USDA

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Office of Inspector General

Food Safety and Inspection Service In-Commerce Surveillance Program

Audit Report 24601-8-At
September 2011

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

DATE: September 30, 2011

AUDIT NUMBER: 24601-8-At

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

ATTN: William C. Smith
Assistant Administrator
Office of Program Evaluation, Enforcement, and Review

FROM: Gil H. Harden /S/
Assistant Inspector General
for Audit

SUBJECT: Food Safety and Inspection Service In-Commerce Surveillance Program

This report presents the results of the subject audit. Your response to the official draft report, dated September 15, 2011, is included in its entirety at the end of the report. Excerpts of your response and the Office of Inspector General's position are incorporated into the Finding and Recommendation section of the report.

Based on your response, we have reached management decision on the report's two recommendations. Please follow your internal agency procedures in forwarding final action correspondence to the Office of the Chief Financial Officer. Also please note that Departmental Regulation 1720-1, requires final action to be taken within 1 year of the date of management decision to prevent being listed in the Department's annual Performance and Accountability Report.

We appreciate the courtesies and cooperation extended to us by members of your staff during our audit fieldwork and subsequent discussions.

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Food Safety and Inspection Service In-Commerce Surveillance Program

Executive Summary

As part of the Office of Inspector General's goal to strengthen the Department of Agriculture's ability to implement safety measures to protect public health, we examined the effectiveness of the Food Safety and Inspection Service's (FSIS) In-Commerce Surveillance Program. FSIS assesses approximately 145,000 businesses engaged in the interstate transport, storage, distribution, and sale of meat, poultry, and egg products and conducts approximately 7,000 unannounced reviews per year. It is responsible for assuring the American public that the nation's commercial supplies of these foods are safe, wholesome, and correctly labeled and packaged. To protect public health, FSIS investigators examine products, facilities, and records at these firms for the purpose of detecting food safety violations such as unsanitary conditions that can cause food-borne illness and preventing food safety violations through proactive monitoring of compliance with regulations. FSIS' Office of Program Evaluation, Enforcement and Review estimates it can devote only about 10 percent of its personnel resources to conducting these preventative reviews due to the various other demands put on FSIS to respond to threats to food safety such as *E.coli* outbreaks, product adulteration or misbranding violations, or terrorist threats to the food supply. It is therefore critical to maximize the effectiveness and efficiency of this proactive tool for safeguarding public health.

We found that FSIS conducts surveillance reviews and pursues followup appropriately; however, FSIS can improve its methodology for selecting firms for surveillance review. Although FSIS policy requires investigators to prioritize surveillance based on the risk that the firm could pose if there were a problem, the agency has not established a selection criterion that makes risk a primary consideration when it targets firms for review. FSIS officials explained that they prioritize surveillance based on risk in accordance with their in-commerce surveillance directive and also consider clusters of the most critical firms in a geographical area.[1] However, we found that in practice, surveillance reviews are being decided primarily based on proximity and convenience to the investigator. In addition, we found that the In-Commerce System (ICS), the web-based application that stores FSIS' program data, had a significant number of duplicate or inactive firms listed, which impacts the agency's ability to efficiently search for or select firms for review. FSIS' approach to targeting firms for in-commerce surveillance had included reviews of only 18 percent of the firms with the most potential impact on public health, as of February 2010. As of August 2011, FSIS indicated significant progress by completing reviews of 68 percent of firms with the most potential impact on public health.

Recommendation Summary

We recommend that FSIS develop and implement a selection methodology for in-commerce surveillance reviews that prioritizes risk considerations among and within risk tiers. We also recommend that FSIS enhance and implement a better search capability in ICS or develop

[1] FSIS Directive 8010.1, Revision 2 – "Methodology for Conducting In-Commerce Surveillance Activities."

additional guidance for investigators on how to identify irregular records and to eliminate duplicate entries in ICS.

Agency Response

In general, FSIS agreed with the report's two recommendations. However, FSIS disagreed with our statement that in practice, surveillance reviews are being decided primarily based on proximity and convenience to the investigator. FSIS stated that proximity and convenience are not inconsistent with public health priorities, and are only one of several factors investigators use in determining which businesses to visit for surveillance activities. In addition, FSIS states that the percentage of tier 1 businesses covered by the Compliance and Investigations Division (CID) surveillance as of August 2011 is now even higher at 68 percent. In other words, CID was able to conduct surveillance activities in 50 percent of all tier 1 firms in 18 months, increasing from 18 percent in February 2010 to 68 percent in August 2011.

FSIS' September 15, 2011, response is included in its entirety at the end of the report.

OIG Position

During our review, we visited two FSIS regional offices and five field offices and we interviewed and accompanied investigators on surveillance reviews. We found that decisions about how to weight various factors when targeting firms for an in-commerce surveillance review are delegated to local supervisors and, in practice, are being primarily decided based on proximity and convenience to the investigator. As a result, investigators were performing the majority of reviews at non-critical firms, at some firms repeatedly, and at others not at all.

FSIS agreed to issue a notice to advise CID Investigators, Supervisory Investigators, and Regional Directors of the changes to the ICS business tier structure and to update instructions for prioritizing surveillance activities. The new notice will explicitly prioritize tier 1 and tier 2 businesses that have never been surveilled, over tier 1 and tier 2 businesses, respectively, that have been visited recently. We agree that FSIS actions will remedy our concerns regarding targeting firms for an in-commerce surveillance review.

Based on FSIS' responses, we have reach management decision on each of the report's two recommendations.

Background & Objectives

Background

Under the Federal Meat Inspection Act,[2] the Poultry Products Inspection Act,[3] and the Egg Products Inspection Act,[4] the Food Safety and Inspection Service (FSIS) inspects all meat, poultry, and egg products sold in interstate commerce to ensure they are safe, unadulterated, and properly labeled. Within FSIS, surveillance of commercial firms engaged in the transport, storage, distribution, and sale of meat, poultry, and egg products is the responsibility of the Office of Program Evaluation, Enforcement and Review (OPEER), Compliance and Investigations Division (CID). CID investigators perform in-commerce surveillance activities in areas such as food safety, food defense, non-food safety consumer protection, order verification, imported products, public health response, and emergency response. CID manages and directs investigations, case development, and documentation of violations. If an investigator observes an apparent violation during the course of a surveillance review, the investigator will detain the suspected food products and prepare a referral to OPEER's Evaluation and Enforcement Division. If an investigator identifies a concern not rising to the level of a violation, followup reviews may be scheduled within a period of 3, 6, or 12 months. FSIS conducts approximately 7,000 in-commerce surveillance reviews per year.

FSIS last updated its directive regarding the methodology for conducting in-commerce surveillance activities in 2008.[5] That year, FSIS also proposed a new method for categorizing firms in terms of the potential risk they pose to public health by which firms would be designated critical (tier 1), very important (tier 2), and important (tier 3). FSIS commissioned the National Academy of Sciences (NAS), Division on Earth and Life Studies, to review this newly proposed risk-based method. In 2009 FSIS received the NAS report, which commended the method overall and also made recommendations to improve FSIS' oversight activities.[6] FSIS is acting on NAS' recommendations by revising the allocation of various types of firms within tiers by, for instance, redesignating retail firms from tier 2 to tier 3.[7] FSIS will implement this change in September 2011. The current directive states that investigators are to take the firm's potential risk to public health into account, along with several other factors such as travel time and distance, proximity of the firm to other investigator activities, and followup schedule, as they conduct in-commerce surveillance activities.

Data (i.e., firm location, owners, products handled, surveillance history, etc.,) pertaining to FSIS' in-commerce surveillance activities are stored in the web-based system, In-Commerce System (ICS). ICS data can be incorporated with the public health data infrastructure for analysis with other FSIS data. There are roughly 145,000 firms listed in this system. Nearly 3,000 of these firms were entered manually as new firms since ICS became operational in June 2008. The rest

[2] Title 21, United States Code (U.S.C.), chapter 12.
[3] Title 21, U.S.C., chapter 10.
[4] Title 21, U.S.C., chapter 15.
[5] FSIS Directive 8010.1, Revision 2 – "Methodology for Conducting In-Commerce Surveillance Activities."
[6] "The National Academy of Sciences, Division on Earth and Life Studies' Committee for the Review of the Methodology Proposed by the FSIS for Risk-Based Regulation of In-Commerce Activities," March 13, 2009.
[7] Tier 1 firms remained unchanged.

of the firms are a byproduct of the data purchased from a vendor on the basis of the Standard Industrial Classification Codes of the U.S. Department of Labor. ICS classifies firms into the risk tiers, records surveillance review findings, tracks previously-reviewed firms, provides firm and compliance histories, and assists investigators in monitoring and initiating followup surveillance reviews.

Objectives

The objective of this audit was to determine whether FSIS' policies, procedures, and controls are adequate to provide an effective in-commerce surveillance program for overseeing persons, firms, or corporations for the purpose of detecting and preventing food safety violations and ensuring compliance with the provisions of the meat, poultry, and egg inspection acts and regulations.

Section 1: FSIS Needs to Prioritize Its Surveillance Activities

Finding 1: FSIS Lacks an Effective Method for Prioritizing Surveillance Activities in Relation to Public Health

Although FSIS' policy requires prioritizing firms in order of public health importance, we found that OPEER CID is not, in practice, making public health importance a primary consideration when it selects which firms to target for unannounced reviews. FSIS has not established selection criteria for prioritizing investigator surveillance reviews based on risk. In addition, we found that ICS, FSIS' web-based application that stores program data, had a significant number of duplicate or inactive firms listed, which impacts the agency's ability to efficiently select firms for review. FSIS officials explained that they prioritize surveillance based on risk in accordance with their directive and also consider clusters of the most critical firms in a geographical area; however, we found that decisions about how to weight various factors when targeting firms for an in-commerce surveillance review are delegated to local supervisors and, in practice, are being primarily decided based on proximity and convenience to the investigator. As a result, investigators were performing the majority of reviews at non-critical firms, at some firms repeatedly, and at others not at all. As of February 2010, CID investigators did not perform surveillance reviews at 82 percent of the firms identified as having the most potential impact on the public health. As of August 2011, FSIS officials indicated that 32 percent of these firms were not reviewed.

When selecting from among the approximately 145,000 firms for surveillance activities, FSIS Directive 8010.1 requires investigators to plan activities in a manner that allows for effective use of agency personnel and resources, to prioritize and conduct surveillance activities in order of public health importance, and to take into account a method that categorizes firms in terms of risk. FSIS officials explained that they prioritize surveillance based on risk, in accordance with Directive 8010.1, and added that a cluster of the most critical firms in a geographical area is also a consideration.

FSIS developed a risk-based tier structure that stratifies firms in terms of risk to public health by designating firms as critical (tier 1), very important (tier 2), and important (tier 3), but CID personnel pursue review selection without giving adequate weight to the tier structure. [8] Under the current method for selecting firms for review, CID investigators base their decisions on site selection primarily according to convenience and proximity to the investigator and also, in some firms under review; therefore, CID investigators should rely more heavily on FSIS' planned revisions to the risk-based tier structure in its review selection methodology in order to prioritize visiting the approximately 20,000 critical and very important firms with a very high need for surveillance.

From October 2008 to February 2010, CID investigators conducted 7,758 surveillance reviews of the approximately 145,000 firms listed in ICS. We observed that the distribution of reviews across risk tiers was disproportionate to the risks posed by these firms; the majority of

[8] FSIS' tier risk-analysis structure identifies and categorizes firms according to the magnitude of potential impact that a violation at a given firm would have on public health, and according to whether the firm is inspected by other jurisdictions (i.e., State authorities).

surveillance reviews were not performed at firms in the most critical risk tier. Planned revisions to the tier structure will address this gap, largely because retail firms, the most common type of firm under FSIS jurisdiction, will be re-categorized from tier 2 to tier 3, the lowest risk category in September 2011. While there is reason for investigators to continue to conduct surveillance reviews at retail firms because FSIS reports *E.coli* review figures to Congress, the current review selection process is not adequate to ensure that the most critical firms will be selected for review.

Not only does CID not prioritize targeting critical firms for review, it does not prioritize effectively within tiers. We concluded that CID investigators should prioritize the targeting of firms with no prior surveillance, which would result in FSIS establishing surveillance histories with firms that have the potential to pose the greatest risk to public health (tiers 1 and 2). An independent NAS report commissioned by FSIS also recommends that CID investigators target firms with no prior surveillance history. Under the current method for weighting selection factors, FSIS investigators rarely conduct surveillance reviews at firms which have never been visited.[9] As of February 2010, only 18 percent of firms categorized as critical (tier 1) had been reviewed.[10] However, critical firms with surveillance histories had often been reviewed repeatedly; that is, 65 percent (or 2,144) of the reviews conducted at tier 1 firms were performed at firms that had already been reviewed.[11]

Critical firms were reviewed repeatedly because investigators were, until August 2010, operating under an old principle of visiting tier 1 firms annually, regardless of previous violation history. In order to reduce inefficiencies, FSIS revised its policy to encourage performing followup reviews only on firms found in violation of regulations. While we agree followup reviews need to be conducted at all firms with violations, this shift in priorities should not result in firms found in compliance once never being visited again. This shift will allow FSIS to focus on firms with no prior surveillance history whenever possible, particularly for tier 1 firms with subsequent visits as necessary.

Prioritizing tier 1 firms with no prior surveillance would result in FSIS establishing surveillance histories with the critical and very important firms that have the potential to pose the greatest risk to the public health. We estimated that implementing a methodology that prioritizes reviewing tier 1 firms would result in the review of every critical firm in a 3 to 5 year review cycle. That is, if investigators continue to perform surveillance reviews at a rate of approximately 7,000 reviews per year, it is reasonable to anticipate that the approximately 20,000 tier 1 and tier 2 firms identified under the new tier method can be reviewed every 3 to 5 years.

FSIS officials agreed it is reasonable to complete 20,000 reviews of these tier 1 and 2 firms in a 3 to 5 year review cycle. However, followup reviews may be required when violations are found at these firms and this could occur for at least 15 percent of all reviews conducted. Therefore, it would take closer to five years to complete these 20,000 reviews.

This calculation, it should be noted, assumes figures generated by ICS are reliable. ICS is a web-based application used as the sole repository for data related to in-commerce surveillance.

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[9] See footnote 6.
[10] 3,306 of the total 17,796 tier 1 firms.
[11] As of June 8, 2011, FSIS reported progress noting that repeat reviews of tier 1 firms decreased to 60 percent (or 9,479).

During our audit, we determined that a significant number of duplicate, inactive, and/or non-existent firm records negatively impact the quality and reliability of ICS data.[12] Improving the utility of ICS becomes a greater concern under a selection method that makes risk a primary consideration. A more effective in-commerce site selection methodology would rely more heavily on information drawn from ICS, making enhancements such as a more flexible search function and the ability to sort firms according to their surveillance history more important. Further, reliance upon compromised data could lead to misprioritization among firms for review, performance of redundant reviews, or other inefficiencies. Ensuring that ICS contains reliable data will increase the efficiency of a review selection methodology based on risk analysis.

FSIS officials have agreed that a better search function is a necessary enhancement for ICS, but noted that, due to the expense of such an enhancement, other priorities will be addressed first. If this enhancement proves to be too costly, FSIS should develop additional guidance for its investigators on how to identify irregular records and to eliminate duplicate entries in ICS.

Recommendation 1

Develop and implement a selection methodology for in-commerce surveillance reviews that prioritizes risk considerations among and within risk tiers.

Agency Response

In its September 15, 2011, response, FSIS stated:

> "…FSIS will issue a Notice to advise CID Investigators, Supervisory Investigators, and Regional Directors of the changes to the ICS business tier structure … and to update instructions for prioritizing surveillance activities. The new Notice will explicitly prioritize Tier 1 and Tier 2 businesses that have never been surveilled, over Tier 1 and Tier 2 businesses, respectively, that have been visited recently. FSIS will revise its methodology for conducting surveillance activities and selecting businesses for in-commerce activities in a revised Surveillance Methodology Directive.
>
> Estimated Completion Dates: Enhancements made to ICS, September 12, 2011, FSIS Notice on revised tier structure and prioritization instructions, October 2011, Revised Surveillance Methodology Directive, February 2012."

OIG Position

We accept management decision for this recommendation.

[12] Our fieldwork identified that 45 percent (87 of 194) of the firms in our overall sample either did not exist; did not handle any meat, poultry, or egg products; or were duplicates (firms with more than one firm ID) and thus had to be notated as inactive or deleted from the system.

Recommendation 2

Enhance and implement a better search capability in ICS or develop additional guidance for investigators on how to identify irregular records and to eliminate duplicate entries in ICS. We also recommend that FSIS formalize its guidance for documenting firms that need to be deleted from ICS or marked as inactive.

Agency Response

In its September 15, 2011, response, FSIS stated:

> "…FSIS will issue a Directive to provide ICS users with additional guidance on firm information, preventing duplicate firms, and for identifying and flagging duplicates for removal from the system. The Directive will also include instructions for inactive firms, closed firms, and firms that do not handle amenable products.
>
> FSIS will also develop an SOP [Standard Operating Procedure] for periodically identifying duplicate entries and removing them from the system. …
>
> Estimated Completion Dates: ICS System Directive, February 2012; SOP for deleting duplicates, December 2011."

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We assessed FSIS' in-commerce surveillance activities for fiscal years (FY) 2009 and 2010 and conducted fieldwork from March 2010 through March 2011. We conducted fieldwork at the FSIS national office located in Washington, D.C.; regional offices located in Atlanta, Georgia and Philadelphia, Pennsylvania; and CID field offices in Atlanta, Georgia; Beltsville, Maryland; Sunrise, Florida; Jamaica, New York; and Philadelphia, Pennsylvania. Regional offices were judgmentally selected based on the number of firms in each region and the number of surveillance reviews performed, surveillance reviews requiring a followup, and violations within the region. The five CID field offices were judgmentally selected based on the number of open and closed investigations for each office.

To observe investigators conducting surveillance activities, we accompanied investigators in the field, visiting a total of 194 firms. Of these firms, 141 were judgmentally selected based on their location, identified level of potential risk to public health, prior surveillance history and position on surveillance schedule, or indications of duplicate entries in ICS; 44 appeared to be duplicates; and 9 firms were judgmentally selected while in the field.[13] Investigators performed a total of 89 surveillance reviews at the 194 firms visited.[14] During these surveillance reviews, we observed whether investigators completed the appropriate food safety, food defense, non-food safety consumer protection, order verification, and imported products activities.

In order to evaluate the status, handling, and disposition of investigations that result from in-commerce surveillance reviews, we reviewed all 30 open investigations at the 5 field offices and a sample of 62 (25 percent) of the closed investigations from January 2008 through May 2010, judgmentally selecting closed cases based on start date, primary case type, investigator, and repeat violators. We also reviewed all 23 cases referred for administrative, civil, or criminal prosecution by the field offices we visited in order to determine whether they were properly prepared and submitted to the appropriate authorities.

To test the procedures for processing, handling, tracking, and disposing of consumer complaints, we reviewed all seven complaints handled by OPEER during FYs 2009 and 2010.

In order to gain an understanding of the relationship of ICS to the audit objectives, we evaluated the general controls over the system and physically observed FSIS officials at all agency levels using the system. In addition, because FSIS uses ICS to track and monitor all of its surveillance activities, we performed limited testing on the accuracy of the information in the system relevant only to the surveillance activities performed at the firms selected for the offices visited. We did not verify the completeness of data in ICS.

To accomplish our audit objectives, we:

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[13] The audit team considered duplicates to be either a firm with more than one firm identification number, a firm with similar names at the same address, or more than one firm listed at the same address. FSIS defines duplicates based on firm name.

[14] The difference between the number of firms visited and the number of surveillance reviews performed is that some firms were duplicates that the investigator later consolidated under one firm identification number; some firms were Federal plants under the jurisdiction of FSIS field operations; some firms did not exist; and some firms did not handle any meat/poultry/egg products.

- reviewed pertinent documents, laws, and regulations including the Memorandum of Agreement between FSIS and OIG; FSIS policies and guidance; external reports and program studies including Government Accountability Office reports, and the National Academy of Sciences reviews; Government Performance and Results Act documentation; strategic plan and performance accountability reports, and a previous OIG audit report of FSIS' compliance review program;[15]
- interviewed officials from CID and the Evaluation and Enforcement Division of OPEER; FSIS' Office of Field Operations; Office of Public Health Science; Office of Data Integration and Food Protection; and Office of the General Counsel;
- reviewed FSIS' internal review of CID's management control activities as related to in-commerce surveillance activities;
- identified ICS and the Consumer Complaint Monitoring System[16] as databases used for accountability and accomplishment reporting of in-commerce surveillance activities and consumer complaints, respectively;[17]
- observed investigators conduct surveillance reviews and photographed violations; and
- determined whether subsequent actions taken by investigators were appropriate based on the issues disclosed during the surveillance activities.

We conducted this audit in accordance with generally accepted government auditing standards. Those standards require that we plan and perform our audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe the evidence we obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

[15] "FSIS District Enforcement Operations Compliance Activities," Audit Report 24601-4-At, June 2000.
[16] The Consumer Complaint Monitoring System is an electronic database used by FSIS to record, triage, analyze, and track all consumer complaints reported to FSIS. It also serves as an integral part of the FSIS bio-defense strategy.
[17] We found no problems with the handling or tracking of consumer complaints.

Abbreviations

CID.....Compliance and Investigations Division

FSIS.....Food and Safety Service

FY .....Fiscal Year

ICS .....In-Commerce System

NAS.....National Academy of Sciences

PEER.....Office of Program Evaluation, Enforcement and Review

USC.....United States Code

USDA'S

FOOD SAFETY AND INSPECTION SERVICE

RESPONSE TO AUDIT REPORT

United States Department of Agriculture
Food Safety and Inspection Service
Washington, D.C. 20250

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

FROM: Alfred V. Almanza /s/ September 15, 2011
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service (FSIS) In-Commerce Surveillance Program (Audit 24601-8-At)

We appreciate the opportunity to review and comment on this official draft report. In general, FSIS agrees with the two recommendations in the report. However, while OIG has identified several features of the in-commerce surveillance program that could be improved, we disagree with several of the statements in the Report's Summary, Background and Finding sections.

Summary Section

Language in the Summary section of the official draft states that although FSIS' policy requires prioritizing firms for surveillance in order of public health importance, in practice, Office of Program Evaluation, Enforcement and Review (OPEER) Compliance and Investigation Division (CID) investigators are not making public health importance a primary consideration when they select firms to target for surveillance activities. FSIS prioritizes initial surveillance in relation to risk to public health, and has already implemented a surveillance program that directs more resources at higher-risk businesses. This was accomplished by constructing a tier structure based on risk and then setting performance targets for each tier. Each of the business types was ranked along five public health risk dimensions (Inherent Hazard, Food Defense, Volume, Consumer Susceptibility, and Surveillance by Other Authorities).

Next, three tiers were constructed using the results of the risk rankings and were programmed into the In-Commerce System (ICS). The risk rankings used to construct the tier structure were based on input from agency officials and the National Academies of Sciences (NAS), and reflect considerable food safety and public health expertise. CID investigators take advantage of this expertise and the tier structure to help them make daily decisions and prioritize their work.

Not only does the Tier structure drive surveillance but also provides CID investigators with guidance for response and recovery activities in natural disaster events such as Hurricane damage verification. CID Investigators use the ICS Tier 1 list of distributors, transporters, and

warehouses to determine the status of the firms' operations, vulnerabilities, and potential impacts from the event. During emergency response, investigators consider damage by sustained rains and possible flooding that could affect the distribution of products to critical facilities like hospitals, nursing homes and schools. Investigators also consider products with higher risk (refrigerated verses frozen) and product volume.

In 2008, FSIS established performance targets in its in-commerce management control system for the percentage of Tier 1 (50%), Tier 2 (30%) and Tier 3 (20%) surveillances conducted so that coverage is appropriately distributed among business types based on public health and so that more resources are directed at the highest risk firms. FSIS uses the ICS to monitor progress toward management control performance targets, and investigators, as a group and individually, are measured on their progress toward meeting these targets. Investigators also conduct in-commerce sampling programs such as the one designed for *E. coli* O157:H7 in raw ground beef, and are measured on their progress collecting samples.

The Summary section of the draft also states that CID Investigators are selecting businesses for surveillance activities primarily based on proximity and convenience to the investigator. FSIS' policy, as outlined in FSIS Directive 8010.1, notes that Investigators are to 1) plan activities in a manner that allows for efficient and effective use of resources, 2) prioritize and conduct surveillance activities in order of public health importance, 3) take into account public health tiers and other information for firms in the ICS and 4) take into account other factors such as travel time and distances, proximity, time required, date of last surveillance, and previous findings. We would like to emphasize that proximity and convenience are consistent with public health priorities. For example, if an investigator could perform surveillance activities in three nearby Tier 1 businesses that have never been surveilled in the amount of time it takes to perform first time surveillance at a single Tier 1 business that is much farther away, the investigator would likely conduct the three surveillance activities and would be maximizing the expected public health benefits by doing so. In addition, proximity and/or convenience are only one of several factors Investigators use in determining which businesses to visit for surveillance activities.

The Summary section of the draft also states that FSIS officials have conducted surveillances in only 18 percent of all Tier 1 businesses as of February 2010, and that FSIS had made significant progress by completing surveillances in 41% of all Tier 1 firms by June 2011. The percentage of Tier 1 businesses covered by CID surveillance as of August 2011 is now even higher at 68%. In other words, CID was able to conduct surveillance activities in 50% of all Tier 1 firms in 18 months, increasing from 18% in February 2010 to 68% in August 2011. CID accomplished this by reiterating an earlier change in policy that repeat annual surveillances are no longer required for Tier 1 firms, and by providing lists to CID investigators of all Tier 1 firms that had no surveillance record in ICS. This focused CID on those firms with no prior surveillance history. In addition, in the last 18 months, OPEER has worked to identify and remove Tier 1, 2 and 3 firms from ICS that do not handle meat, poultry or egg products. Removing these firms from ICS continues to be an ongoing process for OPEER.

Background Section

The Background section of the draft states that FSIS last updated its in-commerce surveillance directive in 2008 and states "that year, FSIS also proposed a new method for categorizing firms in terms of the potential risk they pose to public health…." FSIS would like to emphasize that when the new methodology outlined in the 2008 Directive was implemented, it was contemporaneous with the launch of the ICS and the risk tier system was programmed in the system at inception.

Finding 1

Finding 1 of the official draft includes statements that CID investigators are not making public health importance a primary consideration when they select firms to target for surveillance activities, and that CID Investigators are selecting businesses for surveillance activities primarily based on proximity and convenience to the investigator. As noted above FSIS prioritizes initial surveillance in relation to risk to public health, and has already designed and implemented a surveillance program that automatically directs more resources at those businesses with the highest risk. In addition, proximity and convenience are not inconsistent with public health priorities, and are only one of several factors Investigators use in determining which businesses to visit for surveillance activities.

Recommendation 1:
Develop and implement a selection methodology for in-commerce surveillance reviews that prioritizes risk considerations among and within risk tiers.

FSIS Response:
To address the main recommendation of the National Academy of Sciences that "*FSIS CID should consider absence of surveillance by other jurisdictions to be more important in setting priorities for surveillance than the other risk considerations*" FSIS implemented an ICS enhancement on September 12, 2011, that reassigned several business types to different risk tiers based on jurisdiction (e.g. re-designating Retailers from Tier 2 to Tier 3). This enhancement allows CID to focus its resources on those businesses with little oversight by other public health authorities. NAS also recommended that "*FSIS create a single category of high-risk business types and areas where it has sole jurisdiction and that most (potentially 90%) of available resources be devoted to surveillance of such facilities."* To implement this recommendation, the September 12th ICS enhancement also raises the Tier 1 performance measure target from 50% to 85%.

FSIS will issue a Notice to advise CID Investigators, Supervisory Investigators, and Regional Directors of the changes to the ICS business tier structure (outlined above) and to update instructions for prioritizing surveillance activities. The new Notice will explicitly prioritize Tier 1 and Tier 2 businesses that have never been surveilled, over Tier 1 and Tier 2 businesses, respectively, that have been visited recently. FSIS will revise its methodology for conducting surveillance activities and selecting businesses for in-commerce activities in a revised Surveillance Methodology Directive.

Estimated Completion Dates: Enhancements made to ICS, September 12, 2011, FSIS Notice on revised tier structure and prioritization instructions, October 2011, Revised Surveillance Methodology Directive, February 2012.

Recommendation 2:
Enhance and implement a better search capability in ICS or develop additional guidance for investigators on how to identify irregular records and to eliminate duplicate entries in ICS. We also recommend that FSIS formalize its guidance for documenting firms that need to be deleted from ICS or marked as inactive.

FSIS Response:
While it is true that ICS users sometimes inadvertently create duplicate firm entries, this phenomenon was noted almost two years ago and Notice 77-09 was issued in November 2009 to provide guidance to the field on how to prevent duplicates entry and to explain the procedure for removing duplicates from the system. At least twice annually, the system is searched and duplicates are purged from the system. An ICS enhancement fielded in April 2011 also added a "check box" that permits field personnel to request and mark firm records for deletion that they have determined to be duplicate firms or should be deleted for other reasons.

FSIS will issue a Directive to provide ICS users with additional guidance on firm information, preventing duplicate firms, and for identifying and flagging duplicates for removal from the system. The Directive will also include instructions for inactive firms, closed firms, and firms that do not handle amenable products.

FSIS will also develop an SOP for periodically identifying duplicate entries and removing them from the system.

Estimated Completion Date: ICS System Directive, February 2012; SOP for deleting duplicates, December 2011.