow chart, hazard analysis, HACCP plan, supporting documentation, prerequisite programs, decision making documents, and ongoing verification records. The EIAO is to prioritize records directly relevant to sanitary dressing, prerequisite programs, establishment interventions, lethality and stabilization procedures, establishment sampling results, effectiveness of corrective actions, and other records necessary to answer questions in the FSA tools and to evaluate whether the establishment is maintaining an adequate food safety system.

B. The EIAO is to randomly select 13 production days from the preceding 60 days and to review data from those 13 days. The EIAO is not to review each day's records from the preceding 60 days. This limited review will provide the EIAO with knowledge of how the HACCP system design is implemented, and whether it is designed effectively to meet regulatory requirements, while allowing the EIAO to manage time.

C. If an establishment has operated for less than 13 days in the preceding 60 days, the EIAO is to review data that goes back further than 60 days, until he or she has reviewed 13 days of data.

D. The EIAO is to assess the design of the record-keeping system, and whether the establishment implements it to meet HACCP record-keeping requirements. When

assessing the design of the record-keeping system, the EIAO is to evaluate whether the results of the monitoring and on-going verification procedures are recorded appropriately to reflect the implementation of the establishment's HACCP system.

NOTE: The EIAO is not to focus on compliance with basic recordkeeping requirements (e.g., signature and dating requirements in 9 CFR 417.2(d)). IIC verify the compliance of individual records to such requirements. If there is a systemic problem with basic recordkeeping requirements, the EIAO is to notify the CM.

E. The EIAO is also to review the records to determine whether there were any deviations from the establishment's critical limits that were not detected by the establishment monitoring procedure or by IIC verification activities.

F. The EIAO may review more than 13 days of records if the results of his or her record review indicate a larger food safety concern (e.g., numerous deviations are identified that were not identified by the establishment or IIC).

VII. REVIEW OF ESTABLISHMENT VALIDATION DOCUMENTS INCLUDING SCIENTIFIC SUPPORT AND IN-PLANT VALIDATION DATA

A. The EIAO is to review the two types of supporting documentation required under 9 CFR 417.4(a)(1) to determine whether the HACCP system is validated: the scientific or technical support for the HACCP system design (design) and the in-plant validation data (execution). However, establishments have until January 4, 2016 (large establishments) or April 4, 2016 (small and very small establishments) to gather the in-plant validation data.

B. The EIAO is to evaluate whether the establishment has adequate scientific support for the design of its HACCP system (e.g., CCP, prerequisite program, or other program design), and whether the in-plant validation data demonstrates that it can implement its system as designed.

C. If the EIAO determines the establishment has inadequate support, he or she is to document noncompliance. Until January 4, 2016 (large establishments) or April 4, 2016 (small and very small establishments), if the EIAO finds the in-plant validation data inadequate, the EIAO is to note this fact in the FSA but is not to use the lack of in-plant validation data as the only reason for a finding of noncompliance or an enforcement action.

D. The EIAO is to review the *HACCP Systems Validation Guidance* that includes recommendations for meeting the validation requirements.

E. To determine whether the establishment maintains adequate scientific support for the design of its CCP, prerequisite program, or other program, the EIAO is to evaluate whether:

1. The establishment maintains the scientific and technical support for the design of its HACCP system on-file;

2. The scientific support is complete and contains the methodology and results;

3. The methodology is appropriate for the purpose;

4. The results demonstrate that the establishment's process prevents, reduces, or eliminates the hazard to acceptable levels;

5. The scientific and technical support closely relates to the establishment's actual process, product, and hazard identified in the hazard analysis. If it does not closely relate, the EIAO is to evaluate whether the establishment has support or justification (science-based rationale) for why the scientific support should still apply to its process; and

6. The establishment incorporates the same critical operating parameters for the process control measure or intervention described in the scientific and technical support into its CCPs, prerequisite programs, and other programs. If it does not, the EIAO is to evaluate whether the establishment provides additional support or justification (science-based rationale) for the adequacy of the process control measures or interventions that *do not* incorporate the same parameters in the scientific or technical references (e.g., higher concentrations of antimicrobials or higher thermal processing temperatures).

F. To determine whether the establishment maintains adequate in-plant validation data demonstrating that it can implement its CCP, prerequisite program, or other programs, the EIAO is to evaluate whether:

1. The establishment collected in-plant validation data for at least one product from each HACCP processing category;

2. The in-plant validation data consists of data demonstrating that the critical operational parameters of the process are being met. The EIAO is to evaluate whether the in-plant validation data also consists of microbiological data when the establishment does not have adequate scientific or technical support, or when it is not following the parameters in the scientific or technical support. If the establishment has adequate scientific or technical support and is following the parameters in the scientific or technical support, then in-plant microbiological data is not needed to comply with the initial validation requirements;

3. The establishment collected in-plant validation data from 90 calendar days. For large establishments, 90 calendar days equates to approximately 60 production days. For small and very small establishments, 90 calendar days equates to a minimum level of records from 13 production days;

4. The data reflects the process as currently designed, or that changes have been made over time; and

5. The establishment analyzed the in-plant validation data (e.g., reviewed records) during the initial validation period to determine whether it supports that the system can be implemented as designed.

CHAPTER VI – Completing MSA Form 20, Comprehensive Assessment of the Execution and Design of an Establishment's Food Safety Systems Report

A. EIAOs complete MSA Form 20. (Verification Plan, 30-Day Letter, NOIE Letter)

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 Tab of MSA Form 20:

A. The first tab (Assessment) should be completed with the appropriate information in the blocks provided (i.e., establishment number, circuit, circuit manager, IIC, name and address of the establishment, entrance meeting attendants, reason for visit, summary of data assessed prior to visit, and establishment HACCP plans).

B. EIAO provide findings and recommendations. EIAO recommendations are to include:

1. Recommendation:

    a. No further action;

    b. Thirty (30)-day letter;

    c. Notice of Intended Enforcement (NOIE);

    d. Withholding/Suspension;

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.

II. Completing the Second Tab of MSA Form 20:

A. The second tab (Verification Plan) should be completed with the appropriate information in the blocks provided (i.e., establishment number, circuit, CM, IIC, Assessment dates, name and address of the establishment, entrance meeting attendance information.

B. The narrative section of the Verification Plan should include:

1. A summary of the entrance meeting;

2. Findings of the comprehensive food safety assessment, including regulatory citations and appropriate PHIS task;

3. A description of the exit meeting (i.e., who attended and the issues that were discussed).

III. Completing the Third Tab of MSA Form 20:

The third tab (Letter) should be completed with the appropriate information outlining the design and regulatory issues identified during the FSA. The narrative should include the regulatory citations, as well as, the documentation of the agency's position.

IV: Distribution of MSA Form 20

After EIAOs complete the Form, they are to e-mail it to CO. The CO sends the completed report via e-mail to the CM & IIC. CO sends the completed report via certified mail to the establishment.

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. Recommending issuance of a thirty-day letter

Another recommendation that the EIAOs may make is for the CO to issue a thirty-day letter identifying noncompliance with regulatory requirements that may not lead to the adulteration of product or the creation of insanitary conditions that could cause product to become adulterated. 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. The EIAO is to discuss with the IIC and Circuit Manager that these findings are noncompliances that should be documented on a noncompliance record (NR).

III. Recommending issuance of a NOIE

A. For a EIAO to recommend that the CO 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 provisions described in 9 CFR 416 through 417, 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. In addition, when recommending 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 described in 9 CFR 416 through 417.

Part IX – Verification Plans

I. Verification Plan Design

A. A verification plan (VP) is to be developed by the EIAO anytime a recommendation other than "no further action" is made, including when the CO 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 the CO. The EIAO has the primary responsibility for preparing the written verification plan. However, the EIAO may correlate with the IIC, CM, State Establishment Coordinator (SEC), and other MSA/PSQA Central Office staff 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 PHIS task 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 PHIS procedures.

C. The EIAO prepares the final report and has primary responsibility for communicating the final verification plan to the IIC and CM. Any follow-up discussion of the verification plan should be accomplished in conjunction with the EIAO, CO, IIC, CM, and the SEC. 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 CM should ensure that the IIC understands how to implement the verification plan.

II. Verification of Establishment's Corrective Measures

A. On at least a weekly basis, the IIC is to report via e-mail to the CM, with a "Cc" to the SEC, the results of the activities (s)he has conducted under the VP. The corrective action that the establishment has implemented for each finding shall be documented on the VP by the IIC.

B. The IIC has the flexibility to increase the frequency of the verification activities based on her/his findings, and should notify the CM if they do so. The IIC, through the CM, through the SEC, through the PSQA-Meat Group Manager, 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. When the IIC completes the VP, or when the applicable time frame described in the letter to the establishment that is prepared with the final report expires (i.e. thirty days for a thirty-day letter), the IIC shall email the completed VP to the CM, with a "Cc" to the SEC, for review. The CM is to arrange a time with the IIC to verify implementation of the documented corrective actions through an on-site assessment at the establishment. If the CM concurs with the IIC that the establishment has implemented all corrective actions as documented in the VP by the IIC, the CM is to request the VP be closed and forward the completed VP to the EIAO for review. The EIAO shall review the completed VP for accuracy and content. The EIAO shall forward the reviewed, completed VP to the CSRO. The CSRO will submit the completed, closed verification plan into the appropriate EIAO tracking database. If possible, and with permission of the PSQA-Meat Group Manager, the EIAO is to revisit an establishment when the completed, closed verification plan is received. The EIAO should assess the adequacy of the plant's corrective and preventive actions and should provide a report to the CSRO, with a "Cc" to the IIC and CM, as to the appropriateness and adequacy of the corrective actions implemented by the establishment and documented by the IIC. Recommendations made by the EIAO may include continuing to hold the action in abeyance, closing the action, or initiating further enforcement in the event that the establishment's corrective and preventive actions are found not to be effective.

CHAPTER VII - EXIT CONFERENCE

I. SCHEDULING AND CONDUCTING THE EXIT CONFERENCE

A. The EIAO is to schedule the exit conference with establishment management on the last production day of the FSA. The EIAO is to document the date he or she held the exit conference and the attendees in the FSA report.

NOTE: At the request of the CM, a pre-exit conference between IIC, the CM or their designee may be conducted and is strongly encouraged. However, the pre-exit meeting shall not delay the establishment's FSA exit meeting in any way.

B. When the EIAO conducts the exit conference with establishment management, the EIAO is to:

1. Thank the establishment for its cooperation;

2. Describe the FSA findings to the establishment, including any recommendations that the EIAO has made to the CO;

3. Describe the basis for all NRs being issued at the exit conference as well as any enforcement recommendations that the EIAO has made to the CO. If there is an enforcement action, the NOIE or NOS are to be given to the establishment at the exit conference;

4. Provide a draft or final copy of the FSA to the establishment management. If a draft is provided during the exit meeting, a final copy of the FSA is to be sent once the exit meeting information has been added; and

5. Answer any questions from the establishment.

II. QUESTIONS

Refer questions regarding this directive to the MSA Central Office or by telephone at 512-834-6760.

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