



United States Department of Agriculture
Office of Inspector General





Food Safety and Inspection Service— Inspection and Enforcement Activities At Swine Slaughter Plants

Audit Report 24601-0001-41

What Were OIG's Objectives

Our objectives were to identify areas of risk in FSIS' inspection of swine plants, evaluate FSIS' controls over food safety and humane handling, and determine if appropriate enforcement actions were taken against plants that violated FMIA and HMSA.

What OIG Reviewed

FSIS inspects over 600 plants that have grants to slaughter swine. For fiscal years 2008-2011, we reviewed enforcement actions taken against these plants. We also conducted site visits at 30 plants.

What OIG Recommends

FSIS needs to develop a strategy to take progressively stronger enforcement actions against plants with serious or repetitive violations. FSIS should determine what measurable improvement the HIMP program achieved and its suitability as a permanent program. FSIS should also provide a plan on how it will minimize reliance on the inspectors' judgment to ensure they consistently enforce laws.

OIG audited FSIS' inspection and enforcement activities at swine slaughter plants to determine if they complied with food safety and humane handling laws.

What OIG Found

The Food Safety and Inspection Service's (FSIS) enforcement policies do not deter swine slaughter plants from becoming repeat violators of the Federal Meat Inspection Act (FMIA). As a result, plants have repeatedly violated the same regulations with little or no consequence. We found that in 8 of the 30 plants we visited, inspectors did not always examine the internal organs of carcasses in accordance with FSIS inspection requirements, or did not take enforcement actions against plants that violated food safety regulations. As a result, there is reduced assurance of FSIS inspectors effectively identifying pork that should not enter the food supply.

We also found FSIS could not determine whether the goals of a pilot program—Hazard Analysis and Critical Control Point (HACCP)-based Inspection Models Project (HIMP)—were met because FSIS did not adequately oversee the program. In the 15 years since the program's inception, FSIS did not critically assess whether the new inspection process had measurably improved food safety at each HIMP plant, a key goal of the program.

Finally, we found that FSIS inspectors did not take appropriate enforcement actions at 8 of the 30 swine slaughter plants we visited for violations of the Humane Method of Slaughter Act (HMSA). We reviewed 158 humane handling noncompliance records (violations) issued to the 30 plants and found 10 instances of egregious violations where inspectors did not issue suspensions. As a result, the plants did not improve their slaughter practices, and FSIS could not ensure humane handling of swine. FSIS concurred with all of our recommendations.



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



DATE: May 9, 2013

AUDIT
NUMBER: 24601-0001-41

TO: Alfred V. Almanza
Administrator
Food Safety and Inspection Service

ATTN: Joseph L. Garcia
Chief Financial Officer

FROM: Gil H. Harden
Assistant Inspector General for Audit

SUBJECT: FSIS—Inspection and Enforcement Activities at Swine Slaughter Plants

This report presents the results of the subject review. Your written response to the official draft report is included at the end of the report. Excerpts from the response and the Office of Inspector General's position are incorporated into the relevant sections of the report. Based on the information in your written response, we have accepted your management decision on all 11 recommendations.

In accordance with Departmental Regulation 1720-1, final action is 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 the Office of the Chief Financial Officer (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 publically 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 in the U.S. Department of Agriculture (USDA) responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe, wholesome, and correctly labeled and packaged. FSIS operates under the Federal Meat Inspection Act (FMIA)¹ and the Humane Methods of Slaughter Act (HMSA),² in addition to other laws. FMIA authorizes FSIS to inspect all meat products sold through interstate commerce and imported products to ensure that they meet United States food safety standards. FSIS also enforces HMSA to ensure livestock is slaughtered in a humane manner. In fiscal year (FY) 2011, FSIS received a budget of \$905 million for Federal food safety and inspection services.

Prior to October 2012, FSIS inspection operations were overseen by 15 district offices nationwide:³ Alameda, California; Albany, New York; Atlanta, Georgia; Beltsville, Maryland; Chicago, Illinois; Dallas, Texas; Denver, Colorado; Des Moines, Iowa; Jackson, Mississippi; Lawrence, Kansas; Madison, Wisconsin; Minneapolis, Minnesota; Philadelphia, Pennsylvania; Raleigh, North Carolina; and Springdale, Arkansas.

FSIS' Office of Field Operations is responsible for managing inspection and enforcement activities nationwide. To accomplish this, the agency employed about 8,600 inspectors at 6,300 Federally-inspected slaughter and processing plants—616 of these plants had a grant to slaughter swine.⁴ In 2011, over 110 million swine were slaughtered in the United States.

Thirty of the 6,300 plants are operating under a pilot HACCP Inspection Models Project (HIMP) program initiated in 1997.⁵ The program was developed to produce a flexible, more efficient, and fully integrated meat and poultry inspection system. The HIMP program, in contrast to the traditional inspection system, places responsibility on the plant for sorting out diseased and contaminated carcasses prior to FSIS inspection. In 1997, FSIS approved the first of five swine plants to participate in the program.

FMIA requires that inspectors check all livestock before slaughter to determine if the animals are fit for human consumption. These ante-mortem inspections are one of FSIS' primary means of removing diseased animals from the meat supply. When inspectors find animals showing signs of abnormalities or diseases during ante-mortem inspection, they direct the plant to set the

¹ 21 United States Code (U.S.C.), ch.12 (May 22, 2008).

² 7 U.S.C., ch. 48 (October 10, 1978).

³ During our audit, FSIS consolidated its district offices from 15 to 10.

⁴ Inspectors include in-plant and other frontline personnel.

⁵ HACCP, or Hazard Analysis and Critical Control Point, is a scientific system for process control that is used in food production. It is designed to prevent the occurrence of problems by ensuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards can include biological, chemical, or physical contamination of food products.

affected animals aside for further examination by a veterinarian inspector, who may identify the animals as either “U.S. Suspect” or “U.S. Condemned.” Although animals marked with “U.S. Suspect” tags are still slaughtered, the veterinarian inspector examines the carcasses more thoroughly post-mortem to determine if they are safe for human consumption. In contrast, animals marked with “U.S. Condemned” tags are not slaughtered for food.

HMSA states that the slaughtering and handling of livestock are to be carried out only by humane methods to prevent the needless suffering of animals. Inspectors’ duties include: ensuring that there are adequate measures in case of inclement weather, observing truck unloading, checking water and feed availability, observing handling during ante-mortem inspection, observing handling of suspect and disabled livestock, observing electric prod use, monitoring for slips and falls, checking stunning effectiveness, and checking for conscious animals hanging on the slaughter rail.

These laws were enacted to promote food safety and humane handling of the animals. When inspectors identify violations of the laws, FSIS regulations, or directives, they may take enforcement actions. Depending on the seriousness of the violation, inspectors have numerous options ranging in severity from issuing a citation to suspending the plant. Past audits have identified weaknesses in the enforcement of both laws.

Related Prior Audits

This audit is the latest in a series of audits related to FSIS enforcement of food safety and humane handling. The prior audits listed below identified continuing problems with FSIS’ inspections and enforcement:

In 2012, an Office of Inspector General (OIG) audit of shell eggs found that when FSIS identified egregious violations or repeat violators, it did not initiate progressively stronger enforcement actions.⁶ The agency’s lenient enforcement policy did not deter serious violations or repeat violators, and the strongest enforcement actions that FSIS initiated were warning letters.

In 2010, a Government Accountability Office (GAO) audit concluded that inspectors did not take consistent enforcement actions when faced with humane handling violations.⁷ GAO’s review of noncompliance records (NRs) also identified incidents in which inspectors did not suspend plant operations or take regulatory actions when they appeared warranted.⁸

In 2008, OIG performed an audit in response to videos provided by the Humane Society of the United States that documented the egregious abuse of cattle awaiting slaughter at the Hallmark-Westland Meat Packing Company.⁹ OIG found that FSIS needed to strengthen management controls and oversight of food safety and humane handling inspections.

⁶ Audit 50601-0001-23, *USDA Controls Over Shell Egg Inspections* (November 2012).

⁷ GAO-10-203, *HMSA - Actions Are Needed to Strengthen Enforcement* (February 2010).

⁸ An NR is a citation issued to the plant for violating the regulations.

⁹ Audit 24601-0007-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities* (November 2008).

In 2007, an OIG audit of beef and poultry processing plants found that FSIS inspection personnel did not have guidance on when to take further enforcement actions to address repetitive violations.¹⁰

In 2004, an OIG audit found that FSIS' monitoring system did not flag NRs with serious deficiencies,¹¹ such as the presence of fecal material associated with *E. coli* contamination on carcasses.¹² Further, since fecal material noncompliance incidents could result from many different causes, inspectors did not always link them and monitor their total number at each plant.

Objectives

Our audit objectives were to (1) identify areas of risk in FSIS' inspection of swine plants, (2) evaluate if FSIS' controls were sufficient to ensure swine slaughter plants were in compliance with food safety requirements and humane handling standards, and (3) determine if appropriate enforcement actions were taken against plants that failed to comply with the regulatory requirements.

¹⁰ Audit 24601-07-Hy, *Issues Impacting the Development of Risk-based Inspection at Meat and Poultry Processing Establishments* (December 2007).

¹¹ Audit 24601-0003-Ch, *Food Safety and Inspection Service Use of Food Safety Information Systems* (September 2004).

¹² *Escherichia coli* (abbreviated as *E. coli*) are a large and diverse group of bacteria that can cause illnesses such as diarrhea, urinary tract infections, and pneumonia.

Section 1: Food Safety

Finding 1: Enforcement Policies Do Not Deter Repeat Violators

FSIS' enforcement policies do not deter swine slaughter plants from becoming repeat violators of food safety regulations. During FYs 2008 to 2011, FSIS issued 44,128 noncompliance records (NRs)¹³ to 616 plants; only 28 plants were suspended, even though some plants repeated violations as egregious as fecal matter on previously cleaned carcasses.¹⁴ This occurred because FSIS does not (1) always take progressively stronger enforcement action against repeat violators, when warranted; (2) distinguish between serious violations and minor infractions on its NRs; and (3) provide sufficient guidance on what actions to take in specific circumstances. As a result, plants have repeatedly violated the same regulations with little or no consequence. For example, 21 percent of NRs at the 20 most-cited plants were for repeat violations. Without more incentive to improve compliance, the 616 plants—which process about 110 million swine per year—run a higher risk of providing pork for human consumption that should not enter the food supply.

Regulations state “each [plant] must be operated and maintained . . . to prevent the creation of insanitary conditions and to ensure that product is not adulterated.”¹⁵ For all Federally-inspected slaughter plants that do not meet regulatory food safety requirements, FSIS established the following six enforcement actions:

- **Noncompliance Record:** Inspectors cite violations of regulations by issuing NRs.¹⁶ When inspectors identify repeat violations, they link the NRs in FSIS' mission-critical monitoring system, the Public Health Information System (PHIS).¹⁷ As soon as the inspectors identify a trend in violations (e.g., three linked NRs), they may inform the district office, which determines if more aggressive enforcement action should be taken.
- **Regulatory Control Action:** In conjunction with issuing NRs, an inspector can take regulatory control actions by retaining product, rejecting equipment or facilities, slowing or stopping the slaughter line, or refusing to allow plants to process the problematic product until the plant takes immediate corrective action.
- **Notice of Intended Enforcement:** This is a warning notice issued by FSIS district offices. It notifies a plant that, although the violations do not pose an imminent threat to public health, FSIS may either withhold the marks of inspection¹⁸ or suspend the plant,

¹³ An NR is a citation issued to the plant for violating the regulations. For the purposes of this finding, NRs will refer specifically to food safety NRs.

¹⁴ FSIS PHIS Directive 5000.1, pp. 94-95 states that repeat violations are “repetitive failures of the same aspect of the [plant’s] food safety system” and “occurred within a reasonably close period of time” (April 11, 2011). These violations are linked by inspectors in FSIS' monitoring system.

¹⁵ 9 Code of Federal Regulations (CFR) §416.1 (January 1, 2010). Per 9 CFR §301.2, a product is adulterated “if it has been prepared, packed, or held under insanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health” (January 1, 2010).

¹⁶ FSIS Directive 5000.1, Rev. 3, p. 32 (June 24, 2008).

¹⁷ PHIS is a comprehensive data analysis system that FSIS uses to collect, consolidate, and analyze inspection data.

¹⁸ The official USDA inspection legend to be applied to inspected and passed carcasses and parts of carcasses.

unless the plant responds to FSIS within 3 business days to demonstrate how it has or will achieve compliance.

- **Suspension:** During a suspension, plants cease production. FSIS district offices withdraw inspectors from their duties and inform the public of the cause of the suspension through FSIS’ website. The length of suspension is determined by how long it takes the plant to fix the problem. For FYs 2008 to 2011, suspensions for swine plants lasted a median of 7 days before the plants were fully operational again.
- **Withholding the Mark of Inspection:** FSIS district offices may disallow the mark of inspection to be applied to products. Without the mark of inspection, products cannot be sold.
- **Withdrawal of Inspection:** The FSIS Administrator may file a complaint with a USDA Administrative Law Judge to withdraw a grant of Federal inspection. If inspection service is withdrawn, an establishment must reapply to receive Federal inspection.

FSIS regularly issues NRs and regulatory control actions to correct noncompliance issues. However, although FSIS’ enforcement system allows other progressively stronger actions as described above, we found that FSIS rarely suspended plants and did not take any withholding or withdrawal actions over our 4-year scope period (see Table 1). Only 0.0006 of the NRs resulted in a suspension. Although we identified numerous other instances where violations warranted suspensions, the plants were not suspended. See examples 1 to 3 on the following page.

**Table 1: Enforcement Actions for Food Safety Violations
FYs 2008-2011**

Type of Enforcement Action	No. of Enforcement Actions
Noncompliance Record	44,128
Regulatory Control Action	7,413
Notice of Intended Enforcement	140
Suspension	28
Withholding the Mark of Inspection	0
Withdrawal of Inspection*	0
Total	51,709
* FSIS considered a Withdrawal of Inspection for one plant but elected not to pursue the action.	

In reviewing the database of the 44,128 NRs and other enforcement actions, we determined that FSIS’ enforcement policies do not deter swine slaughter plants from repeating the same food

safety violations. For the few plants that were suspended, the suspensions only briefly interrupted plant activity. For the 28 suspensions shown in Table 1, FSIS allowed 22 of the plants to continue to operate within a short period—some as little as one day after suspension.

We attribute deficiencies in enforcement policies, as well as the application of those policies, to the following three causes: FSIS does not (1) always take progressively stronger enforcement action against repeat violators, when warranted; (2) distinguish between serious violations and minor infractions on its NRs; and (3) provide sufficient guidance on what action to take in specific circumstances.

FSIS Does Not Always Take Progressively Stronger Enforcement Action Against Repeat Violators

To determine how many NRs were repeated at the plants, we reviewed the 20 plants with the highest number of violations. We found that for these plants, as many as 21 percent of NRs were repeated, i.e., those linked by inspectors in PHIS. However, as long as a plant was making progress in correcting violations and there was no immediate public health risk, FSIS officials did not feel the need to pursue progressively stronger enforcement action. We disagree with this practice because the plants repeated the same serious violations with little or no consequence. See the following examples:

Example 1: At a plant in South Carolina that slaughtered about 2,700 swine per day, FSIS issued a total of 801 NRs, of which 547 (68 percent) were repeat NRs. These included 14 zero-tolerance repeat NRs, such as fecal contamination on a hog after the final trim;¹⁹ 94 repeat NRs for exposed or possibly adulterated products that had “grease smears” or “black colored liquid substance” on processed meat; and 43 repeat NRs for pest control problems, such as cockroaches on the kill floor. After FSIS issued a Notice of Intended Enforcement, the plant continued to repeat the same violations 202 times throughout the next year. Despite the continuing problems, FSIS did not take a stronger enforcement action such as a suspension.

Example 2: At a plant in Nebraska that slaughtered about 10,600 swine per day, FSIS issued a total of 607 NRs, of which 214 (35 percent) were repeat NRs. These included 50 repeat NRs for contaminated carcasses that included “fecal material which was yellow [and] fibrous” on the carcass, and 39 repeat NRs for other insanitary conditions that included a “yellowish colored residue build up” and “pieces of meat and/or fat particles” inside the vats that the plant prepared for storing product. Despite the continuing problems, FSIS did not take a stronger enforcement action such as a Notice of Intended Enforcement or a suspension.

Example 3: At a plant in Illinois that slaughtered about 19,500 swine per day, FSIS issued a total of 532 NRs, of which 139 (26 percent) were repeat NRs. These included 26 repeat NRs for fecal matter and running abscesses on carcasses, and 43 repeat NRs for

¹⁹ Zero tolerance is a policy of strict, uncompromising enforcement of regulations, specifically related to situations such as fecal contamination of carcasses. In this case, the carcass was previously cleaned and all contaminated parts should have been removed.

other insanitary conditions during operations that included exposed or possibly adulterated products and the presence of pests on the kill floor. Despite the continuing problems, FSIS did not take a stronger enforcement action such as a Notice of Intended Enforcement or a suspension.

Similar issues were reported by OIG in 2007 and 2012.²⁰ When we asked national office officials why FSIS had not implemented more effective changes to the program, an Assistant Administrator stated that the agency planned to focus on improving controls in swine slaughter once it implements new guidance sometime in 2013. Moreover, he believed that microbiological testing is a significantly better measure of food safety than visible inspection and that a high number of NRs does not necessarily correlate to food safety issues. Although the Assistant Administrator considered FSIS' guidance to be outdated, he still emphasized the importance of following existing policy.

Since microbiological tests are performed only on a sample of carcasses (whereas visual and manual inspections are required on all carcasses), we question whether this is a better measure for food safety due to its limited use. In addition, FSIS directives recognize that visual inspections to detect contamination are a significant factor in ensuring food safety. One directive states that “the insanitary conditions may be such that the product produced in the establishment may have become contaminated with filth or otherwise rendered injurious to health.”²¹ Because visible contamination poses a threat to human safety, FSIS directives require inspectors to “look for . . . sanitary dressing defects (e.g., fecal material).”²²

FSIS Does Not Distinguish Between Serious Violations and Minor Infractions on Its NRs

Although NRs document which regulations were violated and FSIS has taken steps to link them, FSIS does not distinguish between violations that pose a higher risk to public safety from those that do not. Food safety NRs range from a plant's inaccurate internal records to severe rodent infestation on the kill floor, fecal matter on carcasses, or contaminated ready-to-eat products. Due to the range of NRs, FSIS should provide guidance to inspectors on classifying NRs and modify PHIS, so that FSIS can more easily identify patterns of severe violations. Without distinguishing between minor and serious violations in PHIS, FSIS would need to read the description of each NR to identify the plants with a history of severe violations. See the following examples:

Example 4: At a plant in Minnesota that slaughtered about 19,000 swine per day, an inspector discovered that a date on the plant's Ante-Mortem Audit Sheet was incorrectly recorded as May 27, 2011, instead of the actual date of April 27, 2011. However, the inspector found that required ante-mortem procedures had been performed. To document

²⁰ Audit 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Establishments* (December 2007); Audit 50601-0001-23, *USDA Controls Over Shell Egg Inspections* (November 2012).

²¹ FSIS Directive 5000.1, Rev. 3, p. 4 (June 24, 2008).

²² FSIS Directive 6100.2, p. 16 (September 17, 2007).

the recordkeeping violation, he issued an NR to the plant. We consider this to be a minor violation since the misreported date would not impact food safety of the product.

Example 5: At a plant in Nebraska that slaughtered about 10,600 swine per day, an inspector observed yellow fibrous fecal material on the left hind foot of one carcass. The contaminated carcass had moved past the plant's quality control employees without being detected. To document this violation, the inspector issued an NR to the plant. We consider this to be a more serious violation than the one above since fecal matter on a carcass (a zero-tolerance violation) would impact food safety of the product.

A similar issue was reported by OIG in 2004 when we found that FSIS' monitoring system could not identify NRs with serious deficiencies,²³ such as the presence of fecal material associated with *E. coli* contamination on carcasses. When we asked FSIS officials why they had not improved PHIS to classify NRs since then, they told us they relied on the inspectors to alert them of major problems.

However, this may not be an ideal practice for the following reasons. First, FSIS national and district officials have oversight responsibilities that include determining how well slaughter plants nationwide comply with food safety regulations, as well as identifying emerging trends and risks. Without classifying the severity of violations, these officials cannot easily determine the frequency of severe violations or if patterns exist at certain plants. The agency has already recognized the importance of classifying egregious violations for humane handling. Second, although FSIS national and district officials rely on the inspectors to alert them of major problems, the inspectors may not know the history of the plant since they often rotate to other plants or leave the agency. Also, some plants receive hundreds of NRs a year, and the inspectors must either rely on their memories or re-familiarize themselves with each NR.

FSIS Does Not Provide Sufficient Guidance on What Action to Take in Specific Circumstances

FSIS has not issued regulations or policies on when to initiate stronger enforcement action for repeat violations. There are no quantifiable criteria explaining when actions such as suspensions or Notices of Intended Enforcement should be issued. Regulations state "FSIS may take a withholding action or impose a suspension" to plants with insanitary conditions "due to multiple or recurring noncompliance."²⁴ However, FSIS directives do not quantify how many violations constitute "multiple or recurring noncompliance;" nor do the directives mandate when to suspend a plant.

There are other instances where FSIS directives are not specific. For example, when a plant has repeat violations, one directive states that "the Frontline Supervisor and [Inspector-in-Charge] are to determine whether the NRs should be linked and whether a

²³ Audit 24601-0003-Ch, *Food Safety and Inspection Service Use of Food Safety Information Systems* (September 2004).

²⁴ 9 CFR §500.4 (January 1, 2010).

Food Safety Assessment should be recommended.”²⁵ While a Food Safety Assessment may lead to a Notice of Intended Enforcement, the directive does not specify when one should be issued or whether a suspension should be imposed.

A similar issue was reported by OIG in 2007.²⁶ When we asked FSIS officials how they quantified multiple or recurring violations, they stated that there is no “magic number” and that as long as there is a distinction between sporadic problems and systemic failure, there is no need for such a measure.

As evidenced in examples 1 through 3 of this finding, we found several plants where recurring NRs revealed a systemic failure and not a sporadic problem, including recurring zero-tolerance violations—most occurred within 3 months of each other. Although the agency stated that the frequency of violations over a specific timeframe is important in determining when to take stronger enforcement action, FSIS’ guidance does not define frequency or specify timeframes. Without more specific criteria, inspectors and officials have the option not to pursue even the most serious violations. FSIS officials may also choose different courses of action, leading to plants being treated inconsistently.

In conclusion, while FSIS’ enforcement system allows progressive actions against repeat violators, the agency rarely pursues stronger actions. Since there are no substantial consequences for plants that repeatedly violate the same food safety regulations, the plants have little incentive to improve their slaughter processes. It is critical that plants work towards preventing violations from occurring in the first place because recurring, severe violations may jeopardize public health. By helping swine slaughter plants move towards this goal, FSIS will improve its assurance that the nation’s commercial supply of pork is safe and wholesome.

Therefore, FSIS should develop a strategy to take progressively stronger enforcement action against plants with serious or repetitive violations, and develop criteria and procedures to classify all severe food safety NRs. The agency should also modify existing criteria to standardize when suspensions and Notices of Intended Enforcement should be applied, as well as define the frequency and specify the timeframes when violations would lead to such enforcement actions.

Recommendation 1

Develop a strategy to take progressively stronger enforcement action against plants with serious or repetitive violations.

²⁵ FSIS Directive 5000.1, Rev. 3, p. 82 (June 24, 2008). An FSIS webcast states that a Food Safety Assessment considers all the food safety aspects that relate to a plant and all the products the plant produces (November 25, 2008).

²⁶ Audit 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Establishments* (December 2007).

Agency Response

In order to facilitate developing a strategy to take progressively stronger enforcement action against plants with serious or repetitive violations, FSIS has implemented PHIS.²⁷ When data indicates repetitive non-compliance with food safety related regulations, it implements enforcement action in accordance with the Rules of Practice, 9 CFR Part 500. Additionally, FSIS is developing a strategy for taking progressively stronger enforcement actions against plants with serious or repetitive violations by using regulatory non-compliance to identify establishments that should be prioritized for “for cause” Food Safety Assessment. FSIS will complete this work and develop a strategy by January 1, 2014.

OIG Position

We accept FSIS’ management decision on this recommendation.

Recommendation 2

Develop criteria and procedures to classify all severe food safety NRs.

Agency Response

FSIS is developing criteria and procedures to classify all severe food safety NRs, by using the PHIS data. FSIS has determined the regulations that have significant potential for public health consequences. The details of this data driven approach to inspection and enforcement was originally detailed in a paper entitled “Data-Driven Inspection for Processing and Slaughter Establishments Public Health Decision Criteria,” published September 2010. A revised approach that defined criteria was developed in 2012 and presented to the National Advisory Committee for Meat and Poultry Inspection (NACMPI) in January 2013. FSIS will incorporate input from the NACMPI and implement these criteria by January 1, 2014.

OIG Position

We accept FSIS’ management decision on this recommendation.

Recommendation 3

Modify existing criteria to standardize when suspensions and Notices of Intended Enforcement should be applied, as well as define the frequency and specify the timeframes when violations would lead to such enforcement actions.

²⁷ OIG is currently conducting an audit on PHIS (24601-0001-23).

Agency Response

FSIS agrees that consistently applying the principles of the Public Health Decision Criteria, which determines how suspensions and Notices of Intended Enforcement should be applied when taking enforcement actions, is in fact necessary. When taking enforcement action, the Agency is guided by the public health criteria as defined in “Data-Driven Inspection for Processing and Slaughter Establishments Public Health Decision Criteria,” published September 2010, and the regulatory Rules of Practice defined in 9 CFR Part 500. The Agency will develop instructions through a notice or directive for its management and supervisory personnel on the Rules of Practice and decision criteria to further advance consistent enforcement of the principles by January 31, 2014.

OIG Position

We accept FSIS’ management decision on this recommendation.

Finding 2: Some Inspectors Performed Insufficient Post-Mortem and Sanitation Inspections

To ensure sanitation and food safety, inspectors are responsible for examining carcasses, as well as the general plant environment. However, we found that in 8 of the 30 slaughter plants we visited, inspectors did not always examine the internal organs of carcasses in accordance with FSIS inspection requirements, or did not always issue NRs to plants that violated food safety regulations. This occurred due to vague guidance as well as insufficient on-the-job training and supervision. As a result, there is reduced assurance that inspectors will effectively identify pork that should not enter the food supply. Together, the 8 plants slaughtered about 16,000 swine per day.

Inspectors serve as the first line of defense against contaminated pork entering the food supply. According to regulations, on-line inspectors, who are stationed at fixed positions along the slaughter line, are required to conduct “a careful post-mortem examination and inspection . . . of the carcasses and parts thereof of all livestock slaughtered at official [plants].”²⁸ Inspectors are required to check “the head, tail, tongue, thymus gland, and all viscera of each animal slaughtered . . . [and to] observe and palpate the mesenteric lymph nodes” as well as “grasp, turn, and observe both sides of the kidneys” to find parasites, inflammation, swelling, or masses that might indicate disease.²⁹ If inspectors find contamination, “they are to verify that the [contaminated parts] are removed in a sanitary manner.”³⁰ If the plant has not complied with sanitation regulations, but the noncompliance does not need immediate attention, inspectors “are to notify the [plant] management of the noncompliance and document the finding on a NR.”³¹

Off-line inspectors are responsible for monitoring plant sanitation, including ensuring that meat is not exposed to environmental contaminants, such as flies and other vermin and poor ventilation. According to an FSIS directive, “Every time the [inspector] finds that the [plant] is not meeting the [sanitation] requirements, he or she should document the noncompliance on the NR.”³²

However, we found that inspectors did not always identify contaminated meat or cite plants for sanitation violations. We observed the entire slaughter process at 30 of the 616 plants, which slaughtered about 137,000 swine per day. Even though inspectors knew we were observing them during the on-line slaughter and sanitation inspection at each plant, we still found the following problems:

On-line Post-mortem Inspections

Some on-line inspectors did not always perform post-mortem inspections, as required by FSIS policy. At a plant in Indiana that slaughtered about 3,140 swine per day, a recently hired on-line inspector neglected to mark as inedible a tray of viscera that was

²⁸ 9 CFR §310.1(a) (January 1, 2010).

²⁹ FSIS Directive 6100.2, p. 16 (September 17, 2007).

³⁰ FSIS Directive 6100.2, p. 16 (September 17, 2007).

³¹ FSIS Directive 5000.1, Rev. 3, p. 72 (June 24, 2008).

³² FSIS Directive 5000.1, Rev. 3, p. 71 (June 24, 2008).

contaminated with feces. The tray became contaminated because a plant employee had cut through the rectum while removing the viscera for inspection. The plant employee marked the carcass with an “x” to indicate that the carcass required further trimming or extra attention. However, the inspector allowed the tray to pass without marking it as inedible. Eventually, an off-line inspector, who was accompanying us on our site visit, caught the error and marked the tray of viscera inedible.

At four plants located in Alabama, Iowa, New Jersey, and South Dakota that slaughtered about 11,800 swine in total per day, some on-line inspectors did not palpate the kidneys of each carcass or fan out the intestines in order to palpate the lymph nodes during viscera inspection. Two inspectors stated they were distracted during our observation of post-mortem inspections, the agency informed us the third inspector had a history of performance issues, and the fourth inspector was new to swine inspection.

These performance issues can be remedied with increased on-the-job training and supervision. When we spoke with FSIS personnel, they explained that, while all new inspectors receive formal training, much of their responsibilities are taught through on-the-job training. District officials stated that new inspectors receive increased supervision; after the first 2 months, this level of involvement decreases. Generally, district officials agreed that the supervisors should have more closely monitored the inspectors in question. When we drew these individual instances to the district officials’ attention, they informed the supervisors, who in turn provided informal refresher training to the inspectors. We encourage FSIS to continue these actions at all plants.

When we discussed this issue with an Assistant Administrator, he emphasized the importance of inspectors performing their duties in accordance with directives and notices. He also stated that questions and concerns about the post-mortem inspection process should be discussed between inspectors and their supervisors at their regular weekly meetings.

Off-line Sanitation Inspections

Some off-line inspectors did not take sufficient steps to cite issues and enforce sanitation regulations because inspectors often believed they had the discretion to forgo required enforcement action. At a plant in Alabama that slaughtered about 100 swine per day, we saw heavy condensation dripping from the ceiling of the cooler room onto unwrapped carcasses that had already passed the final inspection and were ready to be shipped to customers. This constitutes a potential contamination issue. Regulations state that such coolers require ventilation “adequate to control odors, vapors, and condensation to the extent necessary to prevent adulteration of products and the creation of insanitary conditions.” Though the inspector had a discussion with plant personnel about the condensation, she did not document this noncompliance on an NR.

The inspector felt that the required NR was unnecessary because the plant had installed new circulating fans and refrigeration units—although they did not prevent condensation.

This plant had a history of condensation problems, which continued even after the devices were installed. Because the condensation was a regulatory violation, the district agreed that the inspector should have written an NR.

At three plants in California, Pennsylvania, and Illinois that slaughtered about 1,045 swine in total per day, we observed flies on the kill floors. In one plant, flies hovered over an area where blood was being collected to be sold for human consumption.³³ Regulations state that plants' "walls, floors, ceilings, doors, windows, and other outside openings must be constructed and maintained to prevent the entrance of vermin, such as flies, rats, and mice." The inspectors did not document this noncompliance on an NR.

We determined that there is no clear guidance on how to address vermin and whether their presence constitutes a violation. When we questioned the FSIS officials on whether the presence of flies constitutes an NR, they gave us varied responses. At two districts, officials explained that flies in the slaughter area would normally be documented on an NR. Other districts told us, "[the regulation] is not specific." An Assistant Administrator stated that there is no definite rule on how many flies must be present to write an NR. However, he stated that there is an expectation of consistency and that FSIS needs a policy to address this inconsistency.

Although no diseased or contaminated pork appeared to enter the food supply as a result of the incidents we observed, we remain concerned that FSIS cannot ensure this will always be the case if inspectors are not properly performing sufficient post-mortem and sanitation inspections. The inspection process is only as effective as its inspectors are vigilant. Because inspectors are primarily responsible for monitoring plant sanitation and the safety of the meat they inspect, they must be able to adequately identify points of concern, resolve them, and document all violations that occur. Failure to do so can jeopardize public health.

In conclusion, although FSIS has issued guidance to address inspector performance, it was not always followed, as was evidenced by the examples discussed above. Therefore, FSIS should emphasize to supervisors that action is necessary to address inspector performance issues. Actions should include discussing requirements with inspectors and monitoring their progress more closely in the future. During training for inspectors, FSIS should emphasize the importance of following agency policy in documenting NRs. In addition, FSIS should clarify guidance on when the presence of vermin on the kill floor constitutes a violation.

³³ Many cultures consume blood as food, often in combination with meat. The blood may be in the form of blood sausage, as a thickener for sauces, a cured salted form for times of food scarcity, or in a blood soup. Blood can also be used as a solid ingredient, either by allowing it to congeal (uncooked) before use, or by cooking it to accelerate the process. In this case, after we identified the violation, the plant stopped collecting blood and cleaned the area.

Recommendation 4

Emphasize to supervisors that action is necessary to address inspector performance issues. Actions should include discussing requirements with inspectors and monitoring their progress more closely in the future.

Agency Response

FSIS agrees that supervisors should be continually addressing inspection program personnel (inspectors) performance issues by addressing inspectors' understanding of policy and ensuring consistent requirements are applied. Supervisors manage in-plant employees' performance through the In-Plant Performance System, through which they observe and review each employee's performance to determine where there is a need for improvement. The agency issued FSIS Directive 4430.3 in June 2002, to be implemented October 2002. It requires supervisors to perform at least two In-Plant Performance System reviews per employee per year. FSIS will update its future training to emphasize the importance of following In-Plant Performance System policies. FSIS issued a reminder memo to supervisors to follow FSIS Directive 4430.3 on April 1, 2013.

OIG Position

We accept FSIS' management decision on this recommendation.

Recommendation 5

During training for inspectors, emphasize the importance of following agency policy in documenting NRs.

Agency Response

The Agency agrees that documenting noncompliance with regulatory requirements is central to its mission. FSIS will update its training to emphasize the importance of following agency policy in documenting NRs. FSIS will also reinforce this requirement during discussions with field personnel. FSIS will review training content and update, where necessary, to ensure that documenting NRs and Memorandum of Interviews are appropriately emphasized and adjust, if needed, by January 31, 2014.

OIG Position

We accept FSIS' management decision on this recommendation.

Recommendation 6

Clarify guidance on when the presence of vermin on the kill floor constitutes a violation.

Agency Response

The agency agrees that vermin, or other pests on a kill floor, processing area, or in any other part of an establishment pose a sanitary hazard, and clearly violates 9 CFR 416.2(a). FSIS will review training content and relevant notices and directives to ensure that all field personnel understand the regulatory requirements of 9 CFR 416(2) and foster uniform application. FSIS will review training content and relevant notices and directives by January 31, 2014.

OIG Position

We accept FSIS' management decision on this recommendation.

Finding 3: Swine HIMP Pilot Program Lacks Sufficient Oversight

In 1997, FSIS began a pilot program called the HACCP-based Inspection Models Project (HIMP) for swine, which allowed five large plants to have faster line speeds with fewer FSIS on-line inspectors.³⁴ Although program goals were to increase food safety and plant efficiency, FSIS could not determine whether these goals were met because it did not adequately oversee the program. Specifically, FSIS (1) did not evaluate whether the program resulted in a measurable improvement to the inspection process, (2) allowed one HIMP plant to forgo the standard FSIS policy to manually inspect viscera, and (3) did not have formal agreements with the HIMP plants. This occurred because FSIS' focus was on other issues, and it did not consider the swine HIMP program a priority. Since FSIS did not provide adequate oversight, HIMP plants may have a higher potential for food safety risks. Nationwide, 3 of the 10 plants cited with the most NRs continue to participate in the HIMP program.

Beginning in 1997, five plants that slaughter market swine were converted to HIMP plants to test this pilot inspection program.³⁵ FSIS stated in the *Federal Register* that during the project, it “will test and evaluate new approaches to fulfilling inspection requirements by plants and FSIS inspectors. The project will also test new FSIS food safety and other consumer protection activities. . . . The new models are intended to help the Agency determine how best to maintain and improve upon the level of protection provided by current inspection procedures, and at the same time use its resources more effectively.” FSIS further stated that it expected “this system to yield increased food safety and other benefits to consumers.”³⁶

To achieve increased food safety and other benefits for consumers, FSIS provided HIMP plants “the flexibility, within performance and regulatory standards set by FSIS, to design specific processes that address hazards and defects unique to their operations.”³⁷ HIMP plants have fewer FSIS inspectors, and processing lines are allowed to operate at higher speeds than in traditional plants because plant employees—rather than FSIS inspectors—sort out diseased carcasses and parts before they reach FSIS inspectors for final determination of wholesomeness.

Although HIMP was intended to improve food safety, we found that 3 of the 10 plants cited with the most NRs from FYs 2008 to 2011 were HIMP plants. In fact, the swine plant with the most NRs during this timeframe was a HIMP plant—with nearly 50 percent more NRs than the plant with the next highest number. This occurred because of FSIS' lack of oversight, which is evidenced in the following areas:

³⁴ For the purposes of this finding, “HIMP plants” will refer specifically to the swine HIMP plants. HACCP, or Hazard Analysis and Critical Control Point, is a scientific system for process control that is used in food production. It is designed to prevent the occurrence of problems by ensuring that controls are applied at any point in a food production system where hazardous or critical situations could occur. Hazards can include biological, chemical, or physical contamination of food products.

³⁵ Market swine, which are between 5 to 8 months old, represent a significant number of swine slaughtered in the United States. Only plants that slaughter market swine were allowed to participate in the swine HIMP program.

³⁶ *Federal Register*, Docket No. 98-039N (July 29, 1998). No final rule was ever published for the swine HIMP program.

³⁷ *Federal Register*, Docket No. 96-008N (June 10, 1997).

No Measureable Improvement to Inspection Process

In the 15 years since the program's inception, FSIS did not critically assess whether the new inspection process had measurably improved food safety at each swine HIMP plant—a key goal of the HIMP program. FSIS officials told us that, “the [HIMP program was] intended to help the agency . . . improve upon the level of protection provided by current inspection procedures.” Therefore, FSIS needs to determine what measurable improvement to inspection procedures is expected as a result of the HIMP program. As of January 2013, FSIS has not completed the assessment.

Additionally, because HIMP is still in a pilot stage, FSIS needs to review the program's progress to determine its suitability as a permanent program. FSIS should evaluate HIMP plants' noncompliance histories and allow only those plants with a strong history of regulatory compliance to remain in the program. Without a review, HIMP plants that are continually noncompliant—such as the swine plant with the most NRs nationwide—have less assurance of food safety than a traditional plant.

No Manual Inspection of Viscera

At one of the five HIMP plants that slaughtered about 8,100 swine per day, we observed that neither HIMP sorters nor FSIS inspectors manually inspected viscera for signs of disease or contamination.³⁸ As described in Finding 2, this is a key safety inspection that FSIS requires. This plant typically produces and ships more than 50,000 pounds of finished product per day, and receives the FSIS marks of inspection.

When we asked why this plant was the only one in the nation that was not required to manually inspect viscera, FSIS national office officials told us (1) this was not a food safety concern, since market swine are young and “generally” healthy, (2) animal diseases are less a priority now than microbiological contamination, and (3) FSIS allowed “a waiver of the regulations and inspection requirements to be made on the condition that the waiver provides a definite improvement.”

However, we reviewed documents and policies and learned that agency policies require manual inspection of viscera. All other swine plants in the nation manually inspect viscera because some signs of disease and contamination can be detected only through a manual inspection. Examples include tuberculosis nodules embedded within the lymph nodes, parasites within the intestine, and inflamed or degenerated organs that are unusually sticky to the touch or excessively firm. Last, FSIS could not produce a waiver exempting any HIMP plant from this FSIS requirement.

No Formal Agreements

FSIS did not have formal agreements with the five plants participating in HIMP. HIMP plants are granted more flexibility in their operating process than non-HIMP plants,

³⁸ HIMP sorters at this plant manually inspect viscera only if tuberculosis is observed in lymph nodes in the carcass' head, which is rare in market swine.

including being allowed to have faster production line speeds with fewer FSIS inspectors. In return, FSIS should ensure plants understand their obligations as HIMP participants, such as delivering expected improvements over food safety and consistently maintaining compliance with food safety regulations in order to remain a HIMP participant. Therefore, to fully document these obligations, FSIS should establish formal agreements with the plants.

In conclusion, any pilot program, especially one that offers plants flexibility within established performance and regulatory standards, should receive adequate oversight. Instead, the swine HIMP program has shown no measurable improvement to the inspection process; the program was not studied during its first 15 years; three of five HIMP plants had some of the highest numbers of NRs nationwide; and one plant was allowed to forgo an essential food safety procedure.

Therefore, FSIS should determine what measurable improvement the HIMP program achieved and its suitability as a permanent program. FSIS should also develop criteria to terminate plants from HIMP that have a pattern of severe violations, require all HIMP plants to perform visual and manual inspections of viscera, and establish formal agreements with plants participating in the HIMP program.

Recommendation 7

Determine what measurable improvement the HIMP program achieved and its suitability as a permanent program.

Agency Response

FSIS will complete an evaluation of HIMP market hog establishments. The report will include an analysis of HIMP establishments' performance compared to non-HIMP establishments as well as their performance with respect to performance standards established by an independent consulting firm contractor. Such an evaluation may support rule-making to amend regulations to make an inspection system informed by the market hog HIMP pilot permanent. FSIS will complete this evaluation and determine if a permanent program is warranted by March 31, 2014.

OIG Position

We accept FSIS' management decision on this recommendation.

Recommendation 8

Develop criteria to terminate plants from HIMP that have a pattern of severe violations.

Agency Response

The same criteria for regulatory compliance are applied to both non-HIMP and HIMP establishments. Establishments that exhibit a pattern of serious regulatory non-compliance may be subject to a Notice of Intended Enforcement Action, a suspension of inspection activities, and even withdrawal of the grant of inspection. To terminate the HIMP waivers from an establishment operating under those waivers, FSIS has instructed inspectors to report through supervisory channels when a clear trend of repetitive NRs related to the waivers' alternate procedures or *Salmonella* Initiative Program (SIP) protocol are found (FSIS Directive 5020.1). FSIS will review the instructions in FSIS Directive 5020.1 and any available data to provide additional instruction to inspectors on terminating waivers of regulations by October 1, 2013. If needed, updated instructions will be issued by January 31, 2014.

OIG Position

We accept FSIS' management decision on this recommendation.

Recommendation 9

Require all HIMP plants to perform visual and manual inspections of viscera.

Agency Response

FSIS understands the importance of visual and manual inspections of viscera. Therefore, FSIS will convene a scientific workgroup to review FSIS Directive 6100.3 Postmortem Livestock Inspection and the Market Hogs HIMP Inspection Draft dated June 21, 2005. The internal workgroup will determine the basis for visual and manual inspection of viscera and ensure consistency of policies. FSIS will convene this workgroup by October 31, 2013. As needed, updated policies will be issued by March 31, 2014.

OIG Position

We accept FSIS' management decision on this recommendation.

Recommendation 10

Establish formal agreements that address all aspects of HIMP with participating plants.

Agency Response

Establishments volunteering for HIMP agreed to follow information required by a *Federal Register* notice (62 FR 31553, June 10, 1997) which documented the pilot as a waiver of regulations for all establishments participating in the pilot. In a *Federal Register* notice (76 FR 41186, July 13, 2011) FSIS required all establishments operating under a waiver of regulations, including the HIMP Market Hog establishments, to participate in SIP. Establishments requesting

to operate under waivers submit a signed letter to FSIS saying they agree to follow the SIP Letter and SIP Protocol. After evaluation of the submission, FSIS issues a SIP Letter to the establishment documenting the conditions for the establishment to meet to operate under the waiver. The SIP Protocol is a document written and signed by the establishment that includes: (1) identification of the provisions of the regulations that are to be waived, (2) alternative procedures that are to be used in place of any waived provisions of the regulations, (3) description of the microbiological sampling and testing procedures that the establishment will implement, (4) agreement to share microbiological and other data with FSIS, and (5) any other pertinent information.

All HIMP establishments have submitted a written, signed letter requesting to participate in SIP and agreeing to abide by the SIP Letter and SIP Protocol. [By October 2012], FSIS issued a SIP Letter to each participating HIMP market hog establishment to spell out the specific alternative procedures and SIP Protocol that the establishment must meet in order to operate under the waiver(s).

OIG Position

We accept FSIS' management decision on this recommendation.

Section 2: Humane Handling

Finding 4: FSIS Could Not Always Ensure Humane Handling at Swine Slaughter Plants

Inspectors did not take appropriate enforcement actions at 8 of the 30 swine slaughter plants we visited. Specifically, the inspectors did not suspend 6 plants after identifying 10 egregious humane handling violations and did not issue NRs at 2 plants after identifying 2 nonegregious violations.³⁹ This occurred because, although the related FSIS policy was clear and specific, inspectors often made subjective enforcement decisions. At times, these decisions were inconsistent, lenient, and endorsed by district officials. As a result, the plants did not improve their slaughter practices, and FSIS could not ensure the humane handling of swine.

The Humane Methods of Slaughter Act (HMSA) requires that livestock be handled and slaughtered in a humane way.⁴⁰ FSIS policy stated “for situations where there are egregious humane handling noncompliances... the [inspector-in-charge] is to... orally notify plant management of an immediate suspension action.”⁴¹ The policy defines an egregious situation as “any act or condition that results in severe harm to animals,” including “stunning of animals and then allowing them to regain consciousness, multiple attempts... to stun an animal versus a single blow or shot that renders an animal immediately unconscious, and running equipment over conscious animals.”⁴² For nonegregious humane handling violations, FSIS requires inspectors to at least issue an NR.⁴³

Humane handling practice is defined as treatment of animals “that cause[s] a minimum of excitement, pain, injury, or discomfort (e.g., driving animals too fast and causing a few to slip and fall).”⁴⁴ To ensure humane handling, inspectors monitor plant employees in unloading swine from trucks; moving them into holding pens and stunning areas; stunning, sticking, and bleeding procedures; and their treatment of disabled animals.⁴⁵ If inspectors witness inhumane treatment of swine, they must take one of several enforcement actions. These actions range from issuing an NR to suspending a plant.⁴⁶

Unlike post-mortem food safety inspections, humane handling inspections are only performed on a limited basis. Also, unlike most sanitary violations, inspectors may suspend a plant for an egregious humane handling violation without prior notification.⁴⁷ However, under new FSIS policy, a plant that has implemented a “robust” humane handling program and has no history of

³⁹ For the purposes of this finding, “humane handling” means both humane handling and humane slaughter.

⁴⁰ 7 U.S.C. ch. 48, sec. 1902 (October 10, 1978).

⁴¹ FSIS Notice 16-08, p. 7 (March 10, 2008). FSIS issued a new directive on August 15, 2011, but most of our review was conducted prior to that date.

⁴² FSIS Directive 6900.2, Rev. 2, p. 21 (August 15, 2011); FSIS Notice 16-08, p. 3 (March 10, 2008); FSIS Notice 21-09, pp. 2-3 (April 1, 2009); FSIS Notice 19-10, pp. 2-3 (April 6, 2010).

⁴³ FSIS Directive 6900.2, Rev. 1, p. 9 (November 25, 2003) and FSIS Directive 6900.2, Rev. 2, p. 19 (August 15, 2011).

⁴⁴ FSIS Directive 6900.2, Rev. 2, p. 3 (August 15, 2011).

⁴⁵ 9 CFR §313 (January 1, 2010) and FSIS Directive 6900.2, Rev. 2, p. 9 (August 15, 2011).

⁴⁶ FSIS Directive 6900.2, Rev. 2, p. 1 (August 15, 2011).

⁴⁷ 9 CFR §500.3 and §500.4 (November 29, 1999).

prior violations may receive a lesser enforcement action (i.e., Notice of Intended Enforcement), rather than an immediate suspension.⁴⁸ In considering which enforcement action to take, district officials allowed inspectors to frequently use their own judgment. To determine if the inspectors' decisions were appropriate, we observed the stunning process and reviewed humane handling NRs at the 30 plants we visited. We identified 12 instances where FSIS did not take appropriate enforcement actions.

At the Sampled Plants

We observed the stunning process for no more than 30 minutes at each plant. During that time, the plants committed the following violations, for which inspectors did not issue the required NRs:

Example 1: At a plant in California that slaughtered about 1,000 swine per day, we observed a hog regain consciousness after it was stunned and hoisted upside-down on a rail. We alerted the inspector-in-charge that the hog was trying to lift itself and had eye movement. After the inspector-in-charge confirmed that the hog was conscious, an employee re-stunned it. Although the stunning process was neither rapid nor effective, the inspector-in-charge elected not to issue an NR.

However, HMSA requires “all animals are rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut.”⁴⁹ Because the hog required two stuns, the plant violated HMSA and, according to FSIS policy, the inspector should have at least issued an NR.⁵⁰ A national office official stated that because this was an egregious incident, the inspector-in-charge should have issued a Notice of Intended Enforcement or suspension.

Five months later, a district official observed another unsuccessful stun at this plant. The official had to twice instruct a plant employee to re-stun the hog before the employee did so. This incident finally led to the plant's suspension.

Example 2: At a plant in Minnesota that slaughtered about 9,400 swine per day, we observed a hog come out of the carbon dioxide chamber still conscious. It was alert and it was breathing rhythmically, but it appeared to be weak and did not move when it was hit with several empty shackles. Instead of immediately re-stunning the hog, it took plant employees over 1½ minutes to administer a stun with the captive bolt gun while deciding on the best way to reach the hog.

⁴⁸ FSIS Directive 6900.2, Rev. 2, p. 22 (August 15, 2011). A Notice of Intended Enforcement is a warning notice issued by the FSIS district office for an egregious humane handling violation. The district may issue a Notice of Intended Enforcement to a plant which, in addition to a strong humane handling program and no recent history of egregious humane handling violations, immediately and effectively addressed the violation.

⁴⁹ 7 U.S.C. ch. 48, sec. 1902 (October 10, 1978).

⁵⁰ FSIS Directive 6900.2, Rev. 1, p. 8 (November 25, 2003).

The inspector-in-charge did not issue an NR because he believed there was no violation under current regulations and policies. This decision was supported by district officials and the frontline supervisor because they believed the hog was “never unconscious” and viewed the incident as though the animal had never been stunned.

We disagree with the officials’ position because the hog went through a functioning carbon dioxide chamber (a chemical stunning) and should have been rendered unconscious—the fact that the animal emerged conscious does not mean it did not experience the chemical stun. Regulations require that “on emerging from the carbon dioxide tunnel, the animals shall be in a state of surgical anesthesia and shall remain in this condition throughout the shackling, sticking, and bleeding.”⁵¹

In the incidents above, both plants violated humane handling laws and regulations. The inspectors did not take appropriate enforcement actions—their decisions were lenient, yet endorsed by district officials. If this occurred when our audit team and FSIS officials were present, we are concerned that this might be more prevalent when the plants and inspectors are not being observed.

Review of NRs

In addition to our observation of the stunning process, we reviewed 158 humane handling NRs issued to the 30 plants we visited. We found 10 instances of egregious violations where inspectors did not issue suspensions. See the following examples:

Example 3: At a plant in Indiana that slaughtered about 3,140 swine per day, an inspector observed an attempt to stun a hog with a captive bolt gun. It appeared to misfire and became lodged in the hog’s skull. The hog remained conscious and aware while the plant sent for another gun, which was about 2 minutes away. The second gun also appeared to misfire causing the hog to squeal, but it remained conscious and aware. The hog then managed to dislodge the first gun from its skull. Ultimately, a portable electric stunner had to be used to successfully render the hog unconscious. Following this incident, FSIS cited another violation for a hog regaining consciousness on the rail. The plant was not suspended for either egregious incident.

Example 4: At a plant in Pennsylvania that slaughtered about 450 swine per day, a hog that had been stunned and bled regained consciousness. The hog was able to right its head, make noise, kick, and splash water in reaction to being placed in a scalding tank. One plant employee immediately re-slit the hog’s throat without re-stunning it. Although plant management was informed about the incident and the line was stopped for 80 minutes, the inspector only issued an NR. The plant was not suspended.

Example 5: At the previously mentioned plant in Minnesota that slaughtered about 9,400 swine per day, an inspector observed a plant employee in a skid loader (similar to a

⁵¹ 9 CFR §313.5 (November 2, 1987). The regulation continues, “In swine, carbon dioxide may be administered to induce death in the animals before they are shackled, hoisted, thrown, cast, or cut.”

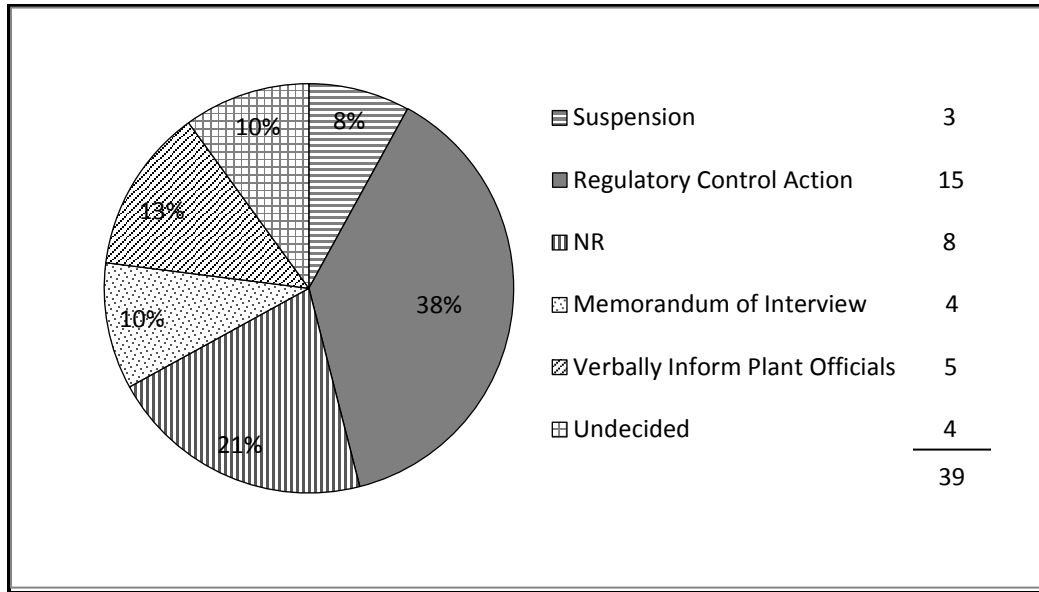
fork lift) attempting to move a non-ambulatory hog. The employee repeatedly drove into the live hog, pushing it with the skid loader, attempting to lift the hog into the loader bucket. On one attempt, the operator was able to lift the back half of the hog into the loader, but the load was so imbalanced that the hog fell out of the loader and onto the concrete floor. The inspector only issued an NR. Following this incident, FSIS cited another egregious violation when a plant employee forcefully hit a hog in the head and face with a paddle. The plant was not suspended for either egregious incident.

The district officials agreed that the three examples above were egregious violations, and the plants should have been suspended. They claimed that the term “egregious” was not formally defined until the new directive was issued in August 2011.⁵² However, we found a comparable definition for egregious in an FSIS notice as early as 2004.⁵³ The definition was also incorporated in several other FSIS notices issued between 2005 and 2011.

Inconsistency in Inspectors’ Judgment

To determine which enforcement action inspectors might take in a particular circumstance, we interviewed 39 inspectors at the plants we visited. We asked them what action they would take if they witnessed one unsuccessful stun. Their responses were inconsistent and ranged from issuing a suspension to informing plant officials verbally during regular meetings (see Chart 1).

Chart 1: Inspectors’ Decisions on Actions to Take for One Unsuccessful Stun



⁵² FSIS Directive 6900.2, Rev. 2, pp. 2-3 (August 15, 2011).

⁵³ FSIS Notice 35-04, pp. 5-6 (June 15, 2004).

HMSA requires that, “all animals are rendered insensible to pain by a single blow or gunshot or an electrical, chemical or other means that is rapid and effective, before being shackled, hoisted, thrown, cast, or cut.”⁵⁴ Therefore, if more than one stun is necessary to render the animal unconscious, the plant would be in violation of Federal law. According to FSIS policy, the inspector should at a minimum issue an NR for an unsuccessful stun.⁵⁵ However, if the unsuccessful stun caused severe harm to the animal, it constitutes an egregious violation, and the inspector “is to take a regulatory control action and recommend . . . an immediate suspension of operation.”⁵⁶

One district official told us that, even though some directives appear straightforward to outsiders, “there is room for interpretation.” However, the varied responses from the 39 inspectors support our concern that when district officials allow inspectors to make subjective enforcement decisions, inspectors will be frequently inconsistent. Similar issues were reported by GAO and OIG in 2010 and 2008, respectively. In 2010, a GAO audit concluded that inspectors did not take consistent enforcement actions for humane handling violations.⁵⁷ GAO’s review of NRs also identified incidents in which inspectors did not suspend plant operations when it appeared warranted. In 2008, OIG performed an audit in response to the Humane Society of the United States’ videos that documented the egregious abuse of cattle at the Hallmark-Westland Meat Packing Company in Chino, California.⁵⁸ OIG found that FSIS management did not detect the inconsistent application and/or noncompliance with required inspection procedures.

When we discussed the above issues with FSIS’ National Humane Handling Enforcement Coordinator, he told us that inspectors completed a nationwide humane handling training course in January 2012. The course consisted of two modules: one for humane handling situations prior to stunning and one for stunning/consciousness situations. With the completion of the training, FSIS believed that inspectors would be able to better identify egregious violations.

Despite the history of similar issues in the last 9 years and both OIG and GAO’s recommendations for nationwide humane handling training, FSIS did not complete the training until early 2012.⁵⁹ Additionally, based on our interviews of some district officials in March 2012, we are concerned whether the training was effective. In example 1 above, the inspector-in-charge and the district official who trains inspectors for humane handling both believed that the unsuccessful stun was not a violation, even after receiving the training. These actions indicate the training did not improve the inspectors’ ability to identify violations, since this incident was a violation of HMSA.

In conclusion, the issues and examples discussed above indicate an inconsistency in how FSIS regulations and policies were applied. Inspectors did not always take necessary enforcement

⁵⁴ 7 U.S.C. ch. 48, sec. 1902 (October 10, 1978).

⁵⁵ FSIS Directive 6900.2, Rev. 1, p. 9 (November 25, 2003).

⁵⁶ FSIS Directive 6900.2, Rev. 2, p. 19 (August 15, 2011).

⁵⁷ GAO-10-203, *HMSA - Actions Are Needed to Strengthen Enforcement* (February 2010).

⁵⁸ Audit 24601-0007-KC, *Evaluation of FSIS Management Controls Over Pre-Slaughter Activities* (November 2008).

⁵⁹ GAO reported on FSIS’ inconsistent enforcement actions in humane handling back in January 2004 (GAO-04-247, *HMSA - USDA Has Addressed Some Problems but Still Faces Enforcement Challenges*).

actions required by regulations and policies. In addition, using their own judgment, some inspectors did not suspend plants for egregious violations. To ensure consistency, FSIS needs to provide a plan describing how it will minimize reliance on the inspectors' judgment to ensure consistent application and enforcement of HMSA and related regulations.

Recommendation 11

Provide a plan describing how FSIS will minimize reliance on the inspectors' judgment to ensure consistent application and enforcement of HMSA and related regulations.

Agency Response

FSIS plans to minimize reliance on the inspectors' judgment to ensure they consistently enforce HMSA and related regulations, by implementing the numbered actions below:

1. Since an inspector's subjective judgment during an inhumane handling event can determine the enforcement outcome, the agency implemented required supplemental training [completed in January 2012] after the release of Directive 6900.2 Revision 2, Humane Handling and Slaughter of Livestock, to improve objective observation and assessment skills. The Situation Based Humane Handling training Module I and Module II teach inspectors how to interpret an egregious or non-egregious inhumane handling event objectively, and take appropriate enforcement actions. The Situation-based Humane Handling training modules were well received by inspectors and industry, and contain fictional scenarios of inhumane and egregious events that describe in detail how the inspector is to proceed with regulatory enforcement.

New situation-based fictional scenarios meant to provide continued education for inspectors are under development, and will be posted through the Humane Interactive Knowledge Exchange (HIKE) on the FSIS website. The HIKE scenarios consist of a detailed description of an inhumane event, the enforcement development of regulatory noncompliance, and a review of applicable FSIS regulations. New scenarios will be posted on the FSIS HIKE website in 2013, the first of which will be released by May 30, 2013. Inspectors will be notified of new scenarios, released by December 31, 2013, and will be encouraged to review and discuss the documents with fellow colleagues.

2. FSIS plans to hire a new Humane Handling Enforcement Coordinator. With the installation of the new Humane Handling Enforcement Coordinator, the noncompliance review frequency will increase to monthly, and include direct commentary to the body of each noncompliance that the District Veterinary Medical Specialists will share with the inspectors. This specific correlation will improve the inspector's objective analysis when enforcing HMSA and related regulations, and reduce subjective interpretation of inhumane events and their regulatory outcome. In addition, the Humane Handling enforcement coordinator will develop a database to track the review of noncompliance records; as well as review and track suspensions and Notices of Intended Enforcement in a similar database.

The Humane Handling Enforcement Coordinator will review humane handling noncompliances monthly, and forward to the humane handling specialists in each district a summary of the number of noncompliance records that sound egregious and should have received a Regulatory Control Action, suspension or a Notice of Intended Enforcement. The review will also include instances of how many noncompliance records were poorly written, or cited the wrong regulation for the noncompliant event.

FSIS will establish a new Humane Handling Enforcement Coordinator; increase review frequency of noncompliances, suspensions, and Notices of Intended Enforcement; and develop a database tracking these reviews by August 31, 2013.

OIG Position

We accept FSIS' management decision on this recommendation.

Scope and Methodology

We conducted a nationwide review of FSIS' inspections of swine slaughter plants and its enforcement of laws, regulations, and policies during FYs 2008 through 2011. We performed fieldwork at the FSIS national office in Washington D.C.; seven district offices (Alameda, California; Chicago, Illinois; Des Moines, Iowa; Raleigh, North Carolina; Jackson, Mississippi; Minneapolis, Minnesota; and Philadelphia, Pennsylvania); and 30 plants in 12 States (see exhibit A for a complete list of audit sites). We performed fieldwork from July 2011 through October 2012.

Generally, we selected the seven districts with the highest number of NRs. Using analytical software, we judgmentally selected 30 of 616 plants in our sampled districts based on the (1) number of NRs and suspensions during our scope, (2) size of the plant, (3) elapsed time since the last suspension, (4) number of swine each plant slaughtered, (5) availability of swine slaughter activity, and (6) proximity to other plants in our sample.

To accomplish our audit, we:

- **Reviewed criteria:** We reviewed pertinent laws and regulations governing the FSIS program and the current policies and procedures FSIS established as guidance for inspections and enforcement. These laws, regulations, and policies include FMIA, HMSA, and FSIS Directives and Notices.
- **Interviewed FSIS personnel:** We interviewed FSIS national and district office officials, as well as inspectors at the plants, to gain an understanding about the FSIS program, its inspections, and enforcement procedures.
- **Reviewed and analyzed NRs:** We analyzed NRs and other documentation that we obtained from the national and district offices for the plants we reviewed to determine if they received appropriate enforcement actions and whether or not repeat noncompliance incidents were adequately addressed.⁶⁰
- **Conducted 30 site visits:** We visited 30 plants to observe the inspectors performing their duties to (1) determine if the plant employees were in compliance with laws, regulations, and policies, and (2) evaluate if appropriate enforcement actions were taken in case of violations.
- **Reviewed humane handling verification visits:** We reviewed District Veterinary Medical Specialists' schedules of humane handling verification visits to the plants to determine the frequency of their visits and their compliance with the FSIS recommended timeframe. We also reviewed their verification reports to identify any issues they detected.

⁶⁰ FSIS implemented a new information system, PHIS, during our audit. This system is being reviewed by another OIG audit (24601-0001-23). Therefore, we did not verify the accuracy of the data.

- **Consulted with swine welfare experts:** We consulted with two recognized non-FSIS experts (academicians) on swine welfare, who expressed their opinion on specific humane handling examples to determine if they constituted egregious violations.
- **Reviewed training modules:** We reviewed training modules to determine the connection between FSIS policy progression and implementation of changes into the procedures governing inspector activities at swine slaughter plants.

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

Abbreviations

CFR.....	Code of Federal Regulations
FMIA.....	Federal Meat Inspection Act
FSIS.....	Food Safety and Inspection Service
FY	Fiscal Year
GAO.....	Government Accountability Office
HACCP	Hazard Analysis and Critical Control Point
HIKE	Humane Interactive Knowledge Exchange
HIMP.....	HACCP-based Inspection Models Project
HMSA.....	Humane Methods of Slaughter Act
NACMPI.....	National Advisory Committee for Meat and Poultry Inspection
NR.....	Noncompliance Record
OCFO.....	Office of the Chief Financial Officer
OIG	Office of Inspector General
PHIS	Public Health Information System
SIP.....	<i>Salmonella</i> Initiative Program
U.S.C.	United States Code
USDA.....	U.S. Department of Agriculture

Exhibit A: Audit Sites Visited

Exhibit A shows the organization and location of all sites visited.

Organization	Location
FSIS National Office	Washington, D.C.
FSIS Alameda District Office Office of Field Operations Plants: 1 2 3 4 5	Alameda, CA Modesto, CA Vernon, CA Turlock, CA Atwater, CA Orland, CA
FSIS Chicago District Office Office of Field Operations Plants: 6 7 8 9	Lombard, IL Beardstown, IL Grant Park, IL Peoria, IL Logansport, IN
FSIS Des Moines District Office Office of Field Operations Plants: 10 11 12 13	Des Moines, IA Ottumwa, IA Columbus Junction, IA Hospers, IA Fremont, NE
FSIS Jackson District Office Office of Field Operations Plants: 14 15 16 17	Ridgeland, MS Gadsden, AL Florence, AL Moselle, MS Pontotoc, MS

Organization	Location
<p>FSIS Minneapolis District Office Office of Field Operations Plants: 18 19 20 21</p>	<p>Minneapolis, MN Austin, MN Glencoe, MN Worthington, MN Sioux Falls, SD</p>
<p>FSIS Philadelphia District Office Office of Field Operations Plants: 22 23 24 25 26</p>	<p>Philadelphia, PA Green Village, NJ Salem, NJ Gilbert, PA Souderton, PA Hatfield, PA</p>
<p>FSIS Raleigh District Office Office of Field Operations Plants: 27 28 29 30</p>	<p>Raleigh, NC Fayetteville, NC Sims, NC Warsaw, NC Warsaw, NC</p>

**USDA'S
FOOD SAFETY AND INSPECTION
SERVICE'S
RESPONSE TO AUDIT REPORT**



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

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

FROM: Alfred V. Almanza / s / **April 17, 2013**
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Inspections and Enforcement Activities at Swine Slaughterhouses, Report Number 24601-1-41

We appreciate the opportunity to review and comment on this official draft report. The Food Safety and Inspection Service (FSIS) reviewed the official draft report and has responded to each of the recommendations.

Responses to Recommendations

Recommendation 1:

Develop a strategy to take progressively stronger enforcement actions against plants with serious or repetitive violations.

FSIS Response:

In order to facilitate developing a strategy to take progressively stronger enforcement actions against plants with serious or repetitive violations, FSIS has implemented the Public Health Information System (PHIS). When inspection program personnel (IPP) perform a verification task, the data from each verified regulation is recorded in PHIS. The data includes the findings (either compliance or non-compliance) for each verified regulation with that task. IPP in-plant are instructed to review this data in order to guide their scheduling of inspection tasks, and the areas of establishments or production they are to focus on. The Agency also analyzes the data, in PHIS, at headquarters to guide its decisions for scheduling “for cause” Comprehensive Food Safety Assessments” (FSA). When data indicates repetitive non-compliance with food safety related regulations, it implements enforcement action in accordance with the Rules of Practice, 9 CFR Part 5000. Additionally, FSIS is developing a strategy for taking progressively stronger enforcement actions against plants with serious or repetitive violations by using regulatory non-compliance to identify establishments that should be prioritized for “for cause” FSAs.

Estimated Completion Date:

FSIS will complete this work and develop a strategy by January 1, 2014.

Recommendation 2:

Develop criteria and procedures to classify all severe food safety NRs.

FSIS Response:

FSIS is developing criteria and procedures to classify all severe food safety NRs, by using the Public Health Information System (PHIS) data. FSIS has determined the regulations that have

significant potential for public health consequences. The PHIS focuses on recording data on each verified regulation when inspection verification tasks are performed by inspection program personnel. FSIS is utilizing a public health-based decision framework that is an integral component of the Agency's data-driven inspection system. The framework will be implemented in the PHIS. The decision criteria framework will be used to prioritize FSIS activities, such as prioritizing Food Safety Assessments (FSAs) in establishments identified by the public health decision criteria. The details of this data driven approach to inspection and enforcement was originally detailed in a paper entitled "Data-Driven Inspection for Processing and Slaughter Establishments *Public Health Decision Criteria*," published September 2010. A revised approach that defined criteria was developed in 2012 and presented to the National Advisory Committee for Meat and Poultry Inspection (NACMPI) in January 2013. Recently, FSIS received the NACMPI comments and they are currently under review by FSIS officials.

Estimated Completion Date:

FSIS will incorporate input from the NACMPI and implement these criteria by January 1, 2014. The criteria will be used to prioritize FSAs at establishments that represent the greatest potential for loss of process control and food safety issues.

Recommendation 3:

Modify existing criteria to standardize when suspensions and Notices of Intended Enforcement should be applied, as well as define the frequency and specify the timeframes when violations would lead to such enforcement actions.

FSIS Response:

FSIS agrees that consistently applying the principles of the Public Health Decision Criteria, which determines how suspensions and Notices of Intended Enforcement should be applied when taking enforcement actions, is in fact necessary. When taking enforcement action, the Agency is guided by the public health criteria as defined in "Data-Driven Inspection for Processing and Slaughter Establishments *Public Health Decision Criteria*," published September 2010, and the regulatory Rules of Practice defined in 9 CFR Part 500.

Estimated Completion Date:

The Agency will develop instructions through a notice or directive for its management and supervisory personnel on the Rules of Practice and decision criteria (see Recommendation #2 Response) to further advance consistent enforcement of the principles by January 31, 2014.

Recommendation 4:

Emphasize to supervisors that action is necessary to address inspector performance issues. Actions should include discussing requirements with inspectors and monitoring their progress more closely in the future.

FSIS Response:

FSIS agrees that supervisors should be continually addressing IPP performance issues by addressing IPP's understanding of policy and ensure consistent requirements are applied. To that end, the Office of Field Operations has been conducting monthly seminars with all its supervisory personnel to address inspection, sampling, and enforcement issues, both to introduce new directives or initiatives as well as reinforce understanding of long standing issues. Supervisors then are expected to discuss policies and procedures with all IPP during work unit meetings. Supervisors manage in-plant employees' performance through the In-Plant

Performance System (IPPS), through which they observe and review each employee's performance to determine where there is a need for improvement. The Agency issued FSIS Directive 4430.3 in June 2002, to be implemented October 2002. It requires supervisors to perform at least 2 IPPS reviews per employee per year. In March of 2011, due to the implementation of PHIS and accompanying training and workload, OFO authorized supervisors to use their discretion on how often to perform IPPS. In February 2012, the Agency modified the mission support element for CSIs to reflect PHIS, and in October 2012 issued revised IPPS guidelines to reflect PHIS. In April 2012 OFO issued a memo to supervisors to follow IPPS policies. FSIS will update its future training to emphasize the importance of following IPPS policies.

The Agency also manages the AskFSIS system which allows field personnel to ask policy or implementation questions and receive timely responses directly from subject matter experts.

Estimated Completion Date:

FSIS issued a reminder memo to supervisors to follow FSIS Directive 4430.3 on April 1, 2013. The AskFSIS system is implemented.

Recommendation 5:

During training for inspectors, emphasize the importance of following agency policy in documenting NRs.

FSIS Response:

The Agency agrees that documenting noncompliance with regulatory requirements is central to its mission. FSIS will update its training to emphasize the importance of following Agency policy in documenting NRs. FSIS will also reinforce this requirement during discussions with field personnel.

Estimated Completion Date:

FSIS will review training content and update, where necessary, to ensure that documenting noncompliance records (NRs) and Memorandum of Interviews (MOIs) are appropriately emphasized and adjust, if needed, by January 31, 2014.

Recommendation 6:

Clarify guidance on when the presence of vermin on the kill floor constitutes a violation.

FSIS Response:

The Agency agrees that vermin, or other pests on a kill floor, processing area, or in any other part of an establishment poses a sanitary hazard, and clearly violates 9 CFR 416.2(a). FSIS will review training content and relevant notices and directives to ensure that all field personnel understand the regulatory requirements of 9 CFR 416(2) and foster uniform application.

Estimated Completion Date:

FSIS will review training content and relevant notices and directives by January 31, 2014.

Recommendation 7:

Determine what measurable improvement the HIMP program achieved and its suitability as a permanent program.

FSIS Response:

FSIS will complete an evaluation of HIMP market hog establishments. The report will include an analysis of HIMP establishments' performance compared to non-HIMP establishments as well as their performance with respect to performance standards established by an independent consulting firm contractor. Such an evaluation may support rule-making to amend regulations to make an inspection system informed by the market hog HIMP pilot permanent.

Estimated Completion Date:

FSIS will complete this evaluation and determine if a permanent program is warranted by March 31, 2014.

Recommendation 8:

Develop criteria to terminate plants from HIMP that have a pattern of severe violations.

FSIS Response:

The same criteria for regulatory compliance are applied to both non-HIMP and HIMP establishments. Establishments that exhibit a pattern of serious regulatory non-compliance may be subject to a Notice of Intended Enforcement Action, a suspension of inspection activities, and even withdrawal of the grant of inspection. FSIS' regulatory authority to take progressively stronger actions in response to violations of the MPIA and PPIA are not different for HIMP establishments. HIMP Market Hog establishments will be included in FSIS's response to Recommendations 1 through 6 and 11.

To terminate the HIMP waivers from an establishment operating under those waivers, FSIS has instructed inspectors to report through supervisory channels when a clear trend of repetitive NRs related to the waivers' alternate procedures or Salmonella Initiative Program (SIP) protocol are found. (FSIS Directive 5020.1 *Verification of the SIP.*) FSIS will review the instructions in the directive and any available data to provide additional instruction to FSIS inspectors as needed.

Estimated Completion Date:

FSIS will review the instructions in the FSIS Directive 5020.1 and any available data to provide additional instruction to FSIS inspectors on terminating waivers of regulations by October 1, 2013. If needed, updated instructions will be issued by January 31, 2014.

Recommendation 9:

Require all HIMP plants to perform visual and manual inspections of viscera.

FSIS Response:

FSIS understands the importance of visual and manual inspections of viscera. Therefore, FSIS will convene a scientific workgroup to review the FSIS Directive 6100.3 Postmortem Livestock Inspection and the Market Hogs HIMP Inspection Draft dated 06/21/05. The internal workgroup will determine the basis for visual and manual inspection of viscera and ensure consistency of policies.

Estimated Completion Date:

FSIS will convene this workgroup by October 31, 2013. As needed, updated policies will be issued by March 31, 2014.

Recommendation 10:

Establish formal agreements that address all aspects of HIMP with participating plants.

FSIS Response:

Establishments volunteering for the HIMP agreed to follow information required by a Federal Register notice (62 FR 31553, June 10, 1997) which documented the pilot as a waiver of regulations for all establishments participating in the pilot. In a Federal Register notice (76 FR 41186, July 13, 2011) FSIS required all establishments operating under a waiver of regulations, including the HIMP Market Hog establishments to participate in the Salmonella Initiative Program (SIP). Establishments requesting to operate under waivers submit a signed letter to FSIS saying they agree to follow the SIP Letter and SIP Protocol. After evaluation of the submission, FSIS issues a SIP Letter to the establishment documenting the conditions for the establishment to meet to operate under the waiver. The alternative procedures are those procedures an establishment uses in place of certain provisions of the regulations waived by FSIS. To grant the waiver, FSIS requires establishments to meet certain relevant alternative procedures. The SIP Protocol is a document written and signed by the establishment that includes: 1. Identification of the provisions of the regulations that are to be waived; 2. Alternative procedures that are to be used in place of any waived provisions of the regulations; 3. Description of the microbiological sampling and testing procedures that the establishment will implement; 4. Agreement to share microbiological and other data with FSIS and, 5. Any other pertinent information.

Estimated Completion Date:

All HIMP establishments have submitted a written, signed letter requesting to participate in SIP and agreeing to abide by the SIP Letter and SIP Protocol. FSIS has issued a SIP Letter, to each participating HIMP market hog establishment to spell out the specific alternative procedures and SIP Protocol that the establishment must meet in order to operate under the waiver(s). The response to this recommendation is complete.

Recommendation 11:

Provide a plan describing how FSIS will minimize reliance on the inspectors' judgment to ensure they consistently enforce HMSA and related regulations.

FSIS Response:

FSIS plans to minimize reliance on the inspectors' judgment to ensure they consistently enforce HMSA and related regulations, by implementing the numbered actions below:

1. Since an Inspector's subjective judgment during an inhumane handling event can determine the enforcement outcome, the agency implemented required supplemental training after the release of Directive 6900.2 Revision 2, Humane Handling and Slaughter of Livestock, to improve objective observation and assessment skills. The Situation Based Humane Handling training Module I and Module II teach Inspectors how to interpret an egregious or non-egregious inhumane handling event objectively, and take appropriate enforcement actions. The Situation-based Humane Handling training modules were well received by Inspectors and industry, and contain fictional scenarios of inhumane and egregious events that describe in detail how the Inspector is to proceed with regulatory enforcement.

New situation-based fictional scenarios meant to provide continued education for Inspectors are under development, and will be posted through the Humane Interactive Knowledge Exchange (HIKE) on the FSIS website. The HIKE scenarios consist of a detailed description of an inhumane event, the enforcement development of regulatory noncompliance, and a review of applicable FSIS regulations. New scenarios will be posted on the FSIS HIKE website in 2013, the first of which will be released in the second quarter of CY 2013. Inspectors will be notified of new scenarios, and will be encouraged to review and discuss the documents with fellow colleagues.

2. FSIS plans to hire a new Humane Handling Enforcement Coordinator. With the installation of the new Humane Handling Enforcement Coordinator, the noncompliance review frequency will increase to monthly, and include direct commentary to the body of each noncompliance that the District Veterinary Medical Specialists (DVMS) will share with the inspectors. This specific correlation will improve the inspector's objective analysis when enforcing HMSA and related regulations, and reduce subjective interpretation of inhumane events and their regulatory outcome. In addition, the Humane Handling enforcement coordinator will develop a database to track the review of noncompliance records; as well as review and track suspensions and NOIEs in a similar database.

The Humane Handling Enforcement Coordinator will review humane handling noncompliances monthly, and forward to the humane handling specialists (DVM) in each district a summary of the number of noncompliance records that sound egregious and should have received a Regulatory Control Action, suspension or a NOIE. The review will also include instances of how many noncompliance records were poorly written, or cited the wrong regulation for the noncompliant event.

Estimated Completion Date:

FSIS intends to issue the first scenario by May 30, 2013 and the remaining scenarios will be released by December 31, 2013.

FSIS will establish a new Humane Handling Enforcement Coordinator; increase review frequency of noncompliances, suspensions, and NOIEs; and develop a database tracking these reviews by August 31, 2013.

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