EIAO Recommendations

- EIAO recommendations from FSAs vary:
  - No action necessary
  - NRs issued by in-plant inspectors (500.1)
  - NOIE with or without NRs (500.4)
  - Notice of Suspension (NOS) (500.3)

Tool Summaries

- Summarize findings at the end of each tool.
Decision Making Analysis - General Tool

- Length is 1 to 2 pages
- Provide an overall analysis of findings and the thought process used to arrive at the recommendation
- Support the recommendation with:
  - sampling results
  - PHRE
  - in-plant observations
  - HACCP system design and implementation
- Show how the findings impact establishment’s ability to produce safe product
- Show how recommendation is supported by FSIS statutory and regulatory requirements
- Summarize the analysis in an Executive Summary
- State whether follow up is necessary

Analysis - Questions to help the analysis process

- Is there a relationship between past and current noncompliances?
- Do the current findings indicate that repetitive, sustained, or persistent food safety problems continue?
- Is supporting documentation adequate to support decisions in the hazard analysis?
- Has additional information arisen that calls hazard analysis decisions into question?
- Are there flaws in system design or implementation?
- Does the HACCP system prevent the production of adulterated, unsafe products?
- Is there a correlation between test results and findings related to sanitary practices?

Analysis and Recommendations

- Once analysis has been performed and a supportable recommendation determined
  - EIAO formulates and documents a regulatory rationale to support the recommendation
  - Example
    - The establishment’s Raw Non-Intact process is inadequate under 9 CFR 417.6 because the establishment cannot support the decision in its hazard analysis that E. coli O157:H7 is not likely to occur.
    - Discuss significant findings and what lead to this conclusion using the regulations and statutes
Analysis and Recommendations

- FSA report must describe in detail so reader has a clear understanding of the information considered and how that supports the recommendation.
- Identify all documents that had a bearing on the recommendation.

- Many establishments will address noncompliances as they are identified during the FSA
- EIAO will still document those in the FSA and recommend NRs and/or enforcement actions as warranted

- Describe in detail how past noncompliances relate to any present noncompliances
- Describe the public health significance
- If an enforcement action is recommended without evidence of multiple recurring noncompliances clearly document the findings which indicate serious threat to public health

- Identify all documents that had a bearing on the recommendation.
Analysis and Recommendations

• Additional points when writing analysis
  • Directives, Notices, and Guides are not support for enforcement
  • Analysis is not a simple repeating or listing of individual findings
  • Analysis is an explanation of the rationale and support for the enforcement based upon regulations, statutes, and public health

Analysis and Recommendations

• Items to include in the analysis
  • For the recommendation of no further action
    • Describe facts that indicate compliance and that no food safety concerns exist
  • For the recommendation of NRs written
    • Describe noncompliance(s) and why this recommendation is being made.
    NRs issued if not in support of NOIE

Analysis and Recommendations

• Items to include in the analysis
  • For the recommendation of NOIE
    • Clearly describe noncompliances that meet one of the provisions of 9 CFR 500.4
    • Describe how noncompliances resulted in adulterated product or created insanitary conditions
    • Clearly describe the analysis and regulatory thought process that lead to the determination
Analysis and Recommendations

- Items to include in the analysis
  - Recommendation of Notice of Suspension without prior notice
    - Clearly describe noncompliances that meet one of the provisions of 9 CFR 500.3
    - Describe how noncompliances resulted in an imminent threat to public health.
    - Clearly describe the analysis and regulatory thought process that lead to the determination.

Executive Summary

- Emphasize the recommendation - include only the essential or most significant supporting information.
- Show how you arrived at the recommendation.
- Make the summary concise.
- Do not duplicate the Decision Making Analysis. Use the summary question from each tool to construct the executive summary.
- TIP FOR SUCCESS: Imagine that the Executive Summary is the only part of the FSA that anyone can see - Does this summary adequately explain and support the recommendation?

Good Executive Summary contains:
- 1-2 sentences describing establishment/products
- 1-2 sentences describing compliance history
- 2 sentences describing findings leading to recommendation
- 2 sentences discussing analysis of findings and their significance.
Executive Summary

- Emphasizes recommendation and essential support for it
- Organized in coherent manner
- No more than 350 words in most cases
  - Up to 500 words for complex cases

Executive Summary

- First and last sentence of Analysis section often contains key information
- Review summary and remove unnecessary words or sentences
- Do not introduce any “new” information not contained in the FSA Report.

Executive Summary

- How can an EIAO know that enough information has been included?
  - Imagine that the summary is the only part of the FSA report that anyone can see and then ask the question:
  - Does this summary adequately explain and support the recommendation?