

FSIS WAIVER OF REGULATORY REQUIREMENTS



Audit Report 24601-0007-31

March 2021

OFFICE OF INSPECTOR GENERAL

FSIS Waiver of Regulatory Requirements

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We evaluated the policies and procedures FSIS used to waive regulatory requirements and allow establishments, including those participating in SIP, to test new procedures, equipment, and meat and poultry processing techniques.

OBJECTIVE

Our objectives were to evaluate the policies and procedures FSIS used to waive certain regulations that allow establishments to test new procedures, equipment, and processing techniques, including establishments participating in SIP.

REVIEWED

We reviewed relevant regulations, guidelines, directives, notices, and standard operating procedures. We also reviewed other relevant documentation regarding the waiver approval process and interviewed pertinent FSIS staff. We conducted the majority of our work and identified our findings prior to the coronavirus disease prevention measures that were put in place in March 2020.

RECOMMENDS

We recommend that FSIS strengthen waiver documentation procedures and ensure that program managers have access to FootPrints training or a point of contact to improve the use of the system.

WHAT OIG FOUND

The Food Safety and Inspection Service (FSIS) helps prevent foodborne illness by performing food safety inspection activities at more than 6,000 establishments nationwide, ensuring that inspections align with existing and emerging risks, and maximizing domestic and international compliance with food safety policies. The agency also helps ensure safety through a series of policies and regulations that define how establishments can operate to produce a safe and wholesome product. The Salmonella Initiative Program (SIP) offers incentives to meat and poultry slaughter establishments to control Salmonella in their operations. Specifically, the program grants waivers of certain regulatory requirements with the condition that establishments test for Salmonella and other foodborne illnesses and share all sample results with FSIS.

While FSIS project managers did receive adequate documentation to make their overall waiver assessment conclusions, we found they did not adequately document their analysis of the information used to support their decisions regarding line speed waivers and did not consistently use the FootPrints system for maintaining records. This occurred because FSIS procedures did not always contain the level of detail necessary to ensure FSIS project managers follow a consistent method to document and upload their assessments of the supporting information. Furthermore, project managers found FootPrints difficult to use. If FSIS does not have ready access to the documentation and analysis used to support waiver decisions, the waiver process loses transparency and diminishes confidence in the FSIS protocol.

FSIS concurred with our recommendations and we accepted management decision on both recommendations.



OFFICE OF INSPECTOR GENERAL

United States Department of Agriculture



DATE: March 26, 2021

AUDIT

NUMBER: 24601-0007-31

TO: Terri Nintemann
Acting Administrator
Food Safety and Inspection Service

ATTN: Cara LeConte
Chief Financial Officer
Food Safety and Inspection Service

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS Waiver of Regulatory Requirements

This report presents the results of the subject review. Your written response to the official draft is included in its entirety at the end of the report. We have incorporated excerpts from your response, and the Office of Inspector General's (OIG) position, into the relevant sections of the report. Based on your written response, we are accepting management decision for all two audit recommendations in the report, and no further response to this office is necessary. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer (OCFO).

In accordance with Departmental Regulation 1720-1, final action needs to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. For agencies other than OCFO, please follow your internal agency procedures in forwarding final action correspondence to OCFO.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions. This report contains publicly available information and will be posted in its entirety to our website (<http://www.usda.gov/oig>) in the near future.

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Background and Objectives

Background

The Food Safety and Inspection Service (FSIS) is the public health agency within the Department of Agriculture (USDA) responsible for ensuring the Nation’s commercial supply of meat, poultry, and processed egg products is safe, wholesome, and accurately labeled and packaged. FSIS is tasked with reducing contamination and limiting illnesses through the regulation of agricultural food products and is empowered to inspect all meat, poultry, and processed egg products through several acts: the Federal Meat Inspection Act, the Poultry Products Inspection Act, the Egg Products Inspection Act, and select sections of the Agricultural Marketing Act.¹

FSIS helps prevent foodborne illness by performing food safety inspection activities at more than 6,000 establishments nationwide, ensuring that inspections align with existing and emerging risks, and maximizing domestic and international compliance with food safety policies. The agency also helps ensure safety through a series of policies and regulations that define how establishments can operate to produce a safe and wholesome product. Through these efforts, FSIS has mandated that establishments have a Hazard Analysis and Critical Control Point (HACCP) plan.² FSIS deploys over 8,000 inspection program personnel to these establishments to ensure that policies, regulations, and approved HACCP plans are followed and working as intended in the production of safe and wholesome meat, poultry, and processed egg products.

***Salmonella* Initiative Program**

In 2008, FSIS designed and implemented the *Salmonella* Initiative Program (SIP)³ to benefit public health by encouraging slaughter establishments to test for microbial organisms in their products and take corrective actions to maintain process control, thereby minimizing the presence of harmful pathogens in the Nation’s food supply.⁴ The program works to minimize microbial pathogens in food products by offering incentives to meat and poultry slaughter establishments to control *Salmonella* in their operations.⁵ FSIS grants waivers of certain

¹ Federal Meat Inspection Act of 1906, 21 U.S.C. §§ 601–695; Poultry Products Inspection Act of 1957, 21 U.S.C. §§ 451–472; Egg Products Inspection Act of 1970, 21 U.S.C. §§ 1031–1056; and Agricultural Marketing Act of 1946, 7 U.S.C. §§ 1621–1639 (select sections).

² HACCP plans provide a framework for establishments to identify and implement science-based process controls that can be validated as effective in eliminating, preventing, or reducing to an acceptable level the food safety hazards that are reasonably likely to occur in an official establishment’s particular production processes. Under the HACCP regulatory system, establishments assume full responsibility for producing products that are safe for consumers.

³ *Salmonella* Verification Sampling Program: Response to Comments and New Agency Policies, 73 Fed. Reg. 4,767 (Jan. 28, 2008).

⁴ “Pathogen” is defined as any disease-producing agent, especially a virus, bacterium, or other microorganism. Examples of enteric, or foodborne, pathogens include *Salmonella*, *Campylobacter*, *Norovirus*, and *e. coli*. *Pathogen Definition*, Dictionary.com, <http://dictionary.reference.com/browse/pathogen> (last visited Oct. 28, 2020).

⁵ The two species of *Salmonella* are *salmonella enterica* and *salmonella bongori*. Centers for Disease Control and Prevention, <https://www.cdc.gov/salmonella/general/technical.html> (last modified Nov. 13, 2019). *Salmonella* infection (salmonellosis) is a common bacterial disease that affects the intestinal tract most commonly by ingesting

regulatory requirements with the condition that establishments participate in SIP. Under SIP, establishments are required to test for *Salmonella* and other microbial organisms and share all sample results with FSIS.⁶ The FSIS Administrator has the authority to waive, for limited periods, provisions of certain regulations for meat and poultry establishments.⁷ One purpose of the waiver authority is to permit experimentation so that new procedures, equipment, or processing techniques may be tested to facilitate definite improvements in the slaughter, processing, and packaging of meat and poultry products.⁸ Meat and poultry slaughter establishments that wish to obtain a waiver from the regulation that prescribe slaughter line speeds must participate in SIP as a condition of the waiver.

After FSIS receives a line speed waiver request from an establishment, the agency is required to follow the procedures in FSIS Directive 5020.2, *The New Technology Review Process* (Oct. 24, 2017), to verify that the establishment meets the 12 line speed waiver criteria and to evaluate its waiver request submission. The criteria FSIS uses to assess the various waiver requests differ depending on the type of waiver the establishment requests.⁹

Waiver Process

Within FSIS, the Office of Policy and Program Development is responsible for coordinating the evaluation and approval of waiver requests. In order to approve a waiver, the FSIS Office of Policy and Program Development appoints a project manager to oversee a Technical Review Team (TRT) as part of the waiver review process. The TRT reviews and analyzes data and information from the requesting establishment to support the waiver request and reports their findings to the project manager. The project manager is responsible for ensuring an establishment's request for a waiver has met the necessary 12 line speed waiver criteria¹⁰ before forwarding a decision memorandum to upper management for concurrence and signature.¹¹ Before making the determination for approval or denial, the project manager ensures the

contaminated food or water. *Salmonella* bacteria typically live in animal and human intestines and are shed through feces. Humans become infected most frequently through contaminated water or food if not properly treated or cooked. Mayo Clinic, <https://www.mayoclinic.org/diseases-conditions/salmonella/symptoms-causes/syc-20355329> (last modified Oct. 11, 2019).

⁶ Foodborne illness is a preventable public health challenge that comes from eating food contaminated by harmful bacteria or other pathogens in food. It causes an estimated 48 million illnesses and 3,000 deaths each year in the United States. USDA FSIS, *Foodborne Illness: What Consumers Need to Know* (last modified Aug. 7, 2013).

⁷ FSIS grants these meat and poultry slaughter establishments appropriate waivers of certain regulatory requirements under FSIS regulations at 9 Code of Federal Regulations (C.F.R.) 303.1(h) (meat), 9 C.F.R. 381.3(b) (poultry), and 9 C.F.R. 590.10 (egg products).

⁸ FSIS Directive 5020.1, *Verification Activities for the Use of New Technology in Meat and Poultry Establishments and Egg Products Plants* (Oct. 6, 2016), considers "experimentation" to include in-plant trials, which may be associated with a waiver.

⁹ As of April 17, 2020, FSIS had eight types of poultry waivers including NPIS line speed, NPIS for fowl and duck, poultry inspection staffing standards, fowl slaughter under Streamlined Inspection System (SIS) and finished product standards, fowl slaughter under SIS, duck slaughter under SIS, ready-to-cook standard, sampling frequency.

¹⁰ USDA FSIS, *Salmonella Initiative Program Criteria* (last modified Oct. 1, 2018); Petition To Permit Waivers of Maximum Line Speeds for Young Chicken Establishments Operating Under the New Poultry Inspection System; Criteria for Consideration of Waiver Requests for Young Chicken Establishments To Operate at Line Speeds of Up to 175 Birds per Minute, 83 Fed. Reg. 49,048 (Sept. 28, 2018).

¹¹ A "decision memorandum" is the decision memo for the Office of the Administrator, and reflects the project manager's recommendation of whether or not a waiver should be granted to a requesting establishment.

establishment has adequately shown it has met the 12 line speed waiver criteria listed in the Federal Register.¹² For instance, the staff from FSIS' Public Health Science (i.e., microbiologists, chemists, and toxicologists) assesses the adequacy of any scientific information, the proposed study or protocols, and methods used in the waiver request. The staff also ensures the information in the request is consistent with Code of Federal Regulation requirements.

The TRT is also tasked with evaluating those waiver criteria that require a more comprehensive review of the materials submitted by an establishment. For example, the team examines an establishment's ability to maintain process control and its capability to operate at line speeds above 140 birds per minute (bpm).¹³ The project manager gathers all of the establishment-provided information for the waiver and the TRT's analyses, reviews it for completeness, evaluates whether the 12 line speed waiver criteria have been met, and then documents their conclusions regarding whether to approve the waiver. The project manager puts their recommendation for approval or denial into a decision memorandum and sends it to upper management. FSIS management will send a formal letter outlining the approval or denial of a line speed waiver to the establishment. If approved, the waiver will be in place until a plant either demonstrates it cannot consistently meet the conditions of its waiver agreement or until FSIS finalizes the line speed regulation. Lastly, the project manager uses the FootPrints system to store slaughter establishment information, documents, and communications related to their oversight work on the waiver request.¹⁴

New Poultry Inspection System Waivers

The New Poultry Inspection System (NPIS), which was established in 2014, is the latest inspection system for young chicken and all turkey slaughter establishments. One of the criteria for young chicken establishments to be eligible for a line speed waiver is that the establishment must have been operating under the NPIS for at least 1 year. In addition to meeting the line

¹² See Exhibit A for the 12 line speed waiver criteria. The criteria in Exhibit A were obtained from USDA FSIS *Salmonella Initiative Program Criteria*, which has the same criteria as the Federal Register presented in a different order; 83 Fed. Reg. 49,048, 49,050 (Sept. 28, 2018). USDA FSIS, *Salmonella Initiative Program Criteria* (last modified Oct. 1, 2018); Petition to Permit Waivers of Maximum Line Speeds for Young Chicken Establishments Operating Under the New Poultry Inspection System; Criteria for Consideration of Waiver Requests for Young Chicken Establishments to Operate at Line Speeds of Up to 175 Birds per Minute, 83 Fed. Reg. 49,048 (Sept. 28, 2018).

¹³ "Line speed" is essentially the number of animals (in this case, poultry such as young chickens) that an establishment can slaughter or process per minute. There are many factors that contribute to the speed at which an establishment processes young chickens, including facilities, type of equipment, uniformity, flock conditions, size of birds, demand for product, and the ability of the establishment to monitor and maintain process control while operating at a given line speed. Establishments have to be able to maintain process control at whatever line speed they select. As a condition to receiving a line speed waiver, establishments are expected to develop a process for monitoring process control and restoring process control if lost. FSIS sets the maximum line speed, but establishments have the ability to choose a line speed that is less than the maximum. The National Chicken Counsel, *Petition to Permit Waivers of the Maximum Line Speed Rates for Young Chicken Slaughter Establishments under the New Poultry Inspection System and Salmonella Initiative Program* (Sept. 01, 2017); USDA FSIS, Notice 11-17 (Feb. 16, 2017).

¹⁴ FootPrints is the main system for all new technology submissions, including waivers. The system provides FSIS with a place to attach and document items such as: the submission from the requestor (the poultry slaughter establishment), all supporting documents, all technical review team's files, and final issuances.

speed waiver criteria, NPIS young chicken establishments must also participate in SIP.¹⁵ This system allows establishments and FSIS to reconfigure certain aspects of poultry inspection, such as shifting agency resources so FSIS inspectors can perform more offline inspection activities, and the opportunity to increase the maximum bpm line speed. Participation in SIP allows establishments to request a line speed waiver to move from a maximum of 140 bpm to 175 bpm.¹⁶ However, before an establishment can request a waiver for increased line speed, it has to demonstrate that it meets all of the line speed waiver criteria outlined in the Federal Register, including consistent process control, meaning the establishment demonstrated that it consistently minimized the presence of pathogens of public health concern.¹⁷ As of December 2019, 36 of the 47 SIP waivers (76 percent) were NPIS line speed waivers.¹⁸

On March 20, 2020, FSIS stopped accepting additional requests for SIP poultry slaughter line speed waivers while the agency considers transitioning from the use of waivers to amending the current maximum line speed of 140 bpm set by regulation.¹⁹ FSIS analyzed the data collected related to line speed and started the rulemaking process.

Objectives

Our objective was to evaluate the policies and procedures FSIS used to waive certain regulations that allow establishments to test new procedures, equipment, and processing techniques, including establishments participating in SIP.

¹⁵ FSIS allowed young chicken establishments under NPIS, if they met certain requirements, to have the option of requesting a SIP waiver for line speeds. NPIS was informed by the agency's experience under the HACCP-Based Inspection Models Project pilot study. Petition to Permit Waivers of Maximum Line Speeds for Young Chicken Establishments Operating Under the New Poultry Inspection System; Criteria for Consideration of Waiver Requests for Young Chicken Establishments to Operate at Line Speeds of Up to 175 Birds per Minute, 83 Fed. Reg. 49,048 (Sept. 28, 2018).

¹⁶ SIP is for meat and poultry slaughter establishments that agree to share internal food safety data with FSIS in order to receive waivers of regulatory requirements. In this report, we only considered poultry establishments.

¹⁷ *Salmonella* Verification Sampling Program: Response to Comments on New Agency Policies and Clarification of Timeline for the *Salmonella* Initiative Program (SIP), 76 Fed. Reg. 41,186 (July 13, 2011).

¹⁸ Other types of FSIS waivers only made up 11 of 47 active waivers as of December 2019. These waivers pertain to NPIS for other species, inspection staffing standards, slaughtering practices, ready-to-cook standards, and sampling frequency. See the Scope and Methodology section of this report for details regarding the sample of approved poultry waivers selected for review and why we did not select a sample of denied waivers.

¹⁹ USDA [FSIS Constituent Update](#), *FSIS No Longer Accepting Poultry Line Speed Waivers*, vol. 23, no. 29 (April 24, 2020).

Finding 1: FSIS Needs More Uniform and Detailed Procedures for Documenting Waiver Approvals

While FSIS project managers did receive adequate documentation to make their overall waiver assessment conclusions, we found they did not adequately document their analysis of the information used to support their decisions regarding line speed waivers and did not consistently use the FootPrints system.²⁰ This occurred because FSIS procedures did not always contain the level of detail necessary to ensure FSIS managers to follow a consistent method to document and upload their assessments of the supporting information. Furthermore, project managers found it difficult to store documents using FootPrints and often chose to save information in other places. Line speeds and line speed waivers are of interest to numerous stakeholders, and if FSIS does not have ready access to the documentation and analysis used to support waiver decisions, the waiver process loses transparency and diminishes confidence in the FSIS protocol.

Office of Management and Budget’s (OMB) Circular A-123, states that “management is responsible for establishing and maintaining internal controls to achieve specific internal control objectives related to operations, reporting, and compliance.”²¹ Additionally, USDA Departmental Regulation 1110-002, Management’s Responsibility for Internal Control, states that “USDA agencies and staff offices will establish, maintain, evaluate, improve, and report on systems of controls. These systems should constitute the full range of controls necessary to assist managers in attaining program objectives and protecting and using Government resources efficiently and effectively.”²² Lastly, FSIS Directive 1090.1r3 states that FSIS senior managers are required to “establish, maintain, evaluate, improve, and report on controls for their respective program areas.”²³

We reviewed a non-statistical sample of three line speed waivers approved by three different project managers (approximately 8 percent).²⁴ From our review of the waiver approval process, we found that the three project managers did not consistently document the TRT analysis of the supporting information for all three line speed waivers. For example, we requested that each project manager demonstrate, in writing, how each waiver file document supports all of the 12 line speed waiver criteria. From our review, we found that all three project managers were unable to demonstrate their assessment on the correlation of at least 2 of the 12 line speed waiver criteria and the supporting waiver documentation in the file. One project manager was unable to correlate 5 of the 12 line speed waiver criteria in writing.

²⁰ See the Scope and Methodology section of this report for details regarding the sample of approved poultry waivers selected for review and why we did not select a sample of denied waivers.

²¹ OMB, *Management’s Responsibility for Enterprise Risk Management and Internal Control*, Circular A-123 (July 15, 2016).

²² USDA Departmental Regulation 1110-0002, *Management’s Responsibility for Internal Control* (June 17, 2013).

²³ FSIS Directive 1090.1r3, *Management Control Program* (Jan. 2011).

²⁴ At the time our audit started in December 2019, there were 36 SIP line speed waivers and 11 SIP waivers for regulatory requirements other than line speed for young chicken, turkey, fowl, and duck. OIG’s review focused on NPIS SIP line speed waivers because the majority of waivers are for increased line speed. Since 2017, FSIS has denied five SIP line speed applications because the requesting establishment did not meet the criteria in the Federal Register Notice.

During a follow up interview with the project manager, the manager concurred that not all of the 12 line speed waiver criteria were documented consistently, but the manager noted that the Public Health Information System (PHIS)²⁵ retains some of the required information. While the PHIS information could easily be retrieved, not all the assessments the project manager made were as simple as reviewing PHIS data. For other criteria where more analysis is needed, the project manager relies on the expertise of the TRT members. For example, 1 of the 12 line speed waiver criteria required more analytical or assessment work than other criteria.²⁶ This particular criterion reads: “Provides support on how the increased line speed will not negatively impact FSIS employee safety nor interfere with inspection procedures.” To assess that criterion, the project manager and TRT member would have had to gather information and evaluate whether the criterion was met. In contrast, another criterion reads: “Must not have not [sic] had an NR [noncompliance record] for violation of GCP [Good Commercial Practices] (9 CFR 381.65(b)) in the past 120 days.” In this case, the project manager would only need to find and document data as of a specific date.

When we discussed the support for the criterion related to FSIS employee safety and inspection, the project manager stated that this information was likely discussed in the initial waiver request letter received from the establishment. However, based on our review of this waiver file, we did not find his or TRT member’s assessment documented. Although the project manager included the determination for each of the 12 line speed waiver criteria in the decision memorandum, we found the waiver file did not document the assessments of the supporting documents. The other two waiver files in our sample, both of which were handled by two different project managers, also did not fully document the assessments of the information used to support the final determinations.

Furthermore, project managers did not consistently document their decisions or the TRT member’s assessments regarding waivers in the FSIS FootPrints system. FSIS has issued general guidance for maintaining the official electronic file. However, this guidance is general; that is, project managers are allowed to use their own judgement to determine what should and should not be included in the file. As a result, we found that the documentation of information supporting waiver recommendations within FootPrints (such as email chains and assessments) was inconsistent. For example, project managers can choose to file pertinent emails in the system; however, our sample project managers did not consistently retain these emails. As a result, some project managers’ emails and waiver approval notations were more thoroughly documented than others.

Through review of FSIS directives and training materials, as well as interviews with FSIS officials, we determined that FSIS procedures did not always contain enough details to ensure FSIS managers to follow a consistent method to document and upload either the TRT member’s, or their assessment of the supporting information. While the criteria we reviewed focused on the

²⁵ PHIS is a dynamic, comprehensive data analytic system, which is part of FSIS’ effort to collect, consolidate, and analyze data in order to improve public health.

²⁶ The line speed waiver criteria has 12 questions that form the basis for a project manager’s decision to grant or deny a waiver request. Five of the questions are quantitative in nature (questions 1, 2, 3, 5, and 6), while seven of the questions are qualitative in nature (questions 4, 7, 8, 9, 10, 11, and 12). Although not taken verbatim from the regulations, the 12 SIP waiver criteria are based on 83 Fed. Reg. 49,048, 49,050 (Sept. 28, 2018). (See Exhibit A).

general steps for the waiver approval process, we determined that none of the FSIS directives, standard operating procedures (SOP), or training materials²⁷ currently provided to the project managers specifically outline how a project manager is to fully assess each of the 12 line speed waiver criteria or how to adequately document all assessments, including the TRT members, of the 12 line speed waiver criteria in the waiver file system.²⁸

Furthermore, the project managers we spoke with found FootPrints difficult to use and did not store their information in a consistent and accessible manner. Officials stated that FootPrints was problematic and frustrating to use, so they used other means to store the analysis or supporting documentation used to make their determinations. For example, some FSIS project managers said they stored information in Outlook email or in separate hard drive folders, using their own judgment to decide what information goes in which system.

Line speed at poultry establishments and NPIS have been the focus of attention from such stakeholders as Government officials, the media, special interest groups, and the industry. Complete retention of all the information used to make these decisions and standardizing its access is important for FSIS as it will help promote quicker responses and more transparency to stakeholders. Additionally, consistently retaining the project managers' assessments and the supporting documentation helps ensure workplace continuity and accountability in decision-making.

We met with FSIS officials on June 4, 2020, and they generally agreed with our recommendations to strengthen their procedures and training to improve how project managers document their assessments of the 12 line speed waiver criteria.

Recommendation 1

Strengthen FSIS Directives to ensure determinations for waivers are better documented, including providing guidance on the detail needed in the documentation of project managers' assessments of waiver criteria.

Agency Response

In its March 9, 2021, response, FSIS stated:

FSIS will update FSIS Directive 5020.2, *New Technology Review Process*, to provide instructions on how the project manager and Technical Review Team (TRT) members are to document their assessment of compliance with waiver criteria associated with new technology requests that require a waiver from regulatory requirements. Because waiver criteria may vary on the type of waiver requested, FSIS will also ensure that Standard Operating Procedures (SOPs)

²⁷ USDA FSIS, Directive 5020.2, *The New Technology Review Process* (Oct. 2017). USDA FSIS, *FSIS Line Speed Waiver Review*, Word Document (Nov. 2019). USDA FSIS, *Line Speed Waivers*, PowerPoint Presentation (May 2019).

²⁸ The FSIS Line Speed Waiver Review SOPs outline agency procedures to review and approve an establishment's waiver request.

developed for specific waiver criteria describe how project managers and TRT members are to document their assessment of compliance with each waiver criterion.

Estimated Completion Date: January 31, 2022

OIG Position

We accept FSIS' management decision for this recommendation.

Recommendation 2

Ensure program managers have access to FootPrints training or a point of contact to improve the use of the system.

Agency Response

In its March 9, 2021, response, FSIS stated:

FSIS will develop an SOP for the use of the FootPrints New Technology Management System with basic instructions, best practices, commonly asked questions, and contact information for additional support.

Estimated Completion Date: October 31, 2021

OIG Position

We accept FSIS' management decision for this recommendation.

Scope and Methodology

We conducted our audit at the FSIS National Office in Washington, D.C. Our audit covered all active waivers of regulatory requirements from calendar years 2016 through 2019. To complete our audit, we performed audit steps at the FSIS National Office in Washington, D.C., and spoke with key external stakeholders at the National Chicken Council, a non-profit trade association within the chicken industry. Our review was focused on the process that FSIS used to make their decisions regarding NPIS line speed waivers. We conducted audit fieldwork from December 2019 to April 2020. We conducted the majority of our work and identified our findings prior to the coronavirus disease prevention measures that were put in place in March 2020. During our fieldwork, we non-statistically selected 3 line speed waivers of the 36 approved waivers to review. These waivers were selected based on a listing of NPIS establishments obtained from FSIS. As of December 2019, FSIS had approved 36 NPIS SIP line speed waivers for poultry slaughter establishments. Since 2017, FSIS has denied five applications because the requesting establishment did not meet the criteria in the Federal Register Notice. We only reviewed waiver approvals because at the time of our sample selection in December 2019, FSIS had only denied two waivers. Neither of these waivers were NPIS line speed waivers. One denial was for a modification of equipment at a turkey establishment, and the other was a non-NPIS emergency line speed waiver request from a young chicken establishment. FSIS made three more denials in April of 2020 after we concluded the majority of our fieldwork. According to FSIS, these three denials were due to establishments not meeting at least 1 of the 12 line speed criteria.

To accomplish our objective, we:

- reviewed relevant regulations, guidelines, directives, notices, standard operating procedures, verification plans, training, Departmental Regulation (DR 1110-002), OMB Circular No. A-123, *Management's Responsibility for Enterprise Risk Management and Internal Control* (July 2016), and the Government Accountability Office's *Standards for Internal Controls in the Federal Government* (September 2014) in order to gain sufficient knowledge to evaluate FSIS' oversight of the waiver approval process;
- interviewed FSIS officials in order to gain an understanding of the agency's waiver activities, including FSIS' assessment of line speed waiver applications from young chicken NPIS poultry establishments; and
- interviewed an industry stakeholder group in order to gain an understanding of the poultry industry's opinion of the waiver process.

The audit team gained an understanding of the relationship of FSIS' information systems and information technology to the audit objectives by looking at the existence, relationship, impact, and pervasiveness of the system. We documented and assessed the significance and audit risk of information system and related information technology controls for the engagement.

Also, the team did not rely on data processed or generated by these systems in the context of our audit objectives; therefore, we did not verify information contained within those systems in connection with this audit, and we do not make any representation of FSIS information systems related to the adequacy of the systems or the information generated from them.

We assessed internal controls to satisfy the audit objective. In particular, we assessed the control activities and information and communication components of internal control. However, because our review was limited to these components and underlying principles, it may not have disclosed all internal control deficiencies that may have existed at the time of this audit.

We conducted this performance audit in accordance with Generally Accepted Government Auditing Standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objective. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objective.

Abbreviations

BPM	birds per minute
CFR	Code of Federal Regulations
FSIS	Food Safety and Inspection Service
GCP	Good Commercial Practices
HACCP	Hazard Analysis and Critical Control Point
NPIS	New Poultry Inspection System
NR	non-compliance record
OMB	Office of Management and Budget
PHIS	Public Health Information System
SIP	Salmonella Initiative Program
SIS	Streamlined Inspection System
SOP	standard operating procedures
TRT	Technical Review Team
USDA	United States Department of Agriculture

Exhibit A: The 12 FSIS Line Speed Waiver Criteria

This exhibit lists each of the 12 line speed criteria that poultry slaughter establishments must meet prior to being issued a waiver of regulatory requirements by FSIS. The information is provided in FSIS *Salmonella* Initiative Program Criteria, and 83 Fed. Reg. 49,048, 49,050 (Sept. 28, 2018).

- 1 Must have been operating under NPIS for at least 1 year, during which time it has been in compliance with all NPIS requirements.
- 2 Must be in *Salmonella* performance standard category 1 or 2 for young chicken carcasses.
- 3 Must have a demonstrated history of regulatory compliance. More specifically, the establishment has not received a public health alert for the last 120 days; has not had an enforcement action as a result of a food safety assessment conducted in the last 120 days; and has not been the subject of a public health related enforcement action in the last 120 days.
- 4 Must be able to demonstrate that the new equipment, technologies, or procedures that allow the establishment to operate at faster line speeds will maintain or improve food safety.
- 5 Must not have not [sic] had an NR [non-compliance record] for violation of GCP [good commercial practices] (9 CFR 381.65(b)) in the past 120 days.
- 6 Must conduct and submit daily Aerobic Plate Count [...] testing and at least weekly *Salmonella* testing.
- 7 Provides details about the establishment's HACCP system, including how the establishment addresses the inhibition and reduction of *Salmonella*.
- 8 Demonstrates that the establishment has effective process control by submitting 1 year of microbial data, methodology for evaluating that microbial data (e.g., indicator organism data in a process control chart identifying upper and lower control limits), correlation of that microbial data to the establishment's sanitary dressing process control data, correlation of that microbial data to FSIS's *Salmonella* data, and interventions to address seasonality.
- 9 Describes how existing or new equipment, technologies, or procedures will allow for the operation at a faster line speed (e.g., descriptions or names of the equipment, line configuration, and verification activities that will be used).
- 10 Provides support on how the increased line speed will not negatively impact FSIS employee safety nor interfere with inspection procedures (e.g., information about safety protocols or line configuration).
- 11 Supports how the modifications to its food safety system to operate at the faster line speed will maintain or improve food safety (e.g., a statement that explains how the new equipment will provide the same as or cleaner evisceration processes, or how an improved line configuration will continue to prevent cross contamination).
- 12 Indicates the type of records that will be maintained in the new process, including the collection of information that will assist FSIS in performing appropriate rule-making analysis (e.g., laboratory results, weekly or monthly summary production reports, or evaluations from inspection program personnel).

**Food Safety and Inspection Service's
Response to Audit Report**



United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW,
Washington, D.C.
20250

TO: Gil H. Harden
Assistant Inspector General for Audit
Office of Inspector General

FROM: Terri Nintemann /s/ 3/9/2021
Acting Administrator
Food Safety and Inspection Service

SUBJECT: OIG Official Draft Report: Food Safety and Inspection
Service's Waiver of Regulatory Requirements
(Audit 24601-0007-31)

The Food Safety and Inspection Service (FSIS) appreciates the opportunity to review and comment on the subject Official Draft report. FSIS reviewed the Official Draft report and responded with general comments and planned corrective actions for each of the recommendations below.

General Comments

While we agree with the recommendation for FSIS to update its waiver review procedures to provide more detailed instructions for documenting waiver criteria assessments, we believe that the document should also emphasize the fact that FSIS did conduct a thorough review of each waiver request and that the recommendation is solely procedural and related to documentation. In addition, as we have previously stated, the outcomes of the assessment of each waiver criterion are fully documented in the decision memo to the Office of the Administrator. We believe the report should emphasize that fact. For example, on pages 1 and 7, OIG states that it found that FSIS Project Managers (PMs) "did receive adequate documentation to make their overall waiver assessment conclusions...". Although this statement recognizes that FSIS relies on supporting information when determining whether to grant a regulatory waiver, the report should also emphasize that FSIS conducted a thorough analysis of the line speed waiver criteria and that the findings are solely related to the procedures used to document the analysis.

As another example, the discussion on pages 7-8 of the three line speed waivers, approved by three different project managers, states that all three project managers were unable to demonstrate their correlation of establishment data with waiver criteria for at least two of the 12 line speed waivers and that one project manager was unable to correlate establishment data with waiver criteria for five of the 12 line speed waivers criteria. We would like to emphasize that two of the three line speed waivers reviewed by OIG in their sample were former Hazard Analysis and Critical Control Point (HACCP)-Based Inspection Models

Pilot (HIMP) establishments re-applying for their waivers and each had maintained waivers for about a decade.

For one of the former HIMP establishments, OIG found the project manager was unable to demonstrate correlation for Criteria 8 and 11. As a former HIMP establishment, this establishment already met these criteria. Criterion 8 is “Demonstrates that the establishment has effective process control by submitting 1 year of microbial data, methodology for evaluating that microbial data (e.g., indicator organism data in a process control chart identifying upper and lower control limits), correlation of that microbial data to the establishment’s sanitary dressing process control data, correlation of that microbial data to FSIS’s *Salmonella* data, and interventions to address seasonality.” As this establishment was a former HIMP establishment and was already submitting monthly Salmonella Initiative Program (SIP) data, this establishment did not need to submit a year of microbial data. FSIS already had possession of it, as we were updating/reissuing these former HIMP their waiver approvals under the new criteria. Criterion 11 is “Supports how the modifications to its food safety system to operate at the faster line speed will maintain or improve food safety (e.g., a statement that explains how the new equipment will provide the same as or cleaner evisceration),” and again, this establishment was already running above 140 birds per minute (bpm) for years and was not making modifications, they were simply renewing the waiver for the procedures already in place.

For the other former HIMP establishment OIG found the project manager was unable to demonstrate correlation for Criteria 9 and 11. As a former HIMP establishment, this establishment already met these criteria. Criterion 9 is “Describes how existing or new equipment, technologies, or procedures will allow for the operation at a faster line speed (e.g., descriptions or names of the equipment, line configuration, and verification activities that will be used.” Again, this establishment was also a former HIMP establishment, running under a line speed waiver for about a decade before reapplying to have the waiver reissued; they were running above 140bpm and did not need to reprove to the agency that their setup was capable of such speeds. Similarly, criterion 11 was already met as a former HIMP establishment because there were no changes- this was the status quo at this establishment.

Finally, for the only establishment in the sample that was a new waiver application, OIG indicated that the project manager was not able to correlate Criteria 2, 3, 5, 6, and 10. Data were readily available in the Public Health Inspection System (PHIS) for three of these criteria. Criterion 2 is a *Salmonella* Category, which FSIS verifies throughout the process through PHIS. Keep in mind, that this data may need to be extracted numerous times from PHIS throughout the approval process as FSIS Inspection Program Personnel (IPP) continue to collect samples in the establishments. Criterion 3 is the history of regulatory compliance, which is also in PHIS. Criterion 5 is Non-Compliance Reports for Good Commercial Practices, and is also in PHIS. Criteria 2,3, and 5 are all checked repeatedly in PHIS to ensure there are no changes leading up to issuance of a waiver. Another criteria was a stipulation of action once a waiver is granted. Criteria 6

requires the establishment to conduct and submit Aerobic Plate Count data. This is not a criterion by which they are judged meaning they do not have to conduct said sampling to apply, but rather must agree to conduct this sampling and submit to FSIS if the waiver is approved. The agreement to do so is the FSIS signed waiver that states the agreed terms, including what data the establishment will submit and how often.

Criterion 10 is inspection procedures. This criterion is verified during the Technical Review Team (TRT) process with input from Policy Development Staff in the Office of Program and Policy Development (OPPD) and the Office of Field Operations (OFO), including OFO employees onsite at the establishment. The project manager did not include such messages in their chart, although it was a part of their process. In that instance, there was a failure to upload supporting emails from the TRT to the FootPrint Ticket. FSIS intends to address this through our planned corrective actions to the recommendations outlined below.

Finding 1: FSIS Needs More Uniform and Detailed Procedures for Documenting Waiver Approvals

Recommendation 1

Strengthen FSIS Directives to ensure determinations for waivers are better documented, including providing guidance on the detail needed in the documentation of project managers' assessments of waiver criteria.

FSIS Response:

FSIS will update FSIS Directive 5020.2, *New Technology Review Process*, to provide instructions on how the project manager and Technical Review Team (TRT) members are to document their assessment of compliance with waiver criteria associated with new technology requests that require a waiver from regulatory requirements. Because waiver criteria may vary on the type of waiver requested, FSIS will also ensure that Standard Operating Procedures (SOPs) developed for specific waiver criteria describe how project managers and TRT members are to document their assessment of compliance with each waiver criterion.

Estimated Completion Date: January 31, 2022

Recommendation 2

Ensure program managers have access to FootPrints training or a point of contact to improve the use of the system.

FSIS Response:

FSIS will develop an SOP for the use of the FootPrints New Technology Management System with basic instructions, best practices, commonly asked questions, and contact information for additional support.

Estimated Completion Date: October 31, 2021



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