

General FSA Tool vs5

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 \(Questions G1- G10\)](#)
- [General Sanitation \(G11 – G19\)](#)
- [Other General Questions \(G20 – G26\)](#)
- [General Tool Summary \(G27\)](#)

FSA Recommendation (Questions G1- G10)

G1	FSA Recommendation	No Action	NRs (no additional enforcement actions)	Notice of Intended Enforcement (NOIE)	Notice of Suspension (NOS)
	Slaughter	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Raw Intact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Raw Non-Intact	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Fully Cooked, Not Shelf Stable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Heat Treated, Shelf Stable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Not Heat Treated, Shelf Stable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Secondary Inhibitors, Not Shelf Stable	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>
	Thermally Processed Commercially Sterile	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>	<input type="checkbox"/>

G2 If there are any NR(s) associated with this FSA, please include NR number(s) and a one-line statement (maximum) to describe the NR(s) (limit 10,000 characters).

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

[Click here to enter text.](#)

G3 FSA Executive Summary Supporting Recommendation (limit 4,000 characters)

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.](#)

G4 Decision Making Analysis (limit 10,000 characters)

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 or IVT sampling), PHRE, in-plant observations, and the HACCP system design and implementation documented in the tools. Discuss and interpret the major findings and how the findings impact the establishment's ability to produce safe, wholesome, and undiluted product. This decision-making analysis is important to provide context and support for an FSA recommendation that is supported by FSIS statutory and regulatory requirements (i.e., the [Acts](#) and [9 CFR](#)).

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(s). 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.](#)

G5 Date of Entrance meeting (MM/DD/YYYY)

[Click here to enter text.](#)

G6 Attendees (Names and Titles) for Entrance Meeting:

[Click here to enter text.](#)

G7 Date of Exit Meeting (MM/DD/YYYY)

[Click here to enter text.](#)

G8 Attendees (Names and Titles) for Exit Meeting:

[Click here to enter text.](#)

G9 Did the FSA extend beyond 7 production days?

☐ Yes – [If selected, answer the following question\(s\)](#)

☐ No

G9a Indicate the reason for the FSA extending past the 7 production days:

☐ Enforcement Action

☐ Sampling results delayed (RLm)

☐ Intensified Verification Testing (IVT)

☐ Other, please describe – [Click here to enter text \(limit 2,000 characters\).](#)

G10 Does this FSA require a follow-up for a NR corrective action or vulnerability identified during the FSA?

☐ Yes – [If selected, answer the following question\(s\)](#)

☐ No

G10a What is the reason (may select more than one reason) for the follow-up (limit 2,000 characters)?

☐ NR corrective actions – [Click here to enter text.](#)

☐ Vulnerability – [Click here to enter text.](#)

☐ Other, please describe – [Click here to enter text.](#)

General Sanitation (G11 – G19)

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

G11 Provide your assessment of any vulnerability and any noncompliance associated with the condition of the structure (Sanitation Performance Standards) that would hinder the establishment's ability to maintain sanitary conditions (limit 20,000 characters)? If there are no vulnerabilities or noncompliances, leave the free text box blank.

[Click here to enter text.](#)

- G12 Provide your assessment of any vulnerability and any noncompliance with employee hygiene training procedures, training materials, written documents, and employee adherence to Good Manufacturing Practices (GMPs) (limit 5,000 characters).
[Click here to enter text.](#)
- G13 Are there any conditions associated with the equipment or implemented Sanitation SOP that would hinder the establishment's ability to maintain sanitary conditions (limit 2,000 characters)?
☐ Yes – [Click here to enter text.](#)
☐ No – [Click here to enter text.](#)
- G14 Provide your assessment of any vulnerability and any noncompliance with the design of 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 (limit 5,000 characters).
[Click here to enter text.](#)
- G15 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 (limit 5,000 characters).
[Click here to enter text.](#)
- G16 Does the establishment have less than daily (LTD) sanitation procedures, including poultry chillers, if applicable (limit 4,000 characters)?
Provide your assessment of any vulnerability and any noncompliance with the establishment's LTD sanitation 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 – [Click here to enter text.](#)
☐ N/A, the establishment does not have LTD cleaning procedures
- G17 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 (limit 2,000 characters)?
*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 – [Click here to enter text.](#)
☐ No – [Click here to enter text.](#)
☐ N/A, the establishment has not had any deficiencies over the last 60 days
- G18 Describe any vulnerability and any noncompliance not described above that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters). If none, leave the free text box blank.
[Click here to enter text.](#)
- G19 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 (limit 20,000 characters).
[Click here to enter text.](#)

Other General Questions (G20 – G26)

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

- G20 Waiver: Does the establishment have alternative procedures associated with waivers (e.g., Salmonella Initiative Program (SIP)) or no objection letters (NOLs)? Current establishment waivers and NOLs may be found under the Establishment Profile column => “Waivers & Letters” tab. If the establishment provides documentation of a waiver or NOL, but it is not in PHIS, please correlate with OPPD via [askFSIS](#) to determine if the waiver or NOL is current.

NOTE: The EIAO is to review alternative procedures associated with waivers or no objection letters during the assessment of the establishments overall food safety system.

☐ Yes – If selected, answer the following question(s)

☐ No

- G20a Please include FSIS Log Number identified on the waiver or no objection letter and briefly describe any vulnerability or noncompliance associated with the alternative procedure (limit 5,000 characters).

NOTE: Correlate with OPPD via [askFSIS](#) and address implementation criteria before taking any regulatory action(s).

[Click here to enter text.](#)

- G21 Was FSIS sampling performed as part of the FSA (e.g., RLM or IVT)?

☐ Yes – If selected, answer the following question(s)

☐ No

- G21a Briefly describe the implemented sampling plan, the sample sites, and results. Briefly describe any vulnerability or 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 (limit 20,000 characters).

[Click here to enter text.](#)

- G22 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 question(s)

☐ No

☐ No 3rd Party Audit in the last 60 days

☐ The establishment was unwilling to share results of 3rd Party Audit

- G22a 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) (limit 20,000 characters).

[Click here to enter text.](#)

- G23 Recall Procedure: Does the establishment have a documented recall procedure as required by [9 CFR part 418](#) to ensure all products could be recalled? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

☐ Yes – [Click here to enter text.](#)

☐ No – [Click here to enter text.](#)

G24 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 question(s)**

☐ No

G24a 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 a adulteration of FSIS product (limit 20,000 characters).

[Click here to enter text.](#)

G25 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

☐ No – **If selected, answer the following question(s)**

G25a 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 (limit 20,000 characters).

[Click here to enter text.](#)

G26 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 (limit 20,000 characters).

[Click here to enter text.](#)

General Tool Summary (G27):

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.

G27 Summarize 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 an FSA recommendation. Describe the impact the findings have on the establishment's food safety system. Limit your response to three to five bullets (limit 20,000 characters).

[Click here to enter text.](#)