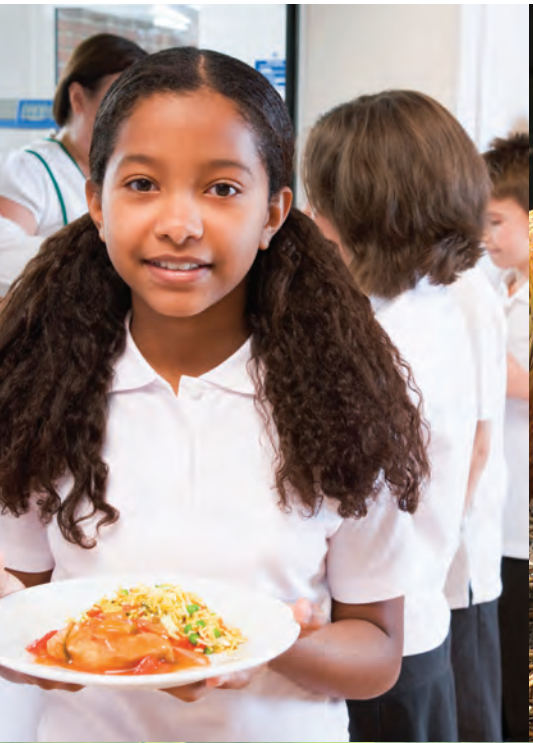
United States Department of Agriculture
Office of Inspector General

USDA Controls Over Shell Egg Inspections



Audit Report 50601-0001-23

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SUBJECT: USDA Controls Over Shell Egg Inspections

This report presents the results of our audit of USDA's Controls over Shell Egg Inspections. Written responses to the official draft report were received from the Food Safety and Inspection Service (FSIS) and Agricultural Marketing Service (AMS). Excerpts from those responses and the Office of Inspector General's (OIG) positions are incorporated into the Findings and Recommendations sections of the report, where applicable.

Based on the agencies' written responses to the official draft report, we are able to accept AMS' management decisions on Recommendations 4, 5, 6, 7, and 8. We can accept FSIS' management decisions on Recommendations 1, 2, 3, 9, and 10, once we have been provided with the information as outlined in the report sections, OIG Position.

In accordance with Departmental Regulation 1720-1, FSIS needs to furnish a reply within 60 days describing the corrective actions taken or planned, and timeframes for implementing the recommendations for which management decisions have not been reached. Please note that the

regulation requires management decision to be reached on all recommendations within 6 months from report issuance, and final action to be taken within 1 year of each management decision to prevent being listed in the Department's annual Performance and Accountability Report. For Recommendations 4, 5, 6, 7, and 8, please follow your agency's internal procedures in forwarding final action correspondence to the Office of the Chief Officer.

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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USDA Controls Over Shell Egg Inspections

Executive Summary

In August 2010, the Department of Health and Human Services' (HHS) Food and Drug Administration (FDA) posted a voluntary market recall of over 500 million shell eggs nationwide that were potentially adulterated with *Salmonella enteritidis* (SE).[1] These shell eggs were reportedly linked to more than 1,900 illnesses in 11 States. Over 230 million shell eggs in that recall were packed in cartons that contained the USDA grade mark for quality. We initiated this audit to evaluate the Department of Agriculture's (USDA) controls to detect and report SE in shell eggs and USDA's coordination within the Department and with FDA to ensure that shell eggs are fit for human consumption.

With over 79 billion shell eggs being packed during calendar year 2011 by over 287 companies nationwide, it takes a well-coordinated effort by Federal Departments and their agencies to protect consumers and reinforce their confidence in the safety of shell eggs and the reliance they historically have placed on the USDA grade mark for quality. Subsequent to those recalls, USDA and FDA have updated their agreements in an effort to improve coordination and the exchange of information. In March 2011, the Agricultural Marketing Service (AMS) and FDA revised their long-standing memorandum of understanding (MOU) on information sharing and other activities relating to the inspection and grading of food products. In addition, in December 2011, the Under Secretaries representing several USDA agencies, including AMS, the Food Safety and Inspection Service (FSIS), and the Animal and Plant Health Inspection Service (APHIS), signed a new MOU with FDA to improve the sharing of information between the two Departments.[2]

However, we have found that USDA agencies need to improve both their coordination of responsibilities and their communication of information in order to ensure consumer safety. Under different regulatory authorities, USDA shares responsibility with FDA for ensuring the safety of shell eggs from the egg-laying barn to the consumer's table.[3] FDA's oversight traditionally covered egg-laying barns, while three USDA agencies have roles to ensure the safety of shell eggs. FSIS, the lead food safety agency within USDA, regulates the storage temperature and labeling of shell eggs in cartons, whether at a shell egg company or a distributor.[4] AMS performs voluntary grading services that provide egg processors with the

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[1] *Salmonella enteritidis* (one of the most common serotypes of *Salmonella* bacteria) is an organism which can cause serious and sometimes fatal infections in very young children, frail or elderly people, and others with weakened immune systems. Healthy people infected with *Salmonella* often experience diarrhea, fever, and abdominal pain.

[2] FDA MOU 225-12-007, approved and accepted by FDA's Commissioner of Food and Drugs on January 19, 2012, enhances the exchange of information between participating agencies, but does not create binding, enforceable obligations against any participant.

[3] An egg-laying barn is the location where the laying hens are quartered and shell eggs are actually produced; an egg producer may have one barn or several, depending on how many laying hens are onsite.

[4] FSIS' traditional role for shell eggs involves inspections performed at a shell egg products processor (i.e., eggs removed from their shells), and distributors that transport whole shell eggs from shell egg companies (i.e., those that maintain egg-laying barns) to retail stores. Additionally, FSIS follows up on reported temperature and labeling violations at shell egg companies, which pack shell eggs destined for the ultimate consumer.

opportunity to apply the USDA grade mark for quality to egg cartons, and offers verification audits of egg-laying barns to determine if a company meets industry developed animal husbandry standards for egg-laying flocks.[5] Finally, APHIS ensures that egg-laying breeding hens are SE-free and provides voluntary testing services to verify SE in samples taken from egg-laying barn environments or individual shell eggs.

We found that, while a 1998 Presidential Executive Order[6] instructed USDA and HHS to enhance coordination on food safety, including shell eggs, the Departments' efforts since then have remained divided and omitted key parts in a "farm to table" approach to shell egg safety.[7]

For example, prior to the August 2010 recall, two USDA agencies possessed critical information; however, because of this divided regulatory environment, Federal agencies within and outside USDA that had both the authority and ability to act on that information were not informed. This occurred because USDA's FSIS has traditionally viewed shell egg safety as FDA's responsibility and therefore has not taken an active role to coordinate the sharing of crucial information with FDA. Additionally, though sanitation was less than fair at nearly one-third of the shell egg companies that FSIS visited in 2001, agency officials prioritized other program responsibilities above the development of sanitation standards for the shell egg packing areas.[8] In March 2011, we requested that FSIS obtain an opinion from the Office of the General Counsel (OGC) regarding its authority to inspect shell eggs and egg-laying barns. In October 2011, OGC opined that FSIS, through the *Egg Products Inspection Act* (EPIA), does have inspection authority over shell eggs. This included the egg-laying barns, which FDA reported as the source of the SE infections that prompted the August 2010 recall, and which were not inspected by FDA officials prior to the August 2010 recall.

Our audit also disclosed that AMS does not have controls in place to either prevent the USDA grade mark for quality from unknowingly being placed on shell eggs that were potentially adulterated with SE, or identify and track potentially-adulterated shell eggs once they left the packing facility to be packed at a different facility.[9] This occurred because AMS officials viewed the USDA grade mark as an attestation only to the quality of a shell egg, not its safety. However, their attestation includes the condition of a shell egg, which AMS defines as "fitness for human food." The condition examination of shell eggs by AMS assures the eggs, at the time of certification, are acceptable, based on a visual and smell inspection, and processed and packaged in a manner so that the eggs are fit for human consumption. We also found that AMS conducted its grading activities without ensuring that either FSIS, FDA, or the shell egg companies informed AMS graders of possible SE contamination. In November 2010, FDA posted another recall for almost 290,000 shell eggs that were potentially adulterated with SE; 94 percent of those shell eggs received the USDA grade mark for quality because the AMS

[5] The USDA Process Verification Program.
[6] Executive Order 13100, *President's Council on Food Safety*, dated August 25, 1998.
[7] A "farm to table" approach for shell eggs is a comprehensive program to control SE contamination throughout the production, distribution, and consumption of shell eggs, as referenced in *the Egg Safety Action Plan*, dated December 10, 1999.
[8] FSIS Shell Egg Pilot Project, performed in October 2001.
[9] Adulterated means any egg which bears or contains any poisonous or deleterious substance that may render it injurious to health. EPIA allows shell eggs known to be adulterated with SE to be processed (i.e., pasteurized) and be made fit for human consumption.

grader was not aware of the potential contamination. On February 16, 2011, we issued a fast report to AMS in which we recommended that the agency immediately require shell egg companies to notify AMS when they become aware of possible SE contamination. In AMS' response, agency officials stated that they took immediate corrective actions by revising their procedures.

Our audit further disclosed that FSIS' shell egg refrigeration policy was not adequately designed to limit the growth of SE in shell eggs, since the maximum storage temperatures allowed exceeded the science-based safety limit of 45 degrees Fahrenheit (F). In addition, FSIS' policy did not consider the amount of time shell eggs are stored at higher temperatures, which is key to determining whether shell eggs were susceptible to increased SE growth.[10] This occurred because FSIS did not develop its policy based on scientifically-proven safety measures, but instead based it upon the agency's assumption that shell eggs have a low risk of contamination with SE. However, scientific studies have estimated that 1 in 20,000 shell eggs, or 1 in 3,600, depending on the egg-laying environment, would have some level of SE contamination.[11] Based on these scientific estimates,with several egg companies, each producing over 1 million shell eggs per day, hundreds of shell eggs per day could enter the marketplace while potentially adulterated with SE. Combined with the fact that FSIS' policy would not ensure these shell eggs are properly refrigerated, at 45 degrees F or below, the SE in those shell eggs would continue to grow and potentially cause SE-related illnesses.

In addition, when FSIS identified egregious or repeat violators of its temperature policy, we found that the agency did not initiate progressively stronger enforcement actions, such as product seizures or civil penalties. Despite scientific studies that show SE can grow inside shell eggs when they are stored above 45 degrees F, agency officials did not fully exercise their authority to regulate shell egg storage temperatures because they considered the risk of shell egg contamination to be low. In addition, FSIS officials were concerned over possible litigation in trying to strictly enforce the temperature requirement. As a result of FSIS' lenient enforcement policy, we noted that almost 35 percent of shell egg companies nationwide repeatedly stored shell eggs at temperatures that would not limit the growth of SE, including one company that stored shell eggs in temperatures that exceeded 80 degrees F. Due to FSIS' lenient enforcement policy, the agency's actions were not effective in deterring serious violations by shell egg companies. One of those companies was later found to be responsible for the August 2010 recall and reportedly linked to over 1,900 SE-related illnesses.

Overall, we concluded that the lack of coordination within USDA and with FDA prevented crucial information from getting to the agencies that could have potentially limited the scope of the August 2010 recall and related illnesses. Furthermore, USDA agencies' policies and

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[10] Even though the EPIA does not specifically address the factor of time, scientific studies (as cited in the following footnote) show that the length of time shell eggs are maintained above 45 degrees F is a key component in the growth of SE in shell eggs.

[11] FDA's proposed rule, *Prevention of Salmonella Enteritidis in Shell Eggs During Production*, dated September 22, 2004, made final on July 9, 2009, cited *Salmonella Enteritidis Risk Assessment-Shell Eggs and Egg Products*, dated August 10, 1998; *Risk Assessments for Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Product*, issued October 2005; and *The Salmonella enterica Serovar Enteritidis Pilot Project, Chapter 32 in Salmonella enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control*, Editor A. M. Saeed, 1999.

enforcement efforts would not ensure that shell eggs potentially adulterated with SE do not reach consumers.

Recommendation Summary

We recommend that FSIS, as USDA's lead food safety agency, coordinate with FDA, AMS and APHIS to implement a plan to ensure a seamless farm-to-table approach to shell egg safety within USDA and ensure crucial information related to shell egg safety is shared within USDA and with FDA. We also recommend that FSIS implement a process to collect data on the current level of sanitation issues at shell egg packing companies nationwide and take corrective actions, as deemed necessary. We further recommend that FSIS implement a science-based policy on shell egg refrigeration and a process to take progressively stronger enforcement actions against companies that repeatedly violate its policy. For AMS, we recommend that it take the necessary steps to prevent the USDA grade mark for quality from being placed on shell eggs potentially contaminated with SE. In addition, AMS should clarify the regulatory definition of "condition" for shell eggs to clearly state whether it relates to quality, is fit for human food, or both.

Agency Response

Both FSIS and AMS officials generally agreed with our findings and recommendations. In FSIS' written response to the official draft report, dated October 29, 2012, agency officials agreed to review its existing coordination with FDA and other USDA agencies to determine if additional coordination efforts are needed regarding the regulation and oversight of shell eggs. FSIS will also review and evaluate the existing food safety practices (i.e., sanitation) in shell egg packing plants and its shell egg temperature policy and procedures to determine if changes are appropriate and necessary. In AMS' written response, dated February 25, 2011, to our fast report, they agreed to amend its Application for Service with shell egg packing companies to require that an egg producer/processor immediately notify the USDA grader assigned to the packing plant when an environmental sample from a layer flock has been confirmed positive for the presence of SE. In AMS' written response to the official draft report, dated October 31, 2012, agency officials agreed to issue a regulatory change on their revised definition of "condition" as it applies to shell eggs. AMS officials also stated that their existing Memorandum of Understanding between FDA and AMS, dated March 4, 2011, requires the sharing of information through the web-based Inter-agency Referral Report system, which includes immediate notification of any positive findings of pathogens of human health significance in product to cause adulteration or contamination. We have incorporated portions of the agencies' written responses, along with the Office of Inspector General's (OIG) Position in the Findings and Recommendations section of this report. Both agencies' written responses are included in their entirety at the end of this report.

OIG Position

We accept AMS' management decisions for Recommendations 4 through 8 of this report. For FSIS, management decision can be reached for Recommendations 1, 2, 3, 9 and 10 once FSIS has provided us with the additional information outlined in the applicable report sections, under OIG Position.

Background and Objectives

Background

The United States Department of Health and Human Services (HHS) and Department of Agriculture (USDA) and its related agencies have historically led the Federal Government's efforts to ensure the safety of shell eggs. HHS' FDA, through its authority under the *Federal Food, Drug and Cosmetic Act* (FFDCA) and the *Public Health Service Act* (PHSA), has provided oversight of shell egg safety at egg-laying barns.[12] USDA's FSIS, through its authority under *the Egg Products Inspection Act* (EPIA), has provided oversight of shell eggs after they have left the barn to either be placed in cartons for consumers or sent to an egg product processor.[13,14]

SE is a leading bacterial cause of food borne illnesses in the United States that affect an estimated 142,000 people each year. SE-adulterated shell eggs contribute to over one-third of these outbreaks.[15] In 1998, based on the outbreaks of SE illnesses at that time, the President ordered the establishment of a Council on Food Safety. The Council required Federal agencies to enhance coordination for shell eggs in a "farm-to-table" approach, and designated FSIS and FDA as the lead agencies in coordinating the Federal Government's efforts. To accomplish a "farm-to-table" approach, several Federal agencies under HHS and USDA play key roles. For HHS, those agencies include FDA and the Center for Disease Control and Prevention (CDC). The key agencies for USDA include FSIS, AMS, and APHIS. These agencies have responsibilities for egg safety and quality under different laws and, as a result, use different regulatory approaches in addressing the issues under their authority.[16]

In late 1999, FSIS and FDA published an *Egg Safety Action Plan* in an attempt to curtail risky egg preparation (i.e., from farm to table) practices in order to reduce outbreaks and illnesses associated with SE contamination. The goal of the 1999 action plan was to eventually eliminate eggs as a source of SE illnesses by 2010. In response, FDA developed standards for inspection and enforcement at egg-laying barns. FSIS, in turn, was to develop inspection and enforcement procedures for shell eggs once they had left the egg-laying barns and were sent to shell egg packing and egg product processing companies.[17] Under the 1999 action plan, FSIS and FDA each pursued its own independent oversight and enforcement activities, with FDA having responsibility for the egg-laying barns and FSIS for the shell egg packing and processing companies.

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[12] *Federal Food Drug and Cosmetic Act (FFDCA) of 1938*, as amended, and *Public Health Service Act (PHSA) of 1944*, as amended.

[13] An egg products processor is a USDA-inspected egg products plant where liquid, frozen, and/or dried egg products are produced.

[14] *Egg Products Inspection Act (EPIA) of 1970*, as amended.

[15] FDA website: *Consumer Updates, FDA Improves Egg Safety,* posted July 7, 2009, and *FDA Final Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Productions, Transportation, and Storage*, Public meeting held in Chicago, Illinois, on September 30, 2009.

[16] FFDCA, PHSA, and EPIA, as well as *the Agricultural Marketing Act of 1946*, as amended, and *the Department of Agriculture Organic Act of 1944*, as amended.

[17] As of April 15, 2012, FSIS has not fully implemented its inspection and enforcement procedures, particularly the sanitation standards for shell egg packing and egg product processing companies.

USDA's authority under the EPIA provides for inspecting certain egg products, restricting the disposition of eggs below a certain quality, providing uniform standards for eggs, and otherwise regulating the processing and distribution of eggs and egg products in commerce that are not adulterated or misbranded.[18] Congress amended the EPIA in 1991, and expanded USDA's authority to include enforcing shell egg refrigeration and labeling (i.e., keep refrigerated) safety requirements at packing companies and during transportation.[19] For USDA, FSIS exercises enforcement authority for shell egg refrigeration and labeling requirements. AMS assists FSIS through an agreement to monitor and report observations to FSIS regarding noncompliances with these requirements when performing quarterly shell egg handler (i.e., producer or packing company) visits mandated under the EPIA.

USDA named FSIS as the Department's lead food safety agency with the responsibility for ensuring food safety, including shell eggs and egg products under the EPIA. FSIS' main role has traditionally been in monitoring the safety of egg products. However, since 1999, FSIS is also responsible for ensuring shell eggs are stored and transported at a maximum temperature of 45 degrees Fahrenheit (F) and that shell egg cartons are properly labeled. To ensure compliance with the temperature and labeling requirements, FSIS officials use a risk-based selection process to primarily inspect distributors that store and transport shell eggs. Through an inter-agency agreement, FSIS utilizes AMS officials to record temperature and labeling compliance at shell egg companies (i.e., shell egg producers). Under the Shell Egg Surveillance Program, AMS officials conduct quarterly inspections at all shell egg companies nationwide to ensure compliance with its grading criteria; while at those locations, they also record the ambient temperatures of coolers where shell eggs are stored.[20] AMS reports those temperature recordings to FSIS compliance officers for consideration of any appropriate enforcement actions, which can range from issuing a warning letter to imposing civil or criminal penalties.[21]

AMS provides a voluntary resident grading service under contract with shell egg companies. A fee for service arrangement to provide grading of shell eggs distributed in commerce is also offered by the agency. Under these services, AMS graders continuously monitor the grading and packing of shell eggs to ensure they meet the applicable quality, size, and condition standards before assigning the USDA grade mark for quality. The USDA grade mark for quality provides a standardized means of describing the marketability of a particular food product. Through the application of uniform grade standards, shell eggs can be classified (i.e., Grade AA, A, or B), according to a range of quality characteristics. For shell eggs, the standards define and measure quality in terms of the appearance and condition of the shell as well as the interior quality of the yolk and albumen (the clear or white part of a raw egg). Shell egg companies and consumers rely on USDA's shell egg grading services to ensure that their requirements for quality, weight, condition, or other factors are met.

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[18] Eggs and egg products that are found to be adulterated or misbranded are not permitted to enter commerce.
[19] Regulations implementing the amendments became effective in August 1999.
[20] The Shell Egg Surveillance Program covers firms with over 3,000 layers that grade and pack their own eggs, firms that grade and pack eggs from production sources other than their own (grading station), and firms that are hatcheries. Inspections are carried out either by AMS employees or by State agency personnel under contract with AMS.
[21] On a quarterly basis, AMS reports all shell egg ambient temperature recordings to FSIS. However, for temperature recordings over 60 degrees F, AMS reports this information immediately to FSIS.

For locations operating under the voluntary shell egg grading program, AMS graders also check and verify a company's sanitary procedures to maintain the egg processing equipment and the facilities, the operating procedures, and assure the labeling of shell eggs meet the refrigeration labeling requirements.[22] AMS official companies (i.e., companies where AMS graders are present) must follow strict sanitation requirements when grading shell eggs containing the USDA grade mark for quality. However, AMS only enforces its sanitation standards when companies are packing shell eggs under the USDA grade mark for quality. Shell egg companies, by meeting these requirements, can sell their product under the USDA grade mark for quality at a premium. AMS also offers voluntary audit, survey, and verification services (on a fee for service basis) at shell egg companies' egg-laying barns or shell egg packing areas in accordance with industry developed, commercial, or international standards.

APHIS' role is independent of the EPIA and involves the administration of animal health programs. APHIS' National Poultry Improvement Program monitors State agencies' oversight of hatcheries to ensure that egg-type breeding hens are free of SE. This voluntary program ensures that the hatching eggs and chicks produced are certified free of SE, and was initiated after scientific studies found SE could be present in the ovaries of egg-laying hens, and that the pathogen could be transferred during the formation of a shell egg.[23] APHIS also administers the National Veterinary Services Laboratories (NVSL), which operate a fee for service testing program under which its scientists characterize *Salmonella* isolates as SE or non-SE from *Salmonella* isolated from individual shell eggs or an egg-laying barn environment.[24] The NVSL provides the results of its SE testing confidentially back to the submitters, which can be either public (i.e., State veterinary diagnostic laboratory, FDA) or private entities. Starting in September 2009, some shell egg companies were required to take regular samples of their egg-laying barn environment and certain individual shell eggs to test for the presence of SE contamination.[25]

In 2010, there were two nationwide recalls, involving more than 500 million shell eggs potentially adulterated with SE, which led to over 1,900 illnesses in 11 States. The first recall, in August 2010, prompted Congress to question the Federal Government's role in ensuring the safety of the nation's egg supply. In November 2010, another shell egg recall was issued for almost 290,000 eggs after SE was detected at a shell egg company at an Ohio facility. Subsequent to those recalls, USDA and FDA have updated their agreements in an effort to improve the exchange of information. In March 2011, AMS and FDA revised their long-standing memorandum of understanding (MOU) on information sharing and other activities relating to the inspection and grading of food products. As part of this MOU, in September 2011, FDA and AMS collaboratively established and implemented a web based inter-agency referral report system to report 1) objectionable sanitary conditions that present a high risk of contamination and 2) the detection of contaminated or adulterated shell eggs. In addition, FDA

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[22] The EPIA requires that shell egg cartons be labeled that refrigeration is necessary.

[23] A pathogen is a microorganism that causes disease, such as a bacterium, virus, or fungus.

[24] Serotyping is the method used to determine the exact type of *Salmonella* that is present within a sample, such as SE or *Salmonella typhimurium.*

[25] *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation* dated July 9, 2009, with an effective date of September 8, 2009. No later than July 9, 2010, shell egg producers with 50,000 or more laying hens were required to take regular samples for SE, and starting on July 9, 2012, this requirement also applied to shell egg producers with fewer than 50,000 but at least 3,000 laying hens.

provided a training module to AMS inspection program personnel that identified examples of food safety-related observations in the supply chain that should be shared with the appropriate agency. In December 2011, five USDA Undersecretaries, representing 13 USDA agencies, signed a new MOU with FDA to enhance informational exchange related to food safety and public health activities beyond existing agreements. Under this MOU, each USDA agency is individually responsible for notifying FDA about food safety related issues its agency officials identify. [26]

Objectives

Our audit evaluated USDA's controls over shell eggs to prevent, detect, and report the presence of SE or other contaminants.[27] In addition, we evaluated the effectiveness of USDA's coordination efforts between its own agencies and with HHS' FDA to ensure the safety and wholesomeness of shell eggs.

[26] FDA MOU 225-12-007, approved and accepted by FDA's Commissioner of Food and Drugs on January 19, 2012, does not create binding, enforceable obligations against any participant.

[27] At a public meeting held in Chicago, Illinois, on September 30, 2009, to discuss *FDA's Final Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage*, an FDA Director for the Office of Food Safety confirmed that an SE-contaminated egg is considered adulterated.

Section 1: USDA's Controls Over Shell Egg Safety

Finding 1: USDA Needs to Strengthen Its Approach to Ensure the Safety of Shell Eggs

USDA, and in particular FSIS as the Department's lead food safety agency, did not ensure a unified approach, either within the Department or in coordination with FDA to prevent, detect, and report the presence of SE in shell eggs. This occurred because, although a 1998 executive order required USDA and HHS to enhance Federal coordination, their respective agencies' (FSIS and FDA) joint action plan instead divided the responsibility of ensuring the safety of shell eggs between the two Departments. Furthermore, key parts of the Plan's "farm-to-table" process, including the sharing of information and development of FSIS sanitation standards for shell egg packing areas, were not covered. For USDA, these included not sharing APHIS' SE testing results, or AMS' observations of the egg-laying barn environment.[28] As a result, neither USDA nor FDA were able to fully utilize crucial information collected by USDA agencies to detect the presence of SE in shell eggs or to identify egg producers with sanitation or other issues that could make shell egg contamination more likely. This crucial information, if timely reported to FDA, might have limited the scope of the August 2010 nationwide recall of over half a billion shell eggs potentially adulterated with SE, to which CDC attributed over 1,900 illnesses.

Under the EPIA, USDA and HHS have the authority and responsibility for ensuring the safety of shell eggs.[29,30] Although AMS and APHIS both have roles related to egg safety, FSIS—as USDA's lead food safety agency—has the primary responsibility within the Department for ensuring the safety of shell eggs and egg products under EPIA. Traditionally, FSIS officials have taken the position that their agency's responsibility for shell eggs was limited to ensuring that carton labeling and ambient storage temperature requirements were met. However, in October 2011, an Office of the General Counsel (OGC) opinion stated that under EPIA, FSIS does in fact have the authority, in coordination with FDA, to regulate egg-laying barns that are contiguous with shell egg packing companies.[31]

However, we determined that FSIS has not fully exercised its authority under EPIA. Specifically, FSIS did not coordinate with other USDA agencies, such as AMS and APHIS, to collect and share crucial information these agencies routinely obtained under their own programs, regarding either the confirmed presence of SE in shell eggs or sanitation conditions that could lead to SE contamination. For example, at one shell egg company, over 4 months passed between the time when APHIS officials became aware of an environmental SE-positive test result and the August 2010 recall of shell eggs coming from that egg-laying barn. This company was later determined to be the source of SE-related illnesses that prompted the August 2010 shell egg recall. In addition, an AMS official visited that company's egg-laying barns 2 weeks before the recall was announced and noted some of the same sanitation issues that

[28] AMS initiated verification audits at egg-laying barns beginning in April 2002, but the Egg Safety Action Plan was not updated to include AMS officials' increased presence at egg-laying barns.
[29] 21 U.S.C. Sections 1031-1056.
[30] HHS' FDA also has authority through *the Food, Drug, and Cosmetic Act*, as amended.
[31] USDA's OGC Opinion, dated October 3, 2011.

FDA later cited as the probable cause of the SE-related illnesses. However, neither APHIS nor AMS officials reported that information outside their own agencies, due to the lack of both a specific reporting requirement, and a process for FSIS to collect and disseminate it as needed. The information which the USDA agencies possessed might have assisted FDA officials in a quicker identification of the source of SE-related illnesses in 2010, had the Department possessed both a mechanism for collecting and analyzing these data and a process for sharing them with relevant agencies outside the Department, such as FDA and CDC.

Coordination of USDA's Efforts

We found that FSIS did not actively coordinate the collection and use of information obtained by APHIS or AMS officials. Both of these agencies possessed information which, if timely shared within USDA, would have made FSIS aware of the problem and possibly enabled the Department to either take action or to assist FDA to limit the number of SE-related illnesses by more quickly identifying the shell egg company that was the subject of the August 2010 shell egg recall.

APHIS Testing Results

APHIS' laboratory operates a voluntary service under which its scientists identify the *Salmonella* serotype to confirm the presence of SE in FDA-required samples, taken either from the environments in the egg-laying barns or from individual shell eggs.[32] Our review of the events prior to the August 2010 recall disclosed that APHIS officials were aware that the company's egg-laying barns had tested positive for SE over 4 months before the recall was issued. However, APHIS never reported this information to other USDA agencies or to FDA. APHIS officials stated they have strict confidentiality agreements with the organizations who submit the test samples to them, and it is their policy not to share their results, even with other USDA agencies. They also noted that there are no regulations in place that require APHIS to share testing results with anyone other than the submitter of the sample. APHIS officials expressed concerns that if only its laboratory was required to report test results to other agencies, shell egg companies would likely send their samples to other laboratories, instead of APHIS' NVSL.[33] However, APHIS officials stated that they would have no issue in sharing their testing results if all public and private laboratories were required to report their SE testing results as well. APHIS officials also stated that if a regulatory authority, such as FSIS, required the mandatory sharing of testing results; they would change their agreements and policies to comply with that new requirement.

[32] *Prevention of Salmonella Enteritidis in Shell Eggs During Production, Storage, and Transportation* dated July 9, 2009, with an effective date of September 8, 2009. Beginning on July 9, 2010, shell egg producers with 50,000 or more laying hens were required to take regular samples for SE, and starting on July 9, 2012, this requirement also applied to shell egg producers with fewer than 50,000 but at least 3,000 laying hens. FDA's Shell Egg Safety Rule requires shell egg companies to test samples from egg-laying barns for SE, but does not require those companies to report the results to FDA. If samples test positive for SE, FDA requires shell egg companies to take additional actions to reduce the health risk.

[33] A submitter may be a shell egg company, a nationwide private organization, or a State or local government agency that sends its samples for testing to APHIS' National Veterinary Services Laboratory (NVSL).

Between July 2010 and September 2011, APHIS received 387 sample submissions, of which 320 tested positive for SE.[34] Any of these SE-positives could be an indicator of increased health risk at a shell egg company's location, particularly when they involve samples taken from actual shell eggs, rather than from the environment of the egg-laying barns.[35] However, because there is not a mandatory laboratory reporting requirement and FSIS had not coordinated with APHIS to implement a process under which these test results could be shared and disseminated as needed, other USDA agencies—including AMS officials that apply USDA's quality grademark to shell eggs—may not be aware of all the SE-positive test results (see Finding 2).

AMS Observations at Egg-Laying Barns

AMS is involved in multiple activities related to shell eggs, such as grading and surveillance performed in packing areas. AMS officials also perform verification audits for shell egg companies' animal husbandry programs within the egg-laying barns.[36] AMS' animal husbandry audits are performed under contract with shell egg companies where the primary purpose of those audits is to certify as to the well-being of the caged birds within the egg-laying barns (i.e., that birds are maintained within space allowance guidelines while caged). Although there was no requirement for AMS personnel to report sanitation deficiencies or to collect samples for SE testing, these Federal officials are often the only government presence onsite at shell egg companies. As such, they may be in a position to observe sanitation and other deficiencies of which FDA officials are unaware. For example, one AMS inspector conducted an animal husbandry audit of egg-laying barns operated by the egg producer involved in the August 2010 recall. The inspector, who was onsite at the egg-laying barns 2 weeks before the recall was announced, stated that he observed some of the same sanitation issues (e.g., rodent activity and high bird manure levels) that FDA later reported as the probable cause of SE contamination in the shell eggs that came from those barns. However, because there was not a requirement in place to do so, AMS officials did not share this information with either FSIS or with FDA.

In March 2011, AMS updated its MOU with FDA to ensure that observations made by AMS inspectors while at the egg-laying barns are fully documented and reported to FDA.[37] In addition, during the summer of 2011, FDA developed criteria that would assist AMS inspectors in identifying if there was a potential food safety violation at an

[34] A farm may have multiple samples taken which all test positive for SE. There were over 10 official AMS shell egg companies (i.e., companies where AMS graders are present) that had multiple SE-positive test results.
[35] APHIS' testing program does not require that the agency be provided with either the source of the sample, or information on whether it is an environmental sample or a sample taken from an actual shell egg.
[36] USDA's animal husbandry audits, performed under its Process Verified Programs (PVP) and United Egg Producers (UEP) audit program, verify a company's conformance with established industry and/or company provided standards. After AMS verifies that the company has met those requirements, the company is allowed to market the product using the PVP shield or UEP logo and terminology.
[37] Memorandum of understanding between AMS and FDA, concerning information sharing and other activities related to the auditing, inspection, and grading of food products, dated March 4, 2011.

egg-laying barn or packing area that should be shared with FDA. In December 2011, USDA signed a separate MOU with FDA to improve information sharing. [38]

While AMS took steps to coordinate the sharing of information with FDA, FSIS has not yet established similar coordination within USDA as a whole to ensure that information collected by APHIS officials is shared with FSIS and AMS, and that AMS observations are shared with FSIS and FDA. USDA personnel, such as AMS auditors and APHIS scientists, are often the only Federal officials who are in a position to be aware of potential safety issues at a company's egg-laying barns. When we spoke to AMS and APHIS officials about this potential weakness in reporting, they stated that the services they provide, such as SE serotyping, are voluntary and they are not under any obligation to report potential violations within or outside USDA. This is of particular concern, because an AMS inspector stated that sanitation issues, such as those he observed at the company responsible for the August 2010 recall, were common in egg-laying barns. However, both agencies did agree that if FSIS set standards to follow and required them to report violations of those standards to either FSIS or FDA, they would comply.

Coordination with FDA

We found that, although FSIS coordinated with FDA at locations where the agencies have dual jurisdiction over other processed food (i.e., beef, swine, poultry, egg product processors, etc.), they did not have that same level of coordination in their oversight of shell egg companies. FSIS officials did not have any written documentation that they had actively coordinated with FDA in regards to shell eggs since July 2000, with the exception of FSIS' work with FDA on the 2005 Risk Assessments for SE, despite both agencies having legal jurisdiction under EPIA to regulate shell eggs.[39] This occurred because, when preparing their Shell Egg Safety Action Plan in 1999, FSIS and FDA agreed to divide, rather than coordinate, their individual responsibilities. This division did not consider the fact that AMS officials often perform grading services in packing facilities connected to the egg-laying barn, an area that FDA also regulates. Furthermore, FSIS did not ensure that AMS officials shared critical observations that could have alerted FDA officials to take appropriate and timely corrective actions. In addition, since FSIS traditionally viewed shell egg safety as the primary responsibility of FDA, it did not determine the extent of FDA's oversight at the egg-laying barns. If FSIS officials had inquired about FDA's oversight, they would have found that FDA did not regularly visit egg-laying barns. We confirmed this with FDA officials and also found that FDA had never visited the egg-laying barns of the company that was responsible for the August 2010 recall. As a result of this divided approach, FSIS did not have a process to share critical information with FDA that could have potentially lessened the magnitude of the August 2010 shell egg recall.[40]

[38] FDA MOU 225-12-007, signed by FDA's Commissioner of Food and Drugs on January 19, 2012, does not create a binding, enforceable obligation against any participant.
[39] *2005 Risk Assessments for Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Product*, issued in October 2005.
[40] While we did not coordinate significantly with HHS-OIG, we did inform them and FDA officials about the issues we disclosed during our audit.

We discussed our conclusions, including those associated with both 2010 shell egg recalls, with FDA officials.[41,42] During those discussions, we found that FSIS and FDA were both key participants in the development of the 1999 Egg Safety Action Plan to ensure the safety of eggs, which was a major focus of the President's Council on Food Safety. A 1998 Executive Order created the Council to "improve the safety of the food supply through science-based regulation and well-coordinated inspection, enforcement, research, and education programs."[43] In response, FDA developed standards for inspection and enforcement at egg-laying barns. FSIS, in turn, was to develop inspection and enforcement procedures for shell eggs once they had left the laying barns and were sent to shell egg packing and egg product processing companies. Under the 1999 action plan, FSIS and FDA each pursued its own independent oversight and enforcement activities, with FDA having responsibility for the egg-laying barns and FSIS for the shell egg packing and processing companies. However, the Action Plan did not require active coordination between FDA and FSIS, despite the Executive Order stating that a well-coordinated inspection and enforcement process was needed for shell eggs. While FSIS has not improved its coordination with FDA over shell egg safety, AMS did so by entering into a new MOU with FDA in March 2011. As part of that MOU, both FDA and AMS agreed to report serious sanitation violations they identified in egg-laying barns, through a web-based Interagency Referral Report system used for notifying designated agency officials of reported incidents.

FSIS' Authority for Shell Egg Safety

Based on our review of the EPIA, we concluded that it granted FSIS, on behalf of USDA, the authority to ensure there was sufficient coordination between USDA and FDA, as it related to the safety of shell eggs. FSIS officials, however, deferred to FDA as the authority over shell egg safety, particularly in the oversight of egg-laying barns, as outlined in the 1999 plan. Therefore, we requested that FSIS obtain an OGC opinion to determine the extent of FSIS' authority under the EPIA. OGC's opinion, issued in October 2011, confirmed that the EPIA grants FSIS the authority to inspect shell eggs and egg-laying barns, although it states that this should be done in coordination with FDA.

We spoke with USDA officials regarding OGC's opinion and the need for better coordination, both within the Department and with FDA. FSIS officials stated that shell egg safety was primarily FDA's responsibility, and despite OGC's opinion they believed that the EPIA also allowed them the discretion to choose whether or not to inspect egg-laying barns. Based upon a consultation with OIG's Office of Counsel, we believe that FSIS has not only the authority, but also the responsibility for conducting periodic inspections of egg-laying barns. FSIS officials should, if they consider it necessary, request a supplemental OGC opinion to clarify whether the

[41] Our audit did not include a review of FDA's processes or controls relating to shell egg safety. According to HHS-OIG, there have been no recent audits regarding shell egg safety.

[42] On August 13, 2010, a shell egg producer in Iowa issued a voluntary market recall of over 500 million shell eggs, of which over 230 million contained the official USDA grade mark for quality. On November 5, 2010, a different shell egg producer in Ohio issued a voluntary market recall of 288,000 shell eggs, of which over 270,000 contained the official USDA grade mark for quality.

[43] Under Executive Order No. 13100, dated August 25, 1998, the President established the President's Council on Food Safety to improve the safety of the food supply by using science-based regulation and well-coordinated surveillance, investigation, inspection, enforcement, research, and educational programs. This was later preceded by the President's Food Safety Working Group that was created in March 2009.

agency does in fact have the discretion to leave the inspection of egg-laying barns entirely to FDA. We believe that FSIS should work in conjunction with FDA, AMS, and APHIS to ensure that shell egg companies that have positive SE environmental test results receive additional scrutiny to ensure the SE-positive eggs do not enter commerce.

Sanitation Standards

The 1999 Egg Safety Action Plan formalized FSIS' agreement to implement sanitation standards at shell egg packing companies that would, in part, assist in eliminating shell eggs as a source of SE-related illnesses by 2010. However, we found that FSIS has yet to issue minimum sanitation requirements for shell egg packing companies. According to FSIS officials, this occurred because FSIS considered shell eggs as a low-risk food and had higher-risk priorities (e.g., contamination by *Escherichia coli* or Bovine Spongiform Encephalopathy in beef) related to other food products.[44] Although we did not observe significant sanitation issues during our visits to shell egg packing companies, there is evidence that sanitation issues have occurred in the past, due to the lack of mandatory minimum sanitation requirements. In addition, while investigating the cause of the August 2010 recall, FDA discovered that one shell egg company involved in the recall used SE-contaminated water to wash shell eggs. AMS officials assigned the USDA grade mark for quality to shell eggs after they were processed through this wash water.

AMS officials expressed concerns regarding inadequate sanitation in shell egg packing areas at both official companies (AMS grader present) and at non-official companies (no AMS grader present). Despite FSIS possessing evidence that supports AMS' concerns, the agency has not yet taken corrective actions. For example, to meet the objectives of the Egg Safety Action Plan, FSIS initiated a nationwide pilot project in 2001 designed to obtain data about sanitation levels and practices in the shell egg packing industry.[45] Through the pilot project, FSIS found that 29 percent (17 of 58) of the shell egg packing companies (official and non-official) it visited had "less than fair" sanitation. The study also found that sanitation errors were significantly higher at non-official shell egg companies versus shell egg companies where AMS inspectors were present. Despite these results, FSIS did not implement sanitation standards to address the issues raised by the pilot project. In 2011, during our field visits, an AMS official stated he had, in the past, observed that shell eggs destined for consumers were being packed in an area where sewage was flowing up from a floor drain. While the AMS official notified company management and halted the placing of USDA grade marks on those particular shell eggs, company management continued to pack non-graded shell eggs in that same area. Since FSIS had not issued sanitation standards for shell egg packing companies, that location was able to continue packing and shipping those shell eggs in commerce, which were packed under unsanitary conditions.[46] AMS officials stated that they did not report the issue at this company because there were no sanitation requirements or processes for them to share sanitation issues within USDA, unless they relate to USDA graded shell eggs.

FSIS officials stated that the implementation of mandatory sanitation standards for shell egg packing companies would take more than a year to execute, as FSIS would have to go through

[44] Bovine Spongiform Encephalopathy is also known as "Mad Cow Disease."
[45] Shell Egg Pilot Project performed in October 2001.
[46] FDA's Shell Egg Safety Rule did not establish sanitation standards for shell egg packing companies.

the rule-making process. They believed that the implementation of mandatory sanitation requirements for shell eggs would take a significant amount of time and money. While we concur that the rule-making process can be lengthy, we continue to believe that FSIS needs to reassess whether minimum sanitation standards should be established for shell egg packing companies. The fact that at least 29 percent of the companies sampled during FSIS' pilot study had sanitation problems, in addition to AMS officials' experience with companies packing shell eggs in unsanitary conditions, demonstrates the need for FSIS to analyze the extent of sanitation issues nationwide. Based on that analysis, FSIS needs to implement appropriate sanitation standards to protect consumers and better ensure the safety of shell eggs.

Although the goal of the Egg Safety Action Plan was to eliminate eggs as a source of human SE illnesses by 2010, the shell egg recalls that took place in that year illustrated that the coordination between FSIS and FDA was not sufficient to meet that goal. Adequate coordination between these agencies could have potentially lessened the magnitude of the August 2010 recall. Because USDA and HHS have shared responsibilities relating to shell egg safety, we believe it is crucial that there be constant coordination of their efforts and that FSIS, as the lead food safety agency within USDA, should ensure that this coordination occurs within USDA and with HHS' FDA. To adequately protect the public from consuming adulterated eggs and possibly contracting SE-related illnesses, USDA—particularly FSIS—needs to fully exercise its authority and responsibility over shell egg safety by implementing a plan to ensure a seamless approach, both within USDA and with FDA. In addition, in order to ensure that unsanitary conditions are addressed promptly, FSIS needs to assess the need for and then implement mandatory sanitation standards at shell egg establishments, as agreed upon in the Egg Safety Action Plan.

Recommendations to Food Safety and Inspection Service

Recommendation 1

Develop a plan to build upon the existing coordination of regulation and oversight of shell eggs between FDA and USDA agencies, with FSIS being the lead agency for USDA to ensure a seamless farm-to-table approach to shell egg safety.

Agency Response

In FSIS' response, dated October 29, 2012, FSIS officials stated that they will identify and review all existing coordination efforts between USDA and FDA, including Memoranda of Understanding, and determine if they need to be revised and enhanced by June 2013. If FSIS determines that additional coordination efforts between USDA and FDA are needed regarding the regulation and oversight of shell eggs, FSIS will build upon the existing public health framework and coordination efforts currently in place. FSIS will collaborate within USDA and with FDA to implement workable procedures that can be accomplished within FSIS's existing statutory authority and available resources.

OIG Position

While we agree that FSIS needs to identify and review all existing coordination efforts between USDA and FDA, the response did not state that the agency would develop a plan to build upon the existing structure of coordination and oversight once the review was completed. As noted in this finding, the existing coordination was not sufficient to identify or correct the issues we found during our audit. In order to reach management decision, FSIS needs to provide a further response to clarify that the agency will document the work that will be performed to identify, review, and determine the adequacy of FSIS' coordination efforts within USDA and with FDA to ensure shell egg safety and to prevent SE-positive eggs from entering commerce. The response should also provide an overview of FSIS' proposed methodology for reviewing and evaluating the existing coordination efforts for shell egg safety.

Recommendation 2

Implement a plan to coordinate and share crucial information related to shell egg safety within USDA and with FDA.

Agency Response

In the agency's response, dated October 29, 2012, FSIS officials stated that they will identify and review all existing coordination efforts between USDA and FDA, including Memoranda of Understanding, and determine if they need to be revised and enhanced by November 2013. If FSIS determines that additional coordination efforts between USDA and FDA are needed regarding the regulation and oversight of shell eggs, FSIS will build upon the existing public health framework and coordination efforts currently in place. FSIS will collaborate within USDA and with FDA to implement workable procedures that can be accomplished within FSIS's existing statutory authority and available resources.

OIG Position

FSIS' response cited the USDA and FDA Memorandum of Understanding, but that document was not supported by a substantive system of communication and coordination between the responsible USDA agencies or with FDA. In order to reach management decision, FSIS needs to provide us with additional information about these existing coordination efforts, including how the agency plans to collect and share APHIS' SE testing information as needed to ensure that appropriate corrective actions are taken.

Recommendation 3

Implement a process to collect data on the current level of sanitation issues at shell egg packing companies nationwide. Based on the analysis of this information, initiate corrective actions, as appropriate, to ensure shell egg companies protect consumers by processing shell eggs in sanitary conditions.

Agency Response

In the agency's response, dated October 29, 2012, FSIS officials proposed to evaluate and analyze two already-completed surveys that examine sanitation and existing food safety practices in shell egg packing plants. The agency will also evaluate and analyze the Final Report and Quarterly Summaries on FDA Inspections Under the Egg Safety Rule, dated July 2012. Based on the findings of these analyses, if needed, FSIS, in collaboration with AMS, will develop a data collection tool/method to evaluate sanitation in a sample of shell egg producer/packers with 3,000 or more layers. The data collection will be conducted by trained individuals and evaluated by May 2013. Results of this data collection will then determine actions, if needed, by November 2013.

OIG Position

While we agree that FSIS needs to utilize readily-available information, the studies FSIS cited in its response were conducted in 2004 and may not reflect current sanitation issues at shell egg packing companies. In addition, the Final Report and Quarterly Summaries on FDA Inspections under the July 2012 Egg Safety Rule cited in FSIS' response reported on sanitation issues within egg-laying barns and not the shell egg packing areas. In order to reach management decision, FSIS needs to provide information which outlines the additional methods it will use to assess the current level of sanitation issues at shell egg packing companies and the timeframe for implementing appropriate corrective actions to ensure that shell eggs are processed (i.e., packed) under sanitary conditions.

Finding 2: AMS Applied USDA Grade Marks on SE-Adulterated Shell Eggs

Although AMS applies the USDA grade mark for quality to shell eggs as a certification of quality, we found that the agency did not have controls in place to prevent these grade marks from unknowingly being placed on shell eggs that were potentially adulterated with SE before they were shipped to consumers. In addition, AMS did not have a process to identify and track potentially-adulterated shell eggs once they left the packing facility to be packed at a different facility.[47] This occurred because AMS officials viewed the USDA grade mark only as an attestation to the quality of a shell egg and believed that determinations regarding their safety were the responsibility of the Federal food safety agencies, FSIS and FDA. However, AMS conducted its grading activities without coordinating with either of these agencies, or with the shell egg companies, to ensure that AMS graders were timely aware of situations where FDA's required SE testing disclosed that shell eggs being graded were potentially adulterated. As a result, the integrity of the USDA grade mark for quality was not being adequately protected, since shell eggs bearing the USDA grade mark for quality had to be recalled in August and November 2010 because of being potentially adulterated with SE.

USDA's FSIS and HHS' FDA are the food safety agencies for their respective Departments. FDA issued a Shell Egg Safety Rule in 2009 that required shell egg companies to routinely test both egg-laying barn environments and individual shell eggs for the presence of SE. FDA

[47] For shell eggs bearing the USDA grade mark for quality.

requires shell egg companies to take certain actions if routine tests are SE-positive, but does not require the company to notify either the USDA's food safety agency or AMS.[48] While FSIS' traditional role in shell egg safety related to shell egg storage temperatures and labeling requirements, AMS graders apply the grademark to shell eggs coming from those egg-laying barns as an attestation to the quality of a shell egg. However, to protect the integrity of the USDA grade mark for quality, AMS prohibits its graders from applying it to any shell eggs that they know are adulterated with pathogens (i.e., SE) or are otherwise contaminated.[49]

Shell Egg Recalls

Prior to the August 2010 nationwide recall of shell eggs, AMS did not have controls in place to ensure that graders were notified when shell eggs potentially adulterated with SE were presented for grading. As a result, AMS unknowingly placed the USDA grade mark for quality on over 230 million shell eggs that were recalled due to potential SE contamination, based on positive test results of shell eggs.[50] AMS officials stated that they were concerned about the USDA grade mark for quality being placed on these eggs, but added that AMS is only responsible for the quality of shell eggs, not their safety. AMS officials stated that they rely on the Federal food safety agencies, FDA and FSIS, to determine the safety of shell eggs. Since their graders were not informed of SE-positive test results by either of the food safety agencies or by shell egg company representatives, they unknowingly applied the USDA grade mark for quality to the shell eggs that were subsequently involved in the August 2010 recall. FSIS is not currently involved in this part of the shell egg production process, and neither FDA nor the shell egg company informed AMS graders that the shell eggs the company presented for grading were potentially SE contaminated shell eggs.

On November 5, 2010, FDA posted a second recall, involving over 280,000 shell eggs, from a company in Ohio. Over 270,000 of these eggs (94 percent) received the USDA grade mark for quality, again because AMS was not notified of an SE-positive test result by either FDA or the shell egg company. AMS officials stated that they did not become aware of this issue until after the recall was posted on FDA's website. In this instance, AMS graders at one company became aware of the SE-positive test result only after the company had depopulated the hens from its egg-laying barn and started the disinfection process.[51] As a result, an AMS grader at another company who received these shell eggs unknowingly applied the USDA grade mark for quality to the potentially-adulterated shell eggs.

We found that there was no requirement that either FDA or shell egg companies notify AMS officials of SE-positive test results. Our review of AMS' template agreement with shell egg companies noted that it did not require that AMS be notified when a company's representative becomes aware of an environmental positive for SE or other pathogens which could increase the health risk to the public. Nor does FDA's Shell Egg Safety Rule—as confirmed in discussions with FDA officials—require a shell egg company representative to report SE-positive test results

[48] FDA's rule, dated July 9, 2009, requires shell egg companies to maintain testing records and make those records available to FDA upon request.
[49] AMS is prohibited from grading an "adulterated" shell egg, such as those contaminated with SE.
[50] This was a voluntary market recall in coordination with FDA due to a CDC illness traceback.
[51] Based on FDA's rule, depopulating an egg-laying barn is one of the options available to a company when an egg-laying barn has a shell egg that tests positive for SE.

to either FDA or AMS, as long as company management takes appropriate action, as defined by FDA.[52]

On February 16, 2011, we issued a fast report to AMS in which we recommended that the agency immediately implement corrective actions.[53] In AMS' response, dated February 25, 2011, agency officials agreed to develop and implement policies and procedures to address our concerns. AMS revised its procedures to require that shell egg companies with AMS contracts immediately notify an AMS grader when SE tests come up positive, and included that requirement in its agreements with shell egg companies. AMS officials also stated that with the implementation of these corrective actions, they would have greater control to ensure that no shell eggs containing the USDA grade mark for quality and that originated from environmental SE-positive egg-laying barns were being shipped to consumers. On March 14, 2011, AMS issued a memorandum to require its graders, upon a shell egg company's notification that an environmental sample from an egg-laying barn tested positive for SE, to monitor the segregation of those shell eggs. AMS will then inform FDA officials, based on the agencies' MOU signed in March 2011, that the company has a shell egg test positive for SE.

Quality Versus Safety

AMS officials have traditionally deferred to FDA as the primary food safety agency for shell eggs, and viewed the USDA grade mark for quality as relating only to the quality of a shell egg, not its safety. However, AMS' requirements for shell eggs to receive the USDA grade mark for quality also state that shell eggs must meet certain conditions that relate, in part, to safety. Federal regulations state that AMS graders, through their grading services, are attesting to the "condition" of a shell egg, which AMS defined as its wholesomeness and fitness for human food.[54] Although AMS' definition of "condition" includes its fitness for use as human food, AMS officials have stated that the USDA grade mark for quality relates only to quality factors such as the shell egg being clean, fresh, and unbroken. AMS officials agreed that they are not permitted to put the USDA grade mark for quality on any shell eggs that are not fit for human food, including shell eggs adulterated with SE, but again reiterated that they rely on FDA or FSIS to make that determination. AMS officials did agree that they need to clarify the definition of the "condition" of a shell egg to remove any food safety implications.

AMS officials stated that FDA is the food safety regulatory authority and, based on FDA's Egg Safety Rule, AMS graders would place the USDA grade mark for quality on shell eggs if FDA deemed they were free to enter consumer channels. FDA's Egg Safety Rule allows shell eggs coming from an egg-laying barn environment that tested SE-positive to be shipped to consumers,

[52] FDA requires shell egg companies to (1) immediately divert shell eggs to processing where they are pasteurized to remove contaminants, or (2) continue to ship shell eggs in commerce while the company tests up to 1,000 shell eggs for SE.

[53] OIG Fast Report 50601-1-23(1), *Agricultural Marketing Service Needs Stronger Controls to Ensure the Wholesomeness of Shell Eggs Bearing USDA's Grademark - USDA Controls Over Shell Egg Inspections*, dated February 16, 2011.

[54] Title 7, Part 56.1, dated March 30, 2008. Condition means any condition (including, but not being limited to, the state of preservation, cleanliness, soundness, wholesomeness, or fitness for human food) of any product which affects its merchantability.

as long as a shell egg company agrees to test individual shell eggs for contamination.[55] The process for testing individual shell eggs can take up to 2 weeks to complete. As a result, all the shell eggs produced during that 2-week period could be shipped to consumers bearing the USDA grade mark for quality before AMS becomes aware that the eggs they graded were potentially unsafe. However, AMS officials have not worked with FDA officials to ensure that AMS graders are timely notified of SE-positive test results.

We concluded that unless AMS works in coordination with FDA to ensure that shell egg companies immediately notify AMS of environmental SE-positive test results or other conditions that may render shell eggs unfit for human consumption, there is no assurance that AMS graders would not unknowingly place the official USDA grade mark for quality on potentially-adulterated shell eggs. Although AMS is not directly responsible for the safety of shell eggs, it cannot adequately protect the integrity of the USDA grade mark for quality unless it improves its controls to ensure that the grademark is only applied to eggs which are wholesome and fit for human consumption.

Recommendations to Agricultural Marketing Service

Recommendation 4

Issue a notice to all shell egg producers under contract with AMS for grading services that requires them to immediately notify AMS grading officials when they have indications of adulterated shell eggs at their facility.

Agency Response

In their response to our fast report dated February 16, 2011, officials stated that AMS would revise its procedures to require that an egg producer/processor immediately notify the USDA grader assigned to the packing plant when an environmental sample from a layer flock has been confirmed positive for the presence of SE and whether the company plans to test the eggs from the identified layer flock or divert the eggs to treatment for the remainder of the life of the flock, as required by FDA regulations. If plant management elects to test the eggs, plant management must provide the grader the date the egg samples are collected for submission to the laboratory for analysis. Any eggs packaged in containers identified with the USDA grade shield from the date the egg samples are taken until egg test results have been received must be placed on hold by the company, using established acceptable documented inventory controls, indicating the

[55] When an environmental sample from a layer flock is confirmed positive for the presence of SE, the shell egg company must decide to either test the shell eggs from the identified layer flock, or divert the shell eggs to treatment for the remainder of the life of the flock, as required by FDA regulations. If plant management elects to test the shell eggs, plant management must provide the AMS grader with the date the egg samples are collected for submission to the laboratory for analysis. Any shell eggs packaged in containers identified with the USDA grade mark for quality from the date the egg samples are taken until test results have been received must be placed on hold by the shell egg company, using established acceptable documented inventory controls indicating the identification and segregation of such product. In response to our fast report issued in February 2011, AMS instructed its graders that they are not permitted to put the USDA grade mark for quality on shell eggs that are placed on hold until SE test results are received.

identity and segregation of such product. All records for products placed on hold by the company pending analysis of the egg samples will be accessible to the USDA grader. In AMS' response dated February 25, 2011, officials stated that they issued policy and guidelines that implemented these revised procedures.

OIG Position

We accept AMS' management decision.

Recommendation 5

Develop an addendum for all new contracts with shell egg producers to require production management to immediately notify AMS officials when they become aware of an environmental positive test for SE or other contaminants.

Agency Response

In their response to our fast report dated February 16, 2011, AMS officials stated that they would add wording to the "Certification" section of the Application for Service, Form PY-32, which will require plant management at official plants to notify the USDA grader and provide detailed information pertaining to any contaminated or adulterated shell eggs produced or received for processing, including the identification and segregation of such product. While awaiting the necessary clearances to modify Form PY-32, as stated, an interim form was to be used. Management at all Resident, Temporary, and Fee shell egg grading locations would be required to sign the "Wholesomeness Certification" document. This certification from the egg processors would continue to be used beyond the approval of the modification of the PY-32 for fee grading locations.

In their response to the official draft audit report dated October 31, 2012, AMS officials confirmed that the corrective actions cited above were completed on March 14, 2012, with the distribution of the policy and guidance that implemented reporting procedures at shell egg processing plants.

OIG Position

We accept AMS' management decision.

Recommendation 6

Amend current procedures to require all AMS shell egg graders to identify the location(s) where adulterated shell eggs were shipped and to take appropriate action to ensure that product does not receive the official USDA grade mark for quality.

Agency Response

In their response to our fast report dated February 16, 2011, AMS officials stated that they would revise Sections 4 and 13 of the *Shell Egg Graders Handbook* to clarify and enhance grader and supervisor responsibilities for reporting and controlling contaminated or adulterated shell eggs. In the response to the official draft audit report dated October 31, 2012, AMS officials confirmed that the Handbook was revised in its entirety and includes policies and procedures for the monitoring and control of eggs identified by plant management as adulterated or originating from a layer house with an environment determined positive for the presence of SE. Officials estimated that the final Handbook would be distributed to their field graders by December 31, 2012.

OIG Position

We accept AMS' management decision.

Recommendation 7

Clarify the regulatory definition of "condition" for shell eggs to clearly state whether it relates to quality, safety, or both.

Agency Response

In their response, dated October 31, 2012, AMS officials agreed to develop a revised definition of "condition" as it applies to shell eggs. The revision will include additional clarity to plainly state the intent desired. Wholesomeness of eggs will continue to be based on the existing FDA and Food Safety and Inspection Service (FSIS) regulations. However, they also proposed to postpone the regulatory change to implement the revised definition until FSIS determines whether regulatory language is required defining sanitary procedures for the processing of shell eggs. If FSIS determines that the current sanitary processing procedures stated in AMS Regulations Governing the Voluntary Grading of Shell Eggs (7 CFR 56) must be modified, AMS would make the modifications to the sanitary processing procedures and revise the definition of "condition." This would result in synchronization of any required regulatory changes. Based on FSIS's current schedule of reviewing the sanitation issues at shell egg packing plants, AMS officials estimated that new regulations will be proposed by November 2013.

OIG Position

We accept AMS' management decision.

Recommendation 8

Work with FDA officials to ensure AMS is notified whenever FDA is aware that either shell eggs or the barn environment tested positive for SE, and implement procedures to prevent AMS graders from placing the USDA grade mark for quality on those shell eggs.

Agency Response

In their response, dated October 31, 2012, AMS officials stated they believe this recommendation has been accomplished. Their existing Memorandum of Understanding between FDA and AMS, dated March 4, 2011, requires the sharing of information including immediate notification of any positive findings of pathogens of human health significance in product to cause adulteration or contamination. This information is shared through the web-based Inter-agency Referral Report system. Additionally, as indicated in Recommendation 5, the revised AMS notification policies and procedures address the concerns identified. AMS started implementation of this new system in September 2011.

OIG Position

We accept AMS' management decision.

Section 2: Shell Egg Temperature Violations

Finding 3: FSIS' Refrigeration Policy Did Not Ensure That Shell Eggs Were Maintained at Safe Temperatures

We found that FSIS' shell egg refrigeration policy did not effectively enforce the EPIA requirements on maximum storage temperature, designed to limit the growth of SE in shell eggs. Based on this policy, FSIS allowed companies to store shell eggs above the science-based safety limit of 45 degrees Fahrenheit (F). Specifically, we found 854 instances from October 2005 through June 2011 where companies stored shell eggs at temperatures that exceeded 45 degrees F, in which FSIS did not document the length of time those shell eggs were exposed to those higher temperatures.[56] This occurred because FSIS did not develop its policy based on scientifically-proven safety measures that consider the length of time shell eggs were stored above 45 degrees F, but, instead, based its policy upon the agency's assumption that shell eggs have a low risk of contamination with SE. However, FDA cited a scientific study performed by FSIS which estimated that 1 in 20,000 shell eggs would have some level of SE contamination.[57] With several egg companies each producing over 1 million shell eggs per day, based on these scientific estimates, hundreds of shell eggs per day could enter the marketplace while adulterated with SE. Scientific evidence has shown that maintaining shell eggs below 45 degrees F was predicted to be effective at reducing human illnesses from SE in shell eggs.[58] As a result, FSIS' temperature policy does not diminish the increased risk of SE-adulterated shell eggs entering commerce.

The EPIA requires that shell eggs packed into containers destined for the ultimate consumer be stored and transported under refrigeration at an ambient temperature not to exceed 45 degrees F.[59] However, based on FSIS' assumption that shell eggs have a low risk of SE contamination, agency officials developed a policy that allows shell egg companies to store shell eggs indefinitely at temperatures between 45 and 49 degrees F without penalty. Additionally, both FSIS and AMS officials stated that this policy was intended to identify the most flagrant violators of the EPIA requirements, and that no action would be taken against companies that stored shell eggs between 50 and 60 degrees F, unless such conditions were found on 3 out of 5 consecutive quarterly visits.[60] FSIS does take immediate action when shell eggs are stored in temperatures in excess of 60 degrees F, but only in the form of a warning letter (see Finding 4). Although FSIS is responsible for setting policy in this area, AMS surveillance

[56] Even though the EPIA does not specifically address the factor of time, scientific studies (as referenced in the footnotes within Finding 3) have linked time as an important component in determining if shell eggs stored at a temperature above 45 degrees F present an increased risk to the public.
[57] *FSIS, USDA, Salmonella Enteritidis Risk Assessment: Shell Eggs and Products*, dated June 12, 1998.
[58] Storage times and temperatures were predicted to be effective for reducing illnesses from SE in shell eggs. If eggs are stored and held at 45 degrees F within 12 hours of lay, the estimated number of human illnesses would be reduced from 130,000 to 28,000. *FSIS, USDA, Risk Assessments of Salmonella Enteritidis in Shell Eggs and Salmonella spp in Egg Products*, dated October 2005.
[59] The EPIA was amended in 1991 to require shell eggs be stored and transported in an ambient temperature not to exceed 45 degrees F.
[60] AMS and FSIS collaborated in the development of FSIS' current shell egg refrigeration policy.

inspectors assist with the actual monitoring under a cooperative agreement between the two agencies.

We analyzed FSIS' data regarding ambient storage temperatures for all 612 shell egg companies nationwide from October 1, 2005, through June 30, 2011, and determined that there were 854 instances where AMS officials found shell eggs stored in excess of 45 degrees F, which, based on FSIS' policy, did not require corrective actions. Our analysis also disclosed that the company responsible for the August 2010 shell egg recall had several instances, over a period of nearly 6 years, where AMS inspectors recorded ambient storage temperatures as high as 60 degrees F. We found that one such recorded incident was near the time when SE illnesses being reported to CDC were on the rise in April 2010, and 4 months before the recall took place.[61] However, since AMS inspectors did not find temperature violations between 50 and 60 degrees F during 3 out of 5 consecutive quarterly visits at that company, FSIS' policy did not require any corrective actions to be taken.

FSIS developed its shell egg refrigeration policy based on its officials' belief that shell eggs were at a low risk of being contaminated with SE. However, reports by FDA and CDC cite SE as a leading bacterial cause of food-borne illness in the United States and further cite shell eggs as the primary source of human SE infections.[62] In addition, FDA's 2004 proposed rule on shell egg safety made reference to scientific studies, which estimated that 1 in 20,000 shell eggs are likely contaminated with SE; this ratio drops to 1 in 3,600 shell eggs that come from egg-laying barn environments that tested positive for SE.[63] An FSIS official stated that the agency's policy was established under the premise that the lack of a company's compliance with the temperature requirement does not jeopardize public health. However, a 2001 risk assessment study by the Food and Agriculture Organization and the World Health Organization found that the risk of SE in shell eggs increases significantly as storage temperature and time increase.[64] This study concluded that a 10 percent increase in storage temperature and time resulted in nearly a 90 percent increase in the risk of SE per serving. Another scientific study prepared for FSIS concluded that there was an 8 percent reduction in illnesses when shell eggs were maintained at ambient temperatures of 45 degrees F or below throughout processing and distribution.[65] FSIS officials stated they were not convinced that these scientific studies were sufficient to alter its

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[61] According to the Center for Disease Control and Prevention, the number of SE illnesses began rising in April 2010 and peaked in early July 2010.

[62] FDA website: *Consumer Updates, FDA Improves Egg Safety,* posted July 7, 2009, and *FDA Final Rule for Prevention of Salmonella Enteritidis in Shell Eggs During Production, Transportation, and Storage*, Public meeting held in Chicago, Illinois, on September 30, 2009.

[63] FDA proposed rule, Prevention of *Salmonella* Enteritidis in Shell Eggs During Production, dated September 22, 2004, made final on July 9, 2009, cited the following: *Salmonella Enteritidis Risk Assessment - Shell Eggs and Egg Products*, dated August 10, 1998; 2005 *Risk Assessments for Salmonella Enteritidis in Shell Eggs and Salmonella spp. in Egg Product*; and *The Salmonella enterica Serovar Enteritidis Pilot Project, Chapter 32 in Salmonella enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control*, Editor A. M. Saeed, 1999.

[64] *Joint Food and Agriculture Organization and World Health Organization Expert Consultation on Risk Assessment of Microbiological Hazards in Foods: Risk characterization of Salmonella spp. in eggs and broiler chickens and Listeria monocytogenes in ready-to-eat foods*, presented at Food and Agriculture Organization's Headquarters, Rome, Italy, April 30 through May 4, 2001.

[65] *Salmonella Enteritidis* Risk Assessment-Shell Eggs and Egg Products, dated August 10, 1998.

current shell egg refrigeration policy; however, they did agree that high storage temperatures over a period of time do create the conditions necessary for the rapid growth of SE in shell eggs.

We also found that FSIS did not require either its personnel or AMS inspectors to determine or document the period of time that shell eggs were maintained above 45 degrees F by companies. An FSIS official stated that this was because the EPIA section requiring temperature compliance made no mention of a time component. In addition, FSIS officials stated that, under their interpretation of the EPIA, shell eggs would not be considered adulterated based solely on the fact that they were stored at temperatures that violated the EPIA requirement. However, based on consultation with OIG's Office of Counsel, we believe that the EPIA would, in fact, allow FSIS to take action when companies stored shell eggs under conditions that violated the EPIA temperature requirement. We also believe that FSIS can establish a policy to take actions against companies, regardless of whether or not the shell eggs they packed were determined to be adulterated. FSIS officials agreed that EPIA authorizes them to take action, such as detention and seizure of shell eggs in violation of the Act,[66] but stated that, since AMS inspectors are on site to observe temperature violations, they were not sure they could delegate their authority to AMS to take immediate corrective actions. Again, in consultation with OIG's Office of Counsel, we believe that the EPIA allows FSIS to utilize AMS surveillance inspectors to take immediate corrective actions if shell eggs are found in violation of the 45 degrees F temperature requirement.

We discussed our findings with AMS and FSIS officials, who were involved in both the development and implementation of FSIS' temperature policy. Both agencies reiterated that, although their current refrigeration policy was not supported by scientific studies, they implemented it based on the low risk of SE contamination in shell eggs and the agencies' limited resources available to monitor compliance. However, we believe that the August 2010 recall of SE-adulterated shell eggs and FDA's issuance of its 2009 rule to prevent SE contamination does not support the agencies' position that SE contamination is low risk.

Although agency officials did not believe that their existing temperature policy would jeopardize public health, this position is not consistent with the results of scientific studies and FDA's 2009 Shell Egg Safety Rule involving shell eggs and SE. In addition, storage of SE contaminated shell eggs, such as those involved in the August 2010 recall, at excessive temperatures increases both the growth of SE and the risk of illness to consumers of those eggs. FSIS needs to amend its enforcement policy on shell eggs, both to ensure that it complies with the requirements of EPIA and that it provides scientifically-based safeguards to the public against the risk of illness due to SE contamination.

[66] At the time we began our audit, FSIS officials took the position that such actions could not be taken unless shell eggs were known to have been adulterated; as a result, the agency had not been using these as enforcement tools when temperature violations were identified.

Recommendation to the Food Safety and Inspection Service

Recommendation 9

Develop and implement a science-based shell egg temperature policy that assesses and considers risks associated with time, temperature, or other factors that affect the safety of shell eggs and implement appropriate corrective actions.

Agency Response

In their response dated October 29, 2012, FSIS officials agreed to assess the effects of temperature deviations, time, or other factors that affect the safety of shell eggs packed for the ultimate consumer, along with the respective cost of corrective action. FSIS would use a previously-developed risk assessment model that the officials stated would be able to determine the effect of different storage conditions. They noted that the risk assessment was extensively peer-and-publicly reviewed, and that it considered the temperature parameters of FSIS' current policy; specifically, the risk assessment considered the effect of different ambient temperatures on the growth of *Salmonella* Enteritidis in internally-contaminated shell eggs. FSIS would determine whether changes to FSIS' shell egg temperature policy and procedures are appropriate and necessary (see Recommendation 10). FSIS officials stated that this approach would allow a basis for developing policies and procedures that are cost-effective and would improve public health. The risk assessment will be completed by April 2013 and revise directives by December 2013.

OIG Position

Although the agency's response cited time as one of the factors that would be assessed in implementing a new policy, the cited risk assessment model did not make reference to how the amount of time spent in storage under excessive temperatures would affect the safety of the eggs. To reach management decision for this recommendation, FSIS needs to provide us documentation on its plan to amend its policy on shell egg safety to include a time component. In addition, if FSIS determines under its new policy that the 45-degree F temperature limit currently incorporated into the EPIA should be amended, officials also need to provide us their plan for implementing this.

Finding 4: FSIS Did Not Sufficiently Enforce Its Shell Egg Refrigeration Policy to Deter Repeat Violators

FSIS did not initiate progressively stronger enforcement actions, such as product seizures or civil penalties, although shell egg companies and distributors were found to have repeatedly violated the EPIA's 45 degrees F temperature limit when storing shell eggs. Although scientific studies show that SE can grow inside shell eggs when they are stored above this temperature, FSIS officials did not fully enforce their authority under the EPIA because they considered the risk of shell egg contamination to be low and they were concerned over possible litigation in trying to

enforce the requirement.[67,68] As a result of FSIS' lenient enforcement policy, almost 35 percent (213 of 612) of shell egg companies nationwide repeatedly stored shell eggs at temperatures that would not inhibit the growth of SE. FSIS' enforcement policy, as implemented, did not deter serious violations by one company that was later found to be responsible for the August 2010 recall.

The EPIA[69] requires that shell eggs destined for the ultimate consumer be refrigerated at 45 degrees F during storage and transportation to inhibit the growth of SE in adulterated shell eggs.[70] FSIS is responsible for enforcing the EPIA, which grants USDA the authority to seize shell eggs and issue civil penalties when shell eggs are found in violation of the EPIA. Although FSIS' directive listed the range of actions that can be taken, including issuing civil or criminal penalties, it did not contain guidance on the conditions necessary for its investigators to take those actions.[71] We found that FSIS issued warning letters, but never pursued progressively stronger actions against a shell egg company or distributor for violating the temperature requirement**.** Since FSIS did not implement adequate enforcement actions, it had little effect in deterring over 200 companies (i.e., producers or distributors) from their repeated failures to comply with the EPIA temperature requirements**.**

Shell Egg Distributors

We found that the strongest enforcement action FSIS ever initiated against a shell egg distributor were the issuance of warning letters, even when inspectors found that shell eggs were being stored at temperatures in excess of 80 degrees F. Although the number of instances documented for distributors that violated EPIA temperature requirements (44 instances among 1,788 distributors) was much lower than those found at shell egg companies (see Shell Egg Companies section below), we found that FSIS issued only warning letters for both.[72] This occurred even when FSIS identified a distributor that flagrantly violated the ambient storage temperature requirement**.**

For example, in June 2010, we participated in a surveillance review with an FSIS investigator at a shell egg distributor. During that review, we observed a pallet of over 10,000 shell eggs sitting in a warehouse area with an ambient temperature of approximately 83 degrees F.[73] Based on

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[67] *FSIS, USDA, Salmonella Enteritidis Risk Assessment: Shell Eggs and Products*, dated June 12, 1998, and *The Salmonella enterica Serovar Enteritidis Pilot Project, Chapter 32 in Salmonella enterica Serovar Enteritidis in Humans and Animals Epidemiology, Pathogenesis, and Control*, A. M. Saeed, 1999.
[68] *Egg Products Inspection Act*, Title 21, Chapter 15, December 1970, as amended**.**
[69] The EPIA, as amended, grants USDA the authority to enforce the refrigeration and labeling requirements for shell eggs at storage locations and transport vehicles.
[70] According to a FSIS scientific study, SE is present in 1 out of 20,000 shell eggs. In addition, according to FDA, the risk of SE being present in shell eggs increases to 1 out of every 3,600 shell eggs when the eggs are laid in a barn environment that tested positive for SE.
[71] FSIS Directive 8840-1, dated June 18, 1999.
[72] The review period for FSIS distributors was October 1, 2008 through July 31, 2011. Due to the low number of instances we did not expand our sample.
[73] OIG Audit Report 24601-0008-At, *Food Safety and Inspection Service In-Commerce Surveillance Program*, dated September 30, 2011. FSIS investigator documented that the violation found during our review included 1 pallet of 59 cases of shell eggs (with a standard of 30 cartons per case), which we calculated (59 x 15 x 12) to be a total of 10,620 shell eggs.

FSIS' stated policy, we considered this a flagrant violation of FSIS' temperature policy, particularly since a company official informed us that these shell eggs had been left unrefrigerated for approximately 5 hours. Although the FSIS investigator agreed and planned to seize and subsequently destroy the eggs, he was directed by his supervisor to release them. FSIS officials stated that they had to release the pallet of shell eggs because before FSIS could seize and destroy the product, they first had to determine that the eggs were adulterated. Since FSIS did not have a process to determine if the shell eggs were adulterated, the FSIS investigator was ordered by his supervisor to release the shell eggs in commerce and then issued the company a warning letter. However, as we discussed in Finding 3, we believe that FSIS can take actions against shell egg companies regardless of whether they determined the shell eggs to be adulterated.

Shell Egg Companies

Our analysis of FSIS' storage temperature data from October 1, 2005, through June 30, 2011, disclosed that 213 of the 612 (nearly 35 percent) shell egg companies nationwide had 854 storage temperature violations that involved storing shell eggs in excess of 45 degrees F. We determined that 20 of those 213 companies stored eggs in excess of 60 degrees F on numerous occasions. Our analysis also disclosed that 30 of the 854 instances showed that the number of coolers that a shell egg company maintained varied between quarterly visits. When we questioned AMS surveillance inspectors about this, they stated that when they found shell eggs in dry storage or in a hallway they would identify the location by assigning a fictitious cooler number and record the ambient temperature at that location. If on subsequent visits, the company did not store shell eggs in the hallway, then they would not list that cooler number again. Instead of documenting this as a serious shell egg storage issue or trying to find out how long the shell eggs were left unrefrigerated, those inspectors stated that when they did find shell eggs stored in a hallway, they would request that the company move the shell eggs back into an actual cooler**.**

We found that FSIS did not take adequate enforcement actions against shell egg companies that repeatedly violated the shell egg temperature requirement. As with the case with shell egg distributors noted above, FSIS' enforcement actions against shell egg companies were limited to the issuance of multiple warning letters. FSIS' enforcement actions were always the same, regardless of how many times a company violated the temperature requirement, or at what temperature shell eggs were stored.

For example, one company violated the ambient storage temperature requirement on 10 separate occasions, over 5 years, by storing over 3.5 million shell eggs in temperatures ranging from 50 to 86 degrees F. FSIS' response to this company was to issue three warning letters; FSIS never initiated actions to seek civil penalties or seize the affected eggs. As stated in Finding 3, both temperature, and time are major factors influencing the growth of SE, and scientific studies have shown that the risk of SE in shell eggs increases significantly as storage time and temperatures increase**.**

FSIS issues a warning letter to a shell egg company or distributor that violated the temperature requirement by 5 to 15 degrees F in 3 out of 5 quarterly visits (3 violations over a 15-month

timeframe).[74] However, after FSIS issues a warning letter the timeframe is reset to start over again, as if no violations had ever occurred. Therefore, a company or distributor can maintain shell eggs over 45 degrees F in 3 out of 5 quarterly visits, get a warning letter, then continue to violate the EPIA temperature requirement until FSIS issues another warning letter, up to 15 months later. Our analysis disclosed that 9 shell egg companies, from October 1, 2005, through June 30, 2011, received a warning letter, but then were cited in subsequent quarterly visits for continuing to violate the temperature requirement. Since FSIS did not take progressively stronger enforcement actions against these companies, they were not deterred from continually violating the EPIA temperature requirement over several years. In our opinion, FSIS actions do not encourage safe food handling or storage.

In discussions with FSIS officials, they stated that they could take enforcement actions stronger than a warning letter, but decided not to until they first proved that the shell eggs were contaminated with SE or otherwise adulterated. However, the language contained in the EPIA does not require such proof. The EPIA states that "any eggs…in violation…shall be liable to be proceeded against and seized and condemned, at any time."[75] In consultation with OIG's Office of Counsel, we determined that the EPIA grants FSIS the authority to take whatever action is necessary in order to protect the health and welfare of consumers by assuring that shell eggs are fit for human consumption. FSIS officials agreed that EPIA does grant them the authority to enforce the Act's provisions (i.e., shell eggs stored at 45 degrees F or less), to include seeking criminal and/or civil penalties against violators. FSIS officials agreed that they could issue civil penalties, but they had not established the specific conditions needed to issue those penalties. They also stated that they have not issued civil penalties against shell egg companies that were repetitive or severe violators of the shell egg storage temperature requirements out of concern for the legal costs involved, similar to those incurred when issuing civil penalties against other food processors (i.e., beef processors).[76] While we acknowledge FSIS' concerns, we believe that this reinforces the need to establish specific conditions necessary to issue civil penalties against shell egg companies and distributors**.**

We concluded that, although FSIS has both the authority and responsibility for enforcing the EPIA temperature requirements intended to ensure shell egg safety, the agency has not implemented an adequate enforcement policy or procedures to ensure that shell egg companies and distributors comply with those standards. FSIS needs to develop procedures to strengthen its enforcement actions, such as issuing civil penalties, against shell egg companies and distributors that violate the EPIA temperature requirement. FSIS also needs to develop procedures to provide for progressively stronger enforcement, up to and including criminal penalties, against shell companies and distributors to deter repeat violators and further enhance the safety of shell eggs.

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[74] If a shell egg company violates the temperature requirement by more than 15 degrees F (i.e., over 60 degrees F), FSIS issues an immediate warning letter.

[75] EPIA, Title 21, Chapter 15, Section 1049 (a), December 1970, as amended.

[76] When FSIS issued civil penalties to other food processors (i.e., slaughtering or processing of other animals such as cattle or pigs) the processors filed a lawsuit to prevent FSIS from collecting those penalties, which cost the agency time and resources to defend. For example, FSIS had a lengthy legal dispute with beef processors in issuing civil penalties concerning *E. coli* in ground beef, but eventually prevailed and was successful at issuing and collecting those penalties.

Recommendation to the Food Safety and Inspection Service

Recommendation 10

Develop and implement an enforcement policy that applies agency, criminal, and administrative authorities, including use of product detention and civil penalties, to appropriately address violations involving shell eggs that present a risk to consumers.

Agency Response

In their response dated October 29, 2012, FSIS officials agreed to complete a risk-based assessment of temperature and other factors that affect the safety of shell eggs packed for the ultimate consumer. Based on the results of this risk assessment and economic analysis, FSIS agreed to revise and update its Directives to include instructions related to the use of detentions, civil penalties, criminal sanctions, or other enforcement authorities for temperature and labeling violations involving consumer-packed shell eggs; the instructions would also add shell egg violations to the list of violation types that are to be referred to the Agency's Evaluation and Enforcement Division for enforcement action. In addition, FSIS will train its personnel responsible for implementing and enforcing the shell egg refrigeration policies, on policy updates. FSIS will reissue the directives and train appropriate personnel by December 2013.

OIG Position

Because FSIS' response makes the agency's new enforcement policies contingent upon the results of its economic analysis and risk assessment (see Recommendation 9), we cannot reach management decision at this time. In order to achieve management decision for this recommendation, FSIS needs to provide us with an updated response once a determination is made as to whether the existing enforcement policies will be strengthened as outlined in our recommendation.

Scope and Methodology

Our audit reviewed USDA's controls in place during fiscal years 2010 and 2011 and the Department's preceding actions and decisions made since the publication of the 1999 Egg Safety Action Plan. We performed our audit at USDA's FSIS and AMS Headquarters in Washington, D.C. We also interviewed APHIS officials at their Headquarters, located in Riverdale, Maryland; NVSL scientists, located in Ames, Iowa; and the director of the agency's National Poultry Improvement Program, located in Conyers, Georgia.

We visited shell egg packing companies operating under AMS' Poultry and Grading Programs in Ohio and Iowa, and interviewed AMS officials at companies located in Iowa, Missouri, Maryland, New Jersey and South Carolina. We visited FSIS egg product processing companies located in Iowa, Nebraska and Wisconsin. We also verbally contacted FSIS egg product processing companies in Iowa, Minnesota and New York. We performed our fieldwork from November 2010 through April 2012.

We judgmentally selected both shell egg packing and egg product processing companies to visit. We judgmentally selected 12 shell egg packing companies monitored by AMS grading officials, 6 of which were selected due to reports of potential environmental SE-positive test results. We went to another six that were involved in the August 2010 and November 2010 nationwide shell egg recalls. AMS reported a total of 612 shell egg packing companies, 198 of which contracted with AMS for voluntary shell egg grading services under AMS' Egg Grading Program. We also visited one shell egg packing operation in Ohio that did not contract for the USDA grade mark for quality, but was part of AMS' Shell Egg Surveillance Inspection Program. We also performed site visits at 4 of the 87 egg product processing companies nationwide, as reported by FSIS, and interviewed FSIS officials at another 3 companies. We selected two of the seven egg product processing companies because they provided egg products to the National School Lunch Program—products that were from shell eggs that were diverted from the company that was responsible for the August 2010 recall. All the egg product processing companies involved in our sample were primarily selected because they were involved in one of the two nationwide shell egg recalls that occurred in August and November 2010.

We performed limited testing of controls of the information technology (IT) systems used by USDA agencies in their monitoring of shell eggs and poultry. We also encountered a scope limitation at the shell egg company responsible for the August 2010 recall, since we were unable to review or analyze its records because FDA officials removed all documents from that location on the date of our planned field visit. We did not question FDA officials about this, since our audit did not include a review of FDA's processes or controls in ensuring the safety of shell eggs. However, we did discuss our issues found during our audit of USDA's oversight of shell egg safety with FDA officials in February 2011 and again in April 2012. For the IT systems used by the three USDA agencies, we applied general and application control steps and did not disclose any material issues. However, we neither relied on nor performed substantive testing to evaluate those IT systems and make no representation on the adequacy of the agencies' IT systems or reports.

To accomplish our audit objectives we:

- Reviewed related acts, laws, regulations, procedures, and memoranda pertaining to the internal controls and processes to detect and report the presence of *Salmonella* or other contaminants in shell eggs.

- Analyzed, in consultation with OIG's Office of Counsel, the EPIA to determine USDA's authority and responsibility for shell egg safety.

- Requested FSIS to obtain OGC's legal opinion on USDA's authority for shell eggs at a shell egg company's egg-laying barn under the EPIA.

- Reviewed OGC's legal opinion on USDA's authority for shell eggs.

- Interviewed AMS and FSIS officials responsible for shell eggs and egg product quality and safety.

- Interviewed APHIS officials responsible for the National Poultry Improvement Program and the agency's NVSL scientists that test samples of *Salmonella* to determine the presence of SE.

- Discussed our audit findings with FDA officials to obtain their comments and perspective.

- Evaluated the effectiveness of USDA agencies' coordination of shell egg safety efforts within USDA and with FDA.

- Analyzed AMS' shell egg storage temperature data from October 2005 through June 2011.

- Analyzed APHIS SE serotyping test results from March 2010 through September 2011.

- Performed field visits at egg processing companies, monitored by FSIS officials, to determine their control procedures for the segregation, processing, and sampling of egg products manufactured from shell eggs potentially contaminated with SE.

- Performed field visits to review records and observe sanitary conditions at the shell egg packing companies, related warehouses, and refrigerated storage areas monitored by AMS officials.

We conducted this 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 the audit objectives.

Abbreviations

AMS.....Agricultural Marketing Service
APHIS.....Animal and Plant Health Inspection Service
CDC .....Center for Disease Control and Prevention
EPIA.....Egg Products Inspection Act
F .....Fahrenheit
FDA.....Food and Drug Administration
FFDCA.....Federal Food Drug and Cosmetic Act
FSIS.....Food Safety and Inspection Service
HHS.....Department of Health and Human Services
IT.....Information Technology
MOU .....Memorandum of Understanding
NVSL .....National Veterinary Services Laboratory
OGC .....Office of the General Counsel
OIG .....Office of Inspector General
PHSA .....Public Health Service Act
SE.....*Salmonella enteritidis*
UEP .....United Egg Producers
U.S. .....United States
USDA.....Department of Agriculture

USDA'S
AGRICULTURAL MARKETING SERVICE
AND
FOOD SAFETY AND INSPECTION SERVICE
RESPONSES TO AUDIT REPORT

USDA Agricultural Marketing Service

Office of the
Deputy Administrator
Livestock, Poultry and
Seed Program

1400 Independence Avenue, SW.
Room 2092-S, STOP 0249
Washington, DC 20250-0249

DATE: October 31, 2012

TO: Gil Hardin
Assistant Inspector General for Audit
Office of the Inspector General

THROUGH: David R. Shipman /s/
Administrator
Agricultural Marketing Service

FROM: Craig A. Morris /s/
Deputy Administrator
Livestock, Poultry and Seed Program

SUBJECT: Agriculture Marketing Service (AMS) Corrective Actions – Office of Inspector General (OIG) Audit Report, U.S. Department of Agriculture (USDA) Controls Over Shell Egg Inspection (50601-0001-23)

Listed below are the proposed AMS corrective actions to the OIG recommendations identified in the subject audit report.

Recommendation number 4 – Issue a notice to all shell egg producers under contract with AMS for grading services that requires them to immediately notify AMS grading officials when they have indications of adulterated shell eggs at their facility.

Agency Response

AMS requires that egg producers/processors immediately notify the USDA grader assigned to the packing plant when an environmental sample from a layer flock has been confirmed positive for the presence of *Salmonella enteritidis* (SE) and whether the company plans to test the eggs from the identified layer flock or divert the eggs to treatment for the remainder of the life of the flock, as required by Food and Drug Administration (FDA) regulations. If plant management elects to test the eggs, plant management must provide the grader the date the egg samples are collected for submission to the laboratory for analysis. Any eggs packaged in containers identified with the USDA grade shield from the date the egg samples are taken until egg test results have been received must be placed on hold by the company, using established acceptable documented inventory controls, indicating the identity and segregation of such product. All records for products placed on hold by the company pending analysis of the egg samples will be accessible to the USDA grader.

Completion Date
In our February 25, 2012, response to the OIG Fast Report, AMS issued policy and guidance implementing reporting procedures that plant management in shell egg processing facilities operating under the Regulations Governing the Voluntary Grading of Shell Eggs must follow.

Recommendation number 5 – Develop an addendum for all new contracts with shell egg producers to require production management to immediately notify AMS officials when they become aware of an environmental positive test for SE or other contaminants.

Agency Response
In the response, dated February 25, 2011, to the Fast Report, AMS stated that wording would be added to the "Certification" section of the Application for Service, Form PY-32, which will require plant management at official plants to notify the USDA grader and provide detailed information pertaining to any contaminated or adulterated shell eggs produced or received for processing, including the identification and segregation of such product. While awaiting the necessary clearances to modify Form PY-32, as stated, an interim form was used. Management at all Resident, Temporary, and Fee shell egg grading locations were required to sign the "Wholesomeness Certification" document. This certification from an egg processor will continue to be used beyond the approval of the modification of the PY-32 for fee grading locations.

Completion Date
AMS completed this task on March 14, 2012, with the distribution of the policy and guidance that implemented reporting procedures at shell egg processing plants.

Recommendation number 6 – Amend current procedures to require all AMS shell egg graders to identify the locations(s) where adulterated shell eggs were shipped and to take appropriate action to ensure that product does not receive the official USDA grade mark.

Agency Response
AMS has instituted policies and procedures to monitor the control of eggs identified by plant management as adulterated or originating from a layer house with an environment determined positive for the presence of SE... Additionally, AMS is revising the entire Shell Egg Graders Handbook to incorporate the new policies and procedures.

Completion Date
The Shell Egg Graders Handbook has been revised in its entirety and includes policies and procedures for monitoring and control of eggs identified by plant management as adulterated or originating from a layer house with an environment determined positive for the presence of SE. The duplication process for the Handbook is currently under bid and we anticipate the final product will be distributed to our field graders by December 31, 2012.

Recommendation number 7 – Clarify the regulatory definition of "condition" for shell eggs to clearly state whether it relates to quality, safety, or both.

Agency Response
AMS will develop a revised definition of "condition" as it applies to shell eggs. The revision will include additional clarity to plainly state the intent desired. Wholesomeness of eggs will continue to be based on the existing FDA and Food Safety and Inspection Service (FSIS) regulations.

AMS proposes to postpone the regulatory change to the definition of "condition" until FSIS determines whether regulatory language is required defining sanitary procedures for the processing of shell eggs. If FSIS determines that the current sanitary processing procedures stated in AMS Regulations Governing the Voluntary Grading of Shell Eggs (7 CFR 56) must be modified, AMS would make the modifications to the sanitary processing procedures and revise the definition of "condition." This would result in synchronization of any required regulatory changes.

Completion Date
FSIS states that they will complete an evaluation of sanitation surveys by May 2013, and, if needed, collect data on the current level of sanitation issues by November 2013. Based on the findings of these data collection efforts, appropriate revisions to the Regulations will be proposed.

Recommendation 8 – Work with FDA officials to ensure AMS is notified whenever FDA is aware of whether shell eggs or the barn environment tested positive for SE, and implement procedures to prevent AMS graders from placing the USDA grademark on those shell eggs.

Agency Response
AMS believes this recommendation has been accomplished. The existing Memorandum of Understanding between FDA and AMS, dated March 4, 2011, requires the sharing of information including immediate notification of any positive findings of pathogens of human health significance in product to cause adulteration or contamination. This information is shared through the web-based Inter-agency Referral Report system. Additionally, as indicated in Recommendation 5, the revised AMS notification policies and procedures address the concerns identified.

Completion Date
The use of the Interagency Referral Report was instituted upon issuing the policy in September 2011.

AMS:LSP:ODA:BPluebell/wpp:10/31/12:720-5705:,10/31/12

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

TO: Gil Harden
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Office of Inspector General

FROM: Alfred V. Almanza / s / October 29, 2012
Administrator
Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – USDA Controls Over Shell Egg Inspections, Report Number 50601-1-23

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

Responses to Recommendations

Recommendation 1
Develop a plan to build upon the existing coordination of regulation and oversight of shell eggs between FDA and USDA agencies, with FSIS being the lead agency to ensure a seamless farm- to-table approach to shell egg safety.

Agency Response
FSIS will identify and review all existing coordination efforts between USDA and FDA, including Memoranda of Understanding, and determine if they need to be revised and enhanced. If FSIS determines that additional coordination efforts between USDA and FDA are needed regarding the regulation and oversight of shell eggs, FSIS will build upon the existing public health framework and coordination efforts currently in place. FSIS will collaborate within USDA and with FDA to implement workable procedures that can be accomplished within FSIS's existing statutory authority and available resources.

Completion Date
FSIS will complete the review of all existing coordination efforts and propose a plan of action, if needed, by June 2013.

Recommendation 2
Implement a plan to coordinate and share crucial information related to shell egg safety within USDA and with FDA.

Agency Response
FSIS will identify and review all existing coordination efforts between USDA and FDA, including Memoranda of Understanding, and determine if they need to be revised and enhanced. If FSIS determines that additional coordination efforts between USDA and FDA are needed regarding the regulation and oversight of shell eggs, FSIS will build upon the existing public health framework and coordination efforts currently in place. FSIS will collaborate within USDA and

with FDA to implement workable procedures that can be accomplished within FSIS's existing statutory authority and available resources.

Completion Date
FSIS will implement its responsibilities under the plan of action by November 2013.

Recommendation 3
Implement a process to collect data on the current level of sanitation issues at shell egg packing companies nationwide. Based on the analysis of this information, initiate corrective actions, as appropriate, to ensure shell egg companies protect consumers by processing shell eggs in sanitary conditions.

Agency Response
FSIS proposes to evaluate and analyze two already completed surveys that examine sanitation and existing food safety practices in shell egg packing plants. FSIS will also evaluate and analyze the *Final Report and Quarterly Summaries on FDA Inspections Under the Egg Safety Rule*, dated July 2012. Based on the findings of these analyses, if needed, FSIS, in collaboration with AMS, will develop a data collection tool/method to evaluate sanitation in a sample of shell egg producer/packers with 3,000 or more layers. The data collection will be conducted by trained individuals. Results of this data collection will then determine actions, if needed.

Completion Dates
FSIS will complete the evaluation of the surveys by May 2013. FSIS will collect data on the current level of sanitation issues, if needed, by November 2013.

Recommendation 9
Develop and implement a science-based shell egg temperature policy that assesses and considers risks associated with time, temperature, or other factors that affect the safety of shell eggs and implement appropriate corrective actions.

Agency Response
FSIS will assess the effect of temperature deviations, time, or other factors that affect the safety of shell eggs packed for the ultimate consumer, along with the respective cost of corrective action. FSIS will use a previously developed risk assessment model that is able to determine the effect of different storage conditions (see: website: http://www.fsis.usda.gov/PDF/SE_Risk_Assess_Oct2005.pdf). This risk assessment was extensively peer and publicly reviewed and considered the temperature in the current policy. Specifically, the risk assessment considered the effect of different ambient temperatures on the growth of *Salmonella* Enteritidis in internally contaminated shell eggs. Based on this risk assessment and cost analysis, FSIS will determine whether changes to FSIS' shell egg temperature policy and procedures are appropriate and necessary (see Recommendation #10). This approach will allow a basis for policy and procedures that are cost-effective and improve public health.

Completion Dates
FSIS will complete the risk assessment by April 2013 and revise directives by December 2013.

Recommendation 10
Develop and implement an enforcement policy that applies agency, criminal, and administrative authorities, including use of product detention and civil penalties, to appropriately address violations involving shell eggs that present a risk to consumers.

Agency Response

In order for FSIS to address most appropriately violations involving shell eggs based on consumer risk, FSIS will complete a risk-based assessment of temperature and other factors that affect the safety of shell eggs packed for the ultimate consumer (see Recommendation #9). The risk assessment and economic analysis findings will inform any changes to FSIS policies to appropriately address shell egg violations that pose a risk to consumers. FSIS will:

- Revise FSIS Directive 8840.1, Enforcement of Refrigeration and Labeling Requirements for Shell Eggs Packed for Consumer Use. The revised Directive will include instructions related to the use of detentions, civil penalties, criminal sanctions, or other enforcement authorities for temperature and labeling violations involving consumer-packed shell eggs.

- Update FSIS Directive 8010.5, Case Referral and Disposition, to add shell egg violations to the list of violation types that are to be referred to the Agency's Evaluation and Enforcement Division for enforcement action.

- Train its personnel responsible for implementing and enforcing the shell egg refrigeration policies, on policy updates.

Completion Date

FSIS will reissue the directives and train appropriate personnel by December 2013.

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