

Food Safety Assessment-FSA

The FSA: Purpose

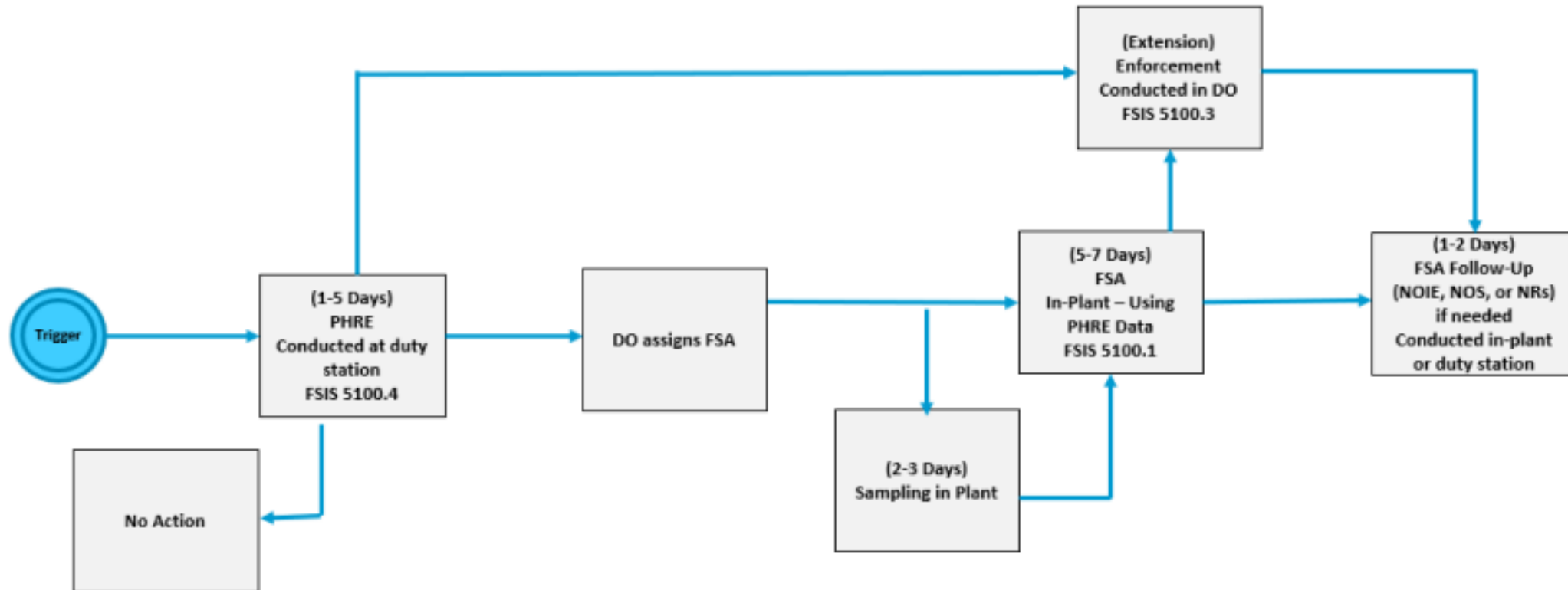
- Focus on certain processes based on the PHRE
- Assess and analyze a plant's food safety system as a whole
- Prepare a written report with a **supportable** recommendation focusing on documenting vulnerabilities and noncompliance.

The FSA: Purpose – 2

- FSA Methodology
 - Focus based approach.
 - Allows for EIAOs to focus time and resources on vulnerable portions of the Establishment's Food Safety System.
 - Allows for EIAO's to focus their observations, review and analysis to focus on public health risk.
 - Increases consistency of FSA in time, analysis and documentation.

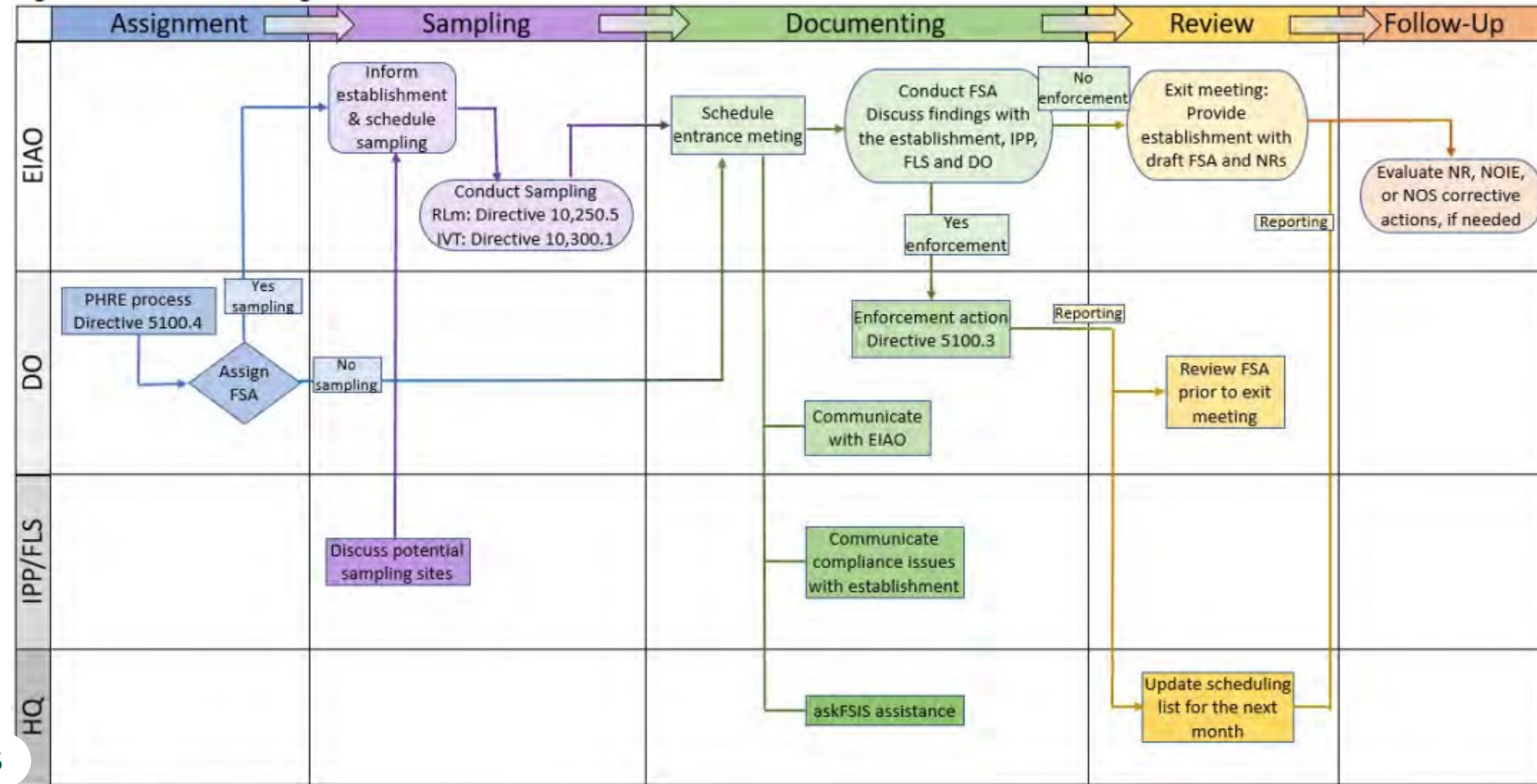
Process from PHRE to Finalizing FSA

Figure 1. EIAO Process Overview



FSA Scheduling Workflow

Figure 2. FSA Scheduling Workflow



Preparing for the FSA

- Define the scope and the tools to be completed.
- Develop a plan for conducting the FSA.
- Complete the General tool for every FSA.
- Any additional tools to complete will depend on the specific scenario.



Preparing for the FSA – 2

- Situations when >2 tools are completed:
 - New establishments coming under inspection
 - All applicable tools
 - Criteria in Directive 5100.4 spans multiple HACCP categories
 - STEC positive in raw non-intact
 - *Lm* positive in RTE
 - Any issues identified during the FSA or PHRE
 - Add tool associated with the issue identified



FSA Tools

| Product Types | HACCP Category | Tool to Use |
|--|--|--|
| Raw Poultry | Slaughter; Raw Intact; Raw Non-Intact | Poultry Tool |
| Raw Meat | Slaughter; Raw Intact; Raw Non-Intact | Meat Tool |
| NRTE Meat or Poultry | HT SS; NHT SS; HT NFC NSS; Secondary Inhibitors NSS | RTE/NRTE Products Tool |
| RTE Meat or Poultry | HT SS; NHT SS; FC NSS; Secondary Inhibitors NSS | RTE/NRTE Products Tool |
| Thermally Processed Meat or Poultry | Thermally Processed Commercially Sterile | Thermally Processed Commercially Sterile Tool |
| Egg Products | Raw, non-intact HT SS; FC NSS | Egg products Tool |
| Siluriformes Fish Products | Raw, intact meat Raw, non-intact meat | Fish Tool |

Scope of the FSA



- Determine if pathogen sampling is to be performed.
 - RLm- sample during the week prior to the FSA and consider the results in the FSA outcome.
 - IVT- Intensified Verification Testing will be discussed later in this course
 - IIT- If an Incident Investigation Team is formed, it will include subject matter experts who will focus on the unique issue of concern.

RLM, IVT, or IIT

- Sampling is completed prior to an FSA.
- Not a part of the 7-day window.
- Provide the establishment with at least 1-week notice that RLM sampling will occur,
- Delay in results or sampling may extend FSA

Notifying Establishment of FSA

- Give the establishment 1-2 weeks advance notice of the visit; and
- Give the FLS and IPP 1-2 weeks advance notice of the establishment visit.



Notifying Establishment of FSA – 2

- Exception to 1-2 week advance notice
 - “For Cause” FSA prompted by
 - Positive sample results
 - Shipment of adulterated product
 - Other high priority food safety incidents
 - See FSIS Directive 5100.4

Notifying Establishment of FSA – 3

- During the Discussion with Est./ FLS/ IPP
 - Communicate documents needed
 - SSOPs, HACCP Plan, HA, PRP, Supporting Documents, Testing Records, etc.
 - At least the last 60 days of records
 - At least 13 productions days for very small plants.
- Must express the need for these documents to be available to accomplish 5-7 day time frame.
- May follow up discussions with a MOI to assure clear communication.



Objective Check-Up

- What is the overall purpose of an FSA?



Pre-FSA Correlation

- Prior to Visiting the Establishment



Prior to Visiting the Plant

- Review PHRE that contains
 - All relevant data available regarding the establishment including any previous FSAs
- Review relevant agency issuances that pertain to plant processes, compliance guidelines, training and AskFSIS questions
- Correlate with the Case Specialist about issues and discuss strategy

Prior to Visiting the Plant –2

- EIAO should also review relevant
 - Policy issuances
 - Guidance materials
 - Training materials



Professionalism reminder:

- *Being prepared improves your credibility*

Pre-Entrance Meeting

- EIAO should meet with FSIS personnel first to discuss the process and any issues
- Advise that EIAO role is not to resolve disputes
- EIAO assesses food safety systems and formulates an agency supportable recommendation based on findings

Professionalism reminder:

- *contact IIC and reach out as a team member*



Entrance Meeting

- Conduct entrance meeting with management, in-plant inspection team, FLS and discuss:
 - Reason for and scope of the FSA
 - Discuss Public Health Regulations
 - How an FSA differs from day-to-day inspection verification
 - Typical work schedule
 - Accessing production areas and special rules
 - Where EIAO will work
 - Where records are stored and access to them
 - Photographs as an extension of inspection authority

Entrance Meeting –2

- Explain
 - EIAO role is not to resolve disputes
 - Communication with in-plant inspection team and establishment management about findings
 - Possible outcomes
 - Exit conference held upon completion of FSA
 - Draft copy of FSA report will be provided at exit conference.
 - Final copy provided by the EIAO or DO.
- EIAO Contact Information
- Document entrance meeting in the General Tool



Performing the Assessment



On-going Communication

Ongoing Communication

- FSIS expects the EIAO to communicate with establishment management throughout the FSA process.
- Remain fair and objective.
- Bring attention to and discuss non-compliances and vulnerabilities as they are identified.



Ongoing Communication -2

- Do not predict the FSA outcome!



Ongoing Communication –3

- Noncompliances will be documented in the FSA even if the establishment comes into compliance after notification
 - NRs by IPP
 - NOIE or suspension letter

IMPORTANT

Ongoing Communication –4

- EIAO communicates with in-plant team and FLS throughout the FSA
- Describe noncompliances and vulnerabilities
- Discuss establishment production practices
- Document in the FSA report any information provided by FLS or in-plant team that may affect outcome if not already captured in NR or MOIs

Ongoing Communication –5

- The EIAO, in-plant inspection team, and FLS work collaboratively to ensure all noncompliances are communicated to plant management and documented for issuance at the exit meeting.

Teamwork!



Ongoing Communication –6

- Example
 - EIAO recommends in-plant team issue NRs
 - Contacts DDM and SEIAO to discuss prior to sending draft FSA for review.
 - After concurrence EIAO contacts FLS and works with IIC and in-plant team to ensure NRs are issued

Teamwork!



Ongoing Communication -7

- FSIS must provide due process to the plant through ongoing communication with plant officials throughout the course of the FSA.

Due Process



Ongoing Communication –8

- EIAO provides frequent updates to SEIAO, DDM, or DM on FSA progress and strategy
- Frequent updates to IIC and FLS on findings and any recommendations
- DDM may request additional info or provide resources



Ongoing Communication – 9

- Request, don't demand!
- Be able to explain statutory authority to examine facilities and copy records
- If EIAO encounters resistance
 - Contact SEIAO or DO to develop strategy
 - DO may contact EARO who may then contact OIEA to get administrative subpoena to obtain records

Objective Check-Up -2

- What are the reasons an FSA is scheduled at an establishment?
- What are the timeframes involved in preparing for, notifying other parties, conducting, and concluding an FSA.



FSA Methodology Overview

- Complete FSA with-in 7 days
- If additional time needed explain to DO
- If a delay is necessary, discuss reasons with establishment and when it will resume
- Possible reasons for an extension:
 - Enforcement
 - 3 or more tools

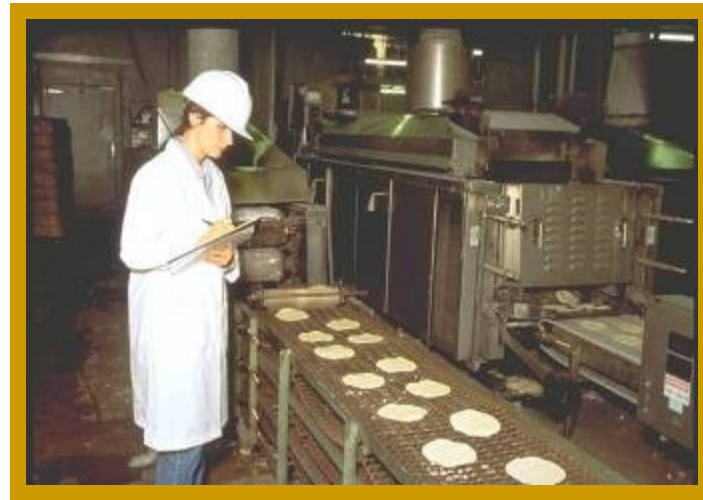


FSA Methodology Overview –2

- Evaluate the HACCP System as a whole.
 - Use system-based approach to determine adequacy
- Focus on:
 - Vulnerabilities and noncompliances - their effect on the food safety system
 - The establishment's ability to produce a safe and wholesome product

FSA Methodology Overview –3


- FSA is conducted by:
 - Records review
 - Direct observation of establishment operations




The FSA Tools


- Every FSA must have:
 - PHRE & General Tool
 - At least one of the processing category tools


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| <p style="text-align: center;">Public Health Risk Evaluation (PHRE) vs2</p> |
| <p>The PHRE is a decision-making process that is to be used to determine whether the District Office needs to schedule a Food Safety Assessment (FSA).</p> <p>*References: FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officers (ELAO) Public Health Risk Evaluation (PHRE) Methodology FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer (ELAO) Comprehensive Food Safety Assessment (FSA) Methodology</p> <hr/> <p>Establishment Information: (Name, Est. Number, Location, Email, Corporate Structure, and District/Circuit)</p> |


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|---|
| <p>United States Department of Agriculture Food Safety and Inspection Service</p> <p style="text-align: right;"></p> <p style="text-align: center;">General FSA Tool vs3</p> |
| <p>This is the General FSA Tool. This tool is to be completed as part of all Food Safety Assessments.</p> <p>The General Tool contains the following sections: FSA Recommendation (Questions G1 - G13) General Sanitation (G14 – G28) Other General Questions (G29 – end)</p> |

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| <p>United States Department of Agriculture Food Safety and Inspection Service</p> <p style="text-align: right;"></p> <p style="text-align: center;">Meat FSA Tool vs2</p> |
| <p>This FSA tool is for establishments that produce <u>RAW MEAT PRODUCTS</u> that are considered to fall under the following HACCP processing categories:</p> <p style="text-align: center;">MEAT SLAUGHTER INTACT MEAT NON INTACT MEAT</p> <p>The FSA Tool contains the following:</p> <ul style="list-style-type: none">• Hazard Analysis and HACCP System (Questions RTE1 - RTE6)• Slaughter and Sanitary Design (Questions RTE7 - RTE10)• Outside Source Materials (Questions RTE11 - RTE13)• Antimicrobial Treatment (Questions RTE14 - RTE16)• Sampling and Testing for Microbial Pathogens (Questions RTE17 - RTE19) |

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| <p>United States Department of Agriculture Food Safety and Inspection Service</p> <p style="text-align: right;"></p> <p style="text-align: center;">Not Ready-To-Eat (NRE) Processed Products FSA Tool vs2</p> |
| <p>This FSA tool is for establishments that produce <u>NOT READY-TO-EAT (NRE) MEAT OR POULTRY PRODUCTS</u> that are considered to fall under the following HACCP processing categories:</p> <p style="text-align: center;">HEAT TREATED, SHELF STABLE; NOT HEAT TREATED, SHELF STABLE; FULLY COOKED, NOT SHELF STABLE; SECONDARY INHIBITORS, NOT SHELF STABLE</p> <p>The FSA Tool contains the following:</p> <ul style="list-style-type: none">• Hazard Analysis and HACCP System (Questions RTE1 - RTE6)• Design of the Heat Treatment (Questions RTE7 - RTE10)• NRE Processed Products (Questions RTE11 - RTE13) |

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|---|
| <p>United States Department of Agriculture Food Safety and Inspection Service</p> <p style="text-align: right;"></p> <p style="text-align: center;">Poultry FSA Tool vs2</p> |
| <p>This FSA tool is for establishments that produce <u>RAW POULTRY PRODUCTS</u> that are considered to fall under the following HACCP processing categories:</p> <p style="text-align: center;">HEAT TREATED, SHELF STABLE NOT HEAT TREATED, SHELF STABLE FULLY COOKED, NOT SHELF STABLE SECONDARY INHIBITORS, NOT SHELF STABLE</p> <p>The FSA Tool contains the following main sections:</p> <ul style="list-style-type: none">• Hazard Analysis and HACCP System (Questions RTE1 - RTE6)• Lethality and Stabilization for Fermentation, Drying, and Salt-curing RTE Processing in the Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; Secondary Inhibitors, Not Shelf Stable HACCP Processing Categories (Questions RTE14 - RTE16)• Non-meat Ingredients for RTE Products (Questions RTE17 - RTE19)• Listeria Rule (9 CFR 430) for RTE Products (Questions RTE24 - RTE28) |

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| <p>United States Department of Agriculture Food Safety and Inspection Service</p> <p style="text-align: right;"></p> <p style="text-align: center;">Ready-to Eat (RTE) Processed Products FSA Tool vs2</p> |
| <p>This FSA tool is for establishments that produce <u>READY-TO-EAT (RTE) MEAT OR POULTRY PRODUCTS</u> that are considered to fall under the following HACCP processing categories:</p> <p style="text-align: center;">HEAT TREATED, SHELF STABLE NOT HEAT TREATED, SHELF STABLE FULLY COOKED, NOT SHELF STABLE SECONDARY INHIBITORS, NOT SHELF STABLE</p> <p>The FSA Tool contains the following main sections:</p> <ul style="list-style-type: none">• Hazard Analysis and HACCP System (Questions RTE1 - RTE6)• Lethality and Stabilization for Fermentation, Drying, and Salt-curing RTE Processing in the Heat Treated, Shelf Stable; Not Heat Treated, Shelf Stable; Secondary Inhibitors, Not Shelf Stable HACCP Processing Categories (Questions RTE14 - RTE16)• Non-meat Ingredients for RTE Products (Questions RTE17 - RTE19)• Listeria Rule (9 CFR 430) for RTE Products (Questions RTE24 - RTE28) |

The FSA Tools -2

- Function of FSA tools questions
 - Provide a structured format
 - Aid in gathering all necessary info
 - Aid in determining risk relative to other establishments

FSA Tools

The FSA Tools –3

- **Each tool is only completed once**
- *For example, if an establishment produces products under multiple HACCP processing categories that fall under the same tool such as raw intact and raw non-intact the tool should be completed once with an assessment of both HACCP categories included throughout.*

The FSA Tools -4

- Be familiar with the tool questions.
 - Enhances your ability to complete FSA in 7 days
 - Limits redundancy.
- Document all noncompliance and vulnerability findings.
 - Vulnerability- a less than perfect finding that may lead to noncompliance if it is not addressed
- Several questions could have similar responses
 - **Respond to each question individually.**
 - **May copy and paste but use caution.**



The FSA Tools -5

- Limit responses in the tools to information related to the HACCP categories being evaluated
- Do not to include information from other categories unless the information has a bearing on the category being evaluated as part of the focused FSA.



The FSA Tools– 6

- Use tools to document all findings
 - Do not keep outside notes
 - If an enforcement is recommended, any notes outside FSA Report must be forwarded to DCS



The FSA Tools – General Tool Overview

- General Tool:
 - The General Tool contains the following sections:
 - FSA Recommendation
 - General Sanitation
 - Other General Questions

United States Department of Agriculture
Food Safety and Inspection Service



General FSA Tool vs3

This is the General FSA Tool. This tool is to be completed as part of all Food Safety Assessments.

The General Tool contains the following sections:

FSA Recommendation (Questions G1 - G13)

General Sanitation (G14 – G28)

Other General Questions (G29 – end)

The FSA Tools – Meat and Poultry Tools Overview

- Meat Tool & Poultry Tool contains:
 - Hazard Analysis and HACCP System
 - Slaughter and Sanitary Dressing
 - Outside Source Materials for Further Processing
 - Antimicrobial Treatment for Slaughter and Further Processing
 - Sampling and Testing for Slaughter and Further Processing



The FSA Tools – RTE Tool Overview

- Ready-to Eat (RTE) Processed Products FSA Tool:
 - Hazard Analysis and HACCP System
 - Lethality and Stabilization: Fully Cooked, Not Shelf Stable
 - Lethality and Stabilization for Fermentation, Drying, and Salt-curing
 - Non-meat Ingredients for RTE Products
 - Listeria Rule (9 CFR 430) for RTE Products



The FSA Tools– NRTE Tool Overview

- Not Ready-To-Eat (NRTE) Processed Products:
 - Hazard Analysis and HACCP System
 - Design of the Heat Treatment, Fermentation, or Other Processes for NRTE Processed Products
 - NRTE Processed Products: Appearance



The FSA Tools – Thermally Processed Tool Overview

- **Thermally Processed:**

- Hazard Analysis and HACCP System
- Following Canning Regulations as Pre-Requisite Program to Prevent Biological Hazards
- Chemical and Physical Hazards



The FSA Tools – Analysis Sections

- EIAO analyzes findings to reach an agency supportable recommendation
- **Summary** documented as part of each tool
- **Analysis** is summarized in the **Decision- Making Analysis Question in the General Tool**
- **The Executive Summary** is documented in the **General Tool**

Guidance

- Use AskFSIS to obtain expert advice on scientific and technical issues. <https://www.fsis.usda.gov/contact-us/askfsis>

The screenshot displays the AskFSIS website. At the top, the USDA Food Safety and Inspection Service logo is visible, along with navigation links for ABOUT FSIS, CONTACT US, CAREERS, NEWS & EVENTS, and EMPLOYEES. Below this, a secondary navigation bar includes FOOD SAFETY, SCIENCE & DATA, POLICY, and INSPECTION. A yellow alert banner at the top right states: "ALERT: Distributors El Paisano Import, LLC... See more details". The main content area is titled "askFSIS" and provides information about the service, including a link to "askFSIS in FSIS Directive 9320.1 Rev. 2 Update askFSIS". It also includes a "How to Submit Attachments" section and a "To Submit a Question" section. A sidebar on the left contains links for "Contact Us", "FSIS Offices", "FSIS Department E-mails", "State Contacts", "askFSIS", "Having trouble with the Webform", "Prefer to e-mail", and "Subscribe for updates". The main form area contains a "Please note" section and a series of input fields for user information: First Name, Last Name, Email, Phone Number, Subject, Details/Question, Inquiry Type, Customer Type, Policy Area, Impacted Zip Code, Country, Establishment Size, Establishment Number Prefix, and Establishment Number.

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You can find answers to hundreds of common questions by using one of our question-and-answer tools:

- [Ask USDA](#): Find askFSIS public Q&As by including "askFSIS" in your search terms. You can also find answers to questions about safe food handling at home or food safety in general and a range of other topics for all USDA regulated products.

If you don't find what you're looking for in the published knowledge articles, please return here to submit your question to askFSIS for a helpful and timely response.

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To Submit a Question: Please complete all required fields marked with an asterisk (*) and the reCAPTCHA box to enable the "Submit" button at the bottom of the page.

askFSIS

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First Name *:

Last Name *:

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Phone Number *:

Subject *:

Details/Question *:

Inquiry Type *:

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Impacted Zip Code *:

Country:

Establishment Size:

Establishment Number Prefix:

Establishment Number: