

# FSA- Analysis and Recommendations



# EIAO Recommendations

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- 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

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- Summarize findings at the end of each tool.

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**Instruction: RTE Tool Summary:**

**This question is designed to focus on the most significant noncompliance or vulnerability findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. Summarize the findings that bear most directly on the FSA recommendation with respect to what action, if any, is necessary with respect to the establishment's HACCP system. The answer to this question is to be used to construct the Executive Summary.**

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RTE44 Summarize any vulnerability or noncompliance findings identified in the RTE Processed Products tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine an FSA recommendation. Describe the impact the findings have on the establishment's food safety system (limit 20,000 characters). Limit your response to three to five bullet points total.

# Decision Making Analysis- General Tool

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- 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

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- 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

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- 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 -2

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- 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 -3

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



# Analysis and Recommendations -4

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

# Analysis and Recommendations -5

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- 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 -6

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- 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 -7

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- 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 -8

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- 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

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- 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?

# Executive Summary

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- 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 -2

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- 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 -3

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- 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 -4

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- 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?