United States Department of Agriculture
Food Safety and Inspection Service

Meat Products FSA Tool VS3

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

MEAT SLAUGHTER
INTACT MEAT
NON-INTACT MEAT

The FSA tool contains the following main sections:

- HACCP (M1-M24)
- Slaughter and Procedures to Prevent Contamination (M25)
- Outside Source Materials for Further Processing (M26)
- Outgoing Products (M27-M31)
- Sampling and Testing for Slaughter and Further Processing (M32-M38)
- Meat Tool Summary (M39)

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, *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 6410.1**,** *Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age**;***
5. FSIS Directive 6410.4, *Verifying Swine Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination of Carcasses and Parts by Enteric Pathogens*;
6. FSIS Directive 6420.2, *Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations;*
7. FSIS Directive 6600.1, *New Swine Slaughter Inspection System: Ante-Mortem and Post-Mortem Inspection and Verification of Food Safety and Ready-To-Cook Requirements;*
8. FSIS Directive 10,010.3, *Traceback Methodology for Escherichia coli (E. coli) O157:H7 in Raw Ground Beef Products and Bench Trim*;
9. Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-producing Escherichia coli (STEC) Organisms or Virulence Markers;
10. FSIS Compliance Guideline for Controlling Salmonella in Market Hogs;
11. FSIS Guideline: Modernization of Swine Slaughter Inspection – Developing Microbiological Sampling Programs in Swine Slaughter Establishments; and
12. 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 (M1-M24)

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.

M1 Select the processing categories assessed during the FSA.

	Cattle / Beef	Swine/ Pork	Sheep and Goat
Slaughter	☐	☐	☐
Raw, Intact	☐	☐	☐
Raw, Non-Intact	☐	☐	☐

M2 Has the establishment considered the relevant food safety hazards throughout the HACCP system? Briefly describe any noncompliances and vulnerabilities (limit 4,000 characters).

☐Yes
☐No

M3 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

☐ No

M4 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

☐ No

M5 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

M5a 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).

M6 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

M6a 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

☐No

M7 Is the establishment reviewing the "Repeat Violators Alert List" as part of their hazard analysis decision-making? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

☐N/A, the establishment does not slaughter species found on the Repeat Violators Alert List

M8 Has the establishment received a "violative" sample result from FSIS testing in the last 6 months? Briefly describe any vulnerabilities or noncompliances (limit 4,000 characters).

☐Yes

☐No

☐N/A, the establishment does not slaughter

M9 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

M9a 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).

M10 Allergens: Does the establishment produce products that contain any of the "Big 9" allergens or other ingredients of public health concern? Big 9 allergens include: Wheat, Crustacean shellfish (e.g., crab, lobster, shrimp), Eggs, Fish, Peanuts, Milk, Tree nuts (e.g., almonds, pecans, walnuts), Soy, and Sesame.

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

☐ No

M10a 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).

HACCP System Validation

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

M11 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

☐ No, support does not relate

☐ No, establishment does not have support

M12 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 (limit 4,000 characters)?

☐ Yes

☐ No, the support does not demonstrate that it meets the performance standards or targets

☐ No, the establishment does not identify performance standards or targets

M13 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

M13a 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

M14 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

☐No

M15 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

☐ No

M16 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).

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.

M17 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 M19.

☐ Yes

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

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

M18 Does the establishment maintain support for the selected monitoring and verification procedures and frequencies? Noncompliances and vulnerabilities are to be described in M19.

☐ Yes

☐ No

M19 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).

M20 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

☐No

M21 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

☐No

☐N/A, the establishment has not had any deficiencies over the last 60 days.

M22 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

☐ No

M23 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).

M24 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).

Slaughter and Procedures to Prevent Contamination (M25)

This section is designed to assess the controls slaughter establishments employ in their food safety systems for preventing contamination by fecal material, ingesta, and milk, considering the factors and questions presented in FSIS Directive 6410.1, FSIS Directive 6410.4, and FSIS Directive 6420.2.

M25 Does the establishment conduct slaughter activities?

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

☐ No

M25a 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 M25f.

☐ Yes

☐ No

M25b 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 M25f.

Note: All swine slaughter establishments are required by the Modernization of Swine Slaughter Inspection Final Rule to have written procedures to prevent the contamination of carcasses and parts by enteric pathogens, and visible fecal material, ingesta, and milk throughout the entire slaughter and dressing operation.

☐ Yes

☐ No

M25c Does the establishment have written job descriptions or employee training procedures for preventing contamination from fecal material, ingesta, and milk through the slaughter and dressing operation? Noncompliances and vulnerabilities are to be described in M25f.

☐ Yes

☐ No

M25d Do employees receive training on the procedures for control of contamination by fecal material, ingesta, and milk? Noncompliances and vulnerabilities are to be described in M25f.

☐ Yes

☐ No

M25e 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 M25f.

☐ Yes

☐ No

M25f 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, ingesta, and milk, 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).

M25g Does the establishment implement procedures for preventing contamination by feces, ingesta, and milk, such as by following the written program, implementing employee training and monitoring, including the location of the CCP(s) 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 M25m.

NOTE: Consider any applicable reoccurring FSIS documented non-compliances, CCP failures, failures of applicable written programs, etc. 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

M25h Do the establishment's procedures maintain sanitary conditions at the live receiving step? Noncompliances and vulnerabilities are to be described in M25m.

NOTE: Consider whether livestock 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, ingesta, and milk

M25i Do the establishment's procedures maintain sanitary conditions at the scalding process step? Noncompliances and vulnerabilities are to be described in M25m.

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, ingesta, or milk

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

M25j 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 M25m.

☐Yes

☐No

M25k Has the establishment developed, implemented, and maintained written protocols for the removal, segregation and disposition of all SRMs (9 CFR 310.22)? Noncompliances and vulnerabilities are to be described in M25m.

*SRMs include: the tonsils and distal ileum of all cattle; the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae and the wings of the sacrum), and dorsal root ganglia of cattle >30 months of age.

☐Yes

☐No

☐N/A, the establishment does not slaughter or process cattle carcasses/parts containing SRMs

M25l Briefly describe your observation of the implemented procedures to prevent contamination by fecal material, ingesta, milk, and SRMs, 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 M25m.

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.

M25m Describe any vulnerability and noncompliance findings with questions regarding procedures to control contamination by fecal material, ingesta, milk, and SRMs, 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).

Outside Source Materials for Further Processing (M26)

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.

M26 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

M26a For beef, does the establishment follow the designated intended use of the products they receive? Noncompliance and vulnerabilities are to be described in M26e.

- ☐ Yes
- ☐ No, the establishment does not follow the designated intended use of the products they receive
- ☐ No, the establishment is not aware of the designated intended use of the products they receive
- ☐ No, the establishment does not follow the designated intended use and the establishment addressed it in the hazard analysis and implemented a process to control the applicable hazards
- ☐ N/A, the establishment does not slaughter or process beef

M26b Does the establishment maintain support that pathogens are addressed on outside source materials, such as COAs? Noncompliance and vulnerabilities are to be described in M26e.

- ☐ Yes
- ☐ No

M26c For products that have an applicable performance standard, is the establishment aware of the supplying establishment's categorization? Noncompliance and vulnerabilities are to be described in M26e.

- ☐ Yes
- ☐ No
- ☐ N/A, the product does not fall under a performance standard

M26d 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? Noncompliance and vulnerabilities are to be described in M26e.

- ☐ Yes
- ☐ No

M26e 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. If the establishment receives beef products for further processing, describe how the establishment addresses STEC. 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).

Outgoing Products (M27-M31)

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.

M27 For beef, does the establishment have a designated "intended use" for the products produced (i.e., intact product remains intact)? Noncompliances and vulnerabilities are to be described in M31.

- ☐ Yes – If selected, answer the following question(s)
- ☐ No
- ☐ N/A, the establishment does not slaughter or process beef.

M27a Does the establishment communicate the "intended use" of the products to the receiving establishment or facility? Noncompliances and vulnerabilities are to be described in M31.

- ☐ Yes
- ☐ No

M28 For beef, does the establishment provide buyers with information about STEC processing controls? Noncompliances and vulnerabilities are to be described in M31.

- ☐ Yes
- ☐ No
- ☐ N/A, the establishment does not slaughter or process beef

M29 Does the establishment provide buyers with sampling information and COAs? Noncompliances and vulnerabilities are to be described in M31.

- ☐ Yes
- ☐ No

M30 Does the establishment remove any lymph nodes? Noncompliances and vulnerabilities are to be described in M31.

- ☐ Yes
- ☐ No

M31 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).

Sampling and Testing for Slaughter and Further Processing (M32-M38)

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.

M32 Does the establishment conduct sampling and testing for microbial organisms to assess process control? Noncompliances and vulnerabilities are to be described in M33.

Note: 9 CFR 310.18 requires swine establishments to analyze for microbial organisms; 9 CFR 310.25 requires non-swine livestock establishments to analyze for generic E. coli. Participation in SIP requires establishment sampling.

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

☐No

M32a Does the establishment have written sampling procedures? Noncompliances and vulnerabilities are to be described in MP32e.

☐Yes

☐No

M32b 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 M32e.

☐Yes

☐No

M32c 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 M32e.

☐Yes

☐No

M32d 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 M32e.

☐Yes

☐No

M32e Briefly describe the organism for which the establishment performs sampling, the sampling location, 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).

M32f 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

M32g 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).

M33 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).

M34 Does the establishment retain control of product pending residue test results (FSIS testing or establishment testing)?

Note: It is required for establishments to maintain control over meat products.

☐Yes

☐No

M35 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

STEC Sampling

M36 Does the establishment conduct sampling and testing for STEC? Noncompliances and vulnerabilities are to be described in M36e.

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

☐No – If selected, answer M36e only

☐N/A, the establishment does not slaughter or process beef.

M36a Does the establishment maintain adequate support for the STEC sample collection method (sampling frequency, sample collection method, sampling portion, aseptic technique, etc.)? Noncompliances and vulnerabilities are to be described in M36d.

☐Yes

☐No

M36b Based on your observations, is the establishment conducting STEC sample collection per the supporting documentation (sample collection method, sample location, sample portion or dimensions, sample weight, etc.)? Noncompliances and vulnerabilities are to be described in M36d.

☐Yes

☐No

☐No, the establishment did not perform sampling during the FSA

M36c Does the establishment maintain adequate support for the STEC testing method (test portion, fit for intended use, validation, etc.)? Noncompliances and vulnerabilities are to be described in M36d.

☐Yes

☐No

M36d For each STEC sample collection protocol (trim, primals/subprimals, ground beef, AMR, variety meats, etc.), briefly describe the sample collection location, methodology, sample portion, testing methodology, test portion, and your observation of the sample 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 and assess the impact your findings have on food safety (limit 20,000 characters).

M36e Summarize how the establishment addresses STEC positives, identifies trends and how the sample results for STECs are used for decision-making within the HACCP system. Briefly describe any vulnerability or noncompliance findings and assess the impact your findings have on food safety (limit 20,000 characters).

High Event Period (HEP)

M37 Does the establishment have HEP procedures and/or similar program?

- ☐ Yes – If selected, answer the following question(s)
- ☐ No
- ☐ N/A, the establishment does not slaughter or process beef

M37a Using the agency's HEP guidance as a reference (localized HEP ≥ 3 positives in 10 samples and systematic ≥ 7 positives in 30 samples), does the program include supportable HEP criteria (e.g., FSIS Compliance Guideline for Establishments Sampling Beef Trimmings for Shiga Toxin-Producing Escherichia coli (STEC) Organisms or Virulence Markers)?

- ☐ Yes, the criteria are based on FSIS recommendations
- ☐ Yes, the criteria are based on other supportable statistical analysis, describe in M37c
- ☐ No, the criteria are not supportable, describe in M37c
- ☐ Other, describe in M37c

M37b Does the HEP program outline the actions to take on all associated products (e.g., primals/subprimals, parts, associated trim, etc.) during the HEP? Noncompliances and vulnerabilities are to be described in M37d.

- ☐ Yes
- ☐ No

M37c Describe the HEP criteria, and the role of intended use in the establishment's evaluation of all associated products entering commerce. For each HEP in the last 6 months, summarize the sample results, how the HEP was determined, and the actions taken on all associated products produced. Briefly describe any vulnerability or noncompliance and assess the impact your findings have on food safety (limit 20,000 characters).

M37d Describe the establishment HEP investigation process, including analysis of the implementation of procedures to control fecal material, ingesta, and milk. Summarize any associated corrective actions and the results of any reassessment. Briefly describe any vulnerability or noncompliance and assess the impact your findings have on food safety (limit 20,000 characters).

Other Sampling and Testing (including Pre-Harvest)

M38 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

M38a 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 M38f.

☐Yes

☐No

M38b 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 M38f.

☐Yes

☐No

M38c 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 M38f.

☐Yes

☐No

☐N/A, the establishment did not perform sampling during the FSA

M38d 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

☐No

☐N/A

M38e 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).

M38f 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).

Meat Tool Summary (M39)

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.

M39 Summarize any vulnerability or noncompliance findings identified in the Meat 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.