TEXAS DEPARTMENT OF STATE HEALTH SERVICES
MEAT SAFETY ASSURANCE UNIT
AUSTIN, TEXAS

MSA DIRECTIVE	5100.12	9/22/2020

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

CHAPTER I – GENERAL

I. PURPOSE

This directive provides instructions on how to score Food Safety Assessments (FSA) based on findings. The scoring methodology is designed to focus the FSAs on public health risk and to increase consistency in administrative and enforcement actions related to FSAs. For the purposes of this directive, the term "EIAO" refers to any EIAO trained Meat Safety Assurance (MSA) staff member conducting FSA activities. The term "Central Office" (CO) includes the State Establishment Coordinator (SEC) and Assistant State Director.

II. CANCELLATION

NA

CHAPTER II – FSA SCORING

I. FSA SCORING OVERVIEW

A. The purpose of a 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, which should include 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 document his or her findings in the final assessment (MSA 20).

D. The EIAO is to focus on documenting vulnerabilities and noncompliance. In particular, the EIAO is to summarize the findings that bear most directly on the recommended action, if any, regarding the establishment's HACCP system. The EIAO is to use the decision-making analysis to evaluate 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).

E. The EIAO is to reach a logical and supportable recommendation based on the findings for one of the following letters; No Further Action (NFA), a Letter of Concern (LOC), Warning Letter (LOW), or Notice of Intended Enforcement (NOIE).

F. The EIAO must rely on their education, training and professional judgment when scoring findings. Careful consideration must be given to the severity of the finding and the public health implications that the finding has on the overall safety of the product.

G. Findings that are essentially the same, but apply to several different HACCP plans, will be scored collectively as one unique finding. However, findings that arise from different root causes will be scored separately, even if they are listed under the same paragraph of the CFR. For example (9 CFR 417.5(a)(1):

1. The establishment does not adequately support the decisions made regarding specified risk materials as not reasonably likely to occur (NRLTO) in the hazard analysis (HA) as written, and
2. The decision-making documentation states that letters from suppliers are updated annually. However, some of the supplier letters are more than a year old. The establishment does not adequately support decisions made in the HA as it is not demonstrating ongoing implementation of the prerequisite program as written and described.

These two findings should be recorded on the CAR as separate findings.

H. All findings identified during the FSA will be included in the report. However, if an establishment provides evidence of effective corrective action to a finding before the exit meeting, this finding will not be counted in the final scoring determination for the number of findings.

II. FSA SCORING DEFINITIONS AND EXAMPLES

A. **Finding**: Regulatory non-compliance that does not meet the criteria of a Major or a Critical finding.

1. Examples:
    - SPS issues without direct impact on food contact surfaces or exposed product;
    - Access for rodents or limited evidence of rodents or pests;
    - Thermometer calibration does not specifically comply with the supporting document;
    - The establishment failed to identify a step in the flow chart as required by the regulations, but the situation does not pose an immediate food safety risk;
    - Decision making documentation is inadequate or does not support decisions made in the HACCP plan (could be elevated to a higher level finding if CCPs are significantly affected);
    - The cumulative effect of multiple Findings may indicate an out-of-control process, which constitutes a Major Finding for every 5 Findings due to the increased risk of impact on food safety.
        - 5 Findings = 1 Major
        - 10 Findings = 2 Majors
        - 15 Findings = 3 Majors and so on.
2. An establishment that has 4 or less Findings and no Major or Critical Findings will receive a No Further Action from the EIAO. The Circuit Manager will verify acceptable corrective actions for the Findings.

B. **Major Finding**: Regulatory noncompliance that does not currently result in adulterated product but indicates lack of verifiable control of a prerequisite program, good manufacturing practice, or supporting part of the food safety system.

1. Examples:
    - Loss of control or inadequate prerequisite programs;
    - Inadequate evidence that food contact surfaces are sanitized

and maintained appropriately (SSOP is inadequate);

- Widespread evidence of rodents (pests) but no evidence of product involvement;
- Recurrence of NRs, trends, or long-standing findings that have not been corrected, indicating system failure;
- Recurrence of associated (linked) findings where the establishment has not implemented appropriate corrective actions to prevent recurrence;
- Listeria testing program does not include all food-contact surfaces on testing plan or is not performed at an appropriate frequency;
- Letter of Concern not addressed appropriately or in accordance with timelines;

2. An establishment that has 5 or more Findings, 2 or less Major Findings and no Critical Findings will receive a LOC.
3. An establishment that has 3 or more Major Findings and/or 1 or more Critical Findings will receive a LOW or a NOIE.

C. **Critical finding**: regulatory non-compliance that has caused or is likely to cause product to become adulterated or unsafe. Requires immediate correction or cessation of operation to prevent injury.

1. Examples:
    - Product is produced or stored in a manner that will likely result in adulteration;
    - Loss of verifiable control of a critical control point;
    - Extensive failures to appropriately monitor and record a Critical Limit
    - Establishment failed to meet a Critical Limit and did not implement appropriate corrective action(s), allowing likely adulterated product to enter commerce;
    - Establishment recorded a Critical Limit but did not recognize the deviation or take appropriate corrective action;
    - Inadequate records or evidence to monitor and verify proper mixing of organic acid;
    - Long-standing or extensive evidence (infestation) of pests or rodents with likely adulteration of product where the establishment did not implement appropriate corrective action(s) (e.g., an inspector finds gnawed packages that the establishment did not identify and segregate);

2. An establishment that has 3 or more Major Findings and/or 1 or more Critical Findings will receive a LOW or a NOIE.

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

A. The EIAO will complete MSA Form 20. (Verification Plan, Letter of Concern, Letter of Warning, NOIE Letter, etc.)

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. The EIAO will provide findings and recommendations. EIAO recommendations are to include:

1. Recommendation:
   a. No further action (NFA);
   b. Letter of Concern (LOC);
   c. Letter of Warning (LOW);
   d. Notice of Intended Enforcement (NOIE);
   e. Withholding/Suspension;
2. A brief summary of why the recommendation was made.
3. A recommendation is required in the report, even if the facts do not support an enforcement action.

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 and phone number 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;
3. A description of the exit meeting (i.e., who attended and the issues that were discussed).
4. Place all the HACCP plan information in the "Summary" section at the bottom of the Verification Plan (VP). HACCP Plan Summaries for each HACCP plan reviewed during the FSA provide the information as it appeared during the assessment as a reference for both inspection staff and for the EIAOs, as the HACCP plan(s) may change as a result of findings documented during the FSA or the establishment's reassessment.

III. Completing the Third Tab of MSA Form 20:

The third tab (Comprehensive Assessment) should be completed with the design and regulatory issues identified during the FSA. The narrative should include the regulatory citations, as well as the agency's position.

Chapter IV –Recommendations and Timelines for Response

I. No further action

A. When EIAOs conduct a 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. If an establishment has 4 or less Findings and no Major or Critical Findings, the EIAO should recommend No Further Action. Documentation in the FSA report should support that the establishment was complying with the regulatory requirements during the visit.

B. The establishment must implement corrective actions within 60 days of the exit meeting for the findings from this FSA, which will be verified by the Circuit Manager. Failure to implement acceptable corrective actions as documented by the Circuit Manager may result in escalated enforcement action(s). Note: Establishments may be allowed more than 60 days to complete extensive facility upgrades or repairs, but the proposed completion date must be defined and be acceptable to the Circuit Manager.

II. Recommending issuance of a LOC

A. If an establishment has 5 or more Findings, 2 or less Major Findings and no Critical Findings the EIAO should recommend a LOC. The LOC should identify noncompliance with regulatory requirements that may lead to the adulteration of product or the creation of insanitary conditions that could cause product to become adulterated.

B. The EIAO is to document in the FSA the noncompliances in a manner that make it clear what regulatory requirements the establishment has failed to meet.

C. Individual Major Findings (not those resulting from the cumulative Findings) will require a written response plan (proposed corrective actions) within 10 days.

D. The establishment must have completely implemented corrective actions within 60 calendar days.

E. Failure to propose (for Individual Major Findings) or implement acceptable corrective actions within the specified time frames may result in escalated enforcement action(s).

III. Recommending issuance of a LOW or a NOIE

A. If an establishment that has 3 or more Major Findings and/or 1 or more Critical Findings the EIAO should recommend a LOW or NOIE.

B. For an EIAO to recommend that the CO issue a LOW, he or she needs to support in the report that conditions in the establishment, or the actions of the establishment, fail to meet the provisions described in 9 CFR, and that such conditions are reasonably likely to lead to the adulteration of product or the creation of insanitary conditions that could cause product to become adulterated and/or failure to follow Humane Handling practices during the slaughter process. In addition, the EIAO is to use his or her findings to clearly and explain how the establishment's noncompliances led to the condition.

C. Major Findings will require a written response plan (proposed corrective actions) within 10 days, except when they are result of a cumulative effect of multiple Findings.

D. Critical Findings will likely result in a regulatory control action (i.e., reject/retain tag) to halt that part of production and will require a written response plan (proposed corrective actions) within 5 days.

E. The establishment must have completely implemented corrective actions within 60 calendar days.

F. Failure to propose (for Individual Major or Critical Findings) or implement acceptable corrective actions within the specified time frames may result in escalated enforcement action(s). The EIAO may also base the decision on the history of the establishment failing to correct the same non-compliances on a prior FSA and/or NR's issued by the inspection personnel.

NOTE: When a regulatory control action is taken in conjunction with the issuance of a LOW or NOIE, times may be extended provided acceptable corrective actions are proposed and implemented prior to the establishment returning to inspected operation. In addition, times may be extended by the MSA Director when he or she determines that circumstances warrant the extension.

IV. Recommending issuance of a NOIE

A. The criteria for the number of findings and the timelines for response for a NOIE will be the same as those for a LOW, except for the following conditions:

1. For an EIAO to recommend that the CO issue a NOIE, the report must document that conditions in the establishment, or the actions of the establishment, fail to meet the provisions described in 9 CFR, and that such conditions are reasonably likely to lead to the adulteration of product or the creation of insanitary conditions that could cause product to become adulterated and/or failure to follow Humane Handling practices during the slaughter process.
2. In addition, when recommending a NOIE the EIAO is to use his or her findings to explain how the establishment's noncompliances led to the condition.
3. The issuance of a NOIE will be determined by the Director (Acting Director) based on the nature of the findings, the likelihood of adulterated product entering commerce and/or the effectiveness of immediate corrective actions taken by the establishment.

Chapter V –Distribution

After EIAOs complete the MSA 20, they are to add it to SharePoint. They should then email the Comprehensive Assessment to the EIAO Manager. After review by the EIAO Manager, the EIAO sends the completed report via e-mail to the CM. After the Verification Plan is completed it should be emailed to the CM and inspector.

Note: The Verification Plan is not given to the establishment; they only receive

the Comprehensive Assessment.

CHAPTER VI - APPEALS

A. The Inspection Staff/Circuit Manager may appeal through the EIAO chain of command. Inspection staff/Circuit Manager should submit appeals prior to the exit meeting to the extent possible.

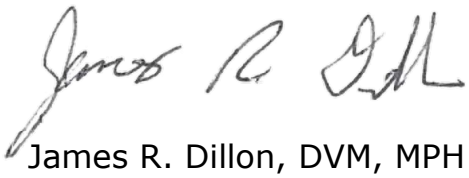
1. EIAO
2. EIAO Manager
3. Assistant Director/Assistant Section Manager
4. Director/Section Manager

B. The establishment may appeal in writing to the CM, who should forward as appropriate to the EIAO chain of command.

1. EIAO
2. EIAO Manager
3. Assistant Director/Assistant Section Manager
4. Director/Section Manager

CHAPTER VII – QUESTIONS

Refer questions through supervisory channels.



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