



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



DATE: February 16, 2011

AUDIT
NUMBER: 50601-1-23 (1)

TO: Rayne Pegg
Administrator
Agricultural Marketing Service

ATTN: Kevin L. Richardson
Director
Planning and Accountability Division
Compliance and Analysis Program

FROM Gil H. Harden /s/
Assistant Inspector General
for Audit

SUBJECT: Agricultural Marketing Service Needs Stronger Controls to Ensure the
Wholesomeness of Shell Eggs Bearing USDA's Grademark - USDA Controls
Over Shell Egg Inspections

We initiated the subject audit due to the August 2010 nationwide recall of over 500 million shell eggs adulterated with *Salmonella Enteritidis* (SE),¹ which are believed to have led to the illness of more than 1,000 people. On November 5, 2010, the Food and Drug Administration (FDA) posted another recall for SE, this one covering 288,000 shell eggs from a single producer in Ohio. The Ohio producer, like other similar shell egg producers, contracted with the Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) for shell egg grading services. AMS graders certify that shell eggs meet certain quality standards, and eggs that meet those standards receive an official USDA grademark (e.g., Grade A). AMS is not permitted to put the grademark on any shell eggs that are not fit for human consumption,² including shell eggs adulterated³ with SE.

Our ongoing audit identified a condition that warrants immediate action by your office. AMS officials informed us that over 270,000 of the 288,000 shell eggs included in the November 5, 2010, recall were granted the official USDA grademark. The AMS grader who placed the grademark on these shell eggs was unaware that the Ohio producer recently had an environmental positive test result for SE at one of its egg laying barns, since neither plant

¹ According to the Center for Disease Control and Prevention, persons infected with *Salmonella* develop diarrhea, fever, and abdominal cramps. Most persons recover without treatment, while others may need to be hospitalized.

² Section 13, Subpart III, AMS *Egg-Graders Handbook*, dated February, 2002.

³ AMS defines adulterated as any egg that contains [any] substance which may render it injurious to health.

management nor FDA officials notified AMS that SE had been detected. As a result, shell eggs containing the official USDA grademark were shipped in commerce, even though the shell eggs were considered adulterated with SE. This issue, along with any others identified, will be compiled into a final report at the conclusion of our audit.

According to the Egg Products Inspection Act,⁴ both USDA and FDA are responsible for ensuring the wholesomeness of shell eggs and egg products. In practice, FDA is responsible for the egg laying barns, while USDA and FDA share responsibility for the products that come from those barns. AMS provides grading services to producers through contractual agreements,⁵ but those agreements do not provide AMS the authority to enter an egg laying barn. AMS graders at a shell egg packing area, certify that shell eggs meet certain quality standards; eggs that meet the required quality standards receive an official USDA grademark. AMS officials stated that the grademark only attests to the quality of shell eggs, but their graders are prohibited from grading shell eggs that are adulterated with pathogens or are otherwise unfit for human consumption.⁶

On November 5, 2010, FDA posted on its website a recall of shell eggs from a producer in Ohio that was receiving grading services from AMS. FDA posted the recall because an environmental sample at a producer's egg laying barn tested positive for SE in early October 2010. However, AMS graders were unaware of this positive test result until after the producer had depopulated the barn of the hens and started disinfecting the affected barn. On October 8, 2010, AMS graders noticed that shell eggs started arriving at the grading area with pink dye on them.⁷ Plant employees told the AMS grader that some of the disinfectant (pink in color) used to clean an egg laying barn was accidentally transferred onto the egg conveyor belts. This resulted in eggs from other laying barns being stained with the pink dye, including barns that may not have been SE-infected. AMS officials stated they diverted⁸ the eggs with pink dye on them because they did not meet their quality standards, not because the shell eggs were adulterated with SE.

We noted that there was no requirement under AMS' contractual agreement with shell egg producers and packers that AMS be notified when producers become aware of an environmental positive for SE or other pathogens that render eggs unfit for human consumption. In addition, we learned that FDA does not require plant management to report SE positive test results to either FDA or AMS, as long as management takes appropriate action. According to an AMS official, the Ohio producer only confirmed that the pink dyed eggs came from the disinfectant used to clean the egg laying barn, and did not inform AMS personnel of the SE environmental positive test result.

⁴ Egg Products Inspection Act, 21 U.S.C. 1031-1056, dated December 1970, as amended.

⁵ AMS enters into agreements with both shell egg producers and packing establishments. Packing establishments may not be co-located with egg laying barns and may purchase eggs from several producers for packing and distributing the eggs for retail.

⁶ AMS is prohibited from grading an "adulterated" egg, such as those adulterated with SE.

⁷ AMS officials stated that this was the first time they saw shell eggs with pink dye on them and prompted the AMS grader to ask plant employees about it.

⁸ In this instance, the shell eggs were discarded as inedible.

AMS officials stated that FDA is required, under a 1975 Memorandum of Understanding (MOU),⁹ to immediately notify AMS when egg laying barns test positive for SE.¹⁰ In this case, however, AMS officials stated that they did not hear about the recall of shell eggs for being affected with SE from FDA officials at all, but only learned of the recall from an internet news article on November 7, 2010.¹¹ AMS officials also stated that, more than one month after the recall was issued, FDA officials still had not contacted them about the recall. In a conversation we had with FDA officials in January 2011, they stated that they contacted USDA officials about the recall. However, FDA officials did not provide evidence of whom they contacted. We did find that a Food Safety and Inspection Service official did receive an email from FDA, but it was several days after the recall was made public.

We discussed the events leading up to the recall with the AMS supervisor responsible for grading services at the Ohio producer's plant. The AMS supervisor informed us that he did not further investigate whether the Ohio producer had an environmental positive test for SE because there was no evidence that shell eggs from the affected barn were ever presented to AMS for grading. He also said they diverted the shell eggs with the pink dye because they did not meet AMS quality standards, and not because they were possibly adulterated with SE. When we asked how he thought adulterated graded shell eggs ended up in the November 2010 recall, he stated that ungraded adulterated shell eggs were mistakenly shipped from the Ohio producer to Arkansas, where they were graded by another AMS grader. The Ohio producer had diverted the shell eggs to a nearby plant for processing, but before the shell eggs were processed, they were mistakenly shipped to a packing establishment in Arkansas where they were graded by an AMS official.

An AMS national official stated that, based on the plant numbers and document review, over 270,000 of the 288,000 shell eggs were graded at a packing plant in Arkansas. We confirmed that the plant numbers did reflect another AMS grading location in Arkansas. We also confirmed that the shell eggs involved in that recall received the official USDA grademark in early October, at least two weeks before FDA posted the recall. An AMS national official stated that without official confirmation (notification) from the producer's management staff that one of their barns had an SE positive test result, there was no reason to implement established procedures to identify and monitor shell eggs that came from those barns.

Our review of AMS' procedures for adulterated shell eggs disclosed that they do require their graders to retain affected shell eggs to prevent their movement into commerce. However, as the events of this current recall demonstrated, adulterated shell eggs were already shipped to another facility for grading. Therefore, the grader in Ohio had no product to retain and the grader in Arkansas was unaware of the adulterated shell eggs being delivered and presented for grading.

⁹ This MOU is currently in effect.

¹⁰ They based this on the MOU provision that states "FDA will immediately notify the appropriate AMS field office concerning the details of objectionable conditions whenever such conditions are found to exist at processing or packing plants where AMS is currently conducting inspections of products, or in other food plants, when FDA believes such information would be of value to AMS in its inspection and grading activities."

¹¹ AMS officials do not routinely contact FDA or the agency's website to check for the latest recall information.

We believe that AMS should amend its current procedures to ensure that graders identify the location(s) to which adulterated product was shipped and require AMS shell egg graders at those locations to take appropriate action to ensure that adulterated shell eggs do not receive the official USDA grademark.

We concluded that unless AMS requires shell egg producers to immediately notify AMS of environmental positive pathogen test results, or other conditions that may render shell eggs unfit for human consumption, there is no assurance that in the future AMS graders would not unknowingly place the official USDA grademark on adulterated shell eggs. Although AMS is not directly involved with the prevention of egg adulteration, it can improve its controls when production management has evidence that shell eggs may be adulterated. We continue to assess USDA's controls over shell eggs, but believe that AMS officials need to take immediate action to improve their detection and communication efforts to prevent placing an official USDA grademark on adulterated shell eggs.

We discussed our conclusions regarding this weakness in detail with AMS national officials on November 30, 2010. They generally agreed with our conclusions and agreed to implement our corrective actions. During the meeting, we recommended several measures that would mitigate this internal control weakness. The recommendations included:

- 1) Issue an immediate 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.
- 2) 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.
- 3) 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 grademark.

We acknowledge that FDA implemented a new rule for the safety of shell eggs in July 2010, with full implementation planned for July 2012. In that rule, producers are required to perform routine environmental tests for SE of their egg laying barns. However, FDA's rule does not require producers to notify either FDA or AMS of environmental positives. These recommendations were designed to ensure AMS officials have the information they need to decide whether they can grade the shell eggs that a producer presents for grading.

Our audit work continues. Please provide a written response within 5 days outlining your proposed corrective action for this issue. If you have any questions, please contact me at (202) 720-6945, or have a member of your staff contact Theresa Bulla, Director, Food and Marketing Division, at (202) 720-5907.

USDA'S

AGRICULTURAL MARKETING SERVICE

RESPONSE TO AUDIT REPORT



1400 Independence Avenue, SW.
Room 3071-S, STOP 0201
Washington, D.C. 20250-0201

DATE: February 25, 2011

TO: Gil H. Harden
Assistant Inspector General for Audits

FROM: Rayne Pegg /s/
Administrator

SUBJECT: Agricultural Marketing Service Controls of Shell Eggs Bearing USDA's
Grademark

We have completed our review of the Office of Inspector General (OIG) audit report number 50601-1-23 (1), dated February 16, 2011. The audit report addresses existing controls that the Agricultural Marketing Service (AMS) has over shell eggs processed, packed, and identified with the official USDA grade shield and suggests that additional controls are needed to ensure the wholesomeness of USDA grade identified eggs.

Ensuring food safety continues to be one of our primary goals. It has been long standing AMS policy that we will not grade or certify product unless it has been deemed safe and wholesome by the applicable regulatory agency. AMS has existing controls in place to address shell egg adulteration and contamination issues and, upon notification by the responsible regulatory agency, these controls are activated. Over the last several years, we have documented instances where these controls have been successfully activated.

Nevertheless, AMS agrees that under certain circumstances, additional controls may be warranted for shell eggs graded, packed, and officially identified with the USDA grade shield. In developing new controls, it must be recognized that the regulatory agency for shell egg safety oversight is the Food and Drug Administration (FDA). Accordingly, any proposed changes to AMS policies and procedures must be consistent with the FDA regulations for the Prevention of Salmonella Enteritidis (SE) In Shell Eggs During Production, Storage, and Transport.

It is important to note that the FDA does not classify shell eggs from a flock in a layer house in which the environment has tested positive for the presence of SE as adulterated. Current FDA regulatory requirements state that shell eggs originating from an environmental positive house may be processed and distributed in commerce until the eggs have been tested and confirmed positive for SE. If the eggs subsequently tested from the identified flock are confirmed positive for SE, any recall would include eggs produced since the date of the collection of the egg sample

submitted for analysis. Based upon existing FDA regulatory requirements, AMS believes that any action to detain processed and packed shell eggs that are identified with the USDA shield while awaiting egg test results for the presence of SE, must be consistent with applicable FDA market recall requirements.

To address the concerns identified in the audit report, AMS agrees to develop and implement the following policies and procedures:

1. AMS will revise 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 identity and segregation of such product. All records for product placed on hold by the company pending analysis of the egg samples will be accessible to the USDA grader.
2. AMS will add wording to the “Certification” section of the Application for Service, Form PY-32, which will require plant management in an official plant 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 will be used. Management at all Resident, Temporary, and Fee shell egg grading locations will be required to sign the “Wholesomeness Certification” document (attached). 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.
3. AMS will 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.

We appreciate the opportunity to work with the OIG to address these issues to improve the AMS controls over shell eggs presented for USDA certification. If you have further questions upon review of the above information, please contact me.

Attachment