Poultry FSA Tool VS2

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 POULTR
NON-INTACT POULTRY

The FSA Tool contains the following main sections:

- **Hazard Analysis and HACCP System (Questions P1 – P19)**
- **Slaughter and Sanitary Dressing (P20 –P39)**
- **Outside Source Materials for Further Processing (P40 – P47)**
- **Antimicrobial Treatment for Slaughter and Further Processing (P48 – P55)**
- **Sampling and Testing for Slaughter and Further Processing (P56 – end)**

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 contribute to 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 5000.2*, *Review of Establishment Data by Inspection Personnel.***
3. ***FSIS Compliance Guideline for Controlling Salmonella and Campylobacter in Poultry*;**

NOTE: For all questions in this FSA tool, please note that some FSA tool questions are not required questions and will only appear based on the answer responses provided. Also, it is not necessary to copy and paste information into a text box that you've provided in a previous text field question within the tool.

Hazard Analysis and HACCP System (Questions P1 – P24)

This section is designed to assess the establishment's HACCP system. The HACCP system includes the 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.

NOTE: If there are findings specific to the antimicrobial treatments, sampling and testing, or sanitary dressing, briefly reference and provide more details in their respective sections of this tool.

P1 **Has the establishment considered the relevant food safety hazards throughout the HACCP system?**

☐Yes

☐No- If selected, answer the following questions P2

P2 **Briefly describe the hazard(s) not considered or identified. Also, describe any vulnerability and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

P3 **Does the HACCP system include a prerequisite program/supporting documentation for any hazard that the establishment determines is not reasonably likely to occur?**

***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

☐No - Click here to enter text.

P4 **Does each prerequisite program and/or supporting document support the decisions made?**

****If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P5 **Has the establishment properly developed and implemented a written HACCP plan to address each food safety hazard determined to be "reasonably likely to occur"?**

Yes

No

P6 **Does the establishment maintain credible scientific or technical support for initial validation? (1st part – design)**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P7 **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 – execution)**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P8 **Does the establishment incorporate all appropriate critical operating parameters outlined in the validation documentation?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P9 **Does the establishment maintain support for the selected monitoring and verification procedures and frequencies?**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P10 **Does the establishment conduct the CCP monitoring and verification (procedure and frequency) as written?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P11 **Does the establishment conduct the pre-shipment review? (Including a review of records associated with each specific production of product or lots before shipment into commerce)**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P12 **Has the establishment had a deviation in the previous 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.

☐Yes - If selected, answer the following questions P13

☐No

P13 **Did the corrective actions meet the requirements of 417.3?**

☐Yes

☐No

P14 **Does the HACCP system provide for a recordkeeping system that documents the monitoring of the critical control points and critical limits?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P15 **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?**

☐Yes

☐No

P16 **Do the records document the verification procedures and results?**

☐Yes

☐No

P17 **Did a significant development occur in the last 60 days that affects the hazard analysis such as major process or product changes but the establishment did not reassess?**

☐Yes - If selected, answer the following questions P18

☐No

P18 **Was the hazard analysis and/or HACCP plan reassessed? If the reassessment showed that the HACCP plan or hazard analysis needed changes to meet regulatory requirements, was the HACCP plan or hazard analysis modified immediately?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P19 **Briefly describe any vulnerability and any noncompliance regarding the HACCP system that was not included in your previous responses.**

Click here to enter text.

Slaughter and Sanitary Dressing (P20 -P39)

This section is designed to assess the sanitary dressing and process controls slaughter establishments employ in its food safety systems, considering the factors and questions presented in FSIS Directive 6410.3, *Verifying Sanitary Dressing and Process Control Procedures by Off-line Inspection Program Personnel (IPP) in Poultry Slaughter Operations.*

NOTE: The EIAO is to document all relevant noncompliance and vulnerability findings.

P20 **Does the establishment conduct slaughter activities?**

☐Yes - If selected, answer the following questions P21, P22, P23, P24, P25, P26,P27,P28,P29,P30,P31,P32,P33,P34,P35,P36,P37,P38,P39

☐No

P21 **Are there deficiencies in the slaughter floor design, production process, and equipment used, that could potentially result in carcass contamination?**

☐Yes

☐No

P22 **Does the establishment have written job descriptions and/or specific sanitation procedures that address sanitary dressing?**

☐Yes

☐No

P23 **Do employees receive training on the sanitary dressing procedures?**

☐Yes

☐No

P24 **Has the establishment incorporated procedures for chilling poultry into its HACCP systems, as is now required by 9 CFR 381.66(b)?**

☐Yes

☐No

P25 **Does the establishment have written sanitary dressing procedures on how the employees are trained, and how the monitoring is designed (employee technique audits, carcass audits, etc.) to show sanitary conditions are maintained?**

***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

Instruction: Sanitary Dressing Procedures - Implementation

P26 **Does the establishment monitor the overall effectiveness of the sanitary dressing procedures?**

☐Yes

☐No

P27 **Does the establishment use sanitary dressing standards or process control criteria to identify when the sanitary dressing procedures are not effective, as now required by 9 CFR 381.65(g)?**

☐Yes

☐No

P28 **Based on your review of the FSIS and establishment findings, have there been multiple or recurring sanitary dressing failures?**

☐Yes

☐No

P29 **Does the establishment implement sanitary dressing procedures, verify the effectiveness of the procedures/techniques, and review the associated results generated?**

NOTE: Consider any reoccurring sanitary dressing failures over the previous 60 days, and evaluate the establishment's corrective actions. 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 no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P30 **Do the establishment's procedures maintain sanitary conditions at the live receiving step?**

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.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

☐**Establishment has no procedures at live receiving**

P31 **Do the establishment's procedures maintain sanitary conditions at the scalding process step?**

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

***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P32 **Do the establishment's procedures maintain sanitary conditions at the feather picking process step?**

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.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

☐**Establishment has no procedures at the feather picking step**

P33 **Do the establishment's procedures maintain sanitary conditions at the chilling process step?**

NOTE: Consider whether the establishment developed, implemented, and maintained written procedures to ensure that carcasses contaminated with visible fecal material do not enter the chiller, as required by 9 CFR 381.65(f) and if so, does the establishment apply the procedures consistently and are they effective.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

☐**Establishment has no procedures at the chilling process step**

P34 **Does the establishment designate intended use, provide COAs, or provide buyers with processing and sampling information?**

NOTE: Consider how the establishment designates intended use,provides COAs and/or any other information provided to buyers regarding their processing and sampling information.

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P35 **Describe the any vulnerability and noncompliance findings with sanitary dressing questions 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.**

Click here to enter text.

P36 **Does the establishment consider drug and biological residues a hazard likely to occur, and address drug and biological resides with a CCP in the HACCP plan?**

☐Yes

☐No

P37 **Does the establishment have a prerequisite program to prevent drug and biological residues and/or supporting documentation for why the drug and biological residues are not reasonably likely to occur?**

☐Yes

☐No

P38 **Has the establishment received a "violative" tissue sample result from FSIS testing in the last 6 months?**

☐Yes

☐No

P39 **Describe the any vulnerability and noncompliance findings with any control(s) in place and documentation available to address animal drugs and biological residues that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

Outside Source Materials for Further Processing (P40 – P42)

This section is designed to assess the establishment's STEC 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.

P40 **Does the establishment use poultry from outside sources (materials other than those slaughtered onsite) for further processing?**

Yes - If selected, answer the following questions P41,P42

No

P41 **Does the establishment know the intended use of the products they receive?**

☐Yes

☐No

P42 **Does the establishment follow the designated intended use?**

☐Yes

☐No

P43 **Whether addressed on the product prior to entering the establishment or applied at the establishment, does the establishment maintain support that pathogens are addressed on outside source materials?**

☐Yes

☐No

P44 **Based on the measures applied to address pathogens, does the establishment conduct ongoing verification to demonstrate the measures continue to function as intended?**

☐Yes

☐No

P45 **For the products produced, does the establishment incorporate the "intended use" or consumer-cooking practices to support its hazard analysis decision-making?**

☐Yes

☐No

P46 **Does the establishment produce not ready-to-eat (NRTE) non-intact product that receives a heat treatment but is not fully cooked (e.g., char-marked heat-treated but not fully cooked chicken patties, or breaded/stuffed chicken breast that is heated-treated but not fully cooked)?**

NOTE: If yes, these products should be addressed in the NRTE FSA Tool.

Yes

No

P47 **Briefly describe any vulnerability and any noncompliance findings regarding the intended use, including the source materials used and final products produced that was not included in your previous responses.**

Click here to enter text.

Antimicrobial Treatment for Slaughter and Further Processing (P48 – P55)

This section is designed antimicrobial treatments (e.g., CCPs, prerequisite programs, or other programs) that support decisions in the hazard analysis.

The EIAO is to document all relevant noncompliance and vulnerability findings for all HACCP processing

categories covered in this tool.

P48 **Does the establishment have an antimicrobial treatment(s) (e.g., CCPs, prerequisite programs, or other programs) that may impact decisions in the hazard analysis?**

☐Yes - If selected, answer the following questions P48,P49,P50,P51,P52,P53,P54,P55

☐No

P49 **Does the establishment's supporting documentation show the antimicrobial treatment(s) (e.g., CCPs, prerequisite programs, or other programs) that support decisions in the hazard analysis are safe and suitable (FSIS Directive 7120.1)?**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P50 **Does the establishment's supporting documentation show the expected reduction of the target pathogen described in the hazard analysis?**

***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P51 **Has the establishment incorporated all appropriate critical operating parameters (complete coverage, concentration, temperature, time, pressure, etc.)?**
***If no, briefly describe any vulnerability or noncompliance, and assess the impact your findings have on the food safety system. If the answer is yes, leave the free text box blank.**

☐Yes

☐No - Click here to enter text.

P52 **Does the establishment apply the antimicrobial treatment according to the supporting documentation (complete coverage, contact time, concentration, etc.)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P53 **Does the establishment require all antimicrobial treatments to be implemented and functional during production (i.e., Multi-Hurdle effect)?**

☐Yes

☐No

P54 **In the event of a worst-case scenario when not all antimicrobial treatments are operational, does the establishment have support that the remaining antimicrobial treatments will adequately reduce the pathogen to an acceptable level?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

☐Establishment does not require all antimicrobial treatments to be operational at all times

P55 **Briefly describe any vulnerability and any noncompliance finding that is not provided in the any of the previous responses regarding the antimicrobial treatments applied, the critical operating parameters for each, and include any situations when the antimicrobial treatments are not operational.**

Click here to enter text.

Sampling and Testing for Slaughter and Further Processing (P56 – P73)

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; and**
- **Document all relevant noncompliance and vulnerability findings for all HACCP processing categories covered in this tool.**

References: 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

Instruction: Sampling and Testing for Pathogens

P56 **Does the establishment conduct sampling and testing for pathogens?**

☐Yes - If selected, answer the following questions P56,P57,P58,P59,P60

☐No

P57 **Does the establishment maintain adequate support for the sample collection method? (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P58 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P59 **Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P60 **For each sampling protocol (carcass rinse, comminuted, parts, etc.), briefly describe any additional**

vulnerability and any noncompliance of the sample collection methodology, sample portion, testing methodology, and test portion that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.

Click here to enter text.

P61 **Summarize how the establishment addresses positives, identifies trends and how the sample results for pathogens 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.**

Click here to enter text.

Sampling and Testing for Process Control Organisms

P62 **Does the establishment conduct sampling and testing for process control organisms? (NOTE: poultry slaughter establishments are required to sample process control organisms, see Modernization of Poultry Slaughter Inspection Final Rule for requirements 9 CFR 381.65 (g)?**

Yes - If selected, answer the following questions P63,P64,P65,P66,P67

No

P63 **Does the establishment maintain adequate support for the sampling method? (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P64 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P65 **Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P66 **Briefly describe the sampling methodology, sample portion, testing methodology, test portion, and summarize how the sample results are used 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 and any noncompliance that can affect the establishment's ability to produce safe, wholesome, and unadulterated product.**

Click here to enter text.

P67 **Summarize how the establishment addresses positives, identifies trends and how the sample results for process control organisms 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.**

Click here to enter text.

Other Sampling and Testing for Microorganisms (including Pre-Harvest)

P68 **Does the establishment conduct any other sampling and testing for microorganisms (including pre-harvest) that were not described above? (equipment, environment, etc.)**

☐Yes - If selected, answer the following questions P69,P70,P71,P72,P73

☐No

P69 **Does the establishment maintain adequate support for the sample collection method? (sampling frequency, sampling method, sampling portion, aseptic technique, etc.)?**

***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P70 **Does the establishment maintain adequate support for the testing method? (test portion, fit for intended use, validation, etc.)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P71 **Do the establishment employees perform the sampling as described in the sampling protocol (aseptic technique, sample size and type, lab methods)?**
***If no, briefly describe any vulnerability and any noncompliance findings that can affect the establishment's ability to produce safe, wholesome, and unadulterated product. If yes, leave the text box blank.**

☐Yes

☐No - Click here to enter text.

P72 **Briefly describe any vulnerability and any noncompliance with the sampling and testing methodology and frequency, and summarize how the sample results are used within the HACCP system. If there are positive or unacceptable result over the past 60 days, and consider how the establishment addressed corrective actions.**

Click here to enter text.

P73 **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.**

Click here to enter text.

Poultry Tool Summary:

This question is designed to focus on the <u>most significant</u> 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.

P74 **Summarize in up to three bullets of 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 a FSA recommendation. Describe the impact the findings have on the establishment's food safety system.**

Click here to enter text.