Analysis and Recommendations



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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)

No Action NRS NOIE NOS

Tool Summaries

• Summarize findings at the end of each tool.

Instruction: RTE Tool Summary:

- This question is designed to focur affect the establishment's ability findings that bear most directly o necessary with respect to the esta construct the Executive Summar that can rize the ion, if any, is stion is to be used to HACCPSV
- ity to produce safe, wholesome tion. Describe the immediate RTE99 Summarize in up to three bullets of any vulnerability or noncor Processed Products Tool that have an impact on the establishm unadulterated product and are critical to determine a FSA reco findings have on the establishment's food safety system.

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 . PHR 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

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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?

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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.

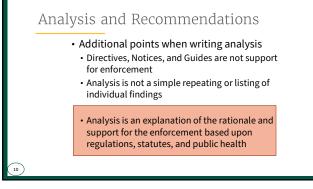
Analysis and Recommendations

- 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
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- Analysis and Recommendations
- 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



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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

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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

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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

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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?

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Executive Summary

- 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

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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.

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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?

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