United States Department of Agriculture
Food Safety and Inspection Service

Poultry Products FSA Tool VS3

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

POULTRY SLAUGHTER
INTACT POULTRY
NON-INTACT POULTRY

The FSA tool contains the following main sections:

- HACCP (P1-P22)
- Slaughter and Procedures to Prevent Contamination (P23)
- Outside Source Materials for Further Processing (P24)
- Outgoing Products (P25-P26)
- Sampling and Testing for Slaughter and Further Processing (P27-P30)
- Other Sampling and Testing (Including Pre-Harvest) (P31)
- Poultry Tool Summary (P32)

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 Data by Inspection Personnel;*
4. FSIS Directive 6420.5, *Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens*;
5. FSIS Directive 6500.1, *New Poultry Inspection System – Post-Mortem Inspection and Verification of Ready-to-Cook Requirement;*
6. FSIS Guideline for Controlling Salmonella in Raw Poultry;
7. FSIS Guideline for Controlling Campylobacter in Raw Poultry; and
8. Meat and Poultry Hazards and Controls Guide

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 (P1-P22)

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.

P1 Select the categories assessed during the FSA (multiple categories may be selected).

	Chicken	Turkey	Other
Slaughter	☐	☐	☐
Raw Intact	☐	☐	☐
Raw Non-Intact	☐	☐	☐

P2 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.

P3 Does the HACCP system include a prerequisite program or supporting documentation (including 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.

P4 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.

P5 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

P5a 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.

P6 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

P6a Does the supporting documentation show the antimicrobial treatments 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.

P7 Reprocessing: Does the establishment have reprocessing or reconditioning procedures in place and implemented (if observed) that prevent cross contamination of product?

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

☐No

P7a Briefly describe the establishment's procedures for reprocessing or reconditioning. Include any vulnerability and any noncompliance with how the establishment's food safety system addressed reprocessing (limit 20,000 characters).

Click here to enter text.

P8 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

P8a 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.

HACCP System Validation

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

P9 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, including chilling/cooling if the establishment slaughters (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.

P10 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.

P11 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

P11a 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

P12 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.

P13 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.

P14 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.

P15 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 P17.

☐Yes

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

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

P16 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in P17.

☐Yes

☐No

P17 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.

P18 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.

P19 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.

P20 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.

P21 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.

P22 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.

Slaughter and Procedures to Prevent Contamination (P23)

This section is designed to assess the controls slaughter establishments employ in their food safety systems for preventing contamination by fecal material (9 CFR 381.65(f)) and procedures for preventing contamination by enteric pathogens (9 CFR 381.65(g)), considering the factors and questions presented in FSIS Directive 6420.5

P23 Does the establishment conduct slaughter activities?

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

☐No

P23a Are there deficiencies in the slaughter floor design, production process, and equipment used, that could potentially result in carcass contamination? Noncompliances and vulnerabilities are to be described in P23f.

☐Yes

☐No

P23b Does the establishment have written procedures, which are incorporated into the HACCP system, to prevent contamination of the carcass? Noncompliances and vulnerabilities are to be described in P23f.

Note: All poultry slaughter establishments are required by the Modernization of Poultry Slaughter Inspection Final Rule to develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens and fecal material throughout the entire slaughter and dressing operations.

☐Yes

☐No

P23c Does the establishment have written job descriptions or employee training procedures for preventing contamination from fecal material and enteric pathogens through the slaughter and dressing operation? Noncompliances and vulnerabilities are to be described in P23f.

☐Yes

☐No

P23d Do employees receive training on the procedures for control of contamination by fecal material and enteric pathogens? Noncompliances and vulnerabilities are to be described in P23f.

☐Yes

☐No

P23e Does the establishment have written procedures for monitoring employees (employee technique audits, carcass audits, etc.) to show sanitary conditions are maintained? Noncompliances and vulnerabilities are to be described in P23f.

☐Yes

☐No

P23f Briefly describe any vulnerability or noncompliance with the slaughter floor design, process, or equipment. Briefly describe any vulnerability or noncompliance with the establishment's written procedures for preventing contamination, including fecal material and enteric pathogens, how the employees are trained, and how employee monitoring is performed (employee technique audits, carcass audits, etc.) to show sanitary conditions are maintained. In the absence of written processing procedures for preventing contamination, describe how the establishment ensures sanitary conditions are maintained (limit 20,000 characters).

Click here to enter text.

P23g Does the establishment implement procedures for preventing contamination throughout the slaughter and dressing operation, such as by following the written program, implementing employee training, and monitoring, including the location of the CCP and location of the FSIS zero tolerance location, or utilizing process control criteria? Does the establishment verify the effectiveness of the procedures/techniques, and review the associated results generated? Noncompliances and vulnerabilities are to be described in P23m.

NOTE: Consider any applicable reoccurring zero-tolerance failures, CCP failures and FSIS documented non-compliances over the previous 60 days and evaluate the establishment's corrective actions. 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

☐No

P23h Do the establishment's procedures maintain sanitary conditions at the live receiving step? Noncompliances and vulnerabilities are to be described in P23m.

NOTE: Consider whether poultry are received in a manner adequate to prevent insanitary conditions and whether the establishment applies the procedures consistently and are they effective.

☐Yes

☐No

☐The establishment has no procedures at live receiving to prevent contamination by fecal material

P23i Do the establishment's procedures maintain sanitary conditions at the scalding process step? Noncompliances and vulnerabilities are to be described in P23m.

NOTE: Consider whether the scalding procedures are adequate to prevent insanitary conditions and, if so, does the establishment apply the procedures consistently and are they effective.

☐Yes

☐No, the establishment's procedures do not prevent insanitary conditions

☐No, the establishment does not have procedures at the scalding step to prevent contamination by fecal material and enteric pathogens

☐N/A, the establishment does not apply a scalding step in its process

P23j Do the establishment's procedures maintain sanitary conditions at the feather picking process step? Noncompliances and vulnerabilities are to be described in P23m.

NOTE: Consider whether the procedures are adequate to prevent insanitary conditions and, if so, does the establishment apply the procedures consistently and are they effective.

☐Yes

☐No, the establishment's procedures do not prevent insanitary conditions

☐No, the establishment does not have procedures at the feather picking step to prevent contamination, including fecal material and enteric pathogens

P23k Based on your review of the FSIS and establishment findings, have there been multiple or recurring failures of the procedures to prevent contamination of product through the slaughter process? Noncompliances and vulnerabilities are to be described in P23m.

☐Yes

☐No

P23l Briefly describe your observation of the implemented procedures to prevent contamination through the slaughter and dressing operation, the effectiveness of the procedures/techniques, any tracking controls in place, and the associated results generated. Include any reoccurring sanitation failures over the previous 60 days, and evaluate the corrective actions taken (limit 20,000 characters). Noncompliance and vulnerabilities are to be described in P23m.

NOTE: Answer this question based on your direct observations and review of the selected records (including any additional record review because of a food safety concern) according to FSIS Directive 5100.1.

Click here to enter text.

P23m Describe any vulnerability and noncompliance findings with questions regarding procedures to control contamination, including fecal material and enteric pathogens, that are not provided in previous questions. Also, briefly describe how the findings can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Click here to enter text.

P23n If the establishment is operating under the NPIS, are they maintaining records documenting that the products resulting from their slaughter operations meet the definition of RTC poultry (9 CFR 381.76(b)(6)(ii)(D))?

☐Yes

☐No

☐N/A

P23o Based on the review of records, are the products resulting from their slaughter operations meeting the definition of RTC poultry?

☐Yes

☐No

☐N/A

P23p Describe any vulnerability or noncompliance findings with the questions regarding the establishments ability to produce products from their slaughter operations that meet the definition of RTC poultry (limit 20,000 characters).
Click here to enter text.

Outside Source Materials for Further Processing (P24)

This section is designed to assess the establishment's controls of outside source materials that are part of the establishment's HACCP system (e.g., as ongoing verification for a CCP or prerequisite program).

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

P24 Does the establishment use product from outside sources (materials other than those slaughtered onsite) for further processing?

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

☐No

P24a Does the establishment maintain support that pathogens are addressed on outside source materials? Noncompliances and vulnerabilities are to be described in P24d.

☐Yes

☐No

P24b For products that have an applicable performance standard, is the establishment aware of the supplying establishment's categorization? Noncompliances and vulnerabilities are to be described in P24d.

☐Yes

☐No

P24c Does the establishment have purchase specifications that their suppliers must meet and does the establishment have procedures to verify that the suppliers are meeting the purchase specifications? Noncompliances and vulnerabilities are to be described in P24d.

☐Yes

☐No

P24d Briefly describe the incoming source received and the intended use of the source materials. Document any instances where the product is not used in accordance with the intended use. Briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).
Click to enter text.

Outgoing Products (P25-P26)

This section is designed to assess the establishment's controls of biological hazards in outgoing product.

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

P25 Does the establishment provide buyers with sampling information and COAs? Noncompliances and vulnerabilities are to be described in P26.

☐Yes

☐No

P26 Briefly describe the products produced, and how the food safety system information and sample results are supplied to buyer(s). Describe how the establishment utilizes intended use and supports its assertion that the products are used as intended. Briefly describe any vulnerability or noncompliance and assess the impact your findings have on food safety (limit 20,000 characters).

Click here to enter text.

Sampling and Testing for Slaughter and Further Processing (P27-P30)

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 performed 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.

P27 Does the establishment conduct sampling and testing for microbial organisms to assess process control? Noncompliances and vulnerabilities are to be described in P28.

Note: Poultry slaughter establishments are required to sample for microbial organisms, see Modernization of Poultry Slaughter Inspection Final Rule for requirements 9 CFR 381.65(g).

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

☐No

P27a Does the establishment have written sampling procedures? Noncompliances and vulnerabilities are to be described in P27e.

☐Yes

☐No

P27b Does the establishment maintain adequate support for the sample collection method (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)? Noncompliances and vulnerabilities are to be described in P27e.

☐Yes

☐No

P27c Does the establishment maintain adequate support for the testing method (test portion, fit for intended use, validation, etc.)? Noncompliances and vulnerabilities are to be described in P27e.

☐Yes

☐No

P27d Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)? Noncompliances and vulnerabilities are to be described in P27e.

☐Yes

☐No

P27e Briefly describe the sampling methodology, testing methodology, and your observation of the sampling collection. If the establishment performs sample analysis in-house, your assessment should include whether the lab methodology is validated and the establishment is performing as described in the validation. 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 your findings have on food safety (limit 20,000 characters).

Click here to enter text.

P27f 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

P27g 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.

P28 Summarize how the establishment identifies trends and how the sample results for microbial organisms 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 if the establishment sampling results are similar to trends identified in FSIS sampling results (if applicable). Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Click here to enter text.

P29 Does the establishment retain control of the product, pending residue test results (FSIS testing or establishment testing)?

Note: It is encouraged for establishments to maintain control over poultry products, but it is not required.

☐Yes

☐No

P30 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

Other Sampling and Testing (Including Pre-Harvest) (P31)

P31 Does the establishment conduct any other sampling and testing for microorganisms (including pre-harvest) that were not described above (equipment, environment, etc.) or for residues?

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

☐No

P31a Does the establishment maintain adequate support for the sample collection method (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)? Noncompliances and vulnerabilities are to be described in P31e.

☐Yes

☐No

P31b Does the establishment maintain adequate support for the testing method (test portion, fit for intended use, validation, etc.)? Noncompliances and vulnerabilities are to be described in P31e.

☐Yes

☐No

P31c Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)? Noncompliances and vulnerabilities are to be described in P31e.

☐Yes

☐No

☐N/A, the sampling was not observed during the FSA

P31d If the establishment conducts on-site testing, does the establishment perform testing following validated testing methods? Briefly describe any vulnerability or noncompliance (limit 2,000 characters).

NOTE: Consider weaknesses in the implemented testing procedures, which may impact the test results.

☐Yes – Click here to enter text.

☐No – Click here to enter text.

☐N/A

P31e Briefly describe the sampling methodology, testing methodology, and your observation of the sampling collection. Briefly describe any vulnerability or noncompliance and assess the impact your findings have on food safety (limit 20,000 characters).

Click here to enter text.

P31f Summarize how the establishment addresses positives, identifies trends and how the sample results for other microorganisms are used for decision making within the HACCP system. Briefly describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product (limit 20,000 characters).

Click here to enter text.

Poultry Tool Summary (P32)

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.

P32 Summarize any vulnerability or noncompliance findings identified in the Poultry 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). Describe the impact the findings have on the establishment's food safety system. Limit your response to three to five bullet points total.

Click here to enter text.