United States Department of Agriculture
Food Safety and Inspection Service

Fish FSA Tool VS2

This FSA tool is for establishments that produce **SILURIFORMES FISH PRODUCTS** that are considered to fall under the following HACCP processing categories:

Raw, Intact Meat
Raw, Non-Intact Meat

This FSA tool contains the following main sections:

- HACCP (F1-F22)
- Sampling and Testing (F23 – F37)
- Fish Tool Summary (F38)

In responding to questions in this tool, the EIAO is to focus on documenting any vulnerability and noncompliance, not making positive editorial findings.

A vulnerability is an identified weakness in the establishment's process that does not rise to the level of noncompliance but that could impact the establishment's ability to produce safe and wholesome meat or poultry products in accordance with FSIS statutory and regulatory requirements (i.e., the Acts and 9 CFR).

References:

1. FSIS Directive 5100.1, *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment (FSA) Methodology*;
2. FSIS Directive 5000.1, *Verifying an Establishment's Food Safety System*
3. FSIS Directive 5000.2, *Review of Establishment Testing Data by Inspection Program Personnel*;
4. FSIS Directive 14,000.1, *Consumer Safety Inspector Responsibilities at Fish Establishments*;
5. FSIS Compliance Guideline for Establishments that Slaughter or Further Process Siluriformes Fish and Fish Products; and
6. FDA Fish and Fishery Products Hazards and Control.

For all questions in this FSA tool, please note that some FSA tool questions are not applicable questions for the processes being assessed and will only appear based on the answer responses provided. EIAOs are to copy and paste information into a text field if that answer was provided in a previous text field question within the tool, or another tool.

HACCP (F1-F22)

This section is designed to assess the establishment's HACCP system. The HACCP system includes hazard analysis, any supporting documentation, including prerequisite programs supporting decisions in the hazard analysis, and all HACCP records.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.

F1 Select the categories assessed during the FSA (multiple categories may be selected).

☐ Raw, Intact
☐ Raw, Non-Intact

F2 Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4,000 characters).

☐Yes – Click here to enter text.
☐No – Click here to enter text.

F3 Does the HACCP system include a prerequisite program or supporting documentation (including normal consumer cooking practices) for any hazard that the establishment determines is "not reasonably likely to occur" (NRLTO) (9 CFR 417.5(a)(1))? Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F4 Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur" (RLTO) ((9 CFR 417.5(a)(2))? Describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F5 Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product change, categorization change, or unforeseen hazard?
NOTE: Answer this question based on your review of the selected records (including any additional record review because of a food safety concern) as outlined in FSIS Directive 5100.1.

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

☐No

F5a Briefly describe how the hazard analysis and/or HACCP plan was reassessed in response to the change. Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 5,000 characters).
Click here to enter text.

F6 Does the establishment apply antimicrobial treatments or additives that support decisions in the hazard analysis (e.g., CCPs, pre-requisite programs, or other programs)?

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

☐No

F6a Does the supporting documentation show the antimicrobial treatments or additives are safe and suitable (FSIS Directive 7120.1) (limit 4,000 characters)? Briefly describe any vulnerability and noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F7 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 Soy.

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

☐No

F7a 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 (limit 20,000 characters).

Click here to enter text.

F8 Does the establishment receive live fish?

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

☐No

F8a Does the establishment have documented procedures for sorting fish on arrival (to include the removal of other incidental species, removal of diseased/malformed fish, and removal of fish that died prior to harvesting, 9 CFR 539.1)? Briefly describe any vulnerabilities or noncompliances with the establishment's sorting of fish, to include its documented procedures or any direct observations (limit 2,000 characters).

☐Yes - Click here to enter text.

☐No - Click here to enter text.

F8b Indicate the sources of fish received by the establishment and addressed in the hazard analysis.

☐ Establishment receives fish from other ponds, including a co-op that the establishment does not manage

☐ Establishment receives wild caught fish

☐ Establishment receives fish from other ponds and receives wild-caught fish

☐ Establishment receives ALL fish from ponds it owns or manages

☐ Establishment receives ALL fish from ponds it does not own or manage

F8c Briefly describe any vulnerabilities or noncompliances with the establishment's sourcing of fish as it pertains to the hazard analysis (limit 20,000 characters).

Click here to enter text.

HACCP System Validation

This section is designed to assess the establishment's validation of its HACCP system.

F9 Does the establishment maintain adequate scientific or technical support that relates to the establishment's actual process, product, and hazard identified in the hazard analysis (1st part of validation – design)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No, support does not relate – Click here to enter text.

☐No, establishment does not have support – Click here to enter text.

F10 Does the establishment's scientific support demonstrate the process meets the performance standards or targets (i.e., pathogen reduction level) identified in the hazard analysis for each food safety system? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No, the support does not demonstrate that it meets the performance standards or targets – Click here to enter text.

☐No, the establishment does not identify performance standards or targets – Click here to enter text.

F11 Does the establishment use multiple interventions, including antimicrobial interventions, to meet the overall performance standard or target (i.e., multi-hurdle approach)?

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

☐No

F11a In the event of a worst-case scenario when not all antimicrobial interventions are operational, does the establishment have support that the remaining antimicrobial interventions will adequately reduce the pathogen to an acceptable level?

☐Yes

☐No

☐Each antimicrobial intervention is required during production

F12 Does the establishment incorporate the critical operating parameters in the scientific support into its CCP critical limits, prerequisite programs, and other program limits? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F13 Does the establishment maintain in-plant validation data demonstrating the control measures, as written in the HACCP system, achieve the intended food safety outcome (2nd part of validation – execution)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F14 Briefly describe any vulnerability or noncompliance finding with the establishment's HACCP system (i.e., HACCP plan, prerequisite program, or another program) validation that affect the establishment's ability to produce safe, wholesome, and unadulterated food not described above (limit 20,000 characters).

Click here to enter text.

HACCP Monitoring, Verification, and Corrective Actions

This section is designed to assess the establishment's monitoring, verification, and corrective action procedures of those CCPs, prerequisite programs, or other programs.

F15 Does the establishment conduct the monitoring and verification (procedure and frequency) as written in its HACCP program (i.e., HACCP plan, prerequisite program, or another program), including chilling/cooling procedures if the establishment slaughters? Noncompliances and vulnerabilities are to be described in F17.

☐Yes

☐No, the establishment does not conduct monitoring and verification as written

☐No, the monitoring and verification are not written in its HACCP program

F16 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in F17.

☐Yes

☐No

F17 Briefly describe any vulnerability and noncompliance finding with the establishment's monitoring and verification procedures and frequencies, including the support for its monitoring and verification procedures and frequencies in its program (i.e., HACCP plan, prerequisite program, or another program) (limit 20,000 characters).

Click here to enter text.

F18 Does the establishment have corrective action procedures in its written program (i.e., HACCP plan, prerequisite program, or another program)? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F19 Has the establishment taken corrective actions as appropriate in response to deficiencies as required by 9 CFR 417.3 over the last 60 days?

*If yes, note whether all applicable parts of 9 CFR 417.3 were met. If no, note why the establishment did not take appropriate corrective actions (limit 4,000 characters).

☐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.

F20 Do the records include the actual times, temperatures, or other quantifiable values, and include the product code(s), product name or identity, or slaughter production lot? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes – Click here to enter text.

☐No – Click here to enter text.

F21 Based on your review of records and observation of operations, briefly describe any vulnerability and noncompliance findings not described in previous questions with the implementation of monitoring and verification procedures that affect the establishment's ability to produce safe, wholesome, and unadulterated products. Note if the records accurately reflect the process (limit 20,000 characters).

Click here to enter text.

F22 HACCP Summary: Describe any HACCP design findings not described in the previous questions and how your findings impact the establishment's food safety system (limit 20,000 characters).

Click here to enter text.

Sampling and Testing (F23 – F37)

This section is designed to assess whether the establishment's sampling and testing programs that are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program), are designed appropriately and implemented under validated conditions, and that the establishment reacts appropriately to sampling results.

As instructed in FSIS Directive 5100.1, the EIAO is to:

- Directly observe the establishment collecting samples according to its supporting documentation if the establishment conducts sampling during the course of the FSA;
- Review establishment sampling results from the previous 60 days in establishments;
- Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool; and
- Review the Foodborne Pathogen Test Kits Validated by Independent Organizations database to determine whether the method used by the establishment is fit for purpose and performed under validated conditions.

F23 Does the establishment conduct sampling and testing for pathogens? If yes, specify the pathogen (limit 100 characters).

☐Yes - Click here to enter text.

☐No - Click here to enter text.

F24 Does the establishment conduct sampling and testing for antimicrobial and drug residues (9 CFR 539.2)? If yes, specify the antimicrobial and/or drug residues (limit 1000 characters).

☐Yes - Click here to enter text.

☐No - Click here to enter text.

☐No, fish are wild-caught and are not provided antimicrobials or drugs (wild-caught fish are more likely to be exposed to environmental contaminants through run-off rather than antimicrobials and drugs)

F25 Does the establishment conduct sampling of the fish for environmental contaminants (i.e. heavy metals, pesticides, etc.) (9 CFR 534.2 (for farm) and 9 CFR 539.2 (for farm and wild-caught))? If yes, specify the environmental contaminants (limit 1000 characters).

☐Yes - Click here to enter text.

☐No - Click here to enter text.

F26 Does the establishment retain control of the product, pending residue test results (FSIS testing or establishment testing)?
Note: Establishments are required to maintain control of wild-caught fish for FSIS residue testing. It is encouraged for establishments to maintain control over farm-raised product for residue testing, but it is not required.

☐Yes

☐No

F27 Does the establishment conduct sampling of their pond water and feed for environmental contaminants (i.e., heavy metals, pesticides, etc.)?

☐Yes

☐No

☐No, the establishment does not own any ponds

F28 Does the establishment conduct any other sampling and testing (including pre-harvest) that were not described above (equipment, environment, feed, etc.)?

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

☐No

F28a Describe the other sampling and testing not described above (limit 20,000 characters).
Click here to enter text.

F29 Does the establishment maintain adequate support for the sample collection method (sampling frequency, sample collection method, sampling portion, aseptic technique, etc.)? Noncompliances and vulnerabilities are to be described in F33.

☐Yes

☐No

☐N/A, the establishment does not conduct any sampling

F30 Does the establishment maintain adequate support for the testing method (test portion, validation, etc.)? Noncompliances and vulnerabilities are to be described in F33.

☐Yes

☐No

☐N/A, the establishment does not conduct any testing

F31 Do the establishment employees perform the sampling as described in the establishment's sampling protocol (aseptic technique, sample size and type, lab methods)? Noncompliances and vulnerabilities are to be described in F33.

☐Yes

☐No

☐N/A, the establishment does not conduct any sampling

☐N/A, sampling procedures were not observed during the FSA

F32 Has the establishment received a "violative" sample result from FSIS testing in the last 6 months?

☐Yes

☐No

F33 Briefly describe the sample collection methodology, sample portion, testing methodology, test portion, and your observation of the sample collection. Briefly describe any vulnerability or noncompliance (if the sampling and testing is used to support decision in the hazard analysis (9 CFR 417.5(a)(1)) and assess the impact those findings have on food safety (limit 20,000 characters).

Click here to enter text.

F34 Summarize how the establishment addresses positives, identifies trends and how the sample results for microbes, violative residues, and/or environmental contaminants are used for decision making within the HACCP system. Briefly describe each result above the upper control limit over the past 60 days, and the actions taken by the establishment. Briefly describe any vulnerability or noncompliance and assess the impact those findings have on food safety (limit 20,000 characters).

Click here to enter text.

F35 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

F36 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 (limit 20,000 characters).

Click here to enter text.

F37 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, they are to contact the FLS.

☐Yes

☐No

Fish Tool Summary (F38)

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.

F38 Summarize any vulnerability or noncompliance findings identified in the Fish tool that have an impact on the establishment's ability to produce safe, wholesome, unadulterated product and are critical to determine an FSA recommendation (limit 20,000 characters). Limit your response to three to five bullet points total.

Click here to enter text.