

United States (U.S.) Department of Agriculture Food Safety and Inspection Service (FSIS) Responses to the Self-Reporting Tool (SRT)

What is the purpose of this document?

This document is designed to demonstrate to the Central Competent Authority (CCA) that intends to submit answers to SRT questions the level of detail FSIS needs in those answers for FSIS to determine whether the country's documented food safety inspection system achieves a level of sanitary protection equivalent to the U.S. system. In this document, FSIS provides answers to the SRT based on our documented national food safety inspection system governing meat, poultry, and egg products. In addition, FSIS has included links to our supporting documentation (i.e., laws, regulations, inspection procedures, sampling plans, and sampling results) within each SRT answer.

Furthermore, FSIS altered some answers to SRT questions to provide a more applicable response. For example, SRT question #2, "How does the CCA ensure that no meat, poultry, or egg products intended for export to the U.S. are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the U.S.?" was answered from the standpoint of ensuring that no meat, poultry, or egg products intended for export from the U.S. are adulterated or misbranded, and only eligible products are certified for export. Information on ensuring that only eligible products are received for importation was provided in a subsequent question (SRT question #3).

Who is this document designed for?

This document is designed for all countries to use as a reference when providing SRT answers as part of their required annual documentation submission for ongoing equivalence. In addition, this document is a useful tool for countries requesting a reinstatement of equivalence, initial equivalence, or expansion of initial equivalence to demonstrate the type of information that they will need to provide in their SRT submission.

How is this document structured?

This document was structured to provide the U.S. laws, regulations, and inspection procedures applicable to each SRT answer. The primary issuances noted throughout this document are as follows:

- **U.S. laws-** [Federal Meat Inspection Act](#), [Poultry Products Inspection Act](#), and [Egg Products Inspection Act](#)
- **U.S. regulations-** Title 9 of the Code of Federal Regulations ([9 CFR](#)) chapters 300 to 590
- **FSIS inspection procedures-** [FSIS Directives](#)

In addition, this document provides SRT answers to all commodities (meat, poultry, and egg products) produced under various processing categories. Therefore, not all SRT questions and answers will apply to every country. The following chart identifies which SRT questions the CCA needs to provide answers and supporting documentation for based on the specific products the country is eligible to export or interested in exporting to the U.S. To view which products your country is currently eligible to export to the U.S., refer to [FSIS Import Library- Eligible Countries and Products](#). For more information on HACCP product categorization, please refer to the [FSIS Product Categorization Guide](#).

Products	SRT Question Numbers
Standard SRT questions to be answered for all products	1, 2, 3, 4, 5, 7, 9, 13, 14, 15, 16, 18, 23, 24, 26
Raw-Intact and Raw-Non Intact Beef and Veal	6, 10, 11, 12, 17, 22, 25, 27, 28, 29

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Raw-Intact and Raw-Non Intact Pork	6, 10, 11, 12, 22, 25, 27, 28
Raw-Intact and Raw-Non Intact Lamb, Mutton, or Goat	6, 10, 11, 12, 17, 22, 25, 27, 28
Raw-Intact and Raw-Non Intact Poultry and Ratites	6, 10, 11, 12, 22, 25, 27, 28
Raw-Intact and Raw-Non Intact Siluriformes Fish	6, 20, 21, 25
Thermally Processed-Commercially Sterile Meat and Poultry Products	6, 25, 33
Not Heat Treated-Shelf Stable Meat and Poultry Products	6, 25, 30, 31, 32
Heat Treated-Shelf Stable Meat and Poultry Products	6, 25, 30, 31, 32
Fully Cooked-Not Shelf Stable Meat and Poultry Products	6, 25, 30
Heat Treated-Not Fully Cooked-Not Shelf Stable Meat and Poultry Products	6, 25, 32
Product with Secondary Inhibitors-Not Shelf Stable Meat and Poultry Products	6, 25, 30, 32
Egg Products	8, 19, 30

Lastly, in this document, the term “establishments” refers to all official establishments under FSIS inspection eligible to produce meat, poultry, and egg products for domestic commerce and for export (i.e., certified to export product to foreign countries).

Component 1 Government Oversight

- 1. How does the CCA ensure that the laws and regulations governing meat (including beef, veal, pork, sheep, goat, and Siluriformes fish), poultry (including chickens, turkeys, ducks, geese, guineas, ratites, or squabs), and egg products inspection are enforced?**

The Central Competent Authority (CCA) of the United States (U.S.) is the Food Safety and Inspection Service (FSIS), part of the U.S. Department of Agriculture (USDA), and it is organized and administered as part of the national government. FSIS is the public health regulatory agency responsible for ensuring that domestic and imported meat, poultry, and egg products are safe, wholesome, and correctly labeled and packaged. FSIS inspects domestic and imported meat, poultry, and egg products under the authority of the [Federal Meat Inspection Act](#) (FMIA), the [Poultry Products Inspection Act](#) (PPIA), and the [Egg Products Inspection Act](#) (EPIA). On December 2, 2015, FSIS published the Final Rule “Mandatory Inspection of Fish of the Order Siluriformes and Products Derived from Such Fish” ([80 FR 75590](#)). This rule amended the Agency’s regulations to establish a mandatory inspection program for fish of the order Siluriformes, both farm-raised and wild-caught, and for products derived from these fish. Further, the rule explains that, because these fish are amenable to the FMIA ([21 U.S.C. 601\(w\)\(2\)](#)), the Siluriformes inspection program is part of FSIS’s meat inspection program, and is governed by FSIS under the authority of the FMIA. (**NOTE:** Throughout this SRT, regulatory citations to FSIS’s inspection requirements for Siluriformes fish and fish products are provided. In most cases, these regulations reference the existing regulations for meat and meat food products as applying to Siluriformes products).

The authority to enforce these Acts, and maintain a regulatory program aimed at protecting the health and welfare of consumers, is delegated from the Secretary of Agriculture, who is appointed by the President of the United States. In turn, the Secretary of Agriculture appoints a FSIS Administrator to oversee all FSIS activities and program areas, including but not limited to, inspection services, laboratory services and technical support, and training and education.

FSIS comprises several program areas ([FSIS Organizational Chart](#)), including the Office of Field Operations (OFO), which manages regulatory oversight and inspection of establishments that slaughter, process, import and export meat, poultry and egg products. Inspection services are provided by ten (10) OFO district offices spanning across the U.S. The district offices are responsible for coordinating the activities of local inspection circuits, as well as certifying establishments.

FSIS inspection program personnel (IPP) ensure that all provisions in the aforementioned Acts are met and followed by verifying and enforcing that official establishments meet all applicable regulatory requirements in Title 9 of the Code of Federal Regulations ([9 CFR](#)) chapters 300 to 590. Among other provisions, these Acts give FSIS the authority and ability to require corrective actions in establishments and to take additional enforcement measures as necessary when regulatory requirements are not met. FSIS IPP require and verify that establishments implement corrective actions, including measures to prevent recurrence, when the establishment fails to prevent direct contamination or adulteration of product ([9 CFR 416.15](#)), or when a deviation from a critical limit occurs ([9 CFR 417.3](#)). Furthermore, if an establishment fails to take appropriate corrective actions, FSIS has the authority and ability to take additional enforcement measures. These measures include, but are not limited to, retaining product or rejecting equipment; refusing to allow the marks of inspection to be applied to product; and suspending or withdrawing inspection ([9 CFR 500](#) (meat and poultry), [590.160](#) (eggs)). (**NOTE:** The Rules of Practice in 9 CFR 500 apply to fish inspection activities per [9 CFR 561](#). Throughout this SRT, answers referring to the Rules of Practice in 9 CFR 500 apply to meat and poultry products, including

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Siluriformes.) Other circumstances under which FSIS would take enforcement measures (e.g., failure to have or maintain a Hazard Analysis and Critical Control Point (HACCP) plan, failure to have or maintain Sanitation Standard Operating Procedures (Sanitation SOPs), or handling or slaughtering livestock inhumanely) are provided in [9 CFR 500](#) (meat and poultry) and [590.160](#) (egg products). Instructions to FSIS personnel on the types of enforcement actions that may be taken under [9 CFR 500](#), and the enforcement methodology to use when taking enforcement actions, are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). For example, when a FSIS OFO district office decides to pursue an enforcement action under [9 CFR 500.3 Withholding or suspension without prior notification](#), it issues a Notice of Suspension letter. When a FSIS OFO district office decides to pursue an enforcement action under [9 CFR 500.4 Withholding action or suspension with prior notification](#), it issues a Notice of Intended Enforcement letter. In connection with these enforcement actions, the FSIS OFO district office prepares an Administrative Enforcement Report case file to include establishment documentation, FSIS and establishment communications, supporting documents, evidence collected (as described in [FSIS Directive 8010.3 Procedures for Evidence Collection, Safeguarding and Disposal](#)), and verification plans.

Additionally, FSIS conducts public health risk evaluations to determine if risk-based, targeted reviews of establishment food safety systems (i.e., food safety assessments) are necessary. These food safety assessments are conducted by FSIS personnel (i.e., Enforcement Investigation and Analysis Officers-EIAOs) who have received advanced training in the assessment and analysis of establishment food safety systems. Some examples of when a FSA may be conducted include, but are not limited to, when an establishment produces adulterated product, or when an establishment produces product associated with an outbreak. FSIS EIAOs follow instructions outlined in [FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#) when conducting a public health risk evaluation to determine whether a food safety assessment is necessary, and [FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#) when performing food safety assessments.

Furthermore, the Acts provide FSIS with the authority to seize and condemn adulterated or misbranded meat, poultry, and egg products in commerce or being transported in commerce (21 U.S.C. [673](#) (meat), [467\(b\)](#) (poultry), and [1049](#) (egg products)). FSIS's Office of Investigation, Enforcement and Audit (OIEA) is responsible for the enforcement of FSIS criminal, civil, and administrative sanctions and authorities. FSIS OIEA compliance officers follow instructions outlined in FSIS Directives (8000 series) when performing procedures including, but not limited to, conducting in-commerce surveillance activities ([FSIS Directive 8010.1 Methodology for Conducting In-Commerce Surveillance Activities](#)); collecting, safeguarding, and disposing evidence ([FSIS Directive 8010.3 Procedures for Evidence Collection, Safeguarding and Disposal](#)); detention and seizure ([FSIS Directive 8410.1 Detention and Seizure](#)); determining appropriate action and referring enforcement matters ([FSIS Directive 8010.5 Case Referral and Disposition](#)); and writing an investigation report ([FSIS Directive 8010.4 Report of Investigation](#)).

- 2. How does the CCA ensure that no meat, poultry, or egg products intended for export to the U.S. are adulterated or misbranded (i.e., properly labeled and packaged), and only eligible meat, poultry, and egg products are certified for export to the U.S.?**

FSIS ensures that all meat, poultry, or egg products exported from the U.S. are certified, and not adulterated or misbranded, by enforcing the same laws and regulations for all products produced under FSIS inspection, and by certifying that all products eligible for export adhere to both FSIS requirements and the requirements of the importing country.

The FMIA, PPIA, and EPIA provide FSIS with the authority and responsibility to enforce the laws and regulations governing meat, poultry, and egg products inspection, and to certify these products for

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export. Furthermore, [9 CFR 322.1-322.2](#) (meat), [381.106](#) (poultry), [552.1](#) (Siluriformes) and [590.407](#) (egg products) list the requirements that must be met prior to FSIS IPP signing an export certificate. These requirements include, but are not limited to, verifying that the product to be exported is “U.S. inspected and passed,” determining that the product is neither adulterated or misbranded, and verifying that the outside container contains an official USDA mark or a mark containing a unique identifier linking the consignment to the export certificate. FSIS IPP verify that any product tested for adulterants by FSIS receives acceptable testing results prior to receiving the mark of inspection and being eligible for distribution in commerce (both domestically and for export). This includes the confirmation of acceptable official government testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use that is tested for Shiga toxin-producing *Escherichia coli* (STEC); RTE products tested for *Listeria monocytogenes* (*Lm*), *Salmonella*, or STEC (RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* and *Salmonella*; and livestock carcasses subject to FSIS testing for veterinary drugs (e.g., antibiotics, sulfonamides, avermectins).

When performing export verification activities, FSIS IPP follow instructions provided in [FSIS Directive 13,000.5 Public Health Information System Export Certification](#) (for countries active in PHIS) or [FSIS Directive 9000.1 Export Certification](#) (for countries not active in PHIS). This export verification activity includes consulting the FSIS Export Library, which lists export requirements by country for meat, poultry, and egg products, to determine the eligibility of shipments for export. This library is updated when a country notifies FSIS of a change in its requirements, and includes information such as certificate requirements, eligible and ineligible products, facility requirements, and labeling requirements. Further, FSIS IPP perform the following activities during export verification: verify that the export application is accurate and complete, and, if necessary, request additional documentation from the applicant (e.g., laboratory testing results, bill of lading, livestock country of origin, Agricultural Marketing Service (AMS) grading certificate, etc.); verify that the correct export mark number is applied; verify that labels meet the requirements of the receiving country; and, if required, conduct product re-inspection. When not in use, export certificates, official export stamps, and certificate inventory records must be kept under official lock or seal, and any unused export stickers must be returned to FSIS and destroyed. Additional information on IPP export inspection procedures are provided in [FSIS Directives 9000.2 Inspection and Export Certification of Livestock Intestines or Casings](#); [9000.6 Export Certification of Egg Products from Other than Official Egg Products Plants](#); and [9010.1 Export Products Returned to the United States](#).

The FMIA, PPIA, and EPIA all provide statutory definitions for adulterated or misbranded product ([21 U.S.C. 453](#), [601](#), and [1033](#)). The circumstances under which FSIS considers product to be adulterated include, but are not limited to, product that bears or contains any poisonous or deleterious substance which may render it injurious to health; product that consists in whole or in part of any filthy, putrid, or decomposed substance or is for any other reason unsound, unhealthful, unwholesome, or otherwise unfit for human food; or product that has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health. FSIS considers product to be misbranded if it contains false or misleading labeling.

To ensure product is wholesome, unadulterated, and correctly labeled and packaged, FSIS IPP perform routine verification activities in all establishments and enter their inspection results into the Public Health Information System (PHIS), which is a web-based comprehensive data analytic system used to collect, consolidate, and analyze data in order to improve public health. These verification activities include Sanitation SOPs and Sanitation Performance Standards (SPS) verification, HACCP verification, economic adulteration, and labeling verification. The priority and frequency for these verification activities is based on the expected impact on public health. For example, routine verification activities, such as HACCP verification, sanitation verification, and labeling verification are performed by FSIS IPP at least twice per week. For establishments with multiple HACCP process categories (e.g., raw-

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intact, raw-non intact, fully cooked-shelf stable), routine HACCP verification activities are performed at least twice per week per process category. PHIS distributes the appropriate number of verification activities, including sampling activities, to each inspector's PHIS verification task list. In addition to the verification activities generated by PHIS at an expected frequency, FSIS IPP can also perform "as-needed" verification activities. These are known as "directed" verification activities and are initiated in response to inspection findings, sample results, or other available information. For example, when FSIS IPP record a noncompliance record in PHIS, PHIS initiates a directed instance of the same verification activity that resulted in the noncompliance. FSIS IPP are also able to initiate directed instances of routine verification activities based on conditions they observe in establishments. Instructions to FSIS IPP on how to schedule and complete verification activities in PHIS are provided in [FSIS Directives 13,000.1 Scheduling In-Plant Inspection Tasks in the Public Health Information System \(PHIS\)](#); [13,000.2 Performing Sampling Tasks in Official Establishments Using the Public Health Information System](#); and [13,000.5 Public Health Information System Export Certification](#).

If FSIS IPP determine that product may be adulterated or misbranded (as per the definitions provided in the Acts), and the product is not in commerce, FSIS IPP can take a regulatory control action, such as retaining the product, to ensure the product does not enter commerce. This product will remain under FSIS control until the establishment determines product disposition and FSIS verifies that the product disposition is appropriate. Instructions to FSIS IPP on how and when to take a regulatory control action are provided in [FSIS Directive 5000.1 Verifying an Establishment's Food Safety System](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5 Case Referral and Disposition](#).

In the event that adulterated or misbranded product enters commerce, meat and poultry establishments (including both the receiving and producing establishment) are required to notify the appropriate district office within 24 hours and provide information such as the type, amount, origin, and destination of the adulterated or misbranded product ([9 CFR 418.2](#)). In addition, meat and poultry establishments are required to maintain written recall procedures describing their decision making process in determining whether to conduct a product recall, and the method and procedures that will be used to carry out the recall ([9 CFR 418.3](#)). Instructions to FSIS IPP on the actions to take when a meat or poultry establishment produces or receives adulterated product are provided in [FSIS Directive 8140.1 Notice of Receipt of Adulterated or Misbranded Product](#). Instructions to FSIS IPP on how to verify that establishments have prepared and are maintaining required written recall procedures, including how and when to document noncompliance, are provided in [FSIS Directive 5000.8 Verifying Compliance with Requirements for Written Recall Procedures](#).

Recalls are voluntary and are performed by the establishment responsible for shipping the adulterated or misbranded product into commerce. Although it is an establishment's decision to recall product, FSIS coordinates with the establishment to verify it has properly identified and removed recalled product from commerce by verifying the effectiveness of the establishment's recall activities. FSIS also notifies the public about product recalls. If an establishment refuses to recall adulterated or misbranded product from commerce, or if the recall is inadequate, the Acts provide FSIS with the authority to detain or seize this product ([21 U.S.C. 467](#), [673](#), and [1049](#)). When there is reason to believe that the products are adulterated, misbranded, or otherwise in violation of the Acts, FSIS personnel follow instructions in [FSIS Directive 8410.1 Detention and Seizure](#) when detaining, or preparing a recommendation to seize, meat, poultry, and egg products found in commerce. FSIS's role in voluntary recalls is further described in [FSIS Directive 8080.1 Recall of Meat and Poultry Products](#).

3. How does the CCA ensure that source meat, poultry, or egg products used in processing

operations originate from certified establishments in countries that the U.S. has determined have an equivalent meat, poultry, or egg products inspection system (i.e., eligible countries)?

The Acts require that imported meat, poultry, and egg products originate from eligible countries and from establishments that are certified to export to the U.S. ([21 U.S.C. 466](#), [620](#), and [1046](#)). A country becomes eligible following an equivalence determination process completed by FSIS in coordination with the country's CCA. Foreign establishments become eligible when FSIS determines that a country's food safety inspection system achieves a level of sanitary protection equivalent to the level achieved by FSIS, and the foreign country's CCA certifies the foreign establishment as meeting U.S. requirements. The requirements that a foreign inspection system must demonstrate are provided in [9 CFR 327.2](#) (meat), [381.196](#) (poultry), [557.2](#) (Siluriformes), and [590.910](#) (egg products).

Prior to being presented to FSIS for reinspection, importers into the U.S. must file a customs entry form with the appropriate U.S. Customs and Border Protection (CBP) port director and are subject to inspection at the port-of-entry by CBP. CBP verifies that the imported products are permitted entry into the U.S., are represented by the proper paperwork, and comply with USDA Animal and Plant Health Inspection Service (APHIS) regulations, which restrict some products from entering the U.S. due to animal disease conditions in the country of origin.

FSIS IPP perform reinspection on all imported product for appearance, condition, certification, and label compliance before the product is allowed entry into the U.S. ([9 CFR 327.6](#) (meat), [381.199](#) (poultry), [557.6](#) (Siluriformes), and [590.925](#) (egg products)). In addition, FSIS IPP also perform sampling verification on imported products. FSIS IPP follow instructions outlined in FSIS Directives (9900 series) when performing import reinspection procedures including, but not limited to, performing document review and verifying proper presentation of shipments of imported meat, poultry, and egg products ([FSIS Directive 9900.1 Imported Product Shipment Presentation](#)); prioritizing and performing assigned reinspections ([FSIS Directive 9900.2 Import Reinspection of Meat, Poultry, and Egg Products](#)); label verification ([FSIS Directive 9900.5 Label Verification of Imported Meat, Poultry, and Egg Products](#)); and sampling and testing imported products for adulterants recognized by FSIS (including withholding the mark of inspection pending acceptable test results) ([FSIS Directive 9900.6 Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products](#) and [FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments](#)). Instructions to FSIS IPP on how to perform import reinspection on Siluriformes fish and fish products are provided in [FSIS Directive 14,950.1 Inspection Program Personnel Responsibilities at Official Import Inspection Establishments That Receive Shipments of Siluriformes Fish and Fish Products](#).

Once inspected and passed, imported product is stamped with a USDA inspection legend and enters domestic commerce. All meat, poultry, and egg products entering official establishments are required to be inspected and passed and contain a USDA inspection legend per [9 CFR 318.1](#) (meat), [381.145](#) (poultry) and [590.424](#) (egg products). FSIS IPP verify that meat, poultry, and egg products source material meet this regulatory requirement when performing routine government verification activities.

4. How does the CCA ensure that the same set of laws, regulations, and policies are applied consistently to all establishments certified to export meat, poultry, or egg products to the U.S.?

FSIS ensures that the same set of laws, regulations, and policies are applied consistently to all establishments through a uniform system of conducting government verification activities to ensure that these establishments adhere to all statutory provisions and regulatory requirements. In addition, [9 CFR 302](#) (meat), [9 CFR 381 subpart D](#) (poultry), [9 CFR 532](#) (Siluriformes) and [9 CFR 590](#) (egg products) require that all establishments, producing product for sale or transportation in domestic commerce, apply for and receive inspection services unless operating under one of the exemptions defined in the

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regulations. (NOTE: FSIS does not allow product produced under an exemption to be exported.)

FSIS district office personnel are responsible for overseeing and managing the establishment certification process. Prior to granting FSIS inspection services at an establishment, FSIS district office personnel review the establishment's submitted application for completeness. In addition, [9 CFR 304.3](#) (meat), [9 CFR 381.22](#) (poultry), and [9 CFR 532.2](#) (Siluriformes) list the requirements an establishment must demonstrate prior to being granted Federal inspection and include written Sanitation SOP's, written recall procedures, a hazard analysis, and a validated HACCP plan. The requirements that an egg products establishment must demonstrate prior to receiving inspection are listed in [9 CFR 590.146](#), and include an initial survey by FSIS IPP to verify adequate facilities and the submission of drawings/specifications. (NOTE: Egg products establishments are also required to submit updated drawings/specifications when making significant modifications to the interior of their facilities.) FSIS supervisory personnel conduct on-site visits to verify these requirements are met prior to granting an establishment Federal inspection. Instructions to FSIS supervisory personnel on how to verify the appropriate regulatory requirements are met prior to granting Federal inspection are provided in [FSIS Directive 5220.1](#) *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS* (meat and poultry) and [FSIS Directive 5030.5](#) *Review of Egg Products Plants Drawings and Specifications* (egg products). Once an establishment is granted Federal inspection, it is considered an official establishment and is certified to produce meat, poultry, or egg products for domestic commerce and export. FSIS maintains a list of all official establishments in its [Meat, Poultry, and Egg Product Inspection Directory \(MPI\)](#).

Furthermore, FSIS has the authority and ability to withdraw a meat or poultry establishment's grant of inspection under certain circumstances, such as failure to maintain a HACCP plan or Sanitation SOP's ([9 CFR 500.6](#)). Likewise, FSIS has the authority and ability to withdraw an egg products establishment's grant of inspection under certain circumstances, such as failure to maintain premises, facilities, and equipment in a satisfactory state of repair ([9 CFR 590.160](#)). Instructions to FSIS personnel on the methodology to use when determining whether to refuse, deny, suspend, or withdraw inspection services are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.

FSIS disseminates information regarding FSIS requirements from FSIS headquarters to FSIS IPP through written issuances, webinars, classroom training, and supervisory visits. In addition to the rules and regulations published in the Federal Register and Code of Federal Regulations (9 CFR), FSIS disseminates information to FSIS IPP on current FSIS requirements and policies through the issuance of [FSIS Directives](#) and [FSIS Notices](#). FSIS Directives provide official communications and instructions to FSIS IPP in carrying out their functions. FSIS Notices are time sensitive materials issued to provide instruction in support of workplace policies, procedures and food safety regulations and expire one year from the date of publication. If the information provided in the FSIS Notice is still applicable after one year, the FSIS Notice is reissued or the information is incorporated into a FSIS Directive. Furthermore, FSIS IPP often perform verification activities in response to the issuance of a FSIS Directive or FSIS Notice to verify the regulatory requirements (described in the issuance) are met. These are typically "directed" PHIS verification activities, which are in addition to the routine verification activities generated by PHIS.

In addition, FSIS provides administrative and technical support on meeting FSIS requirements to FSIS IPP and establishments through various resources, including [askFSIS](#), and various education and training materials. AskFSIS is a web-based application that allows customers to submit policy-related and technical questions to specific policy staffs (e.g., labeling, sampling, import/export). Furthermore, FSIS publishes compliance guidelines to aid industry in understanding and complying with FSIS policies. The compliance guidelines are intended to be guidance documents and are not regulatory requirements. These guidelines can be found under the [Compliance Guides Index](#) on the FSIS website.

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For information on exports, FSIS provides an [export certification checklist](#) on the FSIS website, which offers an overview of the steps necessary when an establishment wants to export meat, poultry, or processed egg products from the U.S. FSIS also offers an [electronic mail subscription service](#), which allows interested parties to sign up to receive notifications on any information or policy changes regarding exports.

5. **How does the CCA ensure that government inspection personnel assigned to certified establishments exporting meat, poultry, or egg products to the U.S. are employees of and paid by the government?**

FSIS IPP are employed directly by the U.S. government on a permanent or intermittent basis, and are eligible to perform all applicable inspection duties, including: the ante-mortem inspection of livestock and poultry; the post-mortem inspection of each and every livestock carcass, head, and viscera and poultry carcass and viscera¹; sanitation and HACCP verification activities in all meat and poultry establishments; the continuous inspection of egg products; and the official government verification sample collection activities in meat, poultry, and egg products establishments.

The FMIA ([21 U.S.C.](#)) affords the Secretary of Agriculture the authority to “appoint” inspectors to examine and inspect all meat food products prepared for commerce in any slaughtering, meat-canning, salting, packing, rendering, or similar establishment ([§ 606](#)). This includes inspectors examining and inspecting all amenable species (e.g., cattle, sheep, swine, and goats) before slaughter ([§ 603](#)), performing post-mortem examination on each and every carcass and its parts ([§ 604](#)), and assessing sanitary conditions ([§ 608](#)).

The PPIA ([21 U.S.C. 453\(k\)](#)) defines an inspector as an employee or official of the U.S. Government authorized by the Secretary of Agriculture to inspect poultry and poultry products. Authorized inspectors shall perform ante-mortem inspection ([§455\(a\)](#)), post-mortem inspection of each carcass ([§455\(b\)](#)), and inspect the sanitary practices of the premises, facilities, and equipment ([§456\(a\)](#)).

The EPIA ([21 U.S.C. 1033\(k\)](#)) defines an inspector as any employee or official of the U.S. Government authorized to inspect eggs or egg products.

FSIS’s regulatory definition for an inspector is found in [9 CFR 300.4](#). Further, all FSIS employees are paid directly by the national government through payments deposited directly into their bank accounts ([Public Law 104-134](#)).

Lastly, to avoid conflict of interest, FSIS maintains prescriptive requirements in [9 CFR 306.4](#). These requirements include prohibiting FSIS IPP (including supervisory personnel) from working at an establishment where a member of his or her family is employed by the operator of the establishment; and prohibiting FSIS IPP from acquiring product from any establishment unless the product is purchased from a store or outlet open to the general public, and at a price paid by the general public.

6. **How does the CCA ensure that government inspection occurs continuously during slaughter operations, and at least once per production shift during the processing of meat or poultry intended for export to the U.S.?**

The Acts require that FSIS provide government inspection in all meat and poultry slaughter and processing (i.e., non-slaughter) establishments, and egg products establishments. Both the FMIA and

¹ Under FSIS’s New Poultry Inspection System (NPIS), the government inspector’s visual inspection of each carcass also serves as the inspection of the viscera if the inspector’s condemnation of a carcass also requires condemnation of the corresponding viscera.

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PPIA require that government inspection personnel conduct ante-mortem and post-mortem inspection in meat and poultry slaughter establishments ([21 U.S.C. 455](#), [603](#), and [604](#)). The regulatory requirements for government inspection during ante-mortem inspection are provided in [9 CFR 309](#) (meat) and [9 CFR 381.70](#) (poultry). The regulatory requirements for government inspection during post-mortem inspection are provided in [9 CFR 310](#) (meat) and [381.76](#) (poultry). Furthermore, the regulations require that post-mortem inspection be conducted on each and every carcass, or bird, and its parts.

In addition, FSIS requires that FSIS IPP in all meat and poultry processing establishments conduct inspection activities at least once per shift ([21 U.S.C. 455](#) and [606](#)). These provisions are codified in [9 CFR 307.4](#), which requires that any operation requiring inspection be conducted under the supervision of a FSIS employee, meaning a government inspector conducts verification activities at least once per shift, during meat and poultry processing operations. FSIS identifies a “shift” as eight (8) consecutive hours ([9 CFR 307.4](#)).

To ensure that all establishments receive and maintain adequate inspection coverage, establishments are required to submit work schedules to FSIS for review and approval prior to being granted Federal inspection. If an establishment wishes to operate outside of its approved work schedule, including during overtime periods, the proposed change must be submitted for FSIS approval ([9 CFR 307.4](#)). Furthermore, FSIS IPP must receive supervisory approval prior to scheduled absences to ensure adequate inspection coverage. In the case of an unscheduled absence, FSIS supervisory personnel will assign IPP to provide inspection coverage at the establishment.

7. How does the CCA ensure that government inspection personnel have appropriate educational credentials, disciplinary backgrounds, and training to carry out their inspection tasks?

FSIS hires FSIS IPP through the Federal Government’s official employment site, [USAJOBS](#). Each job posting on this site contains basic qualifications, such as specific experience or education requirements, that must be demonstrated in the applicant’s submission for an FSIS IPP position. Further, all FSIS veterinarians are required to possess a Doctor of Veterinary Medicine professional degree. All FSIS employees are also subject to a background investigation and screening assessment prior to being hired. Additional information on the requirements for FSIS IPP positions can be found under [Careers](#) on the FSIS website.

In addition, FSIS conducts classroom training and on-the-job training to ensure that inspection personnel have the appropriate training to carry out their inspection tasks. All FSIS IPP responsible for conducting government verification activities in establishments attend a month long training session on essential FSIS verification activities prior to beginning their assignments. Topics discussed during this initial training session include, but are not limited to, HACCP verification, Sanitation SOP and SPS verification, and labeling verification. At the completion of the month long training session, FSIS IPP must demonstrate a competent knowledge of all course material by passing a written examination. Other training sessions include Slaughter Inspection, Public Health Veterinarian (PHV) training, and Egg Products training. In addition to classroom training, FSIS IPP also take courses on various topics, such as export verification, through an online system called AgLearn. Additional information on the various training opportunities available to FSIS IPP can be found under [Workforce Training](#) on the FSIS website.

8. How does the CCA ensure continuous government inspection during the processing of egg products designated for export to the U.S.?

Continuous government inspection during the processing of egg products is mandated in the EPIA ([21 U.S.C. 1034](#)) and implemented through the regulatory requirement in [9 CFR 590.24](#). In addition,

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“processing” is defined in [9 CFR 590.5](#) as the “manufacturing of egg products, including breaking eggs or filtering, mixing, blending, pasteurizing, stabilizing, cooling, freezing or drying, or packaging egg products at official plants.” The labeling of egg products and final product examinations are also considered processing activities.

FSIS IPP are on the premises during operations, and conduct inspection activities (both observations and records review) that include, but are not limited to, sanitation verification, food safety and operational verification, review of monitoring records, and verification of time/temperature at critical points in the operation.

Furthermore, FSIS has determined that continuous inspection is not required during the entirety of the stabilization processing step and the heat treatment of dried egg whites. In these situations, the inspector is required to be present at the beginning and end of these processing steps.

9. **How does the CCA ensure adequate oversight of laboratories that perform analyses for official government sampling and testing programs for meat, poultry, or egg products that are exported to the U.S., including oversight to ensure that laboratories conducting official government analyses comply with the general quality assurance and control criteria provided in International Organization for Standardization (ISO)/International Electrotechnical Commission (IEC) Guide 17025?**

FSIS ensures that every establishment producing products for domestic commerce or for export is included in official government chemical residue and microbiological sampling and testing programs by assigning official government verification sampling activities to FSIS IPP through PHIS. FSIS ensures that every product for which there is a pathogen performance standard is considered for official government microbiological verification testing. In addition, official government verification testing for chemical residues is assigned to FSIS IPP in establishments producing product eligible for residue testing. The frequency of official government verification sampling and testing is typically determined by the amount of eligible product type (e.g., beef manufacturing trimmings tested for STEC) being produced (production volume). FSIS collects product volume information through PHIS. In all establishments, FSIS IPP routinely verify that establishment profiles in PHIS are up-to-date and accurately reflect which product groups the establishment is producing, and the average daily volumes of the product groups being produced. Instructions to FSIS IPP on how to maintain accurate establishment profiles in PHIS, including instructions on how to enter accurate production volume information, are provided in [FSIS Directive 5300.1](#) *Managing the Establishment Profile in the Public Health Information System* (meat and poultry) and [FSIS Directive 5030.2](#) *Managing the Establishment Profile in the Public Health Information System (PHIS) for Egg Products Inspection*. For imported products, the type of inspection verification PHIS assigns to the imported product informs IPP when samples are to be collected and sent for laboratory analysis. Additional information on the laboratory types of inspections assigned to FSIS IPP in import establishments can be found in [FSIS Directive 9900.6](#) *Laboratory Sampling Program for Imported Meat, Poultry, and Egg Products*.

FSIS oversees three (3) national FSIS Field Service Laboratories, which are responsible for coordinating and conducting laboratory analytical services for official microbiological and chemical samples. FSIS’s Office of Public Health Science (OPHS) maintains direct oversight over all three national laboratories, and provides scientific technical support to other FSIS program areas.

In addition, FSIS administers the Accredited Laboratory Program (ALP), which accredits nonfederal analytical chemistry laboratories to analyze official government samples of meat and poultry food products for moisture, protein, fat, and salt content and/or certain classes of chemical residues. Currently, the specific chemical residues included in analyses conducted by ALP laboratories are chlorinated hydrocarbons, polychlorinated biphenyls, sulfonamides, nitrosamines, and arsenic.

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All FSIS Field Service laboratories that conduct analyses for official government samples of meat, poultry, or egg products are ISO 17025 accredited, and have established and implemented quality control procedures. The ISO 17025 accreditation certificates for FSIS's three Field Service laboratories are available via the following links: [FSIS Western Laboratory](#), [FSIS Eastern Laboratory](#), and [FSIS Midwestern Laboratory](#).

Within OPHS, the Laboratory Quality Assurance Staff (LQAS) is responsible for laboratory quality management system oversight, and maintaining and distributing system policy and procedures. LQAS managers within each of the three laboratories verify that quality control procedures for laboratories are established, effective, and followed by conducting internal audits of each Field Service Laboratory at least three times per year to verify compliance with ISO 17025 requirements, accreditation body requirements (i.e., American Association for Laboratory Accreditation (A2LA) Food Testing Program Requirements), and quality management system requirements.

Regarding external laboratory audits, the A2LA evaluates and assesses each FSIS Field Service laboratory for on-going compliance with ISO/IEC 17025:2005 requirements by performing annual audits of the laboratory system. In addition to the annual A2LA audit, OPHS LQAS auditors also conduct external audits.

FSIS's national laboratories maintain quality control procedures that are consistent with the requirements in ISO 17025 including: monitoring the validity of tests and calibrations, implementing and documenting quality control procedures for each batch of samples; verifying that testing, calibration, and sampling methods are fit for purpose; requiring non-standard methods to be validated; ensuring that samples tested meet the acceptance criteria for releasing batches; and taking corrective actions for all samples outside the acceptance criteria.

In addition, FSIS laboratories participate in proficiency testing for all accredited test methods. FSIS laboratories also perform duplicate analysis, and calibration of instruments and media. Furthermore, quality control samples are tracked to ensure the validity of the results.

To ensure sample integrity, reliability, and chain of custody is maintained in all official samples collected and tested under FSIS's sampling programs, samples remain under direct FSIS control while in the establishment and in the FSIS laboratories, and under FSIS seal during transport from the establishment to the laboratory. Instructions to FSIS IPP on how to use sample seals and identity labels to ensure sample integrity and identity are provided in [FSIS Directive 7355.1 Use of Sample Seals for Laboratory Samples and Other Applications](#). In addition, sample status and sample analysis result information are reported electronically to FSIS personnel and establishments through the Laboratory Information System-Direct (LIMS-Direct), which updates data every 15 minutes. Instructions to FSIS IPP on how to access the LIMS-Direct system are provided in [FSIS Directive 10,210.5 FSIS Sampling Data Reporting Through Laboratory Information Management System - Direct](#). Furthermore, FSIS provides quarterly letters to establishments to summarize official government sampling results covering a 12-month window. Lastly, in the event of a positive or violative result for an official government sample, FSIS does not re-test the sample.

Component 2 Government Verification of Food Safety and Other Consumer Protection Requirements

10. How does the CCA ensure that animals are handled and slaughtered humanely?

The FMIA ([21 U.S.C. 603b](#), [610](#)) and the Humane Methods of Livestock Slaughter Act ([7 U.S.C. 1901](#), [1902](#), and [1906](#)) both mandate that the handling and slaughter of livestock be carried out by humane methods. Further, [7 U.S.C. 1902](#) provides the two acceptable livestock slaughter methods that FSIS

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considers to be humane. These methods include rendering the livestock insensible to pain by a single blow or gunshot, or electrical, chemical, or other means that is rapid and effective, prior to shackling, hoisting, and cutting the animal; or the simultaneous and instantaneous severance of the carotid arteries causing a loss of consciousness.

For livestock, the statutory provisions are implemented through FSIS IPP enforcing and verifying compliance with [9 CFR 313](#). These prescriptive requirements include, but are not limited to, maintaining pens, driveways, and ramps in good repair and free from sharp or protruding objects; slip resistant or waffled flooring; providing water in all holding pens and, if held longer than 24 hours, access to feed; and the prohibition against dragging disabled animals while conscious. [9 CFR 313](#) also prescribes the requirements for using carbon dioxide, captive bolt, gunshot, and electric current during livestock slaughter.

FSIS IPP perform verification of the establishment's humane handling activities for livestock during each shift that animals are slaughtered, or when animals are on site, and record the results in PHIS. Furthermore, [9 CFR 313.50](#) lists the regulatory control actions that IPP can take if they observe an incident of inhumane slaughter or handling. Examples of noncompliance with humane handling requirements include, vehicles or ramps not properly positioned leading to the injury of animals, animals slipping and falling because of poor footing or lack of slip resistant flooring, holding pens lacking access to water, or animals regaining consciousness after stunning. Instructions to FSIS IPP, including how and when to document noncompliance and take enforcement actions, are provided in [FSIS Directive 6900.2 Humane Handling and Slaughter of Livestock](#). Instructions to District Veterinary Medical Specialists conducting humane handling verification visits are provided in [FSIS Directive 6910.1 District Veterinary Medical Specialist \(DVMS\) – Work Methods](#). Furthermore, establishments in violation of the statutory provisions and regulatory requirements, requiring the handling and slaughter of livestock to be carried out through humane methods, are subject to the enforcement actions in [9 CFR 500](#), such as suspension and withdrawal of inspection.

Regarding poultry establishments, [9 CFR 381.65\(b\)](#) requires that poultry be slaughtered “in accordance with good commercial practices in a manner that will result in thorough bleeding of the carcasses and ensure that breathing has stopped prior to scalding.” Also, any poultry carcass showing evidence of having died from causes other than slaughter is considered adulterated and must be condemned ([21 U.S.C. 453\(g\)\(5\)](#), [9 CFR 381.90](#)). FSIS IPP perform verification activities during each shift that poultry is slaughtered to verify compliance with good commercial practices. Examples of noncompliance with the requirement for good commercial practices include, establishment employees mistreating birds or handling them in a way that will cause death or injury, prevent thorough bleeding, or result in excessive bruising; stunning or bleeding equipment that is not functioning properly; or an increased number of bruised wings or legs. Instructions to FSIS IPP on how to verify good commercial practices in poultry establishments, including how and when to document noncompliance, are provided in [FSIS Directive 6110.1 Verification of Poultry Good Commercial Practices](#).

11. How does the CCA ensure that government inspection personnel perform ante-mortem inspection of livestock and poultry prior to slaughter?

The FMIA and PPIA both mandate that government inspectors perform ante-mortem inspection of all livestock ([21 U.S.C. 603](#)) and poultry ([21 U.S.C. 455\(a\)](#)) in establishments. These statutory provisions are codified in [9 CFR 309.1](#) (livestock) and [9 CFR 381.70](#) (poultry).

[9 CFR 309.1](#) requires that all livestock receive ante-mortem inspection on the day of slaughter, prior to entering an establishment. Therefore, if an establishment does not present animals for ante-mortem inspection in accordance with [21 U.S.C. 603](#) and [9 CFR 309.1](#), FSIS IPP are not able to determine that carcasses are not adulterated and, therefore, cannot permit the carcasses to be marked as “inspected and passed.” Carcasses from animals that did not receive ante-mortem inspection are condemned in

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accordance with procedures in [9 CFR 314](#). Furthermore, FSIS does not allow for the emergency slaughter of cattle that did not receive ante-mortem inspection ([9 CFR 309.12](#)).

[9 CFR 309.2-309.18](#) provide the requirements for the proper disposition of certain conditions. For example, [9 CFR 309.2](#) provides the conditions under which livestock would be determined to be “U.S. Suspect” (e.g., livestock that reacted to a tuberculin test). “U.S. Suspect” livestock are set apart and slaughtered separately from other livestock, and identified with a “U.S. Suspect” metal ear tag that can only be removed by FSIS personnel. In addition, any livestock found to be dead, dying, or diseased (per the conditions listed in [9 CFR 311](#)) are identified with a metal ear tag as “U.S. Condemned” and disposed of per the requirements in [9 CFR 309.13](#) and [314](#). Other conditions requiring a disposition of “U.S. Condemned” include, but are not limited to, all non-ambulatory disabled cattle, including non-ambulatory veal calves; and livestock showing symptoms of certain metabolic, toxic, nervous or circulatory disturbances, nutritional imbalances, or infectious or parasitic diseases. After determining that livestock is “U.S. Condemned,” FSIS Public Health Veterinarians (PHVs) verify that the establishment disposes the condemned livestock in accordance with [9 CFR 314](#) and maintains the required records ([9 CFR 320](#)).

During ante-mortem livestock inspection, FSIS IPP observe the animals at rest and in motion (from both sides) to assess the overall condition of each animal; the degree of alertness, mobility, and breathing; and whether there are any unusual swellings or any other abnormalities. In addition, FSIS IPP routinely verify that only livestock that have passed ante-mortem inspection are moved to slaughter, and that the number of livestock receiving ante-mortem inspection is equal to the number of livestock slaughtered. FSIS IPP then enter ante-mortem disposition data into PHIS. Instructions to FSIS IPP on conducting ante-mortem livestock inspection are provided in [FSIS Directive 6100.1 Ante-mortem Livestock Inspection](#).

Regarding poultry establishments, [9 CFR 381.70\(a\)](#) requires that poultry receive ante-mortem inspection on the day of slaughter. [9 CFR 381.71-381.75](#) lists the conditions under which a bird would be condemned, segregated, or quarantined and identified as either “U.S. Suspect” or “U.S. Condemned.” “U.S. Suspect” birds are set apart and slaughtered separately from other birds, and all birds found to be “U.S. Suspect” or “U.S. Condemned” are identified with a tag that can only be removed by FSIS personnel. Further, the list of diseases or conditions that would render a bird “U.S. Condemned” are provided in [9 CFR 381.80-381.93](#) and include, but are not limited to, avian leucosis, septicemia or toxemia, and cadavers. Condemned birds are disposed of in accordance with procedures in [9 CFR 381.95](#).

During ante-mortem poultry inspection, FSIS IPP observe the overall condition of the birds, and determine whether there are any unusual swellings or any other abnormalities on the birds, such as edema of the wattles, gasping and sneezing, off-colored feces, diarrhea, skin lesions, lameness, torticollis (e.g., wry neck), or bone or joint enlargement.

After completing ante-mortem inspection, FSIS IPP enter ante-mortem disposition data into PHIS. Instructions to FSIS IPP on how to perform ante-mortem poultry inspection are provided in [FSIS Directive 6100.3 Ante-mortem and Post-mortem Poultry Inspection](#). Instructions to FSIS IPP on how to perform ante-mortem inspection of ratites (e.g., ostrich, emu) are provided in [FSIS Directive 6170.1](#).

12. How does the CCA ensure that government inspection personnel perform post-mortem inspection of each and every livestock carcass, head, and viscera and each and every poultry carcass and viscera during and after the slaughter of livestock and poultry?

NOTE: In this SRT answer, the term “online” FSIS IPP refers to government inspectors working on the production line and performing post-mortem inspection procedures on each and every livestock carcass,

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head, and viscera and each and every poultry carcass and viscera². The term “offline” FSIS IPP refers to government inspectors performing verification activities throughout the establishment (e.g., HACCP, sanitation, zero tolerance). Offline FSIS IPP do not remain on the production line performing inspection activities throughout the day. Offline FSIS IPP are also referenced in SRT question #22.

Post-mortem inspection of each and every livestock carcass, head, and viscera and poultry carcass and viscera³ by government inspectors during and after slaughter is provided for in the FMIA ([21 U.S.C. 604](#)) and PPIA ([21 U.S.C. 455\(b\)](#)). These statutory provisions are codified in [9 CFR 310.1](#)(livestock) and [9 CFR 381.76](#) (poultry).

Livestock establishments are required to use an identifying device (e.g., ear tag, back tag) identifying all carcass parts (e.g., head, tongue, viscera) to the rest of the carcass ([9 CFR 310.2](#)) until post-mortem inspection by FSIS IPP is complete. Further, any carcass or part identified as either unfit for food purposes or adulterated, and requiring subsequent inspection, is marked with a “U.S. Retained” tag and retained by FSIS IPP pending final inspection by a FSIS PHV. If, at final inspection, the FSIS PHV then determines that the carcass or part is unsound, unhealthful, unwholesome, or otherwise adulterated, the carcass or part is marked as “U.S. Inspected and Condemned” and disposed of in accordance with the requirements in [9 CFR 314](#). 9 CFR 310.1 prescribes livestock government inspection staffing standards detailing how many inspectors must be present at each station dependent on maximum slaughter line speed. 9 CFR 310 also contains the requirements for presentation ([9 CFR 310.12](#)); the procedures for the disposition of thyroid glands, laryngeal muscle tissue, and lungs; and the procedures for the inspection of kidneys and mammary glands. The requirements for identifying and handling carcasses or components with certain disease conditions (e.g., tuberculosis, actinomycosis, melanosis) are provided in [9 CFR 311](#). In addition, FSIS recognizes fecal material, ingesta, and milk on livestock carcasses or carcass parts as common vehicles for microbial pathogens that cause foodborne illness and requires adequate removal of the contamination prior to passing inspection ([9 CFR 310.17-310.18](#)).

Online FSIS IPP perform post-mortem inspection procedures on each and every livestock carcass, head, and viscera to verify that the carcasses and parts are wholesome and not adulterated, including inspection procedures to ensure that each and every livestock carcass, head, and viscera are free of visible fecal material, ingesta, and milk. [FSIS Directive 6100.2 Post-mortem Livestock Inspection](#) provides instructions to online FSIS IPP on how to perform livestock post-mortem inspection on each and every carcass and carcass part (e.g., procedures for examining the head, carcass, and viscera of cattle, calves, swine, sheep, and lamb), and instructions to offline FSIS IPP on how and when to document noncompliance. For example, when examining cattle heads presented with the tongue inside the head, online FSIS IPP are instructed to observe the head's surfaces and eyes, and incise and observe the mandibular, parotid, medial, and lateral retropharyngeal lymph nodes. Further, [FSIS Directive 6100.2 Post-mortem Livestock Inspection](#) provides instructions to online FSIS IPP on the procedures to take if they observe fecal, ingesta, or milk contamination on a livestock carcass, head, or viscera during post-mortem inspection procedures. For example, when online FSIS IPP observe fecal, ingesta, or milk contamination at the final carcass inspection, they are to stop the slaughter line (unless the establishment has a rail-out loop) to allow establishment personnel to trim the contaminated carcass. Online FSIS IPP then re-inspect the trimmed carcass to verify that the contamination was removed in a sanitary manner ([9 CFR 310.18\(a\)](#)). If online FSIS IPP at the final carcass station believe that the establishment’s rail-out procedure is inadequate to prevent carcass accumulation or cross-contamination of other carcasses; or the establishment’s slaughter or dressing processes are not under control based on repeated presentation of contaminated carcasses for post-mortem inspection, the online FSIS IPP notify

² Under FSIS’s New Poultry Inspection System (NPIS), the government inspector’s visual inspection of each carcass also serves as the inspection of the viscera if the inspector’s condemnation of a carcass also requires condemnation of the corresponding viscera.

³ See Footnote 2

the FSIS inspector-in-charge (IIC). The IIC will perform additional verification activities, such as a livestock zero tolerance verification activity, to verify the adequacy of the establishment's procedures. Instructions to offline FSIS IPP on how to perform livestock verification activities are provided in [FSIS Directive 6420.2](#) *Verification of Procedures for Controlling Fecal Material, Ingesta and Milk in Slaughter Operations*. Instructions to FSIS PHVs on how to make post-mortem livestock dispositions for select diseases and conditions are provided in [FSIS Directive 6100.6](#) *Post-mortem Dispositions for Public Health Veterinarians*. After completing post-mortem livestock inspection, FSIS IPP record their inspection findings, along with daily slaughter data, in PHIS.

Regarding poultry establishments, [9 CFR 381.76\(a\)](#) requires post-mortem inspection for each and every poultry carcass and viscera⁴. The specific post-mortem inspection procedures depend on the type of post-mortem inspection system used by the establishment. [9 CFR 381.76](#) lists the six (6) types of post-mortem inspection systems and the requirements for each system (i.e., Traditional Inspection, Streamlined Inspection System (SIS), New Line Speed (NELS) Inspection System, New Poultry Inspection System (NPIS), New Turkey Inspection System (NTI), and Ratite Inspection). Maximum line speeds for each inspection system are provided in [9 CFR 381.67](#) (traditional), [381.68](#) (NTI), [381.69](#) (NPIS), and [381.76](#) (NELS and SIS). Under all poultry post-mortem inspection systems, FSIS IPP conduct post-mortem inspection for each and every poultry carcass and look for condemnable conditions (e.g., septicemia, toxemia), as specified in [9 CFR 381.80-381.94](#). Under every poultry post-mortem inspection system except NPIS, FSIS IPP conduct post-mortem inspection for each and every poultry viscera and look for condemnable conditions (e.g., tumor, inflammatory process). Adulterated product that cannot be reprocessed or reconditioned (i.e., by means of online antimicrobial intervention; offline vacuuming, washing, or trimming) is condemned under the supervision of a government inspector and disposed of in accordance with the requirements in [9 CFR 381.95](#). Examples of condemnable conditions in poultry carcasses include, but are not limited to, tuberculosis ([9 CFR 381.81](#)), septicemia or toxemia ([9 CFR 381.83](#)), and cadavers ([9 CFR 381.90](#)).

In establishments operating under NPIS, offline FSIS government inspectors perform hourly verification checks to verify that carcasses are free of visible fecal material and septicemia or toxemia before the carcasses are presented to the online FSIS government inspector for inspection. In addition, online FSIS government inspectors performing verification activities at establishments operating under NPIS continually verify that the establishment has properly trimmed, sorted (i.e., identified and disposed of poultry carcasses or parts exhibiting condemnable conditions), and reprocessed all carcasses; and carcasses are free from visible fecal material (as required per [381.65\(f\)](#)) and septicemia or toxemia, before the carcasses enter the chiller. Furthermore, FSIS requires NPIS establishments slaughtering young chicken to notify FSIS IPP prior to the slaughter of each new flock to allow the government inspection of viscera for avian visceral leukosis ([9 CFR 381.76\(b\)\(6\)\(iv\)](#)).

Instructions to online FSIS IPP on how to perform post-mortem poultry inspection, including dispositions for certain diseases, are provided in [FSIS Directive 6100.3](#) *Ante-mortem and Post-mortem Poultry Inspection*. For example, when performing online post-mortem inspection, FSIS IPP are instructed to observe the inner surfaces of the carcass for yellow scabbed areas between the skin and subcutaneous tissue of the flaps that could indicate inflammatory process. Instructions to FSIS IPP on how to perform online and offline post-mortem inspection procedures at poultry slaughter establishments operating under NPIS are provided in [FSIS Directive 6500.1](#) *New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirement*. Instructions to FSIS IPP on how to perform post-mortem inspection of ratites are provided in [FSIS Directive 6170.1](#). After completing post-mortem poultry inspection, FSIS IPP record their inspection findings, along with daily slaughter data, in PHIS.

⁴ See Footnote 2

13. How does the CCA ensure that a representative of the government inspection system makes periodic supervisory visits to each certified establishment to evaluate the performance of inspection personnel?

FSIS ensures that FSIS supervisory personnel make periodic supervisory visits to each establishment for the purpose of evaluating the performance of FSIS IPP by requiring that FSIS supervisors conduct at least two (2) in-plant performance reviews for each and every inspector per year. These reviews consist of firsthand, onsite observations to assess FSIS IPP's demonstrated knowledge of job requirements, appropriate regulatory decision making, and ability to execute inspection and verification procedures. Specifically, FSIS supervisory personnel assess FSIS IPP performance in the following areas: ante-mortem inspection; post-mortem inspection; humane handling and good commercial practices; Sanitation SOP's and Sanitation Performance Standards (SPS) verification; HACCP verification; food defense; economic adulteration and labeling verification; sampling methodology and collection procedures; export certification; import inspection; complete separation of official establishments; and official control over condemned material. Furthermore, supervisory IPP (i.e., PHVs) receive at least one in-plant performance review per year from the FSIS area supervisor to evaluate their performance in conducting and overseeing the performance of FSIS IPP in establishments. FSIS EIAOs also receive at least one in-person assessment per year from FSIS supervisory personnel to evaluate their performance in conducting food safety assessments, public health risk evaluations, recall effectiveness checks, and outreach activities.

In addition to the in-plant performance reviews of FSIS IPP, FSIS also maintains a performance management system, as required in [5 U.S.C. 43](#), which identifies and sets performance expectations and monitors performance. All FSIS IPP receive a midyear progress review and an annual performance rating. FSIS IPP who do not receive an acceptable rating are put on a Performance Improvement Plan with clearly defined expectations and a timeline, and failure to improve can lead to reassignment or removal.

Instructions to FSIS supervisory personnel on how to conduct in-plant performance reviews are provided in [FSIS Directive 4430.3](#) *In-Plant Performance System (IPPS)* and [FSIS Directive 4430.5](#) *Supervisory Tool for Assessment Results*. Instructions to FSIS supervisory personnel on how to conduct in-person performance reviews for FSIS EIAOs are provided in [FSIS Directive 4440.1](#) *Enforcement Investigation and Analysis Officer Assessments*.

14. How does the CCA ensure complete separation of certified meat, poultry, or eggs products from non-certified meat, poultry, or egg products?

FSIS ensures complete separation of official from unofficial establishments by verifying compliance, during routine government verification activities and supervisory visits, with [9 CFR 305.2](#) (meat), [381.26](#) (poultry), and [533.1](#) (Siluriformes). These regulations require that official establishments be "separate and distinct" from other establishments. When official establishments produce non-FSIS amenable product (e.g., product produced under the jurisdiction of the U.S. Food and Drug Administration (FDA)), FSIS IPP routinely verify that the FSIS amenable product is produced separately, by time or space, from the non-FSIS amenable product.

In addition, FSIS IPP consult the Export Library to verify that establishments producing product for export are meeting the specific requirements of the importing country, including any requirements necessitating producing product for export separately from domestic product (e.g., product produced without antimicrobial rinses).

15. How does the CCA ensure that meat, poultry, and egg products intended for export to the U.S. meet U.S. labeling requirements?

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FSIS ensures that meat, poultry, and egg products produced for domestic commerce or export comply with the labeling requirements in [9 CFR 317](#) and [319](#) (livestock), [9 CFR 541](#) (Siluriformes), [9 CFR 381 subpart N](#) (poultry), and [9 CFR 590.410- 590.419](#) (egg products). These regulations implement the statutory provisions in [21 U.S.C. 607](#) (meat), [457](#) (poultry), and [1036](#) (egg products).

The FMIA and PPIA both require establishments to obtain prior approval for labels of meat and poultry products before the products enter commerce. Prior approval is granted in one of two ways: sketch approval which is approved by the FSIS Labeling and Program Delivery Staff (LPDS), or generic approval which is approved by FSIS IPP verifying compliance with [9 CFR 412.2](#). In addition, FSIS requires that establishments maintain records of all labeling ([9 CFR 320.1\(b\)\(11\)](#), [381.175\(b\)\(6\)](#), [412.1](#), and [550](#)), to include: the final label applied to the product; product formulation; processing procedures; and supporting documentation, including prior sketch approval from LPDS (if applicable). The labeling requirements for imported meat and poultry products are provided in [9 CFR 327.14 - 327.15](#) (meat), [381.204 - 381.206](#) (poultry), and [557.14 – 557.15](#) (Siluriformes).

For egg products establishments, [9 CFR 590.411](#) requires prior label approval for all egg products before the products enter commerce. Further, [9 CFR 590.950](#) and [590.955](#) list the labeling requirements for imported egg products.

FSIS IPP perform routine labeling verification activities (i.e., no less than two labeling verification activities per week in meat and poultry establishments, and no less than one labeling verification activity per week in egg products establishments) to verify that all regulatory labeling requirements are being met and followed, and all labels are accurate and truthful. When performing the general labeling verification activity, FSIS IPP verify that the label contains all required information; the ingredients statement is accurate, (i.e., that all ingredients are listed in descending order of predominance); the label declares any proteinaceous substances used in the ingredients statement; the establishment used restricted ingredients as per regulatory requirements (e.g., sodium nitrite in bacon) the label is used on appropriate product; and a label approval is on file. Further, during general labeling verification, FSIS IPP review a sample of labels generically approved by the establishment to determine compliance with generic labeling requirements ([9 CFR 412.2](#)). Instructions to FSIS IPP for performing the general labeling verification activity, including how and when to document noncompliance, are provided in [FSIS Directive 7221.1 Prior Labeling Approval](#). Instructions to FSIS IPP for performing labeling verification activities on imported products are provided in [FSIS Directive 9900.5 Label Verification of Imported Meat, Poultry, and Egg Products](#).

In addition to verifying general labeling requirements, FSIS IPP also routinely verify that products are labeled with accurate net weights and not economically adulterated ([9 CFR 442](#)); and that labeled products meet regulatory standards through reviewing formulation records, or observing the preparation of products and comparing the findings to the appropriate regulatory standards (e.g., verifying that labeled products meet the standards of identity in [9 CFR 319](#) (meat) and [9 CFR 381 Subpart P](#) (poultry)). Instructions to FSIS IPP on how to verify that products are labeled accurately and not economically adulterated (e.g., inaccurate net weight), including how and when to document noncompliance, are provided in [FSIS Directive 7000.1, Verification of Non-Food Safety Consumer Protection Regulatory Requirements](#). FSIS IPP also verify that ingredients used in the production of meat, poultry, and egg products are safe and suitable and approved per [21 CFR](#). These approved ingredients are listed in [FSIS Directive 7120.1 Safe and Suitable Ingredients used in the Production of Meat, Poultry, and Egg Products](#), and [9 CFR 424.21](#).

In addition to routine labeling verification activities, FSIS IPP also perform a monthly verification activity to verify that establishments are accurately controlling and labeling the eight most common food allergens (i.e., wheat; crustacean shellfish (e.g., crab, lobster, shrimp); eggs; fish; peanuts; milk;

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tree nuts (e.g., almonds, pecans, walnuts); and soybeans). Instructions to FSIS IPP on how to perform this allergen verification activity, including how and when to document noncompliance, are provided in [FSIS Directive 7230.1](#). If an establishment ships product into commerce containing an undeclared allergen, the product is considered adulterated and misbranded (as defined in [21 U.S.C. 601](#) (meat), [453](#) (poultry), or [1033](#) (egg products)), and the establishment is subject to enforcement actions per [9 CFR 500](#) (meat and poultry) or [9 CFR 590.160](#) (egg products). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5 Case Referral and Disposition](#).

Lastly, FSIS conducts “for cause” species verification testing on both domestic and imported product. Instructions to FSIS IPP on how to collect samples for species verification testing are provided in [FSIS Directives 7000.1](#). Instructions to FSIS IPP on how to collect samples for species verification testing in domestic establishments producing Siluriformes products are provided in [FSIS Directive 14,010.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments](#), and instructions for collecting samples for species verification testing on imported Siluriformes products are provided in [FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments](#).

16. How does the CCA ensure that meat and poultry products designated for export to the U.S. are not restricted by the USDA Animal and Plant Health Inspection Service (APHIS)?

FSIS ensures that its imported meat and poultry originate from regions not currently restricted by APHIS by only importing meat, poultry, and egg products from countries where FSIS has determined, through documentation review and an on-site audit that the country’s food safety inspection system provides a level of sanitary protection equivalent to the level achieved by FSIS. Part of the equivalency process involves determining that the foreign country and establishments are not using source material from a currently restricted region (as identified on the APHIS website) to produce product for export to the U.S. Countries that fail to demonstrate that its source material is from an unrestricted region are deemed not equivalent and, thus, ineligible to export that commodity to the U.S. Furthermore, CBP verifies that the imported products are permitted entry into the U.S. and comply with USDA APHIS regulations prior to the products being received for FSIS reinspection. In addition, APHIS restrictions are programmed into PHIS and alert FSIS IPP if a shipment intended for importation is restricted by APHIS. During import reinspection, FSIS IPP verify that imported product originates from an eligible country with no current APHIS restrictions for that product, and if a violation or defect is observed upon reinspection, FSIS IPP document the finding in PHIS and refuse entry of the product. Instructions to FSIS IPP on how to identify, control, document, and dispose of imported meat, poultry, or egg products that are refused entry into the U.S. are provided in [FSIS Directive 9900.8 Meat, Poultry, and Egg Products Refused Entry Into The United States \(U.S.\)](#).

Furthermore, FSIS IPP verify during ante-mortem inspection that animals presented for slaughter do not display symptoms of foreign animal diseases and reportable conditions. Instructions to FSIS IPP on the conditions to look for when suspecting an animal may have a foreign animal disease or reportable condition, including the actions to take when a condition is suspected (i.e., contact APHIS), are provided in [FSIS Directive 6000.1 Responsibilities Related to Foreign Animal Diseases \(FADs\) and Reportable Conditions](#).

Jurisdiction over imported shell eggs is shared by FDA, APHIS, and USDA Agricultural Marketing Service (AMS). Each individual farm that produces shell eggs for export to the U.S. must register with FDA and comply with the regulatory requirements in [21 CFR 118](#). In addition, APHIS verifies that all

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imported agricultural products shipped to the U.S. from abroad, including shell eggs and egg products, meet APHIS entry requirements to exclude pests and diseases of agriculture. (**Note:** APHIS will allow for the importation of shell eggs from regions with Newcastle disease or Highly Pathogenic Avian influenza provided that the requirements in [9 CFR 94.6](#) are met (i.e., the shipment is accompanied by a certificate signed by an official veterinarian from that region, the eggs are moved under USDA seal directly from the port of arrival to an official breaking and pasteurization establishment)). Furthermore, AMS is responsible for checking imported shell eggs and ensuring that imported eggs originate from foreign farms registered with FDA. Further information can be found on the FSIS website under [Sourcing Egg Products and Shell Eggs from Foreign Countries](#).

17. How does the CCA ensure that all beef products are free of infectious materials associated with bovine spongiform encephalopathy (BSE), and all small ruminants (i.e., sheep and goats) are free of infectious materials associated with transmissible spongiform encephalopathy (TSE)?

FSIS ensures that all beef products are free of infectious materials associated with BSE by requiring and verifying that specified risk materials (SRMs) be removed from the carcasses of cattle, segregated from edible materials, and disposed of in accordance with the provisions in [9 CFR 314.1](#) or [9 CFR 314.3](#).

[9 CFR 310.22](#) identifies the following materials from cattle 30 months of age and older as SRMs: 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. In addition, the distal ileum of the small intestine and the tonsils are recognized as SRMs in cattle of all ages. Further, [9 CFR 310.22\(d\)\(1\)](#) lists the conditions under which the small intestine from all cattle may be used for human food.

[9 CFR 310.22](#) also identifies prescriptive procedures for the removal, segregation, and disposition of SRMs. Establishments that slaughter cattle and establishments that process the carcasses or parts of cattle are required to develop, implement, and maintain written procedures for the removal, segregation, and disposition of SRMs. Furthermore, these procedures must address potential contamination of edible materials with SRMs before, during, and after entry into the establishment, and be incorporated into the establishment's HACCP plan, Sanitation SOPs, or other prerequisite program. If either the establishment or FSIS determines that the establishment's SRM procedures failed to effectively remove, segregate, or dispose of SRM material, the establishment is required to take corrective actions. In addition, the establishment must maintain daily records sufficient to demonstrate adequate implementation and monitoring of the SRM procedures and any corrective actions taken. Lastly, [9 CFR 310.22](#) describes the sanitation requirements for equipment used to cut through SRMs.

Instructions to FSIS IPP on how to verify the adequate removal, segregation, and disposition of SRMs, including instructions on documenting noncompliance and enforcement actions, are provided in [FSIS Directive 6100.3](#) *Ante-mortem and Post-mortem Poultry Inspection*.

In addition to FSIS IPP verifying the adequate removal, segregation, and disposition of SRMs through routine government in-plant verification activities, USDA APHIS administers a national BSE surveillance program where FSIS IPP collect and submit brain tissue samples from cattle condemned on ante-mortem inspection for central nervous system conditions. Instructions to FSIS IPP on how to collect and submit samples for this program are provided in [FSIS Directive 10,400.1](#) *Sample Collection from Cattle under the Bovine Spongiform Encephalopathy (BSE) Ongoing Surveillance Program*.

Lastly, FSIS does not require or verify the removal of SRMs from small ruminants because TSE has not been determined to be a public health risk in the U.S. USDA APHIS conducts a Scrapie Flock Certification Program to certify scrapie-free herds and a Scrapie Eradication Program to accelerate the eradication of scrapie from the U.S.

18. How does the CCA ensure control over condemned animals, which can include portions of inspected carcasses and parts, and inedible material, until destroyed or otherwise denatured?

The FMIA ([21 U.S.C. 603, 604, 606, 641](#)), PPIA ([21 U.S.C. 455, 460](#)), and EPIA ([21 U.S.C. 1034\(c\), 1039](#)) all contain provisions requiring control over condemned animals or inedible material until destroyed for food purposes in the presence of an inspector, or otherwise denatured. These statutory provisions are codified in [9 CFR 311](#) and [314](#) (meat), [381.95](#) (poultry), [540](#) (Siluriformes), and [590.422](#) (egg products). In addition, the requirements for denaturing products and acceptable denaturing procedures are provided in [9 CFR 325.11, 325.13](#) (meat), [381.95](#) (poultry), and [540.3](#) (Siluriformes).

During both ante-mortem and post-mortem livestock and poultry inspection activities, FSIS IPP verify that adulterated and condemned materials are properly identified and controlled. FSIS IPP verify that any carcass or part affected with a disease or condition listed in [9 CFR 311](#) (meat) or [9 CFR 381.80-381.94](#) (poultry) is disposed of in accordance with the requirements in [9 CFR 314](#) (meat) or [9 CFR 381.95](#) (poultry). Furthermore, FSIS IPP verify that SRM and inedible materials are properly identified, controlled, and disposed of, and that all inedible materials are denatured prior to leaving the establishment. During routine inspector verification of SPS requirements, FSIS IPP verify that establishments comply with [9 CFR 416.3\(c\)](#), which requires that containers used for storing inedible material be clearly marked for that purpose and cannot be used for storing edible product. Additionally, FSIS maintains the authority and ability to suspend any establishment that fails to destroy a condemned meat or poultry carcass or its components ([9 CFR 500.3](#)).

Regarding egg product establishments, FSIS IPP verify that eggs ineligible for breaking and adulterated egg products are condemned and destroyed for human food purposes under the supervision of an inspector ([9 CFR 590.422](#)); and that all loss or inedible eggs or egg products are placed in a container clearly labeled “inedible,” and sufficiently denatured per the requirement in [9 CFR 590.504\(c\)](#).

19. How does the CCA ensure the implementation and maintenance of an egg products food safety inspection system that prevents food safety hazards that arise before, during, and after the intake of shell eggs for processing; and that only shell eggs determined to be fit for human food are used to produce processed egg products designated for export to the U.S.?

FSIS’s regulatory oversight of egg products establishments ensures that food safety hazards are being prevented before, during, and after receiving shell eggs for processing by providing continuous government inspection to verify compliance with the statutory provisions in the EPIA and all regulatory requirements in [9 CFR 590](#).

Examples of regulatory requirements that FSIS IPP verify compliance with include operating requirements for the following: candling and transfer room facilities and equipment ([9 CFR 590.506, 590.508](#)); proper sorting and identification of shell eggs to ensure that ineligible eggs as listed in [590.510](#) are not used to produce FSIS-inspected egg products; washing shell eggs with a continuous cleaning method ([9 CFR 590.515](#)); sanitizing (with potable water containing 100-200 ppm of available chlorine) and drying prior to breaking ([9 CFR 590.516](#)); and breaking rooms, freezing rooms, defrosting tanks or vats, spray process and albumen flake process dryers, blending and packaging equipment, air flow filtration, and heat treatment rooms ([9 CFR 590.520-590.548](#)). In addition, FSIS IPP verify that liquid egg products are properly pasteurized per the minimum temperature and holding time requirements in [9 CFR 590.570](#), or are heat-treated per the methods in [9 CFR 590.575](#); and meet the minimum cooling and freezing temperature requirements listed in [9 CFR 590.530](#) and [590.536](#).

FSIS IPP verify that only shell eggs determined to be fit for human food are used to produce FSIS-inspected egg products by verifying that shell eggs are properly classified and sorted so only eligible

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eggs are presented for breaking ([9 CFR 590.510](#)). FSIS IPP follow instructions in [FSIS Directive 5030.1](#) *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants* to verify that egg products establishments are meeting all food safety regulatory requirements in [9 CFR 590](#), including the requirement that shell eggs, when presented for breaking, be of edible interior quality and the shell be sound and free of adhering dirt and foreign material ([9 CFR 590.510\(c\)](#)).

Instructions to FSIS IPP on how to verify that egg products establishments meet all applicable regulatory requirements, including how and when to document noncompliance and take additional enforcement actions, are provided in [FSIS Directive 5030.1](#) *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants*. Additional instructions to FSIS IPP on performing egg products verification activities are provided in FSIS Directives [5020.1](#) *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants*, [5030.5](#) *Review of Egg Products Plants Drawings and Specifications*, and [5040.1](#) *Uses of FSIS Form PY-200 Egg Products Inspection Certificate*.

Component 3 Government Sanitation Verification

20. How does the CCA ensure that Siluriformes fish and fish products are raised and transported under sanitary conditions?

FSIS IPP verify that Siluriformes fish and fish products are raised and transported under sanitary conditions by verifying compliance with the regulatory requirements in [9 CFR 534](#). These requirements include, but are not limited to, ensuring that Siluriformes fish harvested for use as human food have grown and lived under conditions that will not render the Siluriformes fish or their products unsound, unwholesome, unhealthful, or otherwise unfit for human food ([9 CFR 534.1](#)); and vats or containers used to transport the Siluriformes fish from the producer to the processor are maintained in a sanitary condition ([9 CFR 534.4](#)).

FSIS IPP verify compliance with the regulatory requirements in [9 CFR 534](#) during a weekly verification activity by reviewing establishment records pertaining to pre-harvest standards and transportation to the processing establishment, such as water quality records for ponds and other waters where the Siluriformes fish are harvested. After reviewing the establishment records, if FSIS IPP have concerns that the Siluriformes fish may have been raised under insanitary conditions that may lead to adulterated or unwholesome product (e.g., evidence of heavy metals, pesticides, fertilizers, industrial chemicals, or drugs), FSIS IPP perform a HACCP verification activity to verify whether the establishment took appropriate corrective actions according to its HACCP system, adequately addressed chemical hazards in its hazard analysis, and implemented controls for the identified chemical hazards. In addition, Siluriformes fish arriving at the establishment that are dead, dying, diseased, or contaminated with substances that may adulterate fish products, are condemned (**NOTE:** FSIS does not require that wild-caught Siluriformes fish that die on the way to the establishment be condemned unless they are in a diseased or spoiled state). Instructions to FSIS IPP on how to verify compliance with [9 CFR 534](#) are provided in [FSIS Directive 14,000.1](#) *Consumer Safety Inspector Responsibilities at Fish Establishments*. Instructions to FSIS IPP on how to verify HACCP regulatory requirements are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment's Food Safety System*. Instructions to FSIS IPP on how to verify that establishments adequately address hazards in their HACCP system are provided in [FSIS Directive 5000.6](#) *Performance of the Hazard Analysis Verification (HAV) Task*.

Furthermore, if FSIS suspects that Siluriformes fish are being raised under insanitary conditions, [9 CFR 534.2](#) provides FSIS with the authority to collect samples of feed, fish, and water from producers for the purpose of verifying that the Siluriformes fish are being raised under conditions that will yield safe, wholesome products.

Lastly, if an establishment produces and ships adulterated Siluriformes products, FSIS has the authority and ability to suspend or withdraw inspection per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5 Case Referral and Disposition](#).

21. How does the CCA ensure that Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products?

FSIS IPP verify that Siluriformes fish that have died from circumstances other than under the controlled circumstances of commercial fishing are separated from eligible Siluriformes fish and fish products by verifying compliance with the regulatory requirements in [9 CFR 539.1](#) and [540.1](#). The types of conditions that would preclude a fish or fish part from being eligible for further processing include, but are not limited to, abscesses; lesions; parasites; flukes; spoilage or decomposition; and gross deformities caused by disease or chemical contamination.

FSIS IPP verify compliance with the regulatory requirements in [9 CFR 539.1](#) and [540.1](#) during a monthly verification task by observing points in the process where the establishment examines whole fish and fish products for quality or acceptability (e.g., initial sorting of live fish; after evisceration of whole fish; or after the fillet, trim, and cutup processes).

In addition, FSIS IPP verify establishment control for various conditions including, but not limited to, abscesses; sores; ulcers; evidence of spoilage or decomposition in whole fish or processed product; unusual gross deformities caused by disease or chemical contamination; and disease, spoilage or decomposition of dead fish arriving at the establishment. (**NOTE:** FSIS does not require that wild-caught Siluriformes fish that die on the way to the establishment be condemned unless they are in a diseased or spoiled state).

Instructions to FSIS IPP on how to verify compliance with the regulatory requirements in [9 CFR 539.1](#) and [540.1](#), including how and when to document noncompliance, are provided in [FSIS Directive 14,000.1 Consumer Safety Inspector Responsibilities at Fish Establishments](#). Further, if an establishment produces and ships adulterated Siluriformes products, FSIS has the authority and ability to suspend or withdraw inspection per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5 Case Referral and Disposition](#).

22. How does the CCA ensure that livestock and poultry are slaughtered and processed in a sanitary manner?

FSIS ensures that livestock are slaughtered and processed in a sanitary manner by verifying that establishments implement adequate sanitary dressing and process control procedures to prevent carcass contamination and comply with the regulatory requirements in [9 CFR 310.3](#), [310.17\(a\)](#), [310.18\(a\)](#), [318.2\(b\) and \(d\)](#), [318.4\(b\)](#), [416](#), and [417](#). Furthermore, the presence of visible fecal material, ingesta, or milk on livestock carcasses or carcass parts is considered an adulterant by FSIS per [21 U.S.C. 601\(m\)\(3\)](#).

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FSIS utilizes a system wide approach and verifies that the design of the establishment's slaughter operation includes a means to measure how well the sanitary dressing and process control procedures accomplish this purpose, and that the establishment responds if the measure shows that carcasses are adulterated and exposed to food safety hazards. The requirements concerning sanitary dressing include, but are not limited to, the removal of lactating and diseased mammary glands in livestock ([9 CFR 310.17\(a\)](#)); handling livestock in a sanitary manner to prevent contamination with fecal material, urine, hair, bile, dirt, or foreign material ([9 CFR 310.18\(a\)](#)); and ensuring that all livestock products are available for government reinspection as often as necessary for FSIS IPP to verify that products are not adulterated or misbranded at the time they enter or leave establishments ([9 CFR 318.2\(b\)](#)).

In beef slaughter establishments, FSIS IPP perform a sanitary dressing verification activity at least once per month to verify that establishments are implementing effective sanitary dressing and process control procedures to prevent contamination of carcasses (as required per [310.18\(a\)](#)), and properly applying decontamination and antimicrobial intervention treatments to carcasses and parts to address any contamination that may occur. FSIS IPP perform this monthly sanitary dressing verification activity prior to the carcass receiving final inspection. Furthermore, FSIS IPP verify that establishments are properly assessing any microbial testing results, including results for indicators of process control, at any point during slaughter and at subsequent trim fabrication and grinding operations. Examples of microorganisms used as indicators of process control in raw beef operations include *Enterobacteriaceae*, generic *Escherichia coli* (*E. coli*), *E. coli* O157:H7, non-O157 STECs, and *Salmonella*. Instructions to FSIS IPP on how to verify sanitary dressing and process control procedures in beef slaughter establishments, including how and when to document noncompliance, are provided in [FSIS Directive 6410.1 Verifying Sanitary Dressing and Process Control Procedures in Slaughter Operations of Cattle of Any Age](#).

In addition to the monthly sanitary dressing verification activity in beef slaughter establishments, FSIS IPP also perform weekly SPS verification activities to verify that establishments maintain sanitary conditions in compliance with [9 CFR 416.1-416.5](#). Furthermore, in livestock establishments that incorporate written sanitary dressing and process control procedures as part of their HACCP Plan, Sanitation SOP, Good Manufacturing Practices (GMP), or other pre-requisite programs, FSIS IPP perform routine HACCP and sanitation verification activities to verify that establishments are implementing and following their procedures as written. Instructions to FSIS IPP on how to verify compliance with HACCP, Sanitation SOP, and SPS requirements, including how and when to document noncompliance, are provided in [FSIS Directive 5000.1 Verifying an Establishment's Food Safety System](#).

Furthermore, offline FSIS IPP perform livestock zero tolerance verification activities at least once per shift in livestock slaughter establishments. This activity includes verifying that livestock carcasses are free of visible fecal material, ingesta, and milk at or immediately after the final rail and before the final wash; and head, cheek, and weasand meat are free of visible fecal material, ingesta, and milk at the end of the harvesting process (e.g., at the packaging step or when the product is placed into a container for storage). Additionally, FSIS IPP verify that establishments implement controls (i.e., Critical Control Points) to prevent contamination of carcasses with fecal contamination, ingesta, and milk. Instructions to FSIS IPP on how to perform the livestock zero tolerance verification activity, including how and when to document noncompliance, verify appropriate corrective actions (as required per [9 CFR 417.3](#)), and take enforcement measures, are provided in [FSIS Directive 6420.2 Verification of Procedures for Controlling Fecal Material, Ingesta, and Milk in Livestock Slaughter Operations](#) and [FSIS Directive 5000.1 Verifying an Establishment's Food Safety System](#).

Regarding poultry establishments, 9 CFR 381.65(f) requires all establishments that slaughter poultry (other than ratites) to develop, implement, and maintain written procedures to ensure that poultry

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carcasses contaminated with visible fecal material do not enter the chiller (as fecal material on poultry carcasses entering the chiller is considered by FSIS to be an adulterant per [21 USC 453\(g\)\(3\)](#)). [9 CFR 381.65\(g\)](#) requires establishments that slaughter poultry (other than ratites) to develop, implement, and maintain written procedures to prevent contamination with enteric pathogens and feces throughout the slaughter process. [9 CFR 381.65\(g\)](#) also requires poultry slaughter establishments to determine which microbial organisms will be effective in monitoring process control and implement their own sampling plans, specifically for enteric pathogens and indicators of fecal contamination (e.g., generic *E. coli*). Further, [9 CFR 381.65 \(f\)](#) and [381.65\(g\)](#) require poultry slaughter establishments to incorporate the above written procedures into their HACCP plan, Sanitation SOP, or other prerequisite program. Lastly, [9 CFR 381.145\(b\)](#) requires that all poultry products be available for government reinspection as often as necessary for FSIS IPP to verify that the products are not adulterated or misbranded at the time they enter or leave official establishments ([9 CFR 381.145\(b\)](#)).

In establishments operating under poultry inspection systems other than NPIS (e.g., traditional, streamlined inspection system (SIS), new line speed (NELS) inspection system), offline FSIS IPP perform zero tolerance verification activities to verify that establishments are preventing carcasses with fecal material from entering the chiller. This activity is performed at least two times per production line on each shift that poultry is slaughtered, and consists of selecting and examining 10 poultry carcasses after the final wash and before the chilling tank, to verify that the establishment complies with [9 CFR 381.65\(f\)](#). In establishments operating under NPIS, the zero tolerance verification activity is performed at an increased frequency of at least 8 times per production line on each shift that poultry is slaughtered (i.e., at least once per hour, offline FSIS IPP select and examine 10 carcass samples prior to the chiller to verify compliance with [9 CFR 381.65\(f\)](#)).

FSIS IPP perform routine HACCP and sanitation verification activities to verify that poultry establishments are maintaining and implementing written procedures for preventing contamination with feces throughout the slaughter process. For example, if a poultry slaughter establishment produces giblets (i.e., edible livers, hearts, or gizzards) and maintains a procedure in its Sanitation SOP plan to prevent fecal contamination on giblets, FSIS IPP perform a sanitation verification activity to verify that the establishment is following its written procedures and giblets are free from fecal contamination. Instructions to offline FSIS IPP on how to verify poultry slaughter establishments maintain adequate procedures for preventing contamination with feces and enteric pathogens throughout the slaughter process, including how and when to document noncompliance, verify appropriate corrective actions (as required per [9 CFR 417.3](#)), and take enforcement measures, are provided in [FSIS Directive 6420.5](#) *Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens*. Additional instructions to FSIS IPP on how to perform verification activities in establishments operating under NPIS, including how and when to document noncompliance, verify appropriate corrective actions (as required per [9 CFR 417.3](#)), and take enforcement measures, are provided in [FSIS Directive 6500.1](#) *New Poultry Inspection System: Post-Mortem Inspection and Verification of Ready-To-Cook Requirement*. Instructions to FSIS IPP on how to verify compliance with HACCP, Sanitation SOP, and SPS requirements, including how and when to document noncompliance, are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment's Food Safety System*.

Lastly, FSIS has the authority under [9 CFR 500](#) to implement enforcement measures including, but not limited to, suspension of inspection if sanitary conditions are such that products in the establishment are or would be rendered adulterated ([9 CFR 500.3](#)), and withdrawal of inspection for failure to maintain sanitary conditions ([9 CFR 500.6\(d\)](#)). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive](#)

[8010.5](#) *Case Referral and Disposition.*

23. How does the CCA ensure that the condition of certified establishments' construction, facilities, and equipment is adequate to prevent the contamination or adulteration of meat, poultry, or egg products designated for export to the U.S.?

FSIS ensures that establishments' construction, facilities, and equipment are maintained in a sanitary manner to prevent the contamination or adulteration of meat, poultry, or egg products by FSIS IPP verifying compliance with the SPS requirements in [9 CFR 416.1-416.6](#) (meat and poultry), and the sanitation requirements in [9 CFR 590.500-590.575](#) (egg products) at least once per week. These regulations implement the statutory provisions in 21 U.S.C. [608](#) (meat), [456](#) (poultry), and [1035](#) (egg products), which require that all establishments maintain sanitary conditions in their premises, facilities, and equipment, or FSIS will refuse to provide inspection.

Prior to granting a meat or poultry establishment Federal inspection, FSIS surveys each establishment to determine whether the construction and facilities of the establishment are in accordance with the SPS regulations ([9 CFR 304.2](#) (meat), [381.20](#) (poultry), and [532.2](#) (Siluriformes)). Once an establishment is granted Federal inspection, FSIS verifies ongoing compliance with these regulations through routine verification activities and on-site supervisory reviews. If FSIS determines that a meat or poultry establishment's construction and facilities are creating insanitary conditions, FSIS can take an enforcement action, such as a regulatory control action or suspension, per [9 CFR 500](#). Instructions to FSIS personnel on granting, refusing, suspending or withdrawing inspection are provided in [FSIS Directive 5220.1](#) *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS*. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.

Examples of the SPS regulatory requirements that FSIS IPP verify compliance with include, but are not limited to, maintaining a pest management program; separate and distinct rooms for the handling and processing of edible and inedible products; adequate lighting and ventilation; a potable water supply with adequate pressure; and cleaning and sanitizing both food contact surfaces and non-food contact surfaces, as frequently as necessary, to prevent the creation of insanitary conditions and the adulteration of product ([9 CFR 416.2-416.4](#)). Instructions to FSIS IPP on how to verify compliance with the SPS regulatory requirements, including how and when to document noncompliance and how to verify appropriate establishment corrective actions after instances of noncompliance, are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment's Food Safety System*.

Prior to receiving continuous government inspection in egg product establishments, the establishment must demonstrate compliance with the sanitation requirements in 9 CFR 590, including requirements for equipment and facilities ([9 CFR 590.146](#)). The regulatory requirements for facilities/sanitation in egg products establishments are provided in [9 CFR 590.500-590.575](#). Examples of these requirements include, but are not limited to, maintaining buildings in sound construction and good repair to prevent the entrance of vermin; efficient drainage and plumbing; a potable water supply with adequate pressure; and separate and enclosed refuse rooms ([9 CFR 590.500](#)). Instructions to FSIS IPP on how to verify construction, facility, and equipment requirements in egg processing establishments, including how and when to document noncompliance, are provided in [FSIS Directive 5030.1](#) *Inspection Methodology Utilizing the Public Health Information System (PHIS) for the Verification of Regulatory Compliance in Egg Products Plants*. Furthermore, FSIS maintains the authority and ability to suspend inspection at egg product establishments that fail to maintain their premises, facilities, and equipment in a

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satisfactory state of repair ([9 CFR 590.160](#)).

24. How does the CCA ensure that certified establishments develop, implement, and maintain daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products designated for export to the U.S.?

FSIS ensures that each establishment develops, implements, and maintains daily pre-operational and operational sanitation procedures sufficient to prevent the direct contamination or adulteration of meat, poultry, and egg products by verifying compliance with the Sanitation SOP requirements in [9 CFR 416.11-416.17](#) (meat and poultry) and [9 CFR 537.1](#) (Siluriformes), and the sanitation requirements in [9 CFR 590.500-590.575](#) (egg products). These regulations implement the statutory provisions in 21 U.S.C. [608](#) (meat), [456](#) (poultry), [1035](#) (egg products), which require that all establishments comply with the sanitation regulations to prevent adulterated product from entering commerce, or FSIS will refuse to render inspection. Furthermore, these regulations were created with the enactment of the “Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems” Final Rule ([61 FR 38806](#)) in 1996 which requires that each meat and poultry establishment develop and implement written Sanitation SOP’s.

As previously mentioned, meat and poultry establishments are required to develop written Sanitation SOP’s prior to receiving Federal inspection ([9 CFR 304.3](#) (meat), [381.22](#) (poultry), and [532.2](#) (Siluriformes)). Instructions to FSIS personnel on how to verify these regulatory requirements are met prior to granting Federal inspection, and how to refuse, suspend or withdraw inspection when the requirements are not met, are provided in [FSIS Directive 5220.1](#) *Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS*. In addition, the regulatory requirement to develop, implement, and maintain written Sanitation SOP’s is verified through both routine in-plant verification activities and on-site supervisory visits. During Sanitation SOP verification activities, FSIS IPP routinely perform both observational and recordkeeping verification activities (i.e., at least twice per week) to verify that establishments meet all the regulatory requirements in [9 CFR 416.11-416.17](#), such as, describing the procedures and frequencies of all Sanitation SOP’s; identifying the establishment personnel responsible for the implementation and maintenance of the procedures; identifying pre-operational cleaning procedures to include the cleaning of food contact surfaces; performing corrective actions when the Sanitation SOP’s failed to prevent direct contamination or adulteration of product; and maintaining daily records documenting the implementation and monitoring of the Sanitation SOP’s, and any corrective actions taken. Instructions to FSIS IPP on how to perform both operational and pre-operational sanitation verification activities, including enforcement measures and how and when to document noncompliance, are provided in [FSIS Directives 5000.1](#) *Verifying an Establishment’s Food Safety System* and [5000.4](#) *Performing The Pre-Operational Sanitation Standard Operating Procedures Verification Task*. [FSIS Directive 5000.1](#) also provides instructions to FSIS IPP on how to verify that establishments meet all the requirements in [9 CFR 416.15](#) when taking corrective actions, including how and when to take a regulatory control action when the establishment does not comply with the corrective action requirements in [9 CFR 416.15](#). Furthermore, if a meat or poultry establishment fails to implement or maintain written Sanitation SOP’s, FSIS has the authority and ability to suspend or withdraw inspection per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.

In addition to verification during routine in-plant sanitation verification activities, FSIS supervisory personnel conduct on-site visits to verify that FSIS IPP are adequately performing sanitation

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verification activities and the establishment in meeting the requirements in [9 CFR 416](#). Furthermore, FSIS EIAOs verify compliance with sanitation regulatory requirements during food safety assessments. During these assessments, EIAOs verify that the design and implementation of the establishment's Sanitation SOPs is adequate to prevent insanitary conditions and product adulteration. Instructions to FSIS EIAOs on how to perform this activity are described in [FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#).

Egg products establishments must also demonstrate compliance with sanitation requirements prior to receiving continuous government inspection ([9 CFR 590.146](#)). On-going compliance with the egg products sanitation regulations ([9 CFR 590.500-590.575](#)) is verified through both in-plant verification activities and on-site supervisory reviews. During government verification activities, FSIS IPP routinely perform both observational and recordkeeping verification activities to verify that the establishment is meeting all sanitation requirements. These requirements include cleaning and sanitizing utensils and equipment prior to operations, and maintaining equipment and utensils in clean and sanitary conditions during all processing operations ([9 CFR 590.504\(n\)](#)). Instructions to FSIS IPP on how to perform sanitation verification activities in egg products establishments, including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System \(PHIS\) for the Verification of Regulatory Compliance in Egg Products Plants](#). In addition, if an egg products establishment fails to maintain sanitary conditions, FSIS has the authority and ability to refuse, suspend, or withdraw inspection per [9 CFR 590.160](#).

Component 4 Government HACCP System Verification

25. How does the CCA ensure that certified establishments develop, implement, and maintain a HACCP system to ensure that food safety hazards are identified, and prevented or controlled when producing meat or poultry products for export to the U.S.?

FSIS ensures that meat and poultry establishments identify food safety hazards and control identified food safety hazards by verifying compliance with all HACCP regulatory requirements in [9 CFR 417](#). These regulations were created with the enactment of the "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems" Final Rule ([61 FR 38806](#)) in 1996 which requires that all meat and poultry establishments develop and implement a HACCP system for the purpose of reducing the occurrence and numbers of pathogenic microorganisms on meat and poultry products, and reducing the incidence of foodborne illness associated with the consumption of those products.

Prior to receiving a grant of Federal inspection, or producing a new product for distribution in commerce, meat and poultry establishments are required to conduct a hazard analysis, and develop and validate a HACCP plan (if it is determined in the hazard analysis that one or more food safety hazards are likely to occur in the production process) as required by [9 CFR 304.3](#) (meat), [381.22](#) (poultry), and [532.2](#) (Siluriformes). In order to validate their HACCP plan under actual processing conditions, FSIS provides establishments seeking a grant of Federal inspection, or establishments producing new product, a 90-day conditional grant. Further, any establishment that produces product without a HACCP plan is subject to enforcement actions, such as suspension or withdrawal of inspection, per [9 CFR 500](#). Instructions to FSIS personnel on how to verify these regulatory requirements are met prior to granting Federal inspection, and how to refuse, suspend or withdraw inspection when the requirements are not met, are provided in [FSIS Directive 5220.1 Granting or Refusing Inspection; Voluntary Suspending or Withdrawing Inspection; and Reinstating Inspection under PHIS](#).

To verify regulatory compliance with all [9 CFR 417](#) requirements (and [9 CFR 537](#) requirements in establishments producing Siluriformes products), FSIS IPP routinely perform both observational and recordkeeping verification activities (i.e., at least twice per week per process category). During the

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observational and recordkeeping components of the HACCP verification activity, FSIS IPP verify that the establishment meets all HACCP regulatory requirements for all critical control points (CCP's), including monitoring, verification, recordkeeping, and corrective actions. These requirements include, but are not limited to, establishing critical limits; listing the procedures and frequencies used to monitor CCP's; performing and documenting on-going verification activities (i.e., the calibration of process monitoring instruments, direct observations of monitoring activities and corrective actions, and records review); maintaining CCP monitoring records that record the actual time, temperature, or other quantifiable value; reassessing the HACCP plan at least annually, or whenever any changes occur (e.g., a change in raw or source material, a change in product formulation); performing pre-shipment review; and developing and implementing corrective actions that will ensure that the cause of the deviation is identified and eliminated, the CCP will be under control after the corrective action is taken, measures to prevent recurrence are established, and no product that is injurious to health or otherwise adulterated as a result of the deviation enters commerce ([9 CFR 417.2-417.5](#)).

Furthermore, when performing routine HACCP verification activities, FSIS IPP verify that establishments review all records associated with the HACCP system and tied to the specific production lot being shipped prior to signing the preshipment review record. This includes verifying that establishments receive acceptable establishment testing results (for establishment testing performed to support a decision made in the hazard analysis) and perform adequate corrective actions (9 CFR 417.3); and verifying that establishments receive and confirm acceptable official government testing results (from all official government samples taken from the specific production lot being shipped) prior to completing and signing the preshipment review record. As outlined in [76 FR 19955](#) "Not Applying the Mark of Inspection Pending Certain Test Results", "the pre-shipment review of records associated with the production lot will not be complete without the pending [official government] test results." This applies to confirmation of acceptable government verification testing results for the following sampled products: raw non-intact beef product or raw intact beef product intended for raw non-intact use that is tested for STEC; RTE products tested for *Lm*, *Salmonella*, or STEC (RTE beef products); RTE product that passed over food contact surfaces that have been tested for the presence of *Lm* and *Salmonella*; and livestock carcasses subject to FSIS testing for veterinary drugs (e.g., antibiotics, sulfonamides, avermectins).

In addition to verification during routine in-plant HACCP verification activities, FSIS supervisory personnel also verify compliance with the HACCP requirements during supervisory visits. FSIS supervisory personnel conduct on-site visits to verify that FSIS IPP are adequately performing HACCP verification activities and the establishment in meeting the requirements in [9 CFR 417](#). Furthermore, FSIS EIAOs verify compliance with HACCP regulatory requirements during food safety assessments. During these assessments, EIAOs analyze and document whether the establishment's HACCP system has identified and prevented or controlled all hazards that are reasonable likely to occur in the production process, and whether the establishment maintains adequate supporting documentation to support its decisions regarding the identified hazards. Instructions to FSIS EIAOs on how to perform this analysis are described in [FSIS Directive 5100.1](#) *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*.

Lastly, FSIS IPP perform quarterly hazard analysis verification activities in all establishments to verify that establishments have conducted a hazard analysis identifying all food safety hazards in their process, and implemented preventive measures to control these hazards. When performing the hazard analysis verification activity, FSIS IPP refer to the FSIS [Meat and Poultry Hazards and Controls Guide](#), which lists potential biological, physical, and chemical hazards and frequently used controls and preventive measures for each step. FSIS IPP also verify that establishments maintain adequate support for all decisions made in their hazard analyses, including support for both CCPs and prerequisite programs. This also includes verifying that establishments maintain both components for HACCP validation: scientific and technical data, and in-plant (implementation) data.

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Instructions to FSIS IPP on how to verify that an establishment is meeting all HACCP regulatory requirements and effectively implementing its HACCP plan, including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment's Food Safety System*. Instructions to FSIS IPP on how to verify that an establishment's hazard analysis meets all [9 CFR 417](#) regulatory requirements, including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directives 5000.1](#) and [5000.6](#) *Performance of the Hazard Analysis Verification (HAV) Task*. Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.

Component 5 Government Chemical Residue Program

26. How does the CCA ensure the implementation and maintenance of an official government chemical residue control program that prevents and controls all specific compounds of concern in the foreign country and in the U.S.?

FSIS considers meat, poultry, and egg products to be adulterated under the FMIA ([21 U.S.C. 601\(m\)\(1\)](#)), PPIA ([21 USC 453\(g\)\(1\)](#)), and EPIA ([21 USC 1033\(a\)\(1\)](#)) if the product contains a chemical compound at a level in excess of an established tolerance or action level, or if the residue detected has no approved tolerance.

Under the authority of the FMIA, PPIA, and EPIA, FSIS administers the [U.S. National Residue Program \(NRP\) for Meat, Poultry, and Egg Products](#), which is an interagency program designed to identify, rank, and analyze for chemical contaminants in meat, poultry, and egg products. FSIS publishes the NRP Residue Sampling Plans (known as the [Blue Book](#)) each year to provide information on the process of sampling meat, poultry, and egg products for chemical contaminants of public health concern. The Blue Book includes information on FSIS's chemical residue sampling plans, a summary of changes from the previous year's NRP, and a list of chemical residues by class/method.

The NRP is developed in consultation with the Surveillance Advisory Team (SAT) which is comprised of technical experts from the following three principal U.S. government agencies: FSIS, FDA, and the Environmental Protection Agency (EPA). The SAT meets annually to decide which compounds represent a public health concern and warrant inclusion in the NRP scheduled sampling plans. In addition, the SAT may propose, based on professional judgment and reliable field information, the initiation of exploratory assessments for directed sampling on a production class or region of the country. These agencies work together to create the annual sampling plan, based on the following: prior NRP findings of chemical residues in meat, poultry, and egg products; FDA veterinary drug inventories completed during on-farm visits and investigation information; and pesticides and environmental contaminants of current importance to EPA.

FSIS's 2018 NRP includes an overview of domestic and import reinspection sampling plans, as well as the policy and procedures for holding or controlling product under the NRP. Chemical compounds analyzed in the program include approved and unapproved veterinary drugs, pesticides, and environmental compounds. The NRP is designed to: (1) provide a structured process for identifying and evaluating chemical compounds used in animal foods, (2) analyze chemical compounds of concern, (3) collect, analyze, and report results, and (4) identify the need for regulatory follow-up subsequent to the identification of violative levels of chemical residues.

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FSIS uses novel multi-residue methods for the detection and confirmation of veterinary drugs, pesticides, and environmental contaminants. Appendix I of the NRP lists the names of the chemical residues by class/method. The analytical methods used for screening and confirmation are provided in the FSIS [Chemistry Laboratory Guidebook](#). Furthermore, the tolerances for veterinary drugs and action levels for environmental contaminants are established by FDA, and listed under [Title 21 CFR](#). Tolerances for registered pesticides are established by the EPA, and listed under [Title 40 CFR](#).

The NRP consists of three separate, but interrelated, chemical residue testing programs: scheduled sampling (Tier 1), targeted sampling at the production or compound class level (Tier 2), and targeted sampling at the herd/flock or compound class level. The NRP also contains the number of analyses per production class by compound class, and the statistical basis for the sampling number (about 800 samples for each of the nine major production classes tested under Tier 1). Furthermore, FSIS laboratory personnel enter detailed residue violation information into an FSIS/FDA interagency database, and post a weekly [Residue Repeat Violator's List](#) on the FSIS website. When a violative result is identified, FSIS notifies the establishment, FSIS IPP, and the producer, of the analysis results. In addition, FSIS shares the violation data with EPA and FDA. FDA has on-farm jurisdiction and works with cooperating State agencies to investigate producers linked to residue violations and, if conditions leading to residue violations are not corrected, can enforce legal action.

FSIS IPP collect and submit official government chemical residue samples through either the scheduled (directed) sampling program or inspector generated sampling. Inspector generated sampling is conducted whenever FSIS IPP suspect, through either herd history or ante-mortem or post-mortem inspection findings, that a carcass may contain a violative residue finding (e.g., FSIS IPP observe mastitis or an injection site when performing ante-mortem inspection) or on any carcass exhibiting signs of systemic conditions (e.g., septicemia, peritonitis, pyemia). Inspector generated sampling is performed through an in-plant screening test known as the Kidney Inhibition Swab (KISTTM), which is an antibiotic screen test for kidney tissue; and through the collection and submission of tissue samples. Other examples of when inspector generated sampling is performed include, but are not limited to, when FSIS PHVs suspect nonsteroidal anti-inflammatory drugs (NSAID) or beta-agonist use in livestock. In addition, FSIS IPP also collect and submit samples for laboratory analyses on imported meat and poultry products. When a KISTTM test and any other inspector-generated sampling is performed, FSIS IPP maintain control of the carcass and its parts pending non-violative test results. If a KISTTM test is positive, FSIS IPP send liver, muscle, and kidney tissue to the laboratory for further analysis. Under the directed sampling program, FSIS IPP send kidney, liver, and muscle tissues to the laboratory for analysis; and verify the appropriate disposition of the livestock carcass pending violative test results. Directed samples are assigned to FSIS IPP through PHIS based on the frequency noted in the NRP. Instructions to FSIS IPP on how and when to collect and submit residue samples; retain livestock carcasses pending non-violative test results (for samples taken under the inspector generated sampling program) or verify establishments are retaining carcasses pending nonviolative test results (for samples taken under the inspector generated sampling program); verify corrective actions; document noncompliance; and take enforcement actions are provided in [FSIS Directive 10,800.1, Residue Sampling, Testing and Other Verification Procedures under the National Residue Program for Meat and Poultry Products](#) and [FSIS Directive 14,010.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes from Domestic Establishments](#). Instructions to FSIS IPP on how to collect KISTTM samples are provided in [KISTTM Test Instructions](#). Lastly, instructions to FSIS IPP on how to collect and submit residue samples for imported meat, poultry, and egg products are provided in [FSIS Directive 9900.6](#) and [FSIS Directive 14,100.1 Speciation, Residue, and Salmonella Testing of Fish of the Order Siluriformes at Official Import Inspection Establishments](#).

In addition, FSIS IPP withhold the mark of inspection on all livestock carcasses subject to FSIS testing (e.g., veterinary drugs, such as antibiotics, sulfonamides, or avermectins or the feed additive carbadox) pending non-violative testing results ([77 FR 73401](#)); and verify that establishments maintain control of

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the livestock carcasses and parts and not allow those carcasses and parts to enter commerce until receipt and confirmation of non-violative official government testing results ([76 FR 19955](#)). If an establishment does not maintain control of a livestock carcass tested by FSIS for chemical residues (under the directed sampling program) and found to be violative, and the product enters commerce, FSIS has the authority and ability to take additional enforcement measures per [9 CFR 500](#).

Accompanying the NRP is a detailed spreadsheet of the previous year's residue sampling results (known as the [Red Book](#)). This sheet provides detailed information regarding samples taken by FSIS for both the domestic scheduled and inspector-generated sampling programs, in addition to the import sampling program results. The detailed results include sample collection and review dates, the project code, the animal class, tissue type, chemical residue name, concentration value, sample results (whether positive non-violative or positive violative), chemical concentration values (if any) and the CFR reference per chemical listed in the data sheet.

Further information on FSIS's NRP, including a link to the Residue Repeat Violator's List and Residue Quarterly Reports, can be found under [Residue Chemistry](#) on the FSIS website.

Component 6 Government Microbiological Pathogen and Process Control Programs

27. How does the CCA ensure that a slaughter establishment's microbiological sampling and testing program for meat and poultry verifies process control using microbiological analyses for indicators of intestinal and fecal contamination?

Under "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems" ([61 FR 38806](#)), FSIS requires that slaughter establishments conduct routine microbiological testing to verify the adequacy of their slaughter and sanitary dressing process controls for the prevention of contamination with fecal material and other intestinal contents and associated bacteria. In livestock and ratite slaughter establishments, establishment testing for generic *E.coli* as an indicator organism allows the establishment to assess process capability and process control. More recently, FSIS implemented "Modernization of Poultry Slaughter Inspection" ([79 FR 49566](#)) which specifies the requirements for how poultry slaughter establishments (excluding ratites) are to monitor process control through analyses for microbiological organisms, including sampling location and sampling frequency requirements. Requirements for process control verification criteria and testing can be found in [9 CFR 310.25](#) (meat), [381.65\(g\)](#) (poultry) and [381.94](#) (ratites).

[9 CFR 310.25](#) requires that all livestock slaughter establishments test for generic *E.coli*, and provides the sampling techniques, methodology, and frequency requirements for testing. These requirements include, developing and maintaining written specimen collection procedures that identify the employees designated to collect samples, the locations of sampling, how randomness is achieved, and measures to ensure sample integrity. Sample collection procedures include sponging or excising tissue from the flank, brisket, and rump for cattle (excluding hide-on calves); and sponging or excising tissue from the ham, belly, and jowl areas for swine. Further, this regulation requires that establishments analyze results using an Association of Official Analytical Chemists (AOAC) approved quantitative method or equivalent method, and maintain records of the analytic results (to be made available for FSIS review).

FSIS IPP perform a weekly verification activity to verify that establishments implement effective control measures for relevant pathogens by reviewing establishment records for trend analysis of testing results and for responses to deviations resulting in food safety hazards. In addition, FSIS IPP perform routine verification activities to verify that establishments are implementing adequate control measures through either their HACCP system, Sanitation SOP's, or other prerequisite programs to control pathogens (e.g., antimicrobial intervention, sanitary dressing). Furthermore, FSIS IPP supervisory personnel verify that establishments maintain adequate control measures for relevant microbiological pathogens during supervisory reviews. Instructions to FSIS IPP on how to verify compliance with the

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regulatory requirements in [9 CFR 310.25](#), including how and when to document noncompliance and how to identify trends of noncompliance, are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment's Food Safety System*. Instructions to FSIS IPP on how to review establishment testing data are provided in [FSIS Directive 5000.2](#) *Review of Establishment Data by Inspection Personnel*.

Additionally, [9 CFR 381.65\(g\)](#) requires that all official poultry establishments (except those that slaughter ratites) develop, implement, and maintain written procedures to prevent contamination of carcasses and parts by enteric pathogens (e.g., *Salmonella* and *Campylobacter*) and fecal material throughout the entire slaughter and dressing operation. At a minimum, these procedures must include sampling and analysis for microbial organisms. Further, each establishment must incorporate these written procedures, including their microbiological sampling plans, into their HACCP plan, Sanitation SOPs, or other prerequisite programs; and maintain daily records documenting the implementation and monitoring of these procedures (also required to be made available for FSIS review). This regulation also specifies that samples are to be collected and analyzed for microbial organisms at the pre-chill and post-chill points in the process (unless a very small or very low volume establishment operating under Traditional Inspection), and that the required sampling frequency is proportional to the establishment's production volume (e.g., once per 22,000 carcasses for chicken, once per 3,000 carcasses for turkeys, ducks, geese, guineas, and squabs). Instructions to FSIS IPP on how to verify compliance with the regulatory requirements in [9 CFR 381.65\(g\)](#), including how and when to document noncompliance, are provided in [FSIS Directives 5000.1](#) *Verifying an Establishment's Food Safety System* and [6420.5](#) *Verifying Poultry Slaughter Establishments Maintain Adequate Procedures for Preventing Contamination with Feces and Enteric Pathogens*.

Official establishments that slaughter ratites must also test for generic *E. coli* ([9 CFR 381.94](#)). These requirements mirror the requirements for generic *E. coli* testing in livestock establishments.

Lastly, if a meat, poultry, or ratite establishment fails to meet the regulatory requirements in [9 CFR 310.25](#), [381.65\(g\)](#), or [381.94](#), FSIS can take enforcement actions per [9 CFR 500](#), including suspension or withdrawal of inspection.

28. **How does the CCA ensure the reduction of *Salmonella* in raw meat and poultry products, and *Campylobacter* in raw poultry products through sampling and other verification activities?**

FSIS ensures that raw meat and poultry products are produced safely and that pathogen levels are reduced or eliminated during slaughter and processing operations by implementing official government sampling and testing programs (i.e., routine, follow-up, and import sampling) for *Salmonella* and *Campylobacter* and performing non-sampling government verification activities (i.e., HACCP, Sanitation SOP, sanitary dressing verification) in establishments.

FSIS IPP perform routine HACCP, Sanitation SOP, and sanitary dressing verification activities in all raw meat and poultry establishments to determine whether an establishment has procedures in place designed to address the control or monitoring of *Salmonella* or *Campylobacter* (e.g., interventions to reduce or eliminate *Salmonella* or *Campylobacter*, pre-harvest practices or purchase specification programs intended to reduce *Salmonella* or *Campylobacter* in live animals or raw materials received at the establishment). FSIS IPP also perform quarterly hazard analysis verification activities to verify that establishments are identifying and adequately addressing *Salmonella* and *Campylobacter* in their hazard analyses. In addition, FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments perform adequate corrective actions in response to positive establishment testing results. Further, FSIS IPP in official poultry establishments verify that establishments meet the chilling performance standards in [9 CFR 381.66\(b\)](#) for poultry (excluding ratites) which include, chilling all poultry carcasses, parts, and giblets immediately after slaughter operations to prevent pathogen outgrowth ([9 CFR 381.66\(b\)\(1\)\(i\)](#)); and developing, implementing, and maintaining written procedures

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for chilling that addresses the potential for pathogen outgrowth, the conditions affecting carcass chilling, and the length of time necessary for adequate chilling ([9 CFR 381.66\(b\)\(3\)](#)). These procedures are required to be incorporated into the establishment's HACCP plan, Sanitation SOPs, or other prerequisite programs. In addition, [9 CFR 381.91\(b\)\(1\)](#) and [381.91\(b\)\(2\)](#) contain requirements for online and offline poultry reprocessing and require official establishments to incorporate procedures for the use of approved online antimicrobial intervention systems or offline reprocessing into their HACCP plans, Sanitation SOPs, or other prerequisite programs (see [List of Approved On Line Reprocessing \(OLR\) and Off Line Reprocessing \(OFLR\) List of Approved On Line Reprocessing \(OLR\) and Off Line Reprocessing \(OFLR\) Antimicrobial Systems for Poultry](#)). Instructions to FSIS IPP on how to verify establishment *Salmonella* and *Campylobacter* control programs are provided in [FSIS Directive 10,250.1 Salmonella and Campylobacter Verification Program for Raw Meat and Poultry Products](#). Instructions to FSIS IPP on how to verify compliance with HACCP and sanitation regulatory requirements, including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directive 5000.1 Verifying an Establishment's Food Safety System](#). Instructions to FSIS IPP on how to review establishment testing data are provided in [FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel](#).

The FSIS *Salmonella* sampling verification program formally began with the issuance of FSIS's final rule, "Pathogen Reduction; Hazard Analysis and Critical Control Point (PR/HACCP) Systems" ([61 FR 38805-38989](#)), published on July 25, 2006. Among other things, the PR/HACCP rule set *Salmonella* performance standards for establishments producing selected classes of raw meat and poultry products. As stated in the PR/HACCP rule (at 61 FR 38835), FSIS selected *Salmonella* for the performance standard because it is the most common cause of foodborne illness associated with meat and poultry products; it is present to varying degrees in all major species; and the interventions targeted at reducing *Salmonella* may help reduce contamination by other enteric pathogens. FSIS continues to use pathogen reduction performance standards to ensure that eligible establishments are consistently controlling or reducing harmful bacteria on raw meat and poultry products.

FSIS has pathogen reduction performance standards listed in 9 CFR for the following products and is currently enforcing compliance with these performance standards:

- Raw chicken and turkey
 - Carcasses ([76 FR 15282](#))
 - Chicken parts ([81 FR 7285](#))⁵
 - Comminuted products ([81 FR 7285](#))⁶

FSIS has pathogen reduction performance standards listed in 9 CFR for the following products; however, these performance standards are not currently enforced by FSIS (see additional information below for information on why FSIS suspended its official government sampling verification program for these products):

- Raw bovine products ([9 CFR 310.25](#))
 - Steer and heifer carcasses
 - Cow and bull carcasses
 - Ground beef, bulk or patties
- Market hog carcasses ([9 CFR 310.25](#))

To that end, FSIS has implemented official government sampling verification programs for *Salmonella* and *Campylobacter* in the following raw poultry products: chicken carcasses, turkey carcasses, chicken

⁵ On November 9, 2018, FSIS published Federal Register Notice "Changes to the Salmonella and Campylobacter Verification Testing Program: Revised Categorization and Follow-Up Sampling Procedure" ([83 FR 56046](#))

⁶ See Footnote 5

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parts (e.g., legs, breasts, wings), comminuted chicken (i.e., product that has been ground, or hand- or mechanically deboned and further chopped, flaked, minced or otherwise processed to reduce particle size), and comminuted turkey. For clarification, “comminuted” means product that is ground, flaked, minced, or otherwise significantly reduced in particle size to less than ¾ inch (1.9 cm)). FSIS also tests the following raw beef products for *Salmonella*: raw ground beef, bench trim (purchased) and manufacturing trimmings, and other raw ground beef components such as head meat, cheek meat, weasand meat, heart meat, and product from advanced meat recovery systems (AMR).

The methods for developing the pathogen reduction performance standards and predictions for the public health effect of those standards are described in the 2015 [Public Health Effects of Raw Chicken Parts and Comminuted Chicken and Turkey Performance Standards](#). FSIS used the same methodology to estimate the public health effects for the chicken and turkey carcass performance standards in 2011. FSIS used a common analytical framework to estimate the improvements in public health (illnesses averted) associated with six separate pathogen reduction performance standards discussed as options. Based on the risk assessment predictions, FSIS estimated the reductions in salmonellosis and campylobacteriosis cases that would result if establishments made changes in their processes.

Do note, in August 2018, FSIS began using an enrichment-based method to analyze poultry samples for *Campylobacter* due to the low sensitivity of the direct plating analytical method. Therefore, at this time, FSIS is not currently assessing *Campylobacter* performance in poultry establishments and is currently revising the *Campylobacter* performance standards based on the enrichment method.

Regarding official government verification sampling for *Salmonella* in raw beef and swine, FSIS suspended official government verification of compliance with the *Salmonella* performance standards in beef (steers/heifers and cows/bulls) and swine (market hog) carcasses (2011), as well as in raw ground beef (2014), because the percentage of positive findings was very low. However, regulatory requirements in [9 CFR 310.25](#) remain in place for cow/bull/steer/heifer and market swine, and establishments that slaughter these livestock are expected to meet these criteria. Although these official government sampling verifications programs were suspended, FSIS continues to monitor the reduction of *Salmonella* by co-analyzing official government samples of raw ground beef, beef manufacturing trimmings, bench trim, and other raw ground beef components collected for STEC analysis for the presence of *Salmonella* (see 79 FR 32436, “[Changes to Salmonella Verification Sampling Program: Analysis of Raw Beef for Shiga Toxin-Producing Escherichia coli and Salmonella](#)”). In addition, FSIS samples raw ground beef products at retail stores, and imported ground beef, trim, and other raw ground beef components for *Salmonella*. For raw pork products, FSIS has initiated sampling and analysis of raw pork cuts and raw comminuted pork to determine the prevalence of *Salmonella* in these products ([Raw Pork Products Exploratory Sampling Program](#)). FSIS will use the data collected from these raw beef and pork products sampling programs to support future policy development, which could include new or updated *Salmonella* performance standards. In addition, FSIS has initiated sampling and analysis of raw Siluriformes fish products to determine the prevalence of *Salmonella* in these products to inform future policy development.

The frequency of routine government verification sample assignment is dependent on slaughter volume data (e.g., higher volume-producing establishments are sampled more frequently (maximum 4-5 samples per month per product type) than lower volume-producing establishments (minimum 1 sample/month per product type)). Additional information can be found in [FSIS Establishment Eligibility Criteria for the Salmonella and Campylobacter Verification Sampling Program and FSIS Scheduling Algorithm for the Salmonella and Campylobacter Verification Sampling Programs for Raw Poultry](#). Instructions to FSIS IPP on how to choose and collect carcass/parts rinses (chicken) and carcass sponge (turkey) samples for *Salmonella* and *Campylobacter* testing, and the actions to take in the event an establishment fails to meet FSIS performance standard criteria (i.e., follow-up sampling) are provided in [FSIS Directive 10,250.1 Salmonella and Campylobacter Verification Program for Raw](#)

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Meat and Poultry Products. Additional information and instructions to FSIS IPP can be found under the [Raw Chicken Parts Sampling Program](#) and [Raw Chicken Parts Sampling Supplies and “How to” Guidance](#); and the [Not Ready-to-Eat Comminuted Poultry Sampling Program](#) and [Comminuted Poultry Sampling Supplies and “How-to” Guidance](#).

In addition, FSIS monitors relevant databases (e.g., those maintained by the Centers for Disease Control and Prevention and the National Institutes of Health) for clinical isolates that match food isolates obtained by FSIS in its sampling of products produced by official establishments.

When not ready-to-eat (NRTE) poultry or meat products are associated with an illness outbreak and contain pathogens that are not considered adulterants, FSIS likely will consider the product linked to the illness outbreak to be adulterated under [21 U.S.C. 453\(g\)\(3\)](#) or [21 U.S.C. 601\(m\)\(3\)](#) because the product is “unsound, unhealthful, unwholesome, or otherwise unfit for human food.” In such cases, FSIS would request that the establishment recall the product if it is still in commerce. FSIS may also perform follow-up sampling and conduct a public health risk evaluation, to analyze the establishment’s food safety system and determine if a food safety assessment is necessary. If deemed necessary, FSIS will schedule a food safety assessment (FSA) and verify whether the establishment is able to produce safe and wholesome poultry products in accordance with FSIS statutory and regulatory requirements. During the FSA, FSIS EIAOs review the establishment’s food safety system as a whole, including the design of the establishment’s HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment’s sampling and testing programs, and the establishment’s reaction to sampling results. Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in [FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer \(EIAO\) Public Health Risk Evaluation \(PHRE\) Methodology](#) and [FSIS Directive 5100.1 Enforcement, Investigations, and Analysis Officer \(EIAO\) Comprehensive Food Safety Assessment Methodology](#).

FSIS’s methods of analysis for official government *Salmonella* and *Campylobacter* verification testing programs are included in the [MLG](#) (Chapter 4 and Chapter 41, respectively). The proposed number of *Salmonella* (and *Campylobacter* in poultry) official government verification samples for raw beef and raw poultry products for the 2017 fiscal year (FY17), the actual number of samples for FY17, and the proposed number of samples for the FY18 can be found in the FSIS [Annual Sampling Program Plan](#). Information on FSIS’s *Salmonella* and *Campylobacter* sampling program for imported products can also be found in the FSIS [Annual Sampling Program Plan](#). Lastly, additional information on FSIS’s *Salmonella* and *Campylobacter* verification testing program for raw meat and poultry, including monthly, quarterly, and annual reports, can be found under [Microbiology](#) on the FSIS website.

29. How does the CCA ensure through sampling and other verification activities that raw beef products are free of STEC at the end of the production process?

FSIS considers all raw non-intact beef and raw intact beef intended for use in raw non-intact product to be adulterated under the FMIA ([21 U.S.C. 601\(m\)\(1\)](#)) if contaminated with *E. coli* O157:H7 or one of six non-O157 STEC (O26, O45, O103, O111, O121, and O145). To ensure that raw beef products are free of STEC, FSIS implements official government verification sampling and testing programs (i.e., routine, follow-up, and import sampling) and performs routine non-sampling government verification activities (i.e., HACCP, Sanitation SOP, sanitary dressing verification).

FSIS IPP conduct routine HACCP verification activities, through review of records and observations, and a quarterly hazard analysis verification activity to verify that the establishment is meeting all [9 CFR 417 PR/HACCP](#) regulatory requirements including, identifying STEC as a hazard in the hazard analysis; maintaining support for decisions made in the hazard analysis and HACCP plan, including prerequisite programs; adequately validating their HACCP plan; reassessment; and conducting monitoring,

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verification, recordkeeping, corrective actions, and preshipment review per the regulatory requirements. FSIS IPP also verify that establishments identify the product's intended use (e.g., intact beef primal and subprimal cuts are intended for intact use) per the requirement in [9 CFR 417.2\(a\)\(2\)](#) and have supporting documentation to support the product's intended use per [9 CFR 417.5\(a\)\(1\)](#). FSIS IPP verify that establishments and retail stores that grind raw beef for sale in commerce maintain specific information about their grinding activities as required per [9 CFR 320.1\(b\)\(4\)](#). Furthermore, FSIS IPP verify that establishments perform ongoing verification activities to ensure their food safety system is functioning as intended and continues to support decisions made in their hazard analysis, such as conducting establishment testing for STEC on an ongoing basis to demonstrate that their HACCP systems are working effectively to eliminate or reduce STEC to a non-detectable level. FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments that received positive STEC results from their establishment testing program identify the sampled lot as adulterated per [21 USC 601\(m\)\(1\)](#) and perform adequate corrective actions per [9 CFR 417.3](#). If an establishment fails to perform adequate corrective actions on product that tested positive for STEC (through establishment testing), and the product is shipped into commerce, FSIS can take enforcement actions per [9 CFR 500](#). Instructions to FSIS IPP on how to perform inspection verification activities other than official government verification sampling (e.g., HACCP verification), including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directive 10,010.2 Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#). Instructions to FSIS IPP on how to review establishment testing data are provided in [FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel](#). Instructions to FSIS IPP on how to verify whether official establishments are maintaining required records concerning suppliers and source materials for raw beef ground at the establishment are provided in [FSIS Directive 5000.10 Verifying that Records are Kept by Official Establishments that Grind Beef](#).

In addition to inspection verification activities, FSIS conducts official government verification sampling of raw ground beef products and raw intact beef products intended for non-intact use, or when the intended use is unclear as described in [FSIS Directive 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#). FSIS collects and analyzes raw beef samples for both *E. coli* O157:H7 and *Salmonella* under four routine sampling programs which are categorized based on the product group (i.e., beef manufacturing trimmings; bench trim; other raw ground beef components, such as head meat, cheek meat, weasand meat, heart meat and product from advanced meat recovery systems (AMR); and raw ground beef products in establishments that grind or form patties). Beef manufacturing trimmings are also analyzed for presence of the six non-O157 STECs (i.e., O26, O45, O103, O111, O121, and O145), in addition to *E. coli* O157:H7 and *Salmonella*. These product samples are collected and submitted by FSIS IPP under the STEC sampling program. FSIS bases the frequency of its domestic sampling program primarily on production volume for each product group. The proposed number of official government verification samples for STEC in raw non-intact beef and raw intact beef intended for use in raw non-intact product for the 2017 fiscal year (FY17), the actual number of samples collected and analyzed for FY17, and the proposed number of samples for the FY18 can be found in the FSIS [Annual Sampling Program Plan](#). Information on FSIS's STEC sampling program for imported beef products can also be found in the FSIS [Annual Sampling Program Plan](#). FSIS's methods of analysis for official *Salmonella* and STEC verification testing programs are included in the [MLG](#) (Chapter 4 and Chapter 5C respectively). Instructions to FSIS IPP on how to collect and submit official government STEC samples, including the actions to take when a test result is positive for STEC, are provided in [FSIS Directive 10.010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#).

FSIS requires establishments to hold or maintain control of raw beef products that FSIS has tested for STEC pending negative FSIS results ([76 FR 19955](#)). In addition, FSIS IPP verify that establishments maintain a supportable basis for their lotting definition. For sampling purposes, lots should be defined

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so that they are microbiologically independent; meaning that if a positive result is found in one lot, the product from the other lot would not be implicated. Factors that FSIS IPP look for when determining if the lot is microbiologically independent include, scientific, statistically-based sampling programs for STEC used to distinguish between segments of production; Sanitation SOP's or other prerequisite programs used to control the spread of STEC cross-contamination between raw beef components during production; co-mingling of products; and processing interventions that limit or control STEC contamination. Product that is implicated with a positive official government test result (i.e., product that is not microbiologically independent from the sample) and was not held would be subject to voluntary recall. [76 FR 19955](#) stipulates that if the establishment has completed preshipment review prior to receiving official government test results, and the official government test results are positive, the establishment has produced and shipped adulterated product into commerce ([21 USC 601\(m\)\(1\)](#)). Under these circumstances, FSIS will take an appropriate enforcement action per [9 CFR 500](#) (e.g., immediately suspending inspection or issuing a Notice of Intended Enforcement Action). In addition, FSIS will request a voluntary recall of product, detain the product in commerce, or institute other product control actions if necessary. Instructions to FSIS IPP on how to verify that establishments hold or retain control of product pending negative FSIS test results for STEC, and maintain support for lot definitions are provided in [FSIS Directive 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#).

When a routine official government verification sample tests positive for STEC, the sampled lot is considered adulterated as per the statutory definition in [21 U.S.C. 601\(m\)\(1\)](#). FSIS IPP conduct follow-up sampling and perform HACCP, Sanitation SOP, and sanitary dressing verification activities, in both the producing and supplying establishments, to determine whether the establishments effectively address control of STEC and implement corrective actions per [9 CFR 417.3](#). Instructions to FSIS IPP on how to perform follow-up sampling when an official government test result is positive for STEC are provided in [FSIS Directive 10,010.1 Sampling Verification Activities for Shiga Toxin-Producing Escherichia Coli \(STEC\) in Raw Beef Products](#).

In addition, when a routine official government sample tests positive for STEC, FSIS EIAOs perform traceback investigations to verify all source materials and potential suppliers of source materials were identified, and any products not microbiologically independent from the adulterated lot are removed from commerce (when applicable). As part of traceback investigations, FSIS IPP review slaughter establishment test results to determine whether the establishment has experienced a high-event period. A high-event period is a high rate of positive STEC sample results over a relatively short period of time, indicating the establishment did not maintain adequate process control over STEC. FSIS IPP use this information to determine whether the establishment has a supportable basis for microbiological independence and can support its decision concerning which products are held from entering commerce. Instructions to FSIS personnel on how to perform traceback investigations, and determine whether the establishment has experienced a high-event period, are provided in [FSIS Directive 10,010.3 Traceback Methodology for Escherichia Coli \(E. coli\) O157:H7 in Raw Ground Beef Products and Bench Trim](#).

Furthermore, if an official government test result is confirmed positive for STEC, FSIS will conduct a public health risk evaluation to assess and analyze the establishment's food safety system and determine if an immediate enforcement action or food safety assessment is necessary. If necessary, FSIS will schedule a food safety assessment and verify whether the establishment is able to produce safe and wholesome beef products in accordance with FSIS statutory and regulatory requirements. During the food safety assessment, FSIS EIAOs review the establishment's food safety system as a whole, including the design of the establishment's HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment's sampling and testing programs, and the establishment's reaction to sampling results. Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in [FSIS Directive 5100.4 Enforcement, Investigations and Analysis Officer](#)

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(EIAO) *Public Health Risk Evaluation (PHRE) Methodology* and [FSIS Directive 5100.1](#) *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*.

Lastly, if an establishment ships STEC positive product into commerce (determined through either establishment testing or official government verification testing), FSIS can take enforcement actions per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.

30. **How does the CCA ensure through sampling and other verification activities that RTE meat and poultry products and all lots of pasteurized egg products are not contaminated with microbiological pathogens or their toxins, including *Lm* and *Salmonella*?**

FSIS considers all RTE meat, poultry products, and pasteurized egg products to be adulterated under the FMIA ([21 U.S.C. 601\(m\)\(1\)](#)), PPIA ([21 U.S.C. 453\(g\)\(1\)](#)), and EPIA ([21 U.S.C. 1033\(a\)\(1\)](#)) if contaminated with any level of *Lm* or *Salmonella*. Further, FSIS identifies RTE product as adulterated if it passes over a food contact surface that has tested positive for *Lm* or *Salmonella*. To ensure that RTE products are free of *Lm* and *Salmonella*, FSIS implements official government verification sampling and testing programs (i.e., routine, follow-up, and import sampling) and performs routine non-sampling government verification activities (e.g., HACCP, sanitation, labeling).

The regulations requiring control of *Lm* in post-lethality exposed RTE products are contained in [9 CFR 430.4](#) (also known as the *Listeria* Rule), and state that *Lm* is a hazard that establishments producing post-lethality exposed RTE meat or poultry products must control through their HACCP plans, or prevent in their processing environment through the implementation of Sanitation SOP's or other prerequisite programs. (NOTE: Establishments producing RTE *Siluriformes* products are subject to the requirements of the *Listeria* rule as specified in [9 CFR 548.5](#).)

In order to maintain the sanitary conditions necessary to meet this requirement, establishments are required to comply with the requirements of one of three *Listeria* alternatives listed in [9 CFR 430.4](#). For example, Alternative 1 uses a post-lethality treatment (PLT) and an antimicrobial agent or process (AMAP) to control *Lm* and requires that the PLT be included in the HACCP plan. Alternative 2b (AMAP alone) and Alternative 3 (sanitation alone) both require establishment testing of food contact surfaces in the post-lethality processing environment for *Lm* or an appropriate indicator organism. Establishments with processes falling in Alternatives 2b or 3 are also required to identify the size, site location, frequency of testing, and conditions under which the establishment will hold and test the product following a positive test for *Listeria* spp. on a food contact surface.

FSIS IPP perform routine verification activities (i.e., HACCP, sanitation, and labeling) to verify that the design and execution of the establishment's programs meet the requirements of [9 CFR 430.4](#). For example, FSIS IPP perform sanitation verification activities at least twice per production week in RTE establishments to verify that establishments design and execute their Sanitation SOPs to prevent contamination of food contact surfaces or adulteration of RTE products with *Lm* and other pathogens prior to and during operations in the post-lethality environment. FSIS IPP also perform routine HACCP verification activities at least twice per production week to verify that establishments design and execute their HACCP plan effectively to control contamination of food contact surfaces or adulteration of RTE products with *Lm* and other pathogens. This includes verifying that establishments that use post-lethality treatments to reduce or eliminate microorganisms on the product include the post-lethality treatment in their HACCP plan (as required per [9 CFR 430.4](#)). FSIS IPP also perform quarterly hazard analysis verification activities to verify that establishments producing RTE products are identifying and

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adequately addressing *Lm* and other pathogens in their hazard analyses. In addition, FSIS IPP perform at least one general labeling verification activity per production week to verify that product that is labeled as RTE product meets the requirements in [9 CFR 318.17](#), [318.23](#), or [381.150](#). Additional information on the routine verification activities used by FSIS IPP to verify establishment compliance with [9 CFR 430.4](#), including instructions to FSIS IPP on how and when to document noncompliance and take enforcement actions, can be found in [FSIS Directive 10,240.4 Verification Activities for the *Listeria monocytogenes* \(Lm\) Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#). Instructions to FSIS IPP on how to review establishment testing data are provided in [FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel](#).

Furthermore, as part of these routine HACCP verification activities, FSIS IPP verify that establishments perform ongoing verification activities to ensure their food safety inspection system is functioning as intended and continues to support decisions made in their hazard analysis, such as conducting ongoing establishment testing for *Lm* (or an indicator organism) on food contact surfaces in the post-lethality processing environment (as required by certain *Listeria* alternatives) to demonstrate that their HACCP and sanitation systems are working effectively to eliminate or reduce *Lm* to a non-detectable level. FSIS IPP review establishment testing data and results at least once per production week for trend analysis. When reviewing establishment testing data, FSIS IPP verify that establishments that received positive *Lm* (or an indicator organism) results from their establishment testing program for food contact surfaces perform corrective actions per [9 CFR 416.15](#) or [9 CFR 417.3](#). For example, in establishments producing RTE products under Alternative 3, FSIS IPP verify that establishments perform follow-up sampling on food contact surfaces for *Lm* or an indicator organism in accordance with [9 CFR 430.4\(b\)\(3\)\(ii\)\(A\)](#). FSIS considers post-lethality exposed RTE product that passed over the food contact surface that tested positive for *Lm* through establishment testing, or the product that tested positive for *Lm* through establishment testing, to be adulterated per [21 USC 601\(m\)\(1\)](#). If the establishment fails to perform adequate corrective actions in response to positive *Lm* establishment test results, and the product is shipped into commerce, FSIS can take enforcement actions per ([9 CFR 500](#)). Instructions to FSIS IPP on how to review establishment testing data are provided in [FSIS Directive 5000.2 Review of Establishment Data by Inspection Personnel](#). Instructions to FSIS IPP on how to verify adequate corrective actions in the event of positive establishment test results are provided in [FSIS Directive 10,240.4 Verification Activities for the *Listeria monocytogenes* \(Lm\) Regulation and the Ready-to-Eat \(RTE\) Sampling Program](#).

In addition to verifying compliance with the *Lm* requirements in [9 CFR 430.4](#) for RTE products, FSIS IPP perform HACCP verification activities to verify that establishments employ adequate lethality and stabilization procedures to meet the lethality performance standards for *Salmonella* in [9 CFR 318.17\(a\)\(1\)](#) (meat) and [9 CFR 381.150\(a\)\(1\)](#) (poultry). FSIS IPP also verify that establishments comply with the stabilization requirements (to prevent the growth of *Clostridium botulinum* (*C. botulinum*) and limit the growth of *Clostridium perfringens* (*C. perfringens*) in RTE products) in [9 CFR 318.17\(a\)\(2\)](#) and [318.23\(c\)\(1\)](#)(meat), and [9 CFR 381.150\(a\)\(2\)](#)(poultry). Additionally, FSIS recommends a 5.0-log₁₀ reduction of *E. coli* O157:H7 in RTE fermented products containing beef. Instructions to FSIS IPP on how to verify that an establishment's lethality and stabilization procedures meet regulatory requirements, including the actions to take in the event of a heating or cooling deviation, are provided in [FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization](#). Furthermore, if FSIS determines that an establishment produced and shipped adulterated RTE products containing pathogens that are injurious to health due to inadequate lethality or stabilization procedures ([21 USC 601\(m\)\(1\)](#) and [453\(g\)\(1\)](#)), or that an establishment has shipped products that were prepared, packed, or held under insanitary conditions ([21 U.S.C. 601\(m\)\(4\)](#) and [453\(g\)\(4\)](#)), FSIS can take enforcement actions per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3 Administrative Enforcement Action Decision-Making and Methodology](#). Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in

[FSIS Directive 8010.5](#) *Case Referral and Disposition.*

FSIS performs government verification testing for *Lm* and *Salmonella* in both post-lethality exposed and non-post-lethality exposed RTE products. These product samples are collected and submitted by FSIS IPP under the RTE routine sampling program. Additional information on the scheduling criteria FSIS uses to assign samples under the RTE routine sampling program can be found under [Updates to Random and Risk-based Scheduling Criteria for the Ready-to-Eat \(RTE\) Product Routine Sampling Program](#). In addition, FSIS performs verification testing for *Lm* in product, and on food contact surfaces and environmental (non-food contact) surfaces under its routine risk-based *Lm* (RLm) sampling program; and verification testing for *Lm* and *Salmonella* on product, food contact surfaces, and environmental surfaces, in response to positive government verification results or a documented change in an establishment's production process that may impact public health, under its Intensified Verification Testing (IVT) program. Further, when performing government verification testing for *Lm* and *Salmonella* in RTE products, FSIS considers the sampled lot to be the product produced from "clean-up to clean-up" (i.e., a product lot separated by complete cleaning and sanitizing), unless the establishment has another supportable lot definition. Additionally, FSIS requires establishments to hold or control RTE product tested by FSIS for *Lm* or *Salmonella*, and RTE product that has passed over food contact surfaces tested by FSIS for *Lm* or *Salmonella*, pending acceptable FSIS test results ([76 FRN 19955](#)). (NOTE: FSIS discontinued testing RTE samples for the presence of *E. coli* O157:H7 in dried/semi-dried, fermented sausages and cooked meat patties after an analysis showed that testing over 10,000 such products over a nine-year period yielded no *E. coli* O157:H7 positive samples.) Instructions to FSIS IPP on how to collect and submit official government verification samples for *Lm* and *Salmonella* in RTE products, including verifying that the establishment holds or retains control of the RTE product pending acceptable FSIS test results, can be found in [FSIS Directive 10,240.4](#) *Verification Activities for the Listeria monocytogenes (Lm) Regulation and the Ready-to-Eat (RTE) Sampling Program*.

Furthermore, if an official government verification test result is confirmed positive for *Lm* or *Salmonella* in RTE product, FSIS IPP verify that establishments take adequate corrective actions per [9 CFR 416.15](#) or [417.3](#). In addition, FSIS will conduct a public health risk evaluation, to assess and analyze the establishment's food safety system and determine if an immediate enforcement action or food safety assessment (including sampling under the IVT testing program) is necessary. If necessary, FSIS will schedule a food safety assessment and verify whether the establishment is able to produce safe and wholesome RTE meat or poultry products in accordance with FSIS statutory and regulatory requirements. During the food safety assessment, FSIS EIAOs review the establishment's food safety system as a whole, including the design of the establishment's HACCP system, supporting documentation for decisions made in the hazard analysis (e.g., validation documents), the design and implementation of the establishment's sampling and testing programs, and the establishment's reaction to sampling results. Further, during food safety assessments, FSIS EIAOs conduct routine RLm sampling and IVT sampling (in response to a positive government verification results for *Lm* or *Salmonella* or a documented change in an establishment's production process that may impact public health). FSIS EIAOs also verify that establishments take adequate corrective actions in the event of a positive official government test result for *Lm* and *Salmonella* (either food contact surface or product). If an establishment does not perform adequate corrective actions in the event of a positive official government test result for *Lm* or *Salmonella* on food contact surfaces or in product, and the post-lethality exposed RTE product that passed over the food contact surface that tested positive for *Lm* or *Salmonella* enters commerce, or the product that tested positive for *Lm* or *Salmonella* enters commerce, FSIS can take enforcement actions ([9 CFR 500](#)). Instructions to FSIS EIAOs on how to conduct public health risk evaluations and perform food safety assessments are provided in [FSIS Directive 5100.4](#) *Enforcement, Investigations and Analysis Officer (EIAO) Public Health Risk Evaluation (PHRE) Methodology* and [FSIS Directive 5100.1](#) *Enforcement, Investigations, and Analysis Officer (EIAO) Comprehensive Food Safety Assessment Methodology*. Instructions to FSIS EIAOs on how to collect and submit samples under the RLm testing program are provided under FSIS [Directive 10,240.5](#)

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Verification Procedures for Enforcement, Investigations and Analysis Officers (EIAOs) for the Listeria monocytogenes (Lm) Regulation and Routine Risk-Based Listeria monocytogenes (RLm) Sampling Program. Instructions to FSIS EIAOs on how to collect and submit samples under the IVT testing program are provided under [FSIS Directive 10,300.1 Intensified Verification Testing \(IVT\) Protocol for Sampling of Product, Food Contact Surfaces and Environmental Surfaces for Listeria Monocytogenes](#).

In egg products establishments, FSIS collects and tests dried, frozen, and liquid pasteurized egg products for *Lm* and *Salmonella* under its egg monitoring (EM) sampling program as described in [FSIS Directive 10,210.1 Unified Sampling Form](#). In addition, egg products establishments are required to submit pasteurized egg products and all lots of dried egg products to an FSIS approved laboratory for *Salmonella* testing and analysis. Any product found to be *Salmonella* positive is required to either be reprocessed, pasteurized, and analyzed for the presence of *Salmonella*, or denatured (9 CFR [590.420\(c\)](#), [590.422](#), [590.504\(o\)\(1\)](#), and [590.580](#)). Instructions to FSIS IPP on how to verify that establishments are complying with their *Salmonella* surveillance program are provided in [FSIS Directive 10,230.4 Salmonella Surveillance Program for Liquid and Frozen Egg Products](#). Instructions to FSIS IPP on how to perform routine verification activities (e.g., sanitation, labeling) in egg products establishments can be found in [FSIS Directive 5030.1 Inspection Methodology Utilizing the Public Health Information System \(PHIS\) for the Verification of Regulatory Compliance in Egg Products Plants](#).

Information on the proposed number of *Lm* and *Salmonella* official government verification samples for FY17 for RTE meat and poultry products and egg products, food contact surfaces, and environmental surfaces, the actual number of samples collected and analyzed for FY17, and the proposed number of samples for FY18 can be found in the FSIS [Annual Sampling Program Plan](#). Information on FSIS's *Lm* and *Salmonella* sampling program for imported RTE meat and poultry products and egg products can also be found in the FSIS [Annual Sampling Program Plan](#). FSIS's validated analytical methods for isolating and identifying *Lm* (Chapter 8) and *Salmonella* (Chapter 4) in RTE meat and poultry products and egg products are contained in the [MLG](#). Lastly, further information on FSIS's sampling program for *Lm* and *Salmonella* in RTE meat and poultry products, including results for 2017, can be found under [Testing Program for RTE Meat and Poultry](#) on the FSIS website; and further information on FSIS's EM sampling program for egg products, including results for 2017, can be found under [Testing Program for Pasteurized Egg Products](#) on the FSIS website.

31. **How does the CCA ensure that RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, achieve adequate lethality and shelf-stability to prevent contamination with microbiological pathogens or their toxins (e.g., *Salmonella*, *Lm* and STEC (in beef products), *C. perfringens*, *C. botulinum*, and *Staphylococcus aureus* (*S. aureus*))?**

FSIS maintains lethality performance standards for *Salmonella* in RTE products in [9 CFR 318.17\(a\)\(1\)](#) (meat) and [9 CFR 381.150\(a\)\(1\)](#) (poultry); and stabilization performance standards to prevent the growth of *C. botulinum* and limit the growth of *C. perfringens* in RTE products in [9 CFR 318.17\(a\)\(2\)](#) and [318.23\(c\)\(1\)](#) (meat), and [9 CFR 381.150\(a\)\(2\)](#) (poultry). In RTE shelf-stable meat and poultry products, FSIS considers achieving at least a 5-log reduction in *Salmonella* and STEC (in beef products) to be a sufficient pathogen reduction target in protecting public health. Further, FSIS requires all establishments to conduct a hazard analysis to identify any food safety hazards that are reasonably likely to occur during the production process ([9 CFR 417.2](#)).

In establishments producing RTE shelf-stable meat and poultry products that do not rely on cooking alone to achieve lethality, such as fermented, acidified, salt-cured or dried meat and poultry products, FSIS IPP perform routine HACCP verification activities (both recordkeeping and observation) and quarterly hazard analysis verification activities to verify that establishments are effectively implementing their HACCP system to control pathogens during the lethality and stabilization processes.

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In particular, FSIS IPP verify during routine HACCP verification activities that establishments have included in their HACCP plan the overall performance standard or pathogen reduction target in the multiple processing steps (e.g., a 2-log reduction of *Salmonella* on source materials through antimicrobial intervention, 2-log reduction of *Salmonella* by marinating product in a low pH marinade, and 2-log reduction of *Salmonella* through drying achieve the pathogen reduction target of at least a 5-log reduction in *Salmonella* in shelf-stable meat and poultry products). FSIS IPP also verify during the quarterly hazard analysis verification activity that establishments maintain adequate scientific support that the lethality steps combined achieve the performance standard or target.

For stabilization, FSIS IPP verify during the quarterly hazard analysis verification activity that establishments have identified and maintain supporting documentation for the amount of growth of *S. aureus* they will allow during processing (e.g., during fermentation/acidification, salt-curing, or drying) and during storage under ambient conditions (e.g., up to 2-logs growth during processing and no growth during storage). In addition, FSIS IPP verify during routine HACCP verification activities that establishments continue to meet the critical operational parameters identified in their HACCP plans to prevent the growth of spore-formers during the stabilization process (e.g., a pH \leq 4.6 before cooling or water activity (aw) <0.93 before cooling to prevent the growth of *C. perfringens* and *C. botulinum*).

Instructions to FSIS IPP on how to perform HACCP verification activities in establishments that achieve lethality and stabilization by processes, such as fermentation/acidification, salt-curing, and drying, including how and when to document noncompliance and take enforcement measures, can be found in [FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization](#).

32. How does the CCA ensure that heat-treated not ready-to-eat (NRTE) meat and poultry products are properly stabilized to prevent outgrowth of microbiological pathogens or their toxins (i.e., *C. perfringens* and *C. botulinum*), and properly labeled to ensure adequate cooking by the consumer?

FSIS maintains stabilization performance standards for NRTE partially cooked and char-marked meat patties in [9 CFR 318.23\(c\)\(1\)](#) and partially cooked poultry breakfast strips (e.g. turkey bacon) in [9 CFR 381.150\(b\)](#). In establishments producing other NRTE, heat-treated, not fully-cooked products, FSIS verifies that establishments consider the food safety hazards that are reasonably likely to occur in their stabilization processes and establish steps to prevent, eliminate, or reduce those hazards to an acceptable level ([9 CFR 417.2](#)).

In establishments producing heat-treated NRTE meat and poultry products, FSIS IPP perform routine HACCP verification activities (both recordkeeping and observation) and quarterly hazard analysis verification activities to verify that establishments are effectively implementing their HACCP system to control pathogens during the stabilization processes. Instructions to FSIS IPP on how to verify that establishments are preventing the outgrowth of microbiological pathogens or their toxins during the stabilization of NRTE meat and poultry products, including how to verify adequate corrective actions in the event of a cooling deviation and how and when to document noncompliance, can be found in [FSIS Directive 7111.1 Verification Procedures for Lethality and Stabilization](#). If FSIS determines that the establishment did not take adequate corrective actions and shipped heat-treated NRTE products that were prepared, packed, or held under insanitary conditions ([21 U.S.C. 601\(m\)\(4\)](#) and [453\(g\)\(4\)](#)), FSIS can take enforcement actions per [9 CFR 500](#).

Furthermore, FSIS IPP perform routine labeling verification activities to verify the following: NRTE products are labeled with safe handling instructions as required per [9 CFR 317.2\(l\)](#) (meat) and [9 CFR 381.125\(b\)](#) (poultry); and NRTE products that are not shelf-stable are labeled with special handling statements, such as keep refrigerated or keep frozen as required per [9 CFR 317.2\(k\)](#) (meat) and [381.125\(b\)](#) (poultry). Instructions to FSIS IPP on how to perform labeling verification activities for NRTE meat and poultry products, including how and when to document noncompliance and take

enforcement measures, are provided in [FSIS Directive 7221.1](#) *Prior Labeling Approval*.

33. How does the CCA ensure that the processing of canned meat and poultry products addresses *C. botulinum* and the finished products are commercially sterile?

FSIS ensures that thermally processed/commercially sterile meat and poultry products are free of microorganisms capable of growing in non-refrigerated conditions in storage and distribution (over 50°F or 10°C) by verifying that establishments employ either HACCP to control microbiological food safety hazards ([9 CFR 417](#)), or follow the regulatory “canning” requirements in 9 CFR 431 to prevent microbiological contamination from occurring during the thermal process. (**NOTE:** FSIS recently consolidated its canning regulations for meat (9 CFR 318, Subpart G) and poultry (9 CFR 381, Subpart X) into one section in 9 CFR. These regulations are now located in 9 CFR 431 as outlined in [83 FR 25302](#) “Elimination of Trichinae Control Regulations and Consolidation of Thermally Processed, Commercially Sterile Regulations”).

In establishments that choose to address the microbiological food safety hazards in the thermal process through their HACCP system, FSIS IPP perform routine HACCP verification activities to verify compliance with all [9 CFR 417](#) regulatory requirements. Instructions to FSIS IPP on how to verify HACCP regulatory compliance, including how and when to document noncompliance and take enforcement measures, are provided in [FSIS Directive 5000.1](#) *Verifying an Establishment’s Food Safety System*.

9 CFR 431.1 provides the regulatory definitions for “thermal process,” “canned product,” and “abnormal container.” Thermal process is defined as the heat treatment necessary to achieve shelf stability as determined by the establishment’s processing authority. It is quantified in terms of time and temperature, or minimum product temperature. Canned product is defined as a meat or poultry product with a water activity above 0.85 that receives a thermal process either before or after being packed in a hermetically sealed container. An abnormal container is defined as a container with any sign of swelling or product leakage or any evidence that the contents of the unopened container may be spoiled.

When establishments follow the regulatory requirements in 9 CFR 431, this can be used to support that a microbiological hazard is not reasonably likely to occur ([9 CFR 417.5\(a\)\(1\)](#)). Thus, establishments are not required to address microbiological hazards in their HACCP plan (9 CFR [417.2\(b\)\(3\)](#)). However, establishments are still required to conduct a hazard analysis per [9 CFR 417.2](#) to address any chemical or physical food safety hazards that could occur during their process. FSIS IPP verify that establishments continue to support their decision in the hazard analysis that microbiological contamination is not reasonably likely to occur, by performing routine verification activities to verify compliance with all FSIS canning requirements, including, but not limited to, the following: posting the process schedules in a location visible to the operator and the government inspector; maintaining a process schedule appropriate for the product and type of container being used; no unauthorized change in product formulation, equipment, or treatment that was not already incorporated in the process schedule; initial temperature was measured and recorded by the establishment; all critical factors associated with the production lot were met; required processing and production information was correctly recorded; any process deviation was handled appropriately; only normal containers were selected for incubation (if applicable), and only normal appearing containers were shipped from the establishment, as determined by an appropriate finished product inspection program; and the establishment reviewed all processing and production records no later than one working day after the actual process, to verify the completeness of the records and to determine whether all products received the process schedule. All records including the temperature/time recorder charts and critical factor control records are signed or initialed and dated by the person conducting the review.

The 9 CFR 431 regulations also specify the corrective actions to be taken whenever there is a deviation

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from the process schedule (9 CFR 431.9). Instructions to FSIS IPP on how to verify compliance with 9 CFR 431 canning regulations, including how and when to document noncompliance and verify appropriate corrective actions, are provided in [FSIS Directive 7530.2](#) *Verification Activities in Canning Operations that Choose to Follow the Canning Regulations*. Instructions to IPP on how to handle a process deviation or abnormal container of thermally processed/ commercially sterile product are provided in [FSIS Directive 7530.1](#) *Handling a Process Deviation or Abnormal Container of Thermally Processed, Commercially Sterile Canned Product*. Instructions to FSIS IPP on how to examine the condition of canned product containers are provided in [FSIS Directive 7520.2](#) *Procedures for Condition of Canned Product Container Examination*.

Lastly, if FSIS determines that an establishment has shipped adulterated thermally processed/commercially sterile products into commerce, FSIS can take enforcement actions per [9 CFR 500](#). Instructions to FSIS personnel, such as FSIS OIEA compliance officers and FSIS OFO District Managers, on the methodology to use when deciding whether to implement administrative enforcement actions are provided in [FSIS Directive 5100.3](#) *Administrative Enforcement Action Decision-Making and Methodology*. Instructions to FSIS OIEA compliance officers on the procedures to follow when taking enforcement actions are provided in [FSIS Directive 8010.5](#) *Case Referral and Disposition*.