

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)

FSA Recommendation (Questions G1- G13)

G1 FSA Recommendation

- No Action
- NRs (no additional enforcement actions)
- Enforcement - If selected, answer the following questions G2

G2 What enforcement actions are recommended?

- Notice of Intended Enforcement (NOIE)
- Notice of Suspension (NOS)

G3 If there are any NR(s) associated with this FSA, please include NR Numbers and a one line statement (maximum) to describe the NR.

NOTE: This question is to be left blank if there are no NRs are associated with this FSA.

Click here to enter text.

G4 FSA Executive Summary Supporting Recommendation (350 words or less)

NOTE: The Executive Summary is a brief overview of the FSA report designed to give readers a quick overview of its recommendations and support.

Click here to enter text.

G5 Decision Making Analysis (1 to 2 pages)

Provide an overall analysis of the FSA findings and the thought process used to arrive at the FSA recommendation. The support for the recommendation is derived from the sampling results (including the results from RLM, IVT, or IIT sampling), PHRE, in-plant observations, and the HACCP system design and implementation documented in the tools. Discuss and interpret the major findings and how that the findings impact the establishment's ability to produce safe, wholesome, and unadulterated product. This decision making analysis is important to provide context and support for a FSA recommendation that is supported by FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR). The EIAO is to summarize the analysis in an Executive Summary (Question G4).

NOTE: The EIAO is to state whether follow up is necessary and is to contact the FLS within 30 days of the exit meeting to determine the status of the NR. Ensuring that an establishment has adequately addressed any noncompliance can reduce the likelihood of repetitive noncompliance in the future that could lead to public health events and additional FSAs.

Click here to enter text.

G6 Date of Entrance meeting (MM/DD/YYYY)

- G7 Attendees (Names and Titles) for Entrance Meeting:**
Click here to enter text.
- G8 Date of Exit Meeting (MM/DD/YYYY)**
Click here to enter text.
- G9 Attendees (Names and Titles) for Exit Meeting:**
Click here to enter text.
- G10 Did the FSA extend beyond 5 -7 production days?**
 Yes - If selected, answer the following questions G11
 No
- G11 Indicate the reason for the FSA extending past the 5 -7 production days:**
 Enforcement Action
 Sampling results delayed (RLm)
 Incident Investigation Team (IIT)
 Intensified Verification Testing (IVT)
 Other, please describe - Click here to enter text.
- G12 Does this FSA require a follow-up for a NR corrective action or vulnerability identified during the FSA?**
 Yes - If selected, answer the following questions G13
 No
- G13 What is the reason (may select more than one reason) for the follow-up?**
 NR Corrective actions - Click here to enter text.
 Vulnerability - Click here to enter text.
 Other, please explain - Click here to enter text.
-

General Sanitation (G14 – G28)

The EIAO is to analyze and document how problems in complying with Sanitation SOP requirements affect the establishment's ability to support decisions in its hazard analysis or to implement its HACCP plan effectively.

- G14 Are there any conditions associated with the structure (Sanitation Performance Standards) that would hinder the establishment's ability to maintain sanitary conditions?**
 Yes - If selected, answer the following questions G15
 No
- G15 Describe any vulnerability and any noncompliance, and document your analysis on how the conditions impact food safety.**
Click here to enter text.
- G16 Does the establishment produce Not Ready-to-Eat (NRTE) or Ready-to-Eat (RTE) processed product?**
 Yes - If selected, answer the following questions G17,G18,G19,G20,G21,G22,G23,G24

No

Sanitation for Ready-to-Eat (RTE) and Not Ready-to-Eat (NRTE) Products (Questions G17 – G24)

Answer the sanitation questions in this section for both NRTE and RTE processed products. NRTE processed products are often produced using similar processes as RTE products, and can be answered together.

RTE processed products are products in the following HACCP processing categories:

Heat treated, shelf stable

Not heat treated, shelf stable

Fully Cooked, not shelf stable

Secondary inhibitors, not shelf stable

NRTE Processed Products in the following HACCP processing categories:

Heat treated, shelf stable

Not heat treated, shelf stable

Secondary inhibitors, not shelf stable

Heat treated, not fully cooked, not shelf stable

- G17** Are the Sanitation SOPs designed to include all procedures necessary to prevent contamination or adulteration of product?
***If no, briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.**
 Yes
 No - Click here to enter text.
- G18** Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 416.15(a), over the last 60 days?
***If yes, note whether all applicable parts of 9 CFR 416.15(b) were met. If no, note why the establishment did not take appropriate corrective actions**
 Yes
 No - Click here to enter text.
- G19** Provide your assessment of any vulnerability and any noncompliance with the Sanitation SOPs. Include concerns with: 1) whether all sanitation procedures are incorporated into the Sanitation SOPs, 2) if the procedures of the Sanitation SOPs address the cleaning of FCSs, and 3) if the Sanitation SOPs specify the frequency of each procedure and identify the establishment employee responsible for implementation and maintenance of each procedure.
Click here to enter text.
- G20** Provide your assessment of any vulnerability and any noncompliance with employee hygiene training procedures, the training materials, and written documents.
Click here to enter text.
- G21** Does the establishment use gloves?
***Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If there are no such findings leave the free text box blank.**
 Yes - Click here to enter text.



No - Click here to enter text.

G22 Provide your assessment of any vulnerability and any noncompliance with hand washing, cross-contamination due to misuse of garments in RTE areas, and hand tools such as knives and food contact utensils being stored in a sanitary manner.

Click here to enter text.

G23 Provide your assessment of any vulnerability and any noncompliance with the sanitizer(s) used, sanitizer rotation cycle (if applicable), and maintaining sanitizer(s) at a level that is both safe and effective.

Click here to enter text.

G24 Less than Daily (LTD) Cleaning: Does the establishment have less than daily (LTD) cleaning procedures?

**If yes, provide your assessment of any vulnerability and any noncompliance with the establishment's LTD cleaning program. Include concerns with how the establishment ensures that: 1) sanitary conditions are maintained and wholesome product is produced, 2) the program is comparable to daily cleanup, and 3) pathogens are effectively addressed as described in FSIS Directive 5000.5*

Yes - Click here to enter text.

No

G25 Has the establishment had a noncompliance regarding sanitation over the last 60 days?

NOTE: Answer this question based on your review of selected of records (including any additional record review because of a food safety concern) as outlined in [FSIS Directive 5100.1](#).

***If yes, consider whether the establishment has taken corrective actions to address the issues. Use the free text box to briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If there are no such findings, leave comment box empty.**

Yes - Click here to enter text.

No - Click here to enter text.

G26 Are there any conditions associated with the equipment or implemented Sanitation SOP that would hinder the establishment's ability to maintain sanitary conditions?

Yes - **If selected, answer the following questions G27**

No

G27 Describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the free text box blank.

Click here to enter text.

G28 Sanitation Summary: Considering the questions in the sanitation section, and the establishment's sanitation program as a whole, please provide your assessment of any additional vulnerability and describe any noncompliance not previously documented.

Click here to enter text.

Other General Questions (G29 – end)

This section contains other general questions across all FSA tools such as questions for waivers, lot definitions, allergens, food defense plans, and recall plans.

G29 Waiver: Does the establishment have alternative procedures associated with waivers (e.g., Salmonella Initiative Program (SIP) program, no objection letters)?



NOTE: The EIAO is to review alternative procedures associated with waivers (e.g., Salmonella Initiative Program (SIP) program, no objection letters) during the assessment of the establishments overall food safety system.

Yes - **If selected, answer the following questions G30**

No

G30 Please include FSIS Log Number identified on the no objection letter and briefly describe any vulnerability or noncompliance associated with the alternative procedure.

NOTE: Correlate with OPPD/RIMS via AskFSIS and address implementation criteria before taking any regulatory action(s).

[Click here to enter text.](#)

G31 Was sampling performed as part of the FSA? (e.g., RLM, or IVT)

Yes - **If selected, answer the following questions G32**

No

G32 Briefly describe the implemented sampling plan (unless RLM), and the sample sites and results. Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. NOTE; If there were positive results, include in your response the establishment's corrective actions.

(Do not document IIT sampling if associated with this FSA document unless directed by your supervisor)

[Click here to enter text.](#)

G33 From any of the establishment's sampling programs has the establishment received positive test results for any pathogen (i.e., Listeria monocytogenes, Salmonella, Campylobacter and/or STEC) in the past 60 days?

Yes - **If selected, answer the following questions G34**

No

G34 Briefly describe the positive(s), the impact on the food safety system, and the actions taken by the establishment in response to the positive(s).

G35 Has the establishment received positive test results from FSIS sampling for any pathogen (i.e., Listeria monocytogenes, Salmonella, Campylobacter and/or STEC) in the past 60 days?

Yes - **If selected, answer the following questions G36**

No

G36 Briefly describe the positive(s), its impact on the food safety system, and the actions taken by the establishment in response to the positive(s).

G37 3rd Party Audit: Has the establishment received a 3rd Party Audit in the last 60 days that revealed any direct food safety related weaknesses?

Yes - **If selected, answer the following questions G38**

No

Establishment was unwilling to share results of 3rd Party Audit

G38 Briefly describe the food safety issue(s) identified by the 3rd Party Audit, and include the actions taken by the establishment to address the food safety issue(s).

[Click here to enter text.](#)

G39 Sampled Lot Definition: Considering rework, returned product, carry-over, commingling, and cross-contamination during processing, does the establishment have a supportable basis for its sampled lot definition (microbiological independence)?



Yes

No

G40 Describe the establishment's sample lot definitions, the support and rationale for lot independence, and any flaws in the process that would question the establishment's microbiological independence determination.

[Click here to enter text.](#)

G41 Based on the products the establishment produces and a review of the laboratory sampling results obtained from the PHRE report, is the in-plant team receiving the appropriate sampling tasks through PHIS according to the establishment's products and production volume?

NOTE: If the EIAO identifies that the appropriate sampling tasks are not being assigned to the in-plant team, he or she is to contact the FLS.

Yes

No

G42 Recall Procedure: Does the establishment have a documented recall procedure to ensure all products could be recalled?

Yes - **If selected, answer the following questions G43**

No

G43 Recall Procedure: Provide your assessment of any vulnerability and any noncompliance with how the establishment has developed its recall procedure.

[Click here to enter text.](#)

G44 Reprocessing: Does the establishment have reprocessing or reconditioning procedures in place and implemented (if observed) that prevent cross contamination of product?

Yes

No

G45 Briefly describe any vulnerability and any noncompliance with how the establishment's food safety system addressed reprocessing.

[Click here to enter text.](#)

G46 Allergens: Does the establishment produce products that contain any of the "Big 8" allergens or other ingredients of public health concern? Big 8 allergens include: Wheat, Crustacean shellfish (e.g. crab, lobster, shrimp), Eggs, Fish, Peanuts, Milk, Tree nuts (e.g. almonds, pecans, walnuts), and Soybeans.

Yes - **If selected, answer the following questions G47**

No

G47 Briefly describe any vulnerability and any noncompliance with how the establishment's food safety system addressed the identification, prevention and control, and declaration of allergens/ingredients. If applicable, address if the establishment has had a recall for undeclared allergens/ingredients in the past 6-months, and the corrective actions taken.

[Click here to enter text.](#)

G48 Non-Inspected Production: Considering dual jurisdiction, retail exempt processing, and custom exempt processing, are there any non-FSIS inspected production practices that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

Yes - **If selected, answer the following questions G49**

No

G49 Describe how the non-FSIS inspected production process impacts the HACCP system, and how the



production process allows for the creation of insanitary conditions or adulteration of FSIS product.

[Click here to enter text.](#)

- G50 Food Defense: Does the establishment have a functional food defense plan? Note: a food defense plan is functional if it meets all four of the following conditions: 1) written/developed (the plan is documented and signed), 2) implemented (preventive measures are implemented to ensure a base level of “common sense” security, 3) tested (security measures are monitored), and 4) reviewed and maintained (the plan is reviewed at least annually and revised as needed).**

Yes - **If selected, answer the following questions G51**

No - **If selected, answer the following questions G52**

- G51 If “yes”, describe how the establishment is implementing their functional food defense plan (i.e., measures in place, how the plan is tested, how frequently the plan is updated). Also describe any lessons learned and/or benefits the establishment has identified from having a functional food defense plan.**

[Click here to enter text.](#)

- G52 If “no”, describe why the establishment has chosen to not implement a functional food defense plan and determine if the establishment is aware of FSIS tools and resources that are available to help develop a functional plan.**

[Click here to enter text.](#)

- G53 Supplemental: Based on your experience, expertise, and knowledge of industry practices, describe any additional questions that came up during the FSA that you sought answers to, based on the unique characteristics of the establishment’s process. Document the answers of your additional investigation.**

[Click here to enter text.](#)

General 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.

- G54 Summarize in up to three bullets of any vulnerability or noncompliance findings identified in the General Tool that have an impact on the establishment’s ability to produce safe, wholesome, unadulterated product and are critical to determine a FSA recommendation. Describe the impact the findings have on the establishment’s food safety system.**

[Click here to enter text.](#)