



United States Department of Agriculture

FSIS Rulemaking Process for the Proposed Rule: Modernization of Swine Slaughter Inspection



Inspection Report 24801-0001-41

June 2020

OFFICE OF INSPECTOR GENERAL

FSIS Rulemaking Process for the Proposed Rule on the Modernization of Swine Slaughter Inspection

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OIG reviewed the proposed Modernization of Swine Slaughter Inspection rule to determine whether FSIS' worker safety analysis complied with applicable rulemaking requirements.

OBJECTIVE

We determined whether FSIS, with respect to its worker safety analysis section of the proposed rule: (1) complied with public transparency requirements under E.O. 13563; (2) made information about its preliminary analysis on worker safety clearly accessible to the public during the comment period; (3) adhered to the Guidelines in developing the proposed rule; (4) came to a reasonable determination about the reliability of the OSHA injury data it used for the proposed rule; and (5) consulted with OSHA and NIOSH about the impact of the proposed rule on workplace safety and health.

REVIEWED

We interviewed FSIS officials and reviewed the proposed and final rules; relevant E.O.s and the Guidelines; worker safety analysis documentation; and communications during the rulemaking process.

RECOMMENDS

We recommend that FSIS update its internal procedures for the rulemaking process, determine the impact of the omissions from the proposed rule, and communicate to the public the actual review period and known limitations of the OSHA data.

WHAT OIG FOUND

The Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) enhances public health and well-being by protecting the public from foodborne illnesses and ensuring that the Nation's meat, poultry, and egg products are safe, wholesome, and correctly packaged. On February 1, 2018, FSIS published its proposed rule, the Modernization of Swine Slaughter Inspection ("the proposed rule"). As part of this rule, FSIS proposed to revoke maximum swine slaughter line speeds for participating establishments and authorize them to set their own line speeds based on their ability to maintain quality and performance measures. In the proposed rule, FSIS compared worker safety data from the Occupational Safety and Health Administration (OSHA) for large establishments with different allowed line speeds ("worker safety analysis").

On March 26, 2019, 16 members of Congress sent a formal request to USDA's Office of Inspector General (OIG) to review USDA's rulemaking process related to the proposed rules' worker safety analysis. Based on our inspection, we concluded that FSIS generally complied with the public participation requirements under Executive Order (E.O.) 13563 and, to the extent required, communicated to OSHA and the National Institute for Occupational Safety and Health (NIOSH) about the impact of the proposed rule. However, we found that FSIS did not fully disclose its data sources in its worker safety analysis. Additionally, we concluded that it did not fully adhere to the USDA Information Quality Activities Guidelines ("Guidelines") data presentation and transparency requirements in the worker safety analysis section in the proposed rule. Finally, we concluded that FSIS did not take adequate steps to determine whether the worker safety data it used for the proposed rule were reliable.

FSIS provided its response to our findings and recommendations, and we accepted management decision on two of the four recommendations.



United States Department of Agriculture
Office of Inspector General
Washington, D.C. 20250



DATE: June 23, 2020

INSPECTION
NUMBER: 24801-0001-41

TO: Paul Kiecker
Administrator
Food Safety and Inspection Service

ATTN: Cara LeConte
Chief Financial Officer
Office of the Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS Rulemaking Process for the Proposed Rule: *Modernization of Swine Slaughter Inspection*

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 Recommendations 1 and 4. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer (OCFO).

We initiated this inspection in order to answer five specific questions raised by members of Congress. These questions—and therefore OIG's inspection work—pertained solely to the worker safety analysis section of the proposed rule.

FSIS has laid out two primary concerns in its response to our report regarding our findings. First, FSIS stated that OIG's inspection of compliance with certain criteria was misguided because it did not believe the criteria applied to the worker safety analysis section of the proposed rule.¹ Although FSIS stated that the worker safety analysis was not a basis for the rulemaking, FSIS also stated that it "recognizes that evaluation of the effects of line speed on

¹ These criteria are Executive Order 13563 and the USDA Information Quality Activities Guidelines. Both are applicable analyses used in support of rulemaking activities.

food safety should include the effects of line speed on establishment employee safety.”² Because FSIS chose to include the worker safety analysis in the rule, it follows that the analysis was prepared and presented in support of the rulemaking activities. Therefore, we feel the criteria is applicable.³

Additionally, FSIS believes that OIG has placed distorted emphasis on minor errors in FSIS’ proposal text, which they described as an omission of a website citation and a typo in a table header.⁴ While we acknowledge that these issues may have been inadvertent, the scope of our inspection addressed specific, Congressional questions, including whether FSIS made information about its worker safety analysis clearly accessible and whether it complied with specific USDA guidelines. We therefore believe that omitting the citation and inaccurate presentation of the worker safety analysis’ scope period fall within the context of our inspection scope. We do not believe that there is disproportionate or distorted emphasis on these errors. (See Objectives 2 and 3 of this report.)

Based on your written response, management decision has not been reached on Recommendations 2 and 3. The information needed to reach management decision on the recommendations is set forth in the OIG Position section following each recommendation. In accordance with Departmental Regulation 1720-1, please furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department’s annual Agency Financial Report.

We appreciate the courtesies and cooperation extended to us by members of your staff during our inspection 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.

² *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

³ The general requirements of the Guidelines apply to all types of information disseminated by USDA agencies and offices. The regulatory supplement of the Guidelines states, “These supplementary guidelines pertain to information disseminated to the public by USDA agencies and offices in conjunction with their regulatory activities, rulemaking activities, and program implementation activities that are subject to notice and comment procedures. Such information includes economic, cost/benefit, scientific, environmental, risk assessment, reporting and record keeping, and other pertinent analyses prepared or presented by agencies in support of those activities.”

⁴ For clarification, the misstated scope of analysis discussed in Objective 3 was not within a table header but in the proposed rule’s narrative discussion of FSIS’ worker safety analysis.

Table of Contents

Background and Objectives	1
Section 1: Transparency and Accessibility of Worker Safety Information in FSIS’ Proposed Rule—Modernization of Swine Slaughter Inspection	5
<i>Objective 1: Did FSIS, with respect to its worker safety analysis section of the proposed rule, comply with public transparency requirements under E.O. 13563?</i>	5
<i>Objective 2: Did FSIS, with respect to its worker safety analysis section of the proposed rule, make information about its preliminary analysis on worker safety clearly accessible to the public during the comment period?</i>	7
Recommendation 1	9
Section 2: Quality of Worker Safety Information used in FSIS’ Proposed Rule—Modernization of Swine Slaughter Inspection	10
<i>Objective 3: Did FSIS, with respect to its worker safety analysis section, adhere to the USDA Information Quality Activities Guidelines in developing the proposed rule?</i>	10
Recommendation 2	12
Recommendation 3	13
Recommendation 4	14
<i>Objective 4: Did FSIS come to a reasonable determination about the reliability of the OSHA injury data it used for the proposed rule?</i>	16
<i>Objective 5: Did FSIS consult with OSHA and NIOSH about the impact of the proposed rule on workplace safety and health?</i>	19
Scope and Methodology	20
Abbreviations	22
FSIS’ Response	23

Background and Objectives

Background

The Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) enhances public health and well-being by protecting the public from foodborne illnesses and ensuring that the Nation's meat, poultry, and egg products are safe, wholesome, and correctly packaged. FSIS operates under multiple food safety statutes,¹ including the Federal Meat Inspection Act (FMIA). Since 1906, FMIA has authorized FSIS to inspect all meat products sold through interstate commerce and imported products to ensure that they meet U.S. food safety standards. For fiscal year 2018, FSIS was appropriated \$1.06 billion to carry out services authorized by FMIA, the Poultry Products Inspection Act, and the Egg Products Inspection Act.

FSIS aims to prevent foodborne illness by performing food safety inspection activities at more than 6,000 establishments nationwide and ensuring that its inspections align with existing and emerging risks. FSIS deploys over 7,500 inspection program personnel to these establishments to ensure compliance with Hazard Analysis and Critical Control Point Systems (HACCP) plans, policies, and regulations.² FSIS' Office of Policy and Program Development develops regulations and associated instructions for inspectors to follow in order to prevent foodborne illnesses and protect public health. The office's mission is to leverage science, use statutes, and interpret data to develop policies and instructions for the field that further promote the safety of meat, poultry, and processed egg products and lead to improvements in FSIS inspections.

Modernization of Swine Slaughter Inspection Proposed Rule

On February 1, 2018, FSIS published a proposed rule in the Federal Register titled Modernization of Swine Slaughter Inspection ("the proposed rule").³ This rule proposed to establish a new optional inspection system for market hog slaughter establishments called the New Swine Slaughter Inspection System (NSIS). Under the proposed rule, NSIS would require swine slaughter establishment employees to sort and remove unfit animals before FSIS' antemortem inspection and to identify defects on carcasses and parts before FSIS' postmortem inspection. The rule was intended to shift FSIS resources to enable inspectors to conduct more offline inspection activities and to reduce the number of online inspectors to a maximum of three

¹ FSIS operates under the following statutes: Poultry Products Inspection Act of 1957, 21 U.S.C. §§ 451-472; Egg Products Inspection Act of 1970, 21 U.S.C. §§ 1031-1056; Agricultural Marketing Act of 1946, 7 U.S.C. §§ 1621-1639s (select sections); Humane Methods of Slaughter Act of 1958, 7 U.S.C. §§ 1901-1907; and Federal Meat Inspection Act of 1906, 21 U.S.C. §§ 601-695.

² HACCP is a science-based process control system for food safety which identifies hazards and measures for their control. HACCP's goal is to assess hazards and establish control systems that focus on prevention rather than relying mainly on end-product testing.

³ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,780 (Feb. 1, 2018).

per line per shift.^{4, 5} Additionally, the proposed rule states that a key element of the proposed NSIS is “revoking maximum [swine slaughter] line speeds [for NSIS establishments] and authorizing establishments to determine their own line speeds based on their ability to maintain process control for preventing fecal contamination and meeting microbial performance measures during the slaughter operation.”^{6, 7}

In the proposed rule, FSIS acknowledged that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety. FSIS also included a summary of its analysis comparing worker safety data for establishments with different allowed line speeds (“worker safety analysis”). To perform its analysis, FSIS used publicly available data from the Occupational Safety and Health Administration (OSHA). The OSHA data included 56 establishments that voluntarily submitted work-related injury and illness data to OSHA within the scope of FSIS’ analysis. FSIS compared in-establishment injury and illness rates from calendar years (CYs) 2002 to 2011 between 5 establishments participating in an FSIS pilot program with higher line speeds (HACCP-Based Inspection Models Project (HIMP) establishments) and 24 traditional establishments.^{8, 9} The results of FSIS’ worker safety analysis found that the HIMP establishments had a lower mean number of reported injuries for three OSHA injury and illness rates: (1) total case rate; (2) days away, restricted, and transfer case rate; and (3) days away from work case rate.¹⁰ However, in its discussion of these findings in the proposed rule, FSIS noted that factors other than line speed may affect injury rates (for example, automation and number of sorters per line).¹¹

Laws and Orders Governing the Federal Rulemaking Process

Congress enacted various laws to protect the integrity of the Federal rulemaking process. One of these laws, the Administrative Procedure Act, requires Federal agencies to publish notices of proposed rulemaking in the Federal Register so the public may participate in the rulemaking process.¹² Further, Executive Order (E.O.) 12866 requires that each agency should, where appropriate, seek the involvement of those who are intended to benefit from and those expected

⁴ Offline inspectors verify that establishments have adopted controls in their food safety system that demonstrate effectiveness in reducing the occurrence of pathogens, including the controls that prevent contamination of carcasses and carcass parts.

⁵ As part of the postmortem inspection, online inspectors in livestock establishments inspect each carcass to ensure it and its attached parts are free of contamination.

⁶ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,781 (Feb. 1, 2018).

⁷ The current maximum swine slaughter line speed is dependent on the size of the slaughter establishment, the number of FSIS inspectors on the slaughter line, and the type of hog being slaughtered. The maximum line speed for establishments similar to those that would be eligible to implement NSIS is 1,106 hogs per hour. Comparable establishments slaughter market hogs and have seven online FSIS inspectors.

⁸ FSIS initiated its HIMP pilot program in October 1999. HACCP refers to a science-based process control system for food safety. There are five swine slaughter establishments nationwide that participate in HIMP.

⁹ The other 27 traditional swine slaughter establishments were excluded due to their low slaughter volume. FSIS believed the 24 traditional establishments with high slaughter volumes would provide a better comparison group because all 5 HIMP establishments have high slaughter volumes.

¹⁰ The days away from work case rate is the number of calendar days away from work as a result of work-related injuries and illnesses. The days away, restricted, and transfer case rate includes the days away from work case rate as well as injury and illness cases with job transfer or restricted work, or both.

¹¹ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

¹² 5 U.S.C. § 553.

to be burdened by any regulation (e.g., State, local, and Tribal officials) before issuing a notice of proposed rulemaking. In addition, agencies are to provide the public a meaningful opportunity to comment on any proposed regulation via a public comment period.¹³ Furthermore, for both proposed and final rules, to the extent feasible and permitted by law, agencies must provide timely online access to the rulemaking docket on [regulations.gov](https://www.regulations.gov), including relevant scientific and technical findings, in an open format that can be easily searched and downloaded.¹⁴ For proposed rules, such access must include an opportunity for public comment on all pertinent parts of the rulemaking docket, including relevant scientific and technical findings.¹⁵

Congressional Interest in the Proposed Rule

On March 26, 2019, a formal request, signed by 16 members of Congress, was sent to USDA's Office of Inspector General (OIG) regarding the findings and methods FSIS used during the rulemaking process for the proposed rule.¹⁶ In the letter, Congressional members expressed concern about reports that FSIS used "flawed worker safety data" in developing the proposed rule, and that the agency's actions raised serious concerns about a lack of required transparency.¹⁷ The letter requested that OIG review specific areas of FSIS' proposed rulemaking process related to its worker safety analysis.

In a letter dated June 21, 2019, the Inspector General responded to Congressional members' concerns and stated that OIG would conduct an inspection to assess FSIS' proposed rulemaking process based on our determined objectives.¹⁸

Final Rule Published During Our Fieldwork

On October 1, 2019, FSIS published the final rule for the Modernization of Swine Slaughter Inspection. In the final rule, FSIS included the results of its worker safety analysis as they were presented in the proposed rule and included additional statements related to its worker safety analysis. Specifically, FSIS stated that "[a]lthough FSIS conducted an analysis of injury rates during the development of the proposed rule, FSIS did not use the analysis to draw conclusions on worker safety in HIMP or non-HIMP establishments." Further, FSIS emphasized that while it "recognizes that working conditions in swine slaughter establishments is an important issue, the [a]gency does not have the authority to regulate issues related to establishment worker safety. OSHA is the Federal agency with statutory and regulatory authority to promote workplace safety and health."¹⁹

¹³ E.O. 12866 (Oct. 4, 1993).

¹⁴ E.O. 13563, § 2(b) (Jan. 18, 2011).

¹⁵ *Ibid.*

¹⁶ Durbin, The Honorable Richard, et al., Letter to The Honorable Phyllis K. Fong (Mar. 26, 2019).

¹⁷ *Ibid.*

¹⁸ Fong, The Honorable Phyllis, Letter to The Honorable Richard J. Durbin, et al. (June 21, 2019).

¹⁹ *Modernization of Swine Slaughter Inspection*, 84 Fed. Reg. 52,300, 52,305 (Oct. 1, 2019) (discussing and responding to comments received during the rulemaking process).

Objectives

Our objectives were to determine whether FSIS, with respect to its worker safety analysis section of the proposed rule: (1) complied with public transparency requirements under E.O. 13563; (2) made information about its preliminary analysis on worker safety clearly accessible to the public during the comment period; (3) adhered to the USDA Information Quality Activities Guidelines in developing the proposed rule; (4) came to a reasonable determination about the reliability of the OSHA injury data it used for the proposed rule; and (5) consulted with OSHA and the National Institute for Occupational Safety and Health (NIOSH) about the impact of the proposed rule on workplace safety and health.

While addressed in this inspection report, we did not make any formal recommendations related to Objectives 1, 4, and 5.

As further described in the Scope and Methodology section of this report, we conducted this inspection in accordance with the Council of the Inspectors General on Integrity and Efficiency's (CIGIE) *Quality Standards for Inspection and Evaluation*.²⁰

²⁰ CIGIE, *Quality Standards for Inspection and Evaluation* (Jan. 2012).

Section 1: Transparency and Accessibility of Worker Safety Information in FSIS' Proposed Rule—Modernization of Swine Slaughter Inspection

Objective 1: *Did FSIS, with respect to its worker safety analysis section of the proposed rule, comply with public transparency requirements under E.O. 13563?*

We concluded that FSIS' discussion of the scientific and technical findings of its worker safety analysis in the proposed rule generally abided by the requirements of E.O. 13563.²¹

E.O. 13563, Improving Regulation and Regulatory Review, requires agencies to provide for both proposed and final rules, to the extent feasible and permitted by law, timely online access to the rulemaking docket on [regulations.gov](https://www.regulations.gov), including relevant scientific and technical findings.^{22, 23} E.O. 13563 also requires agencies to ensure the objectivity of any scientific and technological information and processes used to support the agency's regulatory actions, consistent with the President's March 9, 2009, memorandum regarding scientific integrity and the Office of Science and Technology Policy's (OSTP) Scientific Integrity guidance memorandum.²⁴ The OSTP Scientific Integrity Memo states, "[a]gencies should communicate scientific and technological findings by including a clear explication of underlying assumptions; accurate contextualization of uncertainties; and a description of the probabilities associated with both optimistic and pessimistic projections, including best-case and worst-case scenarios where appropriate."²⁵

In the proposed rule, FSIS stated that it recognized that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety, and it compared in-establishment injury rates between HIMP and traditional establishments.^{26, 27} FSIS included a brief description of this analysis and a summary of its findings in the proposed rule. Specifically, the proposed rule stated, "[t]he preliminary analysis shows that HIMP establishments had lower mean injury rates than non-HIMP establishments."²⁸ It further specified, "[t]he results showed HIMP [establishments] had a lower mean number of injuries using three OSHA injury rate measures."²⁹

However, the agency did not provide enough detail to be consistent with the guidance in the OSTP Scientific Integrity Memo. For example, FSIS performed statistical tests on the OSHA

²¹ For the purpose of this report, our use of "public transparency requirements" noted in Objective 1 refers to the public participation and science requirements under E.O. 13563.

²² For the purposes of this engagement, we reviewed FSIS' scientific analysis and findings based on OSHA collected in-establishment injury and illness rates in HIMP and traditional swine slaughter facilities.

²³ E.O. 13563, § 2 (Jan. 18, 2011).

²⁴ E.O. 13563, § 5 (Jan. 18, 2011).

²⁵ OSTP, Scientific Integrity, Memorandum for the Heads of Executive Departments and Agencies § I.4. (Dec. 17, 2010) ("OSTP Scientific Integrity Memo").

²⁶ HIMP establishments operate at higher line speeds than traditional (non-HIMP) establishments.

²⁷ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

²⁸ *Ibid.*

²⁹ The three OSHA injury and illness rate measures were: (1) total case rate; (2) days away, restricted, and transfer; and (3) days away from work.

data that concluded HIMP establishments had lower mean injury rates than traditional establishments, but did not disclose either which tests it performed to reach its conclusion or the assumptions involved in those tests.³⁰ Therefore, we determined that FSIS did not include a clear explanation of underlying assumptions, as recommended by the OSTP Scientific Integrity Memo.

Further, FSIS disclosed in the proposed rule that factors other than line speed may affect injury rates, such as automation and number of sorters per line. However, the agency did not disclose other known limitations of the data it analyzed, thus hindering the accurate contextualization of uncertainties as recommended in the OSTP Scientific Integrity Memo.³¹

As neither E.O. 13563 nor the OSTP Scientific Integrity Memo explicitly require agencies to include a clear explanation of underlying assumptions of data used or an accurate contextualization of the uncertainties of findings in their proposed rules, we concluded that FSIS' discussion of its scientific and technical findings of the worker safety analysis in the proposed rule abides by the requirements of E.O. 13563. Therefore, we do not make any formal recommendations; however, FSIS may want to ensure it clearly communicates all elements outlined in the OSTP Scientific Integrity Memo when discussing scientific and technical findings in public communication. Full disclosure of this type of information aids the public's ability to make informed decisions and promotes transparency and confidence in the rulemaking process.

³⁰ FSIS performed two statistical tests using OSHA data: a t-test and a Levene's test. According to the agency, a Levene's test was performed to test the assumption of equality of variances between data sets and a t-test for equality of means was performed to test for statistical significance.

³¹ See Objective 3 for further details.

Objective 2: Did FSIS, with respect to its worker safety analysis section of the proposed rule, make information about its preliminary analysis on worker safety clearly accessible to the public during the comment period?

We concluded that, while FSIS provided a summary of its preliminary worker safety analysis in the language of the proposed rule, it did not fully disclose its data sources. This occurred because FSIS considered the discussion of the worker safety data analysis to be non-essential, supplementary information for the proposed rule. As a result, clear and complete information about the data sources used for FSIS' preliminary worker safety analysis was not easily accessible to the public during the proposed rule's comment period.

USDA's Information Quality Activities Guidelines (Guidelines) stipulate that an agency will "ensure transparency of the analysis, to the extent possible, consistent with confidentiality protections, by . . . providing transparent documentation of data sources."³²

In the proposed rule, we found that FSIS did not fully disclose the data source for the OSHA data it analyzed. In the proposed rule, FSIS stated that "[t]he analysis uses injury rate data by occupational injury estimates that are derived from the [Bureau of Labor Statistics'] annual Survey of Occupational Injuries and Illnesses (<http://www.bls.gov/iif/data.htm>). The survey captures data from [OSHA] logs of workplace injuries and illnesses maintained by employers."³³ This language could be interpreted to indicate that FSIS gathered the information for its worker safety analysis from the listed website. However, FSIS did not download the information from the website noted in the proposed rule; the agency acknowledged that the proposed rule did not include the web address for the OSHA data it analyzed. As such, FSIS should have provided more transparent documentation of the data source for its worker safety analysis in the proposed rule.

However, FSIS included this acknowledgement and the web address for the OSHA data it used in the final rule, published in the Federal Register on October 1, 2019.³⁴ Because the agency ultimately provided transparent documentation for this specific data source to the public through the final rule, we do not make a formal recommendation relating to FSIS providing this specific documentation to the public. However, to ensure FSIS includes transparent documentation of data sources in future proposed rules, the agency should update its internal procedures for the rulemaking process to include a review of proposed rules to ensure compliance with the Guidelines, including the Guidelines' data source transparency requirements.

Secondly, we found that FSIS did not clearly identify the 24 traditional establishments it used for worker safety analysis in the proposed rule. During our fieldwork, FSIS explained that, "while FSIS did not post the exact data that the [a]gency pulled from its Public Health Information System (PHIS) to select swine slaughter establishments present in the OSHA data set, the same information can be found in other formats on FSIS's [sic] website. Establishment level

³² USDA Office of the Chief Information Officer (OCIO), *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

³³ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

³⁴ *Modernization of Swine Slaughter Inspection*, 84 Fed. Reg. 52,305 (Oct. 1, 2019).

production volume information is available at <https://www.fsis.usda.gov/wps/porta/fsis/topics/data-collection-and-reports/data>. This [sic] data would allow interested parties to identify the high-volume establishments.”³⁵ However, based on our review of this information, this data set did not explicitly state slaughter volumes. Rather, it included a “slaughter volume category” that used the number designations 1-5 and the “establishment size” category. Subsequent to our fieldwork, FSIS updated its data dictionary defining these fields. However, based on this spreadsheet alone, we could not determine which 24 traditional establishments FSIS included in its analysis.³⁶ Therefore, we concluded that FSIS did not ensure the transparency of the analysis by providing transparent documentation of the data source for its comparison group of traditional establishments.

In the final rule, FSIS stated that it included a list of establishments used in its worker safety analysis in its Freedom of Information Act (FOIA) Electronic Reading Room.³⁷ As such, the agency has now provided transparent documentation for this specific data source and we, therefore, do not make a formal recommendation related to FSIS communicating the names of the 24 traditional establishments to the public. However, as noted previously, to ensure FSIS includes transparent documentation of data sources in future proposed rules, the agency should update its internal procedures for the rulemaking process to include a review of proposed rules to ensure compliance with the Guidelines, including review of data source transparency requirements.

We concluded that FSIS did not fully comply with the Guidelines related to providing transparent data sources when it published its proposed rule.³⁸ Specifically, FSIS’ information about the sources of the data used for its worker safety analysis was not easily accessible to the public during the comment period.³⁹ Although FSIS disclosed the web address for the OSHA data it analyzed in the final rule published on October 1, 2019, and updated its FOIA Electronic Reading Room to include a list of the establishments used in the worker safety analysis, FSIS should also update its internal procedures for the rulemaking process to include a review of proposed rules in order to ensure compliance with data source transparency requirements.

³⁵ PHIS is a web-based FSIS system that contains establishment names, addresses, and general information regarding the establishments.

³⁶ Using the web address FSIS provided during fieldwork, we downloaded FSIS “Establishment Demographic Data,” available as of July 23, 2019. We filtered the spreadsheet for pork slaughter establishments based on “slaughter volume category.” Per the data dictionary on FSIS’ website, establishments in this category labeled as 4s and 5s have slaughter volumes of 100,000 or greater. This information narrowed the universe to 64 establishments. We recognize that establishment slaughter volumes may have changed since FSIS issued the proposed rule in February 2018; however, we noted that the 24 establishments could not be easily identified using the information FSIS provided.

³⁷ FSIS’ FOIA Electronic Reading Room is a webpage included on the agency’s site that contains documents in the following four categories: (1) final opinions and orders made in the adjudication of cases; (2) policy statements and adopted interpretation not published in the Federal Register; (3) administrative staff manuals and instructions that affect the public; and (4) records that are frequently requested/of interest. USDA FSIS, *FOIA Electronic Reading Room* (last accessed, Nov. 5, 2019), <https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/freedom-of-information-act/fsis-electronic-reading-room>.

³⁸ For more information about FSIS’ compliance with the USDA Information Quality Activities Guidelines in publishing the proposed rule, see Section 2, Objective 3.

³⁹ The public comment period for this proposed rule was open from Feb. 1, 2018, through May 2, 2018.

Recommendation 1

Update FSIS' internal procedures for the rulemaking process to include a review of proposed rules to ensure compliance with USDA's Information Quality Activities Guidelines, including data source transparency requirements.

FSIS Response

In its May 21, 2020, response, FSIS stated:

As explained above, FSIS maintains that it complied with Departmental guidance because the preliminary worker injury analysis was not used as a foundation for the rulemaking. Nevertheless, FSIS intends to update FSIS Directive 1232.4, Regulations Development and Clearance, to include additional instructions for FSIS employees who review Federal Register documents before publication. FSIS will include key points from the Department's Information Quality Activities Guidelines.

FSIS provided an estimated completion date of October 30, 2020, for this action.

OIG Position

We accept FSIS' management decision on this recommendation.

Section 2: Quality of Worker Safety Information used in FSIS’ Proposed Rule—Modernization of Swine Slaughter Inspection

Objective 3: *Did FSIS, with respect to its worker safety analysis section, adhere to the USDA Information Quality Activities Guidelines in developing the proposed rule?*

We concluded that FSIS did not fully adhere to the Guidelines in developing the proposed rule and presenting it during the comment period. This occurred because FSIS did not fully satisfy the data presentation and transparency requirements of the Guidelines. As a result, the public may not have fully understood the limitations of the data used for the worker safety analysis in the proposed rule, during the public comment period.

The Guidelines require agencies to “ensure that the information they disseminate is substantively accurate, reliable, and unbiased and presented in an accurate, clear, complete, and unbiased manner.”⁴⁰ Additionally, the Guidelines stipulate that agencies must evaluate the data and ensure their transparency.⁴¹

In the proposed rule, FSIS stated that the new rule would revoke maximum line speeds at participating swine slaughter establishments. FSIS also recognized that evaluation of the effects of line speed on food safety should include the effects of line speed on establishment employee safety.⁴² In this context, FSIS performed a worker safety analysis using injury and illness data obtained from the OSHA website.⁴³ FSIS stated that it compared in-establishment injury incidence rates between 5 HIMP and 24 traditional establishments, from CYs 2002 to 2010, in the proposed rule. Based on its analysis of the data, FSIS stated that HIMP establishments had lower mean injury rates than traditional establishments.⁴⁴

When we reviewed FSIS’ information related to its worker safety analysis, we found that FSIS did not fully comply with the data presentation and data transparency requirements of the Guidelines, as described below:

Data Presentation Requirements

The Guidelines require agencies to “evaluate data quality and, where practicable, validate the data against other information when using or combining data from different

⁴⁰ USDA OCIO, *Information Quality Activities, General Requirements* (in effect since Oct. 1, 2002; last accessed May 23, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>.

⁴¹ USDA OCIO, *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

⁴² *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

⁴³ FSIS downloaded the OSHA injury and illness data from the following website: OSHA, *Establishment Specific Injury & Illness Data (OSHA Data Initiative)* (last accessed July 23, 2019), https://www.osha.gov/pls/odi/establishment_search.html.

⁴⁴ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

sources.”⁴⁵ Additionally, the Guidelines state that agencies must ensure that the data are “presented in an accurate, clear, complete, and unbiased manner.”⁴⁶ We noted that FSIS was not able to verify the injury and illness rates for accuracy and reliability against other information because, according to an FSIS official, the agency used the only reasonably obtainable information concerning the consequences of the intended regulation related to worker safety. However, FSIS checked the OSHA data for completeness and applicability of the included establishments by verifying OSHA establishment information against independent data from PHIS.

The proposed rule stated, “FSIS compared in-establishment injury rates between HIMP and traditional establishments from [CYs] 2002 to 2010.”⁴⁷ However, when we reviewed the universe of data FSIS used in its worker safety analysis, we found that it additionally included CY 2011 results for 5 of 24 traditional establishments, which were outside of its stated scope of CYs 2002 to 2010.⁴⁸ FSIS informed us that the statement in the proposed rule related to the time period reviewed was a typographical error. Therefore, while FSIS took steps to verify OSHA’s data for the establishments, we determined that FSIS did not ensure the data period in the proposed rule was presented in an accurate manner. Because of this error, we concluded that FSIS did not fully adhere to the data presentation requirements of the Guidelines.

FSIS’ final rule was published in the Federal Register on October 1, 2019.⁴⁹ However, FSIS did not disclose the actual period reviewed for its worker safety analysis. For transparency, FSIS should communicate to the public the actual review period for its analysis.

Data Transparency Requirements

The Guidelines require agencies to, “[w]hen using the best available data obtained from or provided by third parties, ensure transparency in its dissemination by identifying known sources of error and limitations in the data.”⁵⁰

We found that FSIS disclosed the following limitations in the data: (1) the data were voluntarily submitted; (2) only 9 percent of all market hog slaughter establishments submitted illness and injury rate data to OSHA; and (3) factors other than line speed may

⁴⁵ USDA OCIO, *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019),

<https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

⁴⁶ USDA OCIO, *Information Quality Activities, General Requirements* (in effect since Oct. 1, 2002; last accessed May 23, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>.

⁴⁷ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

⁴⁸ FSIS documentation did not include evidence of CY 2011 data for the other 19 establishments. As discussed under this Objective’s Data Transparency Requirements subsection, the OSHA data FSIS used for all 29 establishments assessed in its worker safety analysis were incomplete, and it did not include annual injury and illness rates for all establishments for the 10 years between CYs 2002 and 2011.

⁴⁹ *Modernization of Swine Slaughter Inspection*, 84 Fed. Reg. 52,300 (Oct. 1, 2019).

⁵⁰ USDA OCIO, *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019),

<https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

affect injury rates (for example, automation and number of sorters per line).⁵¹ However, FSIS did not disclose other known limitations. For example, FSIS did not disclose that OSHA’s website advised against using the injury and illness data to make any general conclusions.^{52, 53}

In another example, FSIS did not disclose that the OSHA data used for the 29 establishments assessed in its worker safety analysis were incomplete, and it did not include annual injury and illness rates for all establishments for the 10 years between 2002 and 2011. For instance, for 3 of the 24 traditional establishments, injury and illness rates were available for only 1 of the 10 years.⁵⁴ Additionally, three of the five HIMP establishments had injury and illness rates for only 5 of the 10 years. Only 1 of the 29 total establishments had data for all 10 years.

During our discussions with FSIS officials, one official stated that worker safety was considered supplementary to the proposed rule and did not relate to the foundation of the proposed rule as worker safety is outside of FSIS’ jurisdiction. In addition, FSIS officials stated that the agency did not use the analysis to draw conclusions on worker safety in either HIMP or traditional establishments.

We determined that FSIS did not fully adhere to the Guidelines in developing the proposed rule. Specifically, FSIS neither ensured that the data in the proposed rule were presented in an accurate manner nor disclosed all known limitations of the data. FSIS should: (1) communicate to the public the actual review period and known limitations of the OSHA data associated with FSIS’ worker safety analysis; and (2) determine the impact of the omissions from the proposed rule. FSIS should also update its internal procedures for the rulemaking process to include a review of proposed rules in order to ensure compliance with the Guidelines’ data presentation and data transparency requirements. However, we believe Recommendation 1 in this report sufficiently addresses this specific recommendation and, therefore, we did not make a related recommendation under this objective.

Recommendation 2

Communicate to the public the actual review period associated with FSIS’ analysis.

⁵¹ *Modernization of Swine Slaughter Inspection*, 83 Fed. Reg. 4,796 (Feb. 1, 2018).

⁵² U.S. Department of Labor, Establishment Specific Injury and Illness Data (i.e., OSHA Data Initiative) (last accessed July 23, 2019), https://www.osha.gov/pls/odi/establishment_search.html.

⁵³ Specifically, the website states, “[f]or each data collection cycle, OSHA only collects data from a small portion of all private sector establishments in the United States (80,000 out of 7.5 million total establishments). Therefore, these data are not representative of all businesses and general conclusions pertaining to all US business should not be drawn.”

⁵⁴ For one of the three establishments, the OSHA data showed 0 percent for the covered period.

FSIS Response

In its May 21, 2020, response, FSIS stated:

OIG takes issue with the sentence in the proposed rule that states, “FSIS compared in-establishment injury rates between HIMP and traditional establishments from 2002 to 2010” (83 FR 4780, 4796), because the Agency also looked at data from 2011. FSIS has explained several times that the “2010” is a minor typographical error and did not affect the conclusions of the analysis. Further, even with the minor typographical error, the sentence in the proposed rule is factually correct. Regardless of what time span is utilized – 2002-2010 or 2002-2011 – both show that HIMP establishments had lower mean injury rates than non-HIMP establishments. Again, the typographical error did not affect the conclusions of the analysis, so while the dates did contain an error, it had no bearing on the outcome, discussion or understanding of the document.

As FSIS has explained to OIG multiple times, this recommendation has already been addressed with the publication of the final rule “Modernization of Swine Slaughter Inspection” (84 FR 52300). In the final rule (84 FR 52300, 52305), FSIS included a link to its Electronic Freedom of Information Act (FOIA) Reading Room, which contains documents that show FSIS’ full analysis of worker injury data. FSIS believes that this response is sufficient because the preliminary worker injury analysis was not used as a foundation for the rulemaking.

OIG Position

We do not accept FSIS’ management decision for this recommendation. While the linked documents in FSIS’ Electronic Freedom of Information Act (FOIA) Reading Room contain 2011 data for some individual establishments, the documents also contain the erroneous statement that the scope of FSIS’ worker safety analysis was from 2002 to 2010.⁵⁵ To reach management decision, FSIS needs to communicate to the public the actual review period associated with its analysis.

Recommendation 3

Communicate to the public the known limitations of the OSHA data used for FSIS’ analysis.

FSIS Response

In its May 21, 2020, response, FSIS stated:

Similar to the response above, FSIS believes that this recommendation has already been addressed with the publication of the final rule “Modernization of Swine Slaughter Inspection”

⁵⁵ USDA FSIS, *FOIA Electronic Reading Room: Records Frequently Requested/Of Interest* (last accessed, May 27, 2020), https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/freedom-of-information-act/fsis-electronic-reading-room/ct_index3. See linked documents 18-194 (p 40); 18-277 (p 30); and 18-213-c (p 3).

(84 FR 52300). In the final rule (84 FR 52300, 52305), FSIS included a link to its Electronic FOIA Reading Room, which contains documents that show FSIS' full analysis of worker injury data. FSIS believes that this response is sufficient because the preliminary worker injury analysis was not used as a foundation for the rulemaking.

Additionally, FSIS explained to OIG that when the USDA guideline recommends verifying third-party data, it is not referring to data from other Federal agencies. Federal agencies generally accept data from other Federal agencies. FSIS does not have the authority to contact establishments to independently verify OSHA's worker injury data and doing so would place an unnecessary information collection burden on industry.

OIG Position

We do not accept FSIS' management decision for this recommendation. The linked documents in FSIS' Electronic Freedom of Information Act (FOIA) Reading Room disclose additional known limitations that were not included in the language of the proposed or final rule.⁵⁶ However, we determined that FSIS was aware of other limitations but did not disclose them. To reach management decision, FSIS needs to communicate all known limitations to the public. Specifically, FSIS still needs to communicate: (1) the data the agency used in its analysis of the 29 establishments did not include injury and illness rates for all establishments for each of the 10 years, and (2) the data used did not differentiate whether injuries/illnesses occurred on the swine slaughter line or elsewhere within the establishment.

Recommendation 4

Determine the impact of: (1) publishing an inaccurate review period related to the worker safety analysis in the proposed rule; and (2) not disclosing all known limitations related to the data used for the worker safety analysis in the proposed rule.

FSIS Response

In its May 21, 2020, response, FSIS stated:

There is no impact related to the preliminary analysis of worker injury data because, as FSIS has explained multiple times, the preliminary analysis was not used to support the proposed rule. The preliminary analysis was only included as part of a larger request for comments. Many commenters suggested that FSIS should not use the data to inform decisions on worker safety, and FSIS clarified in the final rule that it did not use the data as a foundation for the rulemaking (*see* 84 FR 52300, 52305).

FSIS completed this action on October 1, 2019.

⁵⁶ USDA FSIS, *FOIA Electronic Reading Room: Records Frequently Requested/OfInterest* (last accessed, May 27, 2020), https://www.fsis.usda.gov/wps/portal/footer/policies-and-links/freedom-of-information-act/fsis-electronic-reading-room/ct_index3. See linked documents 18-194 (p 41); 18-277 (p 31); and 18-213-c (p 4).

OIG Position

We accept FSIS' management decision on this recommendation.

Objective 4: *Did FSIS come to a reasonable determination about the reliability of the OSHA injury data it used for the proposed rule?*

While FSIS' rationale for using OSHA's data to perform a worker safety analysis of HIMP and traditional establishments appeared to be reasonable, we determined that the steps FSIS took to determine the reliability of OSHA's data prior to use were not reasonable. FSIS: (1) underestimated the ultimate importance of these data; (2) did not assess the strength or weakness of any corroborating evidence to verify their reliability; and (3) underestimated the anticipated level of risk in using these data. As a result, FSIS' may have used data that were not suitable for its worker safety analysis.

The Guidelines require agencies to ensure they disseminate objective information in conjunction with their rulemaking activities and state that agencies and offices will "[u]se reasonably reliable and reasonably timely data and information."⁵⁷ For our purposes, data reliability refers to the accuracy and completeness of OSHA's computer-processed data, given their use in FSIS' proposed rulemaking.⁵⁸ In order to address this objective, we reviewed FSIS' actions to assess the reliability of OSHA's data. The goal of a data reliability assessment is to determine whether the data can be used to answer the research questions. The extent of an agency's data reliability assessment can depend on three factors: (1) the expected importance of the data; (2) the strength or weakness of any corroborating evidence; and (3) the anticipated level of risk in using the data.⁵⁹ Based on these three factors, we determined that FSIS did not come to a reasonable determination about the reliability of the OSHA injury data.

Expected Importance of the Data

The extent to which an agency is to assess the reliability of data it uses depends, in part, on its perception of the expected importance of the data.⁶⁰ FSIS considered the discussion of the worker safety data analysis to be non-essential, supplementary information for the proposed rule. However, the Regulatory section of the Guidelines states, "[w]ith respect to *influential* scientific information disseminated by USDA regarding analysis of risks to human health, safety, and the environment, USDA agencies and offices will ensure, to the extent practicable, the objectivity of this information."^{61, 62} Since FSIS' worker safety analysis dealt with risks to human safety, we believe that it

⁵⁷ USDA OCIO, *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

⁵⁸ Government Accountability Office (GAO), *Assessing the Reliability of Computer Processed Data*, GAO-09-680G, at 4 (July 2009). While the Guidelines require agencies to use reasonably reliable data, they do not explicitly define how to determine data are reasonably reliable. We chose to use this GAO document as further criteria as we believe it describes a practical approach to data reliability assessments.

⁵⁹ *Ibid.* at 9.

⁶⁰ *Ibid.*

⁶¹ USDA OCIO, *Regulatory* (in effect since Oct. 1, 2002; last accessed July 24, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

⁶² The Guidelines define objectivity as "substantively accurate, reliable, and unbiased and presented in an accurate, clear, complete, and unbiased manner." USDA OCIO, *Information Quality Activities, General Requirements* (in effect since Oct. 1, 2002; last accessed May 23, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>.

qualifies as influential scientific information. As such, we believe the expected importance of the data goes beyond non-essential, supplementary information.

Strength or Weakness of Any Corroborating Evidence

The extent to which an agency assesses the reliability of data it uses depends, in part, on its determination of the strength or weakness of corroborating evidence. When we asked why FSIS selected OSHA's data to perform its worker safety analysis and how the agency verified the accuracy of these data, an FSIS official stated that OSHA's data were from another Federal agency and were the only data available related to worker's safety. This same official also stated that, although FSIS did not perform any tests to verify the accuracy of OSHA's data, FSIS matched the establishments' information in OSHA's data to establishment information in PHIS in order to verify that OSHA's data could be used for the analysis.⁶³ FSIS officials further explained that the agency did not use its analysis to draw conclusions on worker safety in HIMP or non-HIMP establishments, and that establishment worker safety was outside of FSIS' jurisdiction. Based on our review of documentation and discussions with officials, we determined that FSIS did not compare the OSHA data to any corroborating evidence to verify the reliability of these data used.

Anticipated Level of Risk in Using the Data

The extent to which an agency assesses the reliability of data it uses depends, in part, on its anticipated level of risk in using the data. Agencies conduct risk assessments to weigh how the use of such data could have substantial negative consequences on decisions by policymakers and others. FSIS was aware of OSHA's noted data limitations and statement that its data should not be used to draw general conclusions, but the agency ultimately chose to use the data for its worker safety analysis. As noted before, FSIS considered the discussion of the worker safety data analysis to be non-essential, supplementary information for the proposed rule. However, when doing a risk assessment, one must consider whether the data are relevant to a sensitive or controversial subject.⁶⁴ FSIS chose to include this analysis because a similar proposed rule related to poultry slaughter received worker safety-related comments and requests.⁶⁵ This decision indicates FSIS was aware that this was a sensitive or controversial subject and, therefore, could anticipate that use of the data might involve increased risk.

When we discussed FSIS' determination of data reliability with its officials, we found that FSIS decided to use OSHA's occupational injury and illness data to conduct a worker safety analysis and report its results in the proposed rule because the agency anticipated comments about the proposed rule's impact on worker safety. According to an FSIS official, the agency included the results of its worker safety analysis in the proposed rule because a previous, similar proposed

⁶³ We reviewed documentation related to FSIS' data verification activities and found that FSIS compared the names and addresses of establishments in OSHA's data with the agency's data in order to select the relevant swine slaughter establishments for its analysis.

⁶⁴ GAO, *Assessing the Reliability of Computer Processed Data*, GAO-09-680G (July 2009).

⁶⁵ FSIS referred to its *Modernization of Poultry Slaughter Inspection* final rule, published Aug. 21, 2014. 79 Fed. Reg. 49,565.

rule related to poultry slaughter received worker safety-related comments and requests.⁶⁶ The official maintained that the analysis was intended to stimulate public comment, but also maintained that the changes to the swine regulations were not contingent on the results of the worker safety analysis.

In summary, we acknowledge FSIS' position that OSHA's data were the only available data at that time and that FSIS does not have the authority to regulate issues related to establishment worker safety. However, we determined that FSIS did not adequately assess the reliability of OSHA's data as FSIS: (1) underestimated the ultimate importance of these data; (2) did not verify the reliability of the data with corroborating evidence; and (3) underestimated the anticipated level of risk in using these data. We believe Recommendation 1 in this report sufficiently address any recommendations we would make regarding this issue; therefore, we did not make any recommendations under this objective.

⁶⁶ Ibid.

Objective 5: Did FSIS consult with OSHA and NIOSH about the impact of the proposed rule on workplace safety and health?

We concluded that FSIS, to the extent required, communicated to OSHA and NIOSH about the impact of the proposed rule on workplace safety and health.

In a March 26, 2019, letter to the USDA’s Inspector General, Congressional members referenced E.O. 12866, Regulatory Planning and Review, and asked OIG to determine whether the agency: (1) consulted with OSHA and NIOSH about the impact of the proposed rule on workplace safety and health; (2) provided OSHA or NIOSH with its preliminary worker safety analysis; and (3) addressed any concerns raised by OSHA or NIOSH related to its worker safety information.⁶⁷

Based on our review of E.O. 12866, we identified no provisions that explicitly require FSIS to consult with other Federal agencies regarding FSIS’ proposed regulations.⁶⁸ However, we determined that at least three of the E.O.’s provisions and other guidance strongly imply that FSIS should consult with other Federal agencies.⁶⁹ For example, the Office of Management and Budget (OMB) Circular A-4 states, “[a]s you design, execute, and write your regulatory analysis, you should seek out the opinions of those who will be affected by the regulation as well as the views of those individuals and organizations who may not be affected but have special knowledge or insight into the regulatory issues. Consultation can be useful in ensuring that your analysis addresses all of the relevant issues and that you have access to all pertinent data.”⁷⁰

When we asked FSIS officials about their communications with OSHA and NIOSH, we found that FSIS held a meeting with OSHA representatives to discuss the proposed rule before its publication.⁷¹ However, FSIS did not provide OSHA or NIOSH with details of its preliminary worker safety analysis. We also found that FSIS provided these agencies an advance copy of the proposed rule for commenting. Both agencies provided feedback, but neither agency had questions specific to the results FSIS’ worker safety analysis.⁷² FSIS considered the comments from the agencies and incorporated changes into the proposed rule before its publication.

We concluded that FSIS’ communication with OSHA and NIOSH aligned with the requirements of E.O. 12866, which does not explicitly require consultation with Federal agencies. Therefore, we did not make a formal recommendation. However, FSIS may want to consider sharing relevant analysis with organizations (including Federal agencies) that have specific knowledge or insight regarding future proposed regulations.

⁶⁷ In relation to E.O. 12866, the Congressional members’ letter to USDA OIG stated, “[E.O.] 12866 requires agencies to consult with other agencies that have significant interests in proposed regulations.”

⁶⁸ E.O. 12866.

⁶⁹ E.O. 12866, § 1(b)(2), (10), (11); *see also* OMB, *Regulatory Analysis*, Circular A-4, at 3 (Sep. 17, 2003) (recommending consultation with organizations that have special knowledge or insight into the regulatory issues).

⁷⁰ OMB Circular A-4, at 3.

⁷¹ FSIS did not meet with NIOSH prior to publication.

⁷² For example, OSHA requested that FSIS include requests for comments, best practices, and other measures that establishments can take to protect workers throughout the establishment. NIOSH suggested that, before FSIS would allow implementation of a line speed waiver, the agency and involved establishments consider results and recommendations from an evaluation of the effects of line speed waivers on employee health.

Scope and Methodology

We conducted an inspection of the FSIS rulemaking process for the proposed rule on the modernization of swine slaughter inspection. We initiated this inspection in response to a formal request from 16 members of Congress. In their letter to OIG, Congressional members requested that OIG review the proposed rulemaking process “to better understand whether worker safety data was accurately analyzed and appropriately shared with the public.”⁷³ Our inspection scope primarily covered FSIS’ actions related to its worker safety analysis and the Modernization of Swine Slaughter Inspection proposed rule published in the Federal Register on February 1, 2018.⁷⁴ We conducted our fieldwork from June 2019 through October 2019.

To accomplish our inspection objectives, we:

- reviewed the Modernization of Swine Slaughter Inspection proposed and final rules;⁷⁵
- reviewed E.O.s 12866 and 13563, USDA Information Quality Activities Guidelines, and other related guidance;⁷⁶
- interviewed FSIS officials to discuss the compilation, verification, and analysis of the OSHA worker safety data; the process of drafting the proposed rule; the communications between FSIS and OSHA and NIOSH; the public responses to the proposed rule; and the potential changes to the final rule;
- consulted OIG’s Office of Data Sciences regarding FSIS’ use of statistical terminology and methods to evaluate the OSHA injury and illness data cited in the worker safety analysis section of the proposed rule;
- reviewed FSIS-provided supporting documentation for its worker safety analysis, including combined injury and illness data obtained from the OSHA website;
- reviewed communications between FSIS staff members engaged in the drafting of the proposed rule;
- reviewed preliminary summaries of the worker safety analysis;
- reviewed comments provided by OSHA and NIOSH staff about the worker safety analysis; and
- reviewed a summary of the meeting between FSIS and OSHA representatives.

We conducted this inspection in accordance with CIGIE’s *Quality Standards for Inspection and Evaluation*. These standards require that we plan and perform the inspection to obtain sufficient, appropriate evidence to provide a reasonable basis for our conclusions and recommendations

⁷³ Durbin, The Honorable Richard et. al., Letter to The Honorable Phyllis K. Fong (Mar. 26, 2019).

⁷⁴ We primarily reviewed documents related to FSIS’ worker safety analysis for the proposed rule that were dated between June 2015 and May 2018, the month the comment period closed.

⁷⁵ Our inspection was initiated to review the worker safety analysis section of the proposed rule. However, during the inspection, on October 1, 2019, FSIS published the final rule. While addressing our objectives as related to the proposed rule, we performed a limited review of the final rule in formulating our recommendations.

⁷⁶ E.O. 12866; E.O. 13563; President’s 2009 memo on scientific integrity; OSTP Scientific Integrity Memo; OMB Circular A-4; GAO, *Assessing the Reliability of Computer-Processed Data*; and USDA OCIO *Information Quality Activities* (last accessed July 24, 2019), <https://www.ocio.usda.gov/policy-directives-records-forms/information-quality-activities>, <https://www.ocio.usda.gov/policy-directives-records-forms/guidelines-quality-information/regulatory>.

based on our review objectives. We believe that the evidence obtained provides a reasonable basis for our conclusions and recommendations based on our review.

Abbreviations

CIGIE	Council of the Inspectors General on Integrity and Efficiency
CY.....	calendar year
E.O.....	Executive Order
FMIA.....	Federal Meat Inspection Act
FOIA	Freedom of Information Act
FSIS.....	Food Safety and Inspection Service
GAO	Government Accountability Office
HACCP	hazard analysis and critical control point
HIMP.....	HACCP-Based Inspection Models Project
NIOSH.....	National Institute for Occupational Safety and Health
NSIS.....	New Swine Slaughter Inspection System
OCIO.....	Office of the Chief Information Officer
OIG.....	Office of Inspector General
OMB.....	Office of Management and Budget
OSHA.....	Occupational Safety and Health Administration
OSTP.....	Office of Science and Technology Policy
PHIS.....	Public Health Information System
USDA.....	Department of Agriculture

**FSIS'
RESPONSE TO INSPECTION 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
Office of Inspector General

FROM: Paul Kiecker / s / 5 / 21 / 2020
Administrator
Food Safety and Inspection Service

SUBJECT: OIG Official Draft Report, FSIS Rulemaking Process for the
Proposed Rule: *Modernization of Swine Slaughter Inspection*,
Inspection Number 24801-0001-41

FSIS appreciates the opportunity to review and comment on this Official Draft report concerning the New Swine Slaughter Inspection System (NSIS) rulemaking. The Food Safety and Inspection Service (FSIS) reviewed the Official Draft report and has general comments below followed by a response to each recommendation. FSIS believes that the report's findings and recommendations are derived from the misapplication of E.O. 13563 and the USDA Information Quality Activities Guidelines to an analysis in the NSIS proposal, as well as from a distorted emphasis placed by the auditors on minor errors made in the proposal text. In summary:

- The Occupational Safety and Health Administration (OSHA) and the National Institute for Occupational Safety and Health (NIOSH) are the Federal agencies with jurisdiction over meat and poultry establishment worker safety.
- FSIS presented a preliminary analysis comparison of injury rates between HACCP Inspection Models Project (HIMP) and traditional slaughter establishments to solicit comments for use by OSHA and NIOSH and not as a basis for the NSIS rulemaking.
- E.O. 13563 and the USDA Information Quality Activities Guidelines do not apply to the preliminary analysis; therefore, the audit of FSIS compliance with these documents in developing the preliminary analysis was misguided.
- OIG auditors placed too much weight on minor errors made by FSIS in the NSIS proposal (a typographical error in a table header and the failure to cite a specific website) as a basis for their findings.

FSIS General Comments

Members of Congress specifically requested that OIG examine whether FSIS complied with E.O. 13563 and the USDA Information Quality Activities Guidelines (“Guidelines”) when it developed the preliminary analysis comparison of injury rates between HIMP and traditional establishments, which was published in the NSIS proposed rule (83 FR 4796). E.O. 13563 and the Guidelines apply to situations where scientific data and analysis is used as support for regulatory action. However, since the preliminary analysis was not a basis for the NSIS rulemaking, E.O. 13563 and the Guidelines do not come into play. OIG incorrectly accepted the assumption that E.O. 13563 and the Guidelines apply and did not engage in its own analysis to determine

whether those standards were triggered by the NSIS rulemaking. The fact is that they were not.

As FSIS explained to OIG auditors, the preliminary analysis was not used as a basis for the NSIS rulemaking. Likewise, it was not used to draw conclusions on worker safety in HIMP or non-HIMP establishments, nor was it used to determine whether there is an associated impact on food safety. FSIS published the preliminary analysis to solicit comments about line speed and worker safety, specifically for use by the OSHA and NIOSH, the Federal agencies with jurisdiction over worker safety. Notably, immediately following the discussion of the preliminary analysis in the preamble to the proposed rule, FSIS stated at 83 FR 4796:

FSIS is requesting comments on the effects of faster line speeds on worker safety. Specifically, FSIS is requesting comments on whether line speeds for the NSIS should be set at the current regulatory limit of 1,106 hph or some other number. The Agency is also interested in comments on the availability of records or studies that contain data that OSHA or the National Institute for Occupational Safety and Health (NIOSH) may be able to use in analyzing the effects of increased line speed on the safety and health of employees throughout the establishment, including effects prior to and following the evisceration line.

E.O. 13563 and the Guidelines do not apply to the preliminary analysis because the analysis was published to solicit comments for OSHA and NIOSH and not as a basis for the NSIS rulemaking. As such, OIG findings that FSIS did not comply with these documents are false because they are premised on a mistaken assumption about the purpose of the preliminary analysis. FSIS maintains that it complied with all applicable Executive Orders and Departmental guidance in developing the NSIS regulations.

Additionally, OIG gave too much weight to two inadvertent and insignificant errors committed by FSIS. The first error was a typographical one in a table and did not affect the overall outcome of data therein. The second error was failing to list the website address for OSHA data. OIG cites these missteps as support for a finding that FSIS was not adequately transparent in presenting the data sources for the preliminary analysis. As indicated earlier, the preliminary analysis was published not as a basis for the NSIS rulemaking, but to solicit comments on line speed and worker safety for use by OSHA and NIOSH. Furthermore, FSIS has publicly clarified the source of the OSHA data and posted documents that show the full scope of the Agency's analysis. FSIS aims to be as transparent as possible in presenting data and data analysis. Any implication that these minor errors misrepresented the basis for the NSIS rulemaking is false.

Objective 2: Did FSIS, with respect to its worker safety analysis section of the proposed rule, make information about its preliminary analysis on worker safety clearly accessible to the public during the comment period?

Recommendation 1

Update FSIS' internal procedures for the rulemaking process to include a review of proposed rules to ensure compliance with USDA's Information Quality Activities Guidelines, including data source transparency requirements.

FSIS Response

As explained above, FSIS maintains that it complied with Departmental guidance because the preliminary worker injury analysis was not used as a foundation for the rulemaking. Nevertheless, FSIS intends to update FSIS Directive 1232.4, *Regulations Development and Clearance*, to include additional instructions for FSIS employees who review *Federal Register* documents before publication. FSIS will include key points from the Department’s Information Quality Activities Guidelines.

Estimated Completion Date: FSIS estimates that FSIS Directive 1232.4, *Regulations Development and Clearance*, will issue by October 30, 2020.

Objective 3: Did FSIS, with respect to its worker safety analysis section, adhere to the USDA Information Quality Activities Guidelines in developing the proposed rule?

Recommendation 2

Communicate to the public the actual review period associated with FSIS’ analysis.

FSIS Response

OIG takes issue with the sentence in the proposed rule that states, “FSIS compared in-establishment injury rates between HIMP and traditional establishments from 2002 to 2010” (83 FR 4780, 4796), because the Agency also looked at data from 2011. FSIS has explained several times that the “2010” is a minor typographical error and did not affect the conclusions of the analysis. Further, even with the minor typographical error, the sentence in the proposed rule is factually correct. Regardless of what time span is utilized – 2002-2010 or 2002-2011 – both show that HIMP establishments had lower mean injury rates than non-HIMP establishments. Again, the typographical error did not affect the conclusions of the analysis, so while the dates did contain an error, it had no bearing on the outcome, discussion or understanding of the document.

As FSIS has explained to OIG multiple times, this recommendation has already been addressed with the publication of the final rule “Modernization of Swine Slaughter Inspection” (84 FR 52300). In the final rule (84 FR 52300, 52305), FSIS included a link to its Electronic Freedom of Information Act (FOIA) Reading Room, which contains documents that show FSIS’ full analysis of worker injury data. FSIS believes that this response is sufficient because the preliminary worker injury analysis was not used as a foundation for the rulemaking.

Estimated Completion Date: Completed October 1, 2019.

Recommendation 3

Communicate to the public the known limitations of the OSHA data used for FSIS’ analysis.

FSIS Response:

Similar to the response above, FSIS believes that this recommendation has already been addressed with the publication of the final rule “Modernization of Swine Slaughter Inspection” (84 FR 52300). In the final rule (84 FR 52300, 52305), FSIS included a link to its Electronic FOIA Reading Room, which contains documents that show FSIS’ full analysis of worker injury data. FSIS believes that this response is sufficient because the preliminary worker injury analysis was not used as a foundation for the rulemaking.

Additionally, FSIS explained to OIG that when the USDA guideline recommends verifying third-party data, it is not referring to data from other Federal agencies. Federal agencies generally accept data from other Federal agencies. FSIS does not have the authority to contact establishments to independently verify OSHA's worker injury data and doing so would place an unnecessary information collection burden on industry.

Estimated Completion Date: Completed October 1, 2019.

Recommendation 4

Determine the impact of: (1) publishing an inaccurate review period related to the worker safety analysis in the proposed rule; and (2) not disclosing all known limitations related to the data used for the worker safety analysis in the proposed rule.

FSIS Response:

There is no impact related to the preliminary analysis of worker injury data because, as FSIS has explained multiple times, the preliminary analysis was not used to support the proposed rule. The preliminary analysis was only included as part of a larger request for comments. Many commenters suggested that FSIS should not use the data to inform decisions on worker safety, and FSIS clarified in the final rule that it did not use the data as a foundation for the rulemaking (*see* 84 FR 52300, 52305).

Estimated Completion Date: Completed October 1, 2019.

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