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Food Emergency Response Network

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

ATTN: William C. Smith
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FROM: Gil H. Harden */S/*
Assistant Inspector General
for Audit

SUBJECT: Food Emergency Response Network

This report presents the results of the subject review. Your written response to the official draft is included at the end of this report. Excerpts of your March 2, 2011, response and the Office of Inspector General's position are incorporated into the applicable sections of the report.

Based on your response, we have reached management decision on all of the report's 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 completed within 1 year of the date of management decision to preclude 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 Emergency Response Network

Executive Summary

Homeland Security Presidential Directive 9 (HSPD-9), issued January 2004, established a national policy to defend the food supply against terrorist attacks, major disasters, and other emergencies. Among other things, the directive required the development of a nationwide laboratory network for food that integrates existing Federal and State laboratory resources, is interconnected, and utilizes standardized diagnostic protocols and procedures. The Food Emergency Response Network (FERN) was developed to integrate the nation's food testing laboratories at the local, State, and Federal levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food. FERN is coordinated by both the Department of Agriculture's Food Safety and Inspection Service (FSIS) and the U.S. Department of Health and Human Services' Food and Drug Administration (FDA).[1] The Office of Inspector General (OIG) initiated this audit to evaluate the implementation of FERN and determine what progress FSIS has made in meeting the network's objectives, which are to (1) prevent attacks on the food supply by providing an early means of detecting threat agents; (2) prepare member laboratories (Federal, State, local, and tribal) to respond to food-related emergencies; (3) provide and coordinate regional and national surge capacity for laboratories; and (4) assist in recovery efforts to restore confidence in the food supply following a threat or actual emergency.

We found that although FSIS has made progress in providing training and equipment and establishing standardized diagnostic protocols, the agency has not fully implemented FERN, and needs to take steps to formalize the program, ensure that the program's laboratory capacity is sufficient to respond to emergency surges, and improve FERN's readiness to prevent threats to the food supply through targeted food surveillance.

FSIS established the FERN Division in February 2005, but FSIS and FDA have not reached a formal agreement on how the network will operate. FSIS and FDA initially drafted a network charter and subsequently a memorandum of understanding (MOU), but these documents were never formalized through signatures from officials at both agencies, and are now outdated and in need of revision to reflect the current organization of the network. Attempts to formalize the MOU and update the charter have failed because the two agencies were unable to reach agreement on the contents of these documents. Without a formal charter and a formalized MOU between FSIS and FDA, FERN lacks some of the elements an effective interagency emergency network would need to succeed, such as standard operating procedures for the network's critical functions, sufficient staffing, and a clear strategic direction for the network as a whole.

We also found that FSIS needs to better prepare for emergencies that could greatly increase the number of samples its laboratories must test—known as the network's laboratory capacity. The agency lacks formalized procedures for activating all of FERN's resources as the size, severity,

[1] Our review was limited to FSIS' participation in FERN. However, we interviewed the FERN director for FDA to obtain that agency's perspective on FERN.

and geographic scope of an emergency increases. While FSIS has a reasonable idea of the capability and capacity of its Cooperative Agreement Program[2] (CAP) laboratories, it does not have verified information concerning the 95 non-CAP laboratories that it considers part of its network.[3] FSIS management has generally felt that the more laboratories it has available the better, and so it has expanded the number of non-CAP laboratories without devoting resources to verify their capability and capacity.

OIG maintains that relying on unverified capabilities may weaken FERN's effectiveness if laboratories are listed as being able to contribute in ways that they actually cannot—as we found in all three of the laboratories we visited. An FSIS official stated that FERN lacks the resources to verify information for all of these laboratories, but that non-CAP laboratories may volunteer to participate in proficiency tests.[4] However, FERN does not require laboratories not receiving funding from FERN to participate in tests that evaluate their capabilities because some non-CAP laboratories may not have the capability and expertise to participate in all proficiency tests offered by FERN. FSIS agreed that less reliance should be placed on those non-CAP laboratories for which FERN does not have verified capability and capacity information that can be obtained via site visits or evaluation through proficiency testing. OIG maintains that, because FERN has not fully evaluated the capabilities and capacities of non-CAP laboratories, there is little assurance that these laboratories will be able to assume testing responsibilities as needed.

In responding to HSPD-9 and creating the FERN Division, FSIS recognized the need for a surveillance program with capabilities to test for the presence of various chemical, biological, and radiological agents that may be intentionally added to the food supply. Although FSIS and FDA established FERN with an emphasis on targeted surveillance of the food supply, OIG found that FSIS has not established a program for conducting such surveillance. Instead, FERN has relied on occasional targeted surveillance projects, mostly driven by FDA during the last 2 years. FSIS' reluctance to use FERN for this purpose derives from the agency's emphasis on "front line" inspections to ensure food safety during the production process, and a belief that because of the vast amounts of FSIS-regulated product in commerce, routine surveillance in the absence of an actual threat or known contamination is not likely to yield any meaningful results. OIG concludes that FSIS should use FERN for additional food defense surveillance to improve its ability to respond to an actual event. Surveillance assignments should benefit the network by ensuring that emergency response personnel are able to execute their assigned tasks and by bringing to light unanticipated problems.

[2] This program provides funding for supplies, equipment, and personnel to enhance FERN laboratory capacity and capabilities.
[3] FERN consists of 168 labs, 38 of which have cooperative agreements with FSIS, FDA, or both. Of the 130 labs not operating under a cooperative agreement, 35 are Federal labs, which are not included in our count of non-CAP labs.
[4] Proficiency tests involve the preparation and distribution of food samples to laboratories for analysis. They are used to test the technical capability of laboratories.

Recommendation Summary

Through discussions with senior management at FDA, draft and propose an updated charter and memorandum of understanding that include a clear strategy for how the two agencies are to work together to accomplish FERN's mission. Formalize the charter and memorandum of understanding when agreements are reached on the draft proposals.

Through discussions with senior FERN management at FDA, draft and propose standard operating procedures for all of the network's critical functions. Formalize and implement the standard operating procedures when agreements are reached on the draft proposals.

Evaluate and rank non-CAP laboratories in terms of their importance (e.g., testing capability and capacity), reliability (e.g., demonstrated performance), and other factors relevant to FERN's effective operation. Based on these rankings, develop tiers and guidance for activating non-CAP laboratories during an emergency.

Institute a periodic testing program for providing occasional, targeted surveillance of the food supply. Consider including both CAP and non-CAP laboratories as a way of testing the readiness of the network for widespread emergencies.

Agency Response

In its March 2, 2011, written response to the draft report, FSIS agreed with all five of the report's recommendations. We have incorporated FSIS' response, along with our position, in the applicable sections of this report. FSIS' response to the official draft report is included in its entirety at the end of this report.

OIG Position

Based on FSIS' responses, we have reached management decision on all five of the report's recommendations.

Background & Objectives

Background

In response to increased concerns regarding security after the events of September 11, 2001, the Food and Drug Administration (FDA) and Food Safety and Inspection Service (FSIS) initiated interagency collaborations to improve laboratory preparedness for responding to potential attacks on the nation's food supply. The Food Emergency Response Network (FERN) initiative began at the behest of the White House Homeland Security Council and Interagency Food Working Group. In January 2004, Homeland Security Presidential Directive 9 (HSPD-9) directed the U.S. Department of Health and Human Services and the Department of Agriculture (USDA) to protect public health and the food supply by improving the nation's ability to detect, respond to, and recover from terrorist attacks.

HSPD-9 established a national policy to defend agriculture and the food supply against terrorist attacks, major disasters, and other emergencies. The directive tasked Federal agencies with developing nationwide laboratory networks for food, animal health, plant health, and water quality that integrate existing Federal and State laboratory resources, are interconnected, and utilize standardized diagnostic protocols and procedures. FERN has evolved as a collaboration between FDA and FSIS to strengthen the capability and capacity of the nation's food testing laboratories to test for food-borne threat agents, specifically those potentially used by terrorists.[5] Formal FSIS involvement in FERN began in fiscal year (FY) 2005 with the establishment of a FERN Division under the Office of Public Health Science. FSIS' funding for FERN was $10.2 million for FY 2010. Currently, FSIS' FERN Division has 23 full-time equivalent positions.

The mission of FERN is to integrate the nation's food testing laboratories at the Federal, State, and local levels into a network that is able to respond to emergencies involving biological, chemical, or radiological contamination of food.

To accomplish this mission, FERN has four main objectives:

- Prevention – FERN provides for an early means of detecting threat agents in the American food supply;
- Preparedness – FERN prepares the nation's laboratories to be able to respond to food-related emergencies;
- Response – FERN offers surge capacity that will strengthen the nation's response towards widespread complex emergencies, such as contamination of food; and
- Recovery – FERN's laboratories enhance the ability of the country to restore confidence in the food supply following a threat or an actual emergency targeting the nation's food supply.

[5] "Threat agent" is a generic term used by FSIS for substances (e.g., chemicals, microbial agents) that an individual looking to do harm might intentionally add to the food supply.

The FERN organization within FSIS is comprised of four operation units: the National Program Office (NPO), the Regional Coordination Centers (RCC), a Chemical Branch, and a Microbiological Branch.

FERN is co-managed by directors located in Athens, Georgia (FSIS), and Rockville, Maryland (FDA), and is supported by a NPO in each location. The FERN NPO is the operational management unit for the day-to-day activities of FERN. The NPO maintains an inventory of national capability and capacity through oversight of FERN's training, proficiency testing, method development, communication, targeted surveillance, and reporting programs.

There are five RCCs in FERN with which the NPO maintains regular communications.[6] The RCCs organize and coordinate overall regional capability and capacity including screening and confirmatory laboratories, reporting the region's state of readiness to the NPO on a regular basis, and providing a conduit for dissemination of FERN-related information and direction.

FERN partner laboratories are comprised of all FERN members accepted into the network upon completion and review of the FERN checklist.[7] FERN partner laboratories primarily include Federal, State, local, and tribal laboratories. In addition, several academic institutions are partners. FERN laboratory membership is open to food testing laboratories with chemical, microbiological, and radiological analytical capabilities. A laboratory can request membership for any or all of the analytical disciplines based on its current capabilities. There are currently 168 FERN member laboratories.

Laboratories are identified as screening laboratories or confirmatory laboratories based on their current equipment, facilities, or training/personnel for individual agents. Screening laboratories provide the capability to screen large numbers of samples for target substances and confirmatory laboratories are capable of performing all required analyses to fully identify or confirm target substances.

Laboratories that are part of FERN agree to assist in analyzing food samples implicated in threats; responding to terrorist events or contamination; responding to large-scale food emergencies; and providing continual monitoring support. FSIS has cooperative agreements with 25 microbiological laboratories. The bulk of FSIS' FERN funding goes towards supporting these 25 Cooperative Agreement Program (CAP) laboratories. FDA also has cooperative agreements with member laboratories for microbiological, radiological, and chemical disciplines. However, the majority of member laboratories are non-CAP laboratories that do not receive Federal funding from FERN. The non-CAP laboratories primarily provide targeted surveillance activities and additional surge capacity in the event of a large-scale food emergency.

[6] RCCs are located in Jamaica, New York; Athens, Georgia; St. Paul, Minnesota; Denver, Colorado; and, Alameda, California. FSIS has one employee assigned to the Athens, Georgia, RCC and one employee assigned to the St. Paul, Minnesota RCC. FSIS does not have any full-time employees assigned to the other three RCCs, which are staffed by FDA.

[7] FERN Laboratory Qualification Checklist for Membership in the Food Emergency Response Network.

Objectives

The audit was conducted to evaluate FSIS' implementation of FERN and determine what progress the agency has made in establishing capabilities for (1) preventing attacks on the food supply through early detection of threat agents; (2) preparing member (Federal, State, local, and tribal) laboratories to respond to food-related emergencies; (3) providing and coordinating regional and national surge capacity for laboratories; and (4) assisting in recovery efforts to restore confidence in the food supply following a threat or actual emergency.

Section 1: Governance

Finding 1: FSIS Needs to Work With FDA to Formalize FERN and Establish an Overall Strategy for the Network

As part of the national policy to defend the food supply against terrorist attacks, major disasters, and other emergencies, FERN was created to develop a nationwide laboratory network for food testing that integrates existing Federal and State laboratory resources, is interconnected, and utilizes standardized diagnostic protocols and procedures.[8] Although FSIS established the FERN Division in February 2005, FSIS and FDA have not reached a formal agreement on how the network will operate. FSIS and FDA initially drafted a network charter and, subsequently, a memorandum of understanding (MOU), but these documents were never formalized through signatures from senior management at both agencies, and are now outdated and in need of revision to reflect the current organization of the network. For example, although a charter drafted in 2004 established a steering committee authorized to advise FERN and make policy recommendations to ensure that the network could respond to food-related emergencies, the steering committee has not met in the last several years and is not functioning as originally intended. Even though FSIS officials stated that the network no longer needs a formal steering committee because they have other resources that serve the purposes of that committee, the use of these resources is not documented in a formal agreement between the two agencies. An attempt to update the charter in 2006 failed, and the updated charter and MOU remain unsigned. This occurred because the two agencies were unable to reach agreement on the contents of these documents. Without a formal charter and MOU between FSIS and FDA, FERN lacks some of the elements an effective interagency emergency network would need to succeed, such as standard operating procedures for the network's critical functions, sufficient staffing, and a clear strategic direction for the network as a whole.

The Office of Management and Budget (OMB) requires that agency management have a clear, organized strategy for agency activities. When Federal agencies are given the task of completing an objective (e.g., a nationwide food-testing network), they are expected to structure their program so that they will accomplish their desired objectives.[9] In particular, Federal agencies with emergency responsibilities are required to develop the capability to respond to emergencies quickly and with the capacity to address the emergency.[10] The Government Accountability Office (GAO) reported that agencies can strengthen their commitment to work collaboratively by articulating their agreements in formal documents, such as an MOU, interagency guidance, or an interagency planning document, signed by senior officials in the respective agencies. GAO also reported that collaborating agencies should work together to define and agree on their respective roles and responsibilities. In doing so, the agencies should clarify who will do what, organize their joint and individual efforts, and facilitate decision making. Committed leadership by those

[8] HSPD-9, section (8)(c), January 2004.
[9] *OMB Circular A-123*, revised, "Management's Responsibility for Internal Controls," dated December 21, 2004.
[10] HSPD-9, section (14), January 2004.

involved in the collaborative effort, at all levels of the organization, is also needed to overcome the many barriers to working across agency boundaries. [11]

FDA and FSIS jointly developed a charter for FERN in 2004 that described how the network would function and defined organizational components, roles, and procedures. Although this document was never signed by the two agencies, an FSIS official told us that both agencies agreed to the provisions of the charter. Included in the initial FERN charter was a steering committee comprised of representatives from multiple agencies that play a role in food safety and security, such as the Centers for Disease Control and the Department of Homeland Security. This steering committee would be responsible for recommending FERN policy in areas such as surveillance sampling programs. The Office of Inspector General (OIG) maintains that a document such as the charter and the presence of a functioning steering committee would be useful to help both agencies coordinate their FERN-related activities through the implementation of formal policies. In 2006, an effort was made to develop an updated charter to better reflect the organization of the network. However, the two agencies were unable to reach an agreement on the updated charter, and the steering committee for FERN, although initially established, is not currently functioning. Additionally, the two agencies have not documented a replacement for the steering committee, and have instead operated under an informal, verbal understanding.

FDA and FSIS drafted an MOU to define and document the interagency collaborative effort to establish, develop, and manage FERN. The MOU recognized the challenge faced by the two agencies—each with its distinct regulatory authority. According to the document, successfully managing FERN involved unifying existing FDA and FSIS food-testing infrastructures to detect and identify threat agents that may be introduced into the food supply. The MOU sought to define and document how each agency would work towards accomplishing FERN's mission, but like the updated charter, the two agencies were unable to reach an agreement on the MOU and never formalized the document.

Without an updated and relevant, formalized charter and MOU, both FDA and FSIS have each tended to operate their respective parts of FERN within their own parameters. FSIS officials stated that they have an informal, verbal understanding with FDA concerning how the network will operate, and that, so far, that understanding has sufficed. This informal approach to managing the network has resulted in relatively few operating procedures being standardized for both FDA and FSIS, and jeopardizes the network's continuity in the unfortunate event of future conflict between the two agencies. Of the 18 procedures FSIS provided us, only 6 were approved by both agencies—the first of these procedures pertains to document control, while the others are related to the submission, review, and validation of analytical methods for testing for threat agents.

OIG found that the other 12 operating procedures—relating to functions such as emergency response, training, proficiency testing, and laboratory participation in the network—had not been finalized by either agency. Additionally, for several important functions such as overseeing the cooperative laboratory agreements, surveillance, and recovery, there are no standard operating

[11] GAO-06-15, "Results-Oriented Government – Practices that Can Help Enhance and Sustain Collaboration Among Federal Agencies," dated October 2005.

procedures. One of the critical functions of FERN is responding to a large-scale food emergency through activation of the network of laboratories on a regional or nationwide basis. Even though the FERN Division was created in FY 2005, FSIS and FDA only recently began formalizing standard operating procedures for activating the network.[12] OIG was provided a draft of this standard operating procedure in March 2010, but the procedure remains in draft. We maintain that implementing interagency operating procedures for all of FERN's critical functions should have been among the first tasks facing the FERN steering committee, if it had been functioning as established in the initial charter.

In order to ensure FERN's effectiveness in the event of a national emergency, OIG concludes that FDA and FSIS should take steps to more formally establish the network. Those steps should include both agencies signing an MOU, finalizing an updated charter with a clear strategic vision for how the agencies are to work together to accomplish FERN's goals, and implementing standard operating procedures for all of the network's critical functions.

Recommendation 1

Through discussions with senior management at FDA, draft and propose an updated charter and memorandum of understanding that include a clear strategy for how the two agencies are to work together to accomplish FERN's mission. Formalize the charter and memorandum of understanding when agreements are reached on the draft proposals.

Agency Response

In its March 2, 2011, response, FSIS stated the following:

> In light of OIG findings in the course of its audit, a FERN Document Development Workgroup has been established (Jan 2011) to update the current FERN Charter and the FERN Memorandum of Understanding (MOU) draft between FDA and FSIS and to develop and update the necessary FERN SOPs that address FERN's critical functions. The workgroup is made up of representatives from FDA and FSIS FERN with a representative from the FSIS FERN Directors' office providing oversight.
>
> The workgroup's first priority is to update the current FERN draft MOU and submit it to the FSIS and FDA FERN Directors for approval within the next 3-6 months. Upon approval by the FERN FDA and FSIS Directors, the FERN MOU will be submitted to both of their respective agencies for senior management review and concurrence (FSIS Administrator and the FDA equivalent). The FERN Charter will be the next priority for revision by the FERN Document Development Workgroup in order to reflect the current FERN organization and strategy. The Charter will be revised and submitted to the FDA FERN Director for review by the end of the year. This action is to be completed by December 31, 2011.

[12] "Standard Operating Procedures for Coordination of Emergency Response Activities During a Food Emergency," draft dated March 17, 2010.

OIG Position

We accept FSIS' management decision for this Recommendation.

Recommendation 2

Through discussions with senior FERN management at FDA, draft and propose standard operating procedures for all of the network's critical functions. Formalize and implement the standard operating procedures when agreements are reached on the draft proposals.

Agency Response

In its March 2, 2011, response, FSIS stated the following:

> In light of OIG's findings in the course of this audit, the FERN Document Development Workgroup has identified and listed all currently approved SOPs, draft SOPs, and new SOPs that need to be developed to address all of FERN's critical functions. SOPs have been prioritized and proposed timelines have been established for completion. The goal is to have all SOPs developed, approved by the FSIS FERN Director and submitted to the FDA FERN Director for approval within one year. Individual SOPs will be submitted by the workgroup for the FSIS and FDA FERN Directorate approval as they are finalized by the workgroup. This action is to be completed by March 31, 2012.

OIG Position

We accept FSIS' management decision for this Recommendation.

Section 2: Laboratory Preparedness

Finding 2: FSIS Needs to Improve its Preparedness to Increase Laboratory Capacity during an Emergency

FSIS has not established guidelines for how it will expand its network capacity using non-CAP laboratories as the size, severity, and geographic scope of an emergency increases. While FSIS has a reasonable idea of its CAP laboratories' capability and capacity to test for contaminants during an emergency, it does not have verified information concerning the 95 non-CAP laboratories that it considers part of its network. Moreover, the agency does not have plans for how it will expand testing from CAP to non-CAP laboratories as emergencies become larger in size and scope. This occurred because FSIS lacks the resources to develop guidelines and verify information concerning the non-CAP laboratories. However, relying on unverified capabilities may weaken FERN's effectiveness if laboratories are listed as being able to contribute in ways that they actually cannot—as we found in all three of the volunteer laboratories we visited.

Federal agencies are expected to take actions to establish and sustain necessary capabilities to execute a full range of emergency management and incident activities. These agencies should set expectations about the capabilities and resources that will be provided before, during, or after an incident. One critical element of preparedness is the inventorying and categorizing of resources available for an incident.[13]

If the nation's food supply is compromised, part of FERN's goal is to have the capability to quickly identify the contaminant and the extent of contamination by activating a network of testing laboratories. To accomplish this goal, FERN enrolls laboratories through cooperative agreements (25 FSIS CAP laboratories) and voluntary participation (95 non-CAP laboratories).[14] Each must fill out FERN's online laboratory qualification checklist, which uploads information about testing capability into the agency's database. As part of the cooperative agreements, FSIS confirms this information for CAP laboratories through verification procedures such as proficiency testing and site visits. However, since non-CAP laboratories volunteer, FERN cannot require them to comply with any confirmation controls.

FERN typically uses its CAP laboratories as primary responders for laboratory analysis during an emergency, but if the situation worsens or laboratories with different testing abilities are needed, then FERN may recruit non-CAP laboratories. In all three non-CAP laboratories we visited, discrepancies existed between what the laboratories claimed and what they were actually equipped to do, including:[15]

- One laboratory listed itself as being capable of testing for two types of bacteria (*E. coli* and *Campylobacter*) that it could not test for. The laboratory also indicated it could

[13] U.S. Department of Homeland Security's National Incident Management System, December 2008.
[14] FERN consists of 168 labs, 38 of which have cooperative agreements with FSIS, FDA, or both. Of the 130 labs not operating under a cooperative agreement, 35 are Federal labs, which are not included in our count of non-CAP labs.
[15] These discrepancies were identified by an FSIS official who accompanied us on these visits.

analyze up to 2,500 samples for *Salmonella* during an emergency, but the FSIS representative determined that confusion over the required analytical method caused the laboratory to overstate its capacity. The laboratory subsequently reduced the number to 150.

- Another laboratory registered that it was able to conduct Anthrax testing, but it could not. On the other hand, the laboratory was able to test for other types of contaminants but these capabilities were not recorded.
- Similarly, the third laboratory had fewer analysts available to work during an emergency (8) than it had listed (12), but did have testing equipment capable of identifying bacteria such as *Salmonella* and *E. coli*, which was not listed.

In addition to the confusion noted in the first example, an FSIS official explained that some of these discrepancies may have been the result of the laboratories not being able to enter all of their equipment due to database limitations. This official told us that the database has since been updated to allow the laboratories to more accurately enter their equipment.

Unless FSIS has a clear understanding of what tasks CAP and non-CAP laboratories can perform, it is likely to lose valuable time during an emergency. For example, if FSIS discovers during an emergency that laboratories lack their listed testing capabilities, the agency may lose valuable time finding a laboratory that can analyze a sample for a particular threat. Alternately, the agency may needlessly delay testing because it is unaware that a nearby laboratory can provide the testing that it believed could only be performed by a more distant laboratory. In either case, FERN's effectiveness is partly determined by non-CAP laboratories' being able to perform the work they volunteer to do. Although FERN has assured us that it would not send samples to a laboratory based solely on the information in the database, having accurate information would assist FERN in more quickly identifying laboratories that have the ability to respond to the emergency.

We discussed this issue with FSIS officials who agreed that non-CAP laboratories should ideally be subject to similar verification and testing controls as CAP laboratories. They noted, however, that they lacked the resources (money and personnel) for site visits at non-CAP laboratories, and FERN does not require non-CAP laboratories to participate in proficiency testing which would help verify their capabilities. During our review, we found that FSIS initially expected to have 33 employees working for FERN, but as of May 2010, the agency had only 23. In particular, FSIS has provided fewer employees to the RCC than it originally projected, leaving three RCCs entirely without a full-time FSIS employee. We conclude that regional employees would be instrumental in verifying non-CAP laboratories' capabilities and capacities.

FERN drafted a standard operating procedure for network activation that provides for a prioritized list, or tiers, of laboratories. These tiers establish the order in which laboratories will be called upon in an emergency. CAP laboratories are first on this list, followed by non-CAP laboratories. We recommend that FSIS extend this approach by developing different tiers for activating non-CAP laboratories. To accomplish this, FSIS should evaluate the non-CAP laboratories in terms of their testing capability and capacity, reliability (e.g., demonstrated performance), and other factors relevant to FERN's effective operation. Based on its determination, FSIS can then decide which non-CAP laboratories to activate at particular stages

of FERN's activation. For example, FSIS can first activate laboratories with capabilities it is most sure of, and reserve others for later emergencies that require the full network. FSIS agreed that an ideal system would work this way, but stated that FERN lacks the resources to put such a tiering system in place. However, we believe that a tiering system would enable FERN to better determine which laboratories would be best suited to respond to an emergency as more resources are needed.

Recommendation 3

Evaluate and rank non-CAP laboratories in terms of their importance (e.g., testing capability and capacity), reliability (e.g., demonstrated performance), and other factors relevant to FERN's effective operation.

Agency Response

In its March 2, 2011, response, FSIS stated the following:

> FSIS FERN staff will devise an evaluation tool which will be used to rank FERN's partner labs (i.e. to include all non-CAP partners) in terms of their abilities (i.e. capacities and capabilities) to respond to a FERN activation event. Examples of some of the criteria elements that may be used to rank FERN's lab partners are the following: (1) current membership in the FSIS or FDA Cooperative Agreement Program, (2) past performance in FERN activation events, (3) existing laboratory accreditation by a 3rd Party, (4) participation in the FERN Proficiency Testing Program, (5) participation in the FERN Training Program, (6) prior membership in the FERN Cooperative Agreement Program , (7) participation in FERN Table Top Exercises (TTX), and (8) participation in FERN Food Defense Assignments and/or targeted surveillance activities. This list of examples is not all-conclusive and additional criteria elements of evaluation may be used in the ranking process. The evaluation tool will be developed within 3-6 months and the ranking of all FERN partner laboratories will be completed within 9-12 months. This action is to be completed by March 31, 2012.

OIG Position

We accept FSIS' management decision for this Recommendation.

Recommendation 4

Develop tiers based on rankings determined in response to Recommendation 3 and develop guidance for activating non-CAP laboratories during an emergency.

Agency Response

In its March 2, 2011, response, FSIS stated the following:

> FSIS FERN staff will use the ranking of FERN partner labs discussed in Recommendation 3 to develop a Tier system of laboratory response in support of FERN activation events. Since the rankings will be completed within 9-12 months per Recommendation 3, the assignment of FERN partner labs into individual Tiers will be accomplished after the ranking has been completed.
>
> Additionally, FERN has drafted a FERN Emergency Response/Activation SOP (Feb 2010) which addresses the activation of FERN to include the utilization of partner labs in response to FERN activation. The SOP has been given to FDA FERN Directorate and is currently under their review. This SOP will be finalized once FDA completes their annex to the SOP. This action is to be completed by March 31, 2012.

OIG Position

We accept FSIS' management decision for this Recommendation.

Finding 3: FSIS Needs to Improve How it Prevents Attacks on the Food Supply by Periodically Testing for Contaminants

In responding to HSPD-9 and creating FERN, FSIS recognized the need for a surveillance program with capabilities to test for the presence of various chemical, biological, and radiological agents that may be intentionally added to the food supply. Although FSIS and FDA established FERN with an emphasis on targeted surveillance of the food supply, OIG found that FSIS has not established a program for conducting such surveillance. Instead, FERN has relied on occasional targeted surveillance projects, mostly driven by FDA during the last 2 years. FSIS' reluctance to use FERN for this purpose derives from the agency's historically "front line" approach to ensuring food safety during the production process, and a belief that because of the vast amounts of FSIS-regulated product in commerce, routine surveillance in the absence of an actual threat or known contamination is not likely to yield any meaningful results. OIG concludes that FSIS should use FERN for additional food defense surveillance to improve its ability to respond to an actual event. Targeted surveillance assignments should benefit the network by ensuring that emergency response personnel are able to execute their assigned tasks and should also bring to light unanticipated problems.

The President directed the Secretaries of Agriculture and Health and Human Services to develop a robust, comprehensive, and fully coordinated surveillance and monitoring system that provides early detection and awareness of diseases, pests, or poisonous agents that might affect the food supply and public health. When FSIS and FDA drafted the memorandum of understanding for FERN, the two agencies prescribed a targeted surveillance program that would offer an early means of detecting threat agents in the American food supply.

FSIS has used FERN to participate in some occasional targeted surveillance assignments, such as at the 2008 Republican and Democratic National Conventions and the 2009 Presidential Inauguration, as well as testing for the presence of melamine in imported products. Such food surveillance is useful not only for ensuring food security, but also for testing the laboratory network system to ensure that it is ready to respond in the event of a national crisis. Although the most recent assignments were predominantly driven by FDA, they not only offered an opportunity to identify potential weaknesses within the network of laboratories, but they also assisted State and local agencies by providing a better understanding of procedures used when collecting and shipping samples—procedures that may not usually be part of their normal routine.

We believe that FSIS should be more proactive in using FERN for similar purposes, with a focus on USDA-regulated food products and programs. Working within USDA, for example, FSIS could perform targeted surveillance on food served to school children as part of the school meal programs. In 2007, FSIS developed a pilot surveillance project that would test the safety of food in the National School Lunch Program, but it did not continue the project, citing its limited resources. While we recognize the efforts made by FSIS in the past, we conclude that it should be more proactive in initiating targeted surveillance assignments to ensure food safety and to exercise the laboratory network.

FERN should work closely with other USDA agencies to establish and implement a continuing surveillance program that targets meals served to school children, as well as other USDA high-risk programs and events. An FSIS official said that an ongoing, routine surveillance program would not be productive, but he supports the concept of targeted surveillance.

Recommendation 5

Institute a periodic testing program for providing occasional, targeted surveillance of the food supply. Consider including both CAP and non-CAP laboratories as a way of testing the readiness of the network for widespread emergencies.

Agency Response

In its March 2, 2011, response, FSIS stated the following:

> Two targeted surveillance projects will be instituted in the upcoming year. Given current budget constraints, FSIS will consider including both CAP and non-CAP laboratories. FSIS FERN staff has prepared a statement of work (SOW) (i.e., contract) with the Agricultural Marketing Service (AMS) to create a targeted surveillance program focused on school lunch commodities, which tests them for the presence of microbiological and chemical threat agents. The program will run a year, at which time FSIS FERN and AMS will then assess the significance of the targeted surveillance activities.
>
> FERN has contracted with the Customs and Border Protection Service (CBP), DHS and coordinated with the Office of International Affairs (OIA), FSIS, USDA, to conduct a pilot study (targeted surveillance) of imported commodities against a panel of threat

agents. The purpose of this pilot study is to increase threat agent testing of products sampled at FSIS Import Houses and to improve communications and data sharing among the FSIS I-Houses, the Food Emergency Response Network and CBP. The goal is to conduct imported commodity testing in multiple I-Houses involving all seven OIA Regional Offices of the Import Inspection Division within OIA. FERN will institute this pilot study in the Spring of 2011. These actions are to be completed by December 31, 2011.

OIG Position

We accept FSIS' management decision for this Recommendation.

Scope and Methodology

To accomplish our audit objectives, we looked at FERN as a whole, including how the network was established, along with the founding documents, the relevant Presidential Directive, and the structure used to communicate and coordinate among the two responsible agencies.

We conducted our fieldwork between February 2009 and May 2010. We performed our audit at FSIS Headquarters in Washington, D.C.; the FERN NPO and Southeast RCC in Athens, Georgia; the FERN Central RCC in St. Paul, Minnesota; and one laboratory in Minnesota and three laboratories in Pennsylvania. We performed procedures that specifically targeted the four objectives of the audit: preparedness, prevention, response, and recovery.

FSIS Headquarters

At FSIS Headquarters, we determined the responsibilities of the following offices as they relate to FERN administration, and interviewed the appropriate officials:

- The Office of Public Health Science provides expert scientific analysis, advice, data, and recommendations on all matters involving public health and science that are of concern to FSIS.
- The Office of Data Integration and Food Protection oversees all food defense activities of FSIS, developing and implementing procedures to prepare for, respond to, and recover from intentional and unintentional contamination and significant food emergencies and natural disasters affecting meat, poultry, and processed egg products.

FERN National Program Office

At the FERN NPO, we interviewed FSIS officials, examined standard operating procedures, and evaluated operations related to FSIS' administration of FERN. We evaluated the NPO's oversight of FERN laboratories. We also obtained an understanding of FERN's use of electronic communications related to the transfer of information to and from the laboratories. We reviewed information about FERN surveillance assignments, method development and validation, laboratory capabilities and capacities, and recovery activities.

Southeast and Central Regional Coordination Centers

We selected two of the five RCCs for onsite review. We selected these two regions because they represent the only two regions with full-time FSIS personnel. Additionally, at the time of our selection, the central region had the highest number of laboratories of the five. At the regional level, we interviewed FSIS personnel and reviewed documents to evaluate the RCCs' roles and responsibilities related to the administration of FERN. Specifically, we sought to determine how the RCCs coordinate with the NPO and network laboratories to achieve FERN's objectives of preparedness, prevention, response, and recovery. We evaluated the RCCs' roles in providing training to member laboratories, administering and tracking the results of proficiency tests, and their responsibilities during activation of the network.

FERN Laboratories

In all, we visited one laboratory that was participating in CAP and three laboratories that were not. We selected the CAP laboratory for onsite review because it is located in close proximity to the central RCC and would allow us to utilize the expertise of the central RCC staff officer. We did not initiate the visits to the three non-CAP laboratories, but rather accompanied an FSIS official on these visits. At these laboratories, we interviewed laboratory personnel and reviewed documentation related to the CAP laboratory's participation in FERN projects and assignments. For the laboratory that received funding through CAP, we evaluated its compliance with the requirements of the agreement and verified the appropriate use of CAP funding. For those laboratories that did not participate in CAP, we worked with an FSIS staff officer to evaluate the accuracy of laboratory capability and capacity as reflected in the FERN database.

Finally, we also interviewed the FERN director for FDA to obtain that agency's perspective on the progress of FERN.

We conducted the 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 objective.

Abbreviations

CAP	Cooperative Agreement Program
FDA	Food and Drug Administration
FERN	Food Emergency Response Network
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
HSPD-9	Homeland Security Presidential Directive 9
GAO	Government Accountability Office
NPO	National Program Office
OIG	Office of Inspector General
OMB	Office of Management and Budget
RCC	Regional Coordination Center
USDA	Department of Agriculture

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/ March 2, 2011
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Emergency Response Network (Audit 24601-6-At)

We appreciate the opportunity to review and comment on this official draft report. The Food Safety and Inspection Service (FSIS) has carefully reviewed the official draft report and has provided responses to OIG's recommendations.

Responses to Recommendations

Recommendation 1:
Through discussions with senior management at FDA, draft and propose an updated charter and Memorandum of Understanding that include a clear strategy for how the two agencies are to work together to accomplish FERN's mission. Formalize the charter and memorandum of understanding when agreements are reached on the draft proposals.

FSIS Response:
In light of OIG findings in the course of its audit, a FERN Document Development Workgroup has been established (Jan 2011) to update the current FERN Charter and the FERN Memorandum of Understanding (MOU) draft between FDA and FSIS and to develop and update the necessary FERN SOPs that address FERN's critical functions. The workgroup is made up of representatives from FDA and FSIS FERN with a representative from the FSIS FERN Directors' office providing oversight.

The workgroup's first priority is to update the current FERN draft MOU and submit it to the FSIS and FDA FERN Directors for approval within the next 3-6 months. Upon approval by the FERN FDA and FSIS Directors, the FERN MOU will be submitted to both of their respective agencies for senior management review and concurrence (FSIS Administrator and the FDA equivalent). The FERN Charter will be the next priority for revision by the FERN Document Development Workgroup in order to reflect the current FERN organization and strategy. The Charter will be revised and submitted to the FDA FERN Director for review by the end of the year.

Estimated Completion Date:
December 31, 2011

Recommendation 2:
Through discussions with senior FERN management at FDA, draft and propose standard operating procedures for all of the network's critical functions. Formalize and implement the standard operating procedures when agreements are reached on the draft proposals.

FSIS Response:
In light of OIG's findings in the course of this audit, the FERN Document Development Workgroup has identified and listed all currently approved SOPs, draft SOPs, and new SOPs that need to be developed to address all of FERN's critical functions. SOPs have been prioritized and proposed timelines have been established for completion. The goal is to have all SOPs developed, approved by the FSIS FERN Director and submitted to the FDA FERN Director for approval within one year. Individual SOPs will be submitted by the workgroup for the FSIS and FDA FERN Directorate approval as they are finalized by the workgroup.

Estimated Completion Date:
March 31, 2012

Recommendation 3:
Evaluate and rank non-CAP laboratories in terms of their importance (e.g. testing capability and capacity), reliability (e.g. demonstrated performance), and other factors relevant to FERN's effective operation.

FSIS Response:
FSIS FERN staff will devise an evaluation tool which will be used to rank FERN's partner labs (i.e. to include all non-CAP partners) in terms of their abilities (i.e. capacities and capabilities) to respond to a FERN activation event. Examples of some of the criteria elements that may be used to rank FERN's lab partners are the following: 1) current membership in the FSIS or FDA Cooperative Agreement Program, 2) past performance in FERN activation events, 3) existing laboratory accreditation by a 3rd Party, 4) participation in the FERN Proficiency Testing Program, 5) participation in the FERN Training Program, 6) prior membership in the FERN Cooperative Agreement Program , 7) participation in FERN Table Top Exercises (TTX) and 8) participation in FERN Food Defense Assignments and/or targeted surveillance activities. This list of examples is not all-conclusive and additional criteria elements of evaluation may be used in the ranking process. The evaluation tool will be developed within 3-6 months and the ranking of all FERN partner laboratories will be completed within 9-12 months.

Estimated Completion Date:
March 31, 2012

Recommendation 4:
Develop tiers based on rankings determined in response to Recommendation 3 and develop guidance for activating non-CAP laboratories during an emergency.

FSIS Response:
FSIS FERN staff will use the ranking of FERN partner labs discussed in Recommendation 3 to develop a Tier system of laboratory response in support of FERN activation events. Since the rankings will be completed within 9-12 months per Recommendation 3, the assignment of FERN partner labs into individual Tiers will be accomplished after the ranking has been completed.

Additionally, FERN has drafted a FERN Emergency Response/Activation SOP (Feb 2010) which addresses the activation of FERN to include the utilization of partner labs in response to FERN activation. The SOP has been given to FDA FERN Directorate and is currently under their review. This SOP will be finalized once FDA completes their annex to the SOP.

Completion Date:
March 31, 2012

Recommendation 5:
Institute a periodic testing program for providing occasional, targeted surveillance of the food supply. Consider including both CAP and non-CAP laboratories as a way of testing the readiness of the network for widespread emergencies.

FSIS Response:
Two targeted surveillance projects will be instituted in the upcoming year. Given current budget constraints, FSIS will consider including both CAP and non-CAP laboratories. FSIS FERN staff has prepared a statement of work (SOW) (i.e., contract) with the Agricultural Marketing Service (AMS) to create a targeted surveillance program focused on school lunch commodities, which tests them for the presence of microbiological and chemical threat agents. The program will run a year, at which time FSIS FERN and AMS will then assess the significance of the targeted surveillance activities.

FERN has contracted with the Customs and Border Protection Service (CBP), DHS and coordinated with the Office of International Affairs (OIA), FSIS, USDA, to conduct a pilot study (targeted surveillance) of imported commodities against a panel of threat agents. The purpose of this pilot study is to increase threat agent testing of products sampled at FSIS Import Houses and to improve communications and data sharing among the FSIS I-Houses, the Food Emergency Response Network and CBP. The goal is to conduct imported commodity testing in multiple I-Houses involving all seven OIA Regional Offices of the Import Inspection Division within OIA. FERN will institute this pilot study in the Spring of 2011.

Estimated Completion Date:
FSIS will have started these two surveillance projects by December 31, 2011.