



U.S. Department of Agriculture



Office of Inspector General
Midwest Region

Audit Report

Egg Products Processing Inspection

Report No. 24601-0008-Ch
August 2007



UNITED STATES DEPARTMENT OF AGRICULTURE
OFFICE OF INSPECTOR GENERAL
Washington, D.C. 20250



DATE: August 23, 2007

REPLY TO
ATTN OF: 24601-0008-Ch

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

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

FROM: Robert W. Young /s/
Assistant Inspector General
for Audit

SUBJECT: Egg Products Processing Inspection

This report presents the results of our audit of egg and egg product inspections as performed by the Food Safety and Inspection Service. Our audit evaluated management controls over egg and egg product inspection activities.

The agency response to the official draft report is included in exhibit B, with excerpts and the Office of Inspector General's position incorporated into the Findings and Recommendations section of the report. Based on the response, we have reached management decision on all of the recommendations. Please follow your agency's internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

Please note that Departmental Regulation 1720-1 requires final action to be completed within 12 months of management decision.

We appreciate the courtesies and cooperation extended to us by your staff.

Executive Summary

Egg Products Processing Inspection

Results in Brief

Since 1995, the Food Safety and Inspection Service (FSIS) has administered the U.S. Department of Agriculture's (USDA) responsibilities under the Egg Products Inspection Act of 1970 (EPIA) which, until that time, had been the responsibility of the Agricultural Marketing Service (AMS). The Act provides for mandatory and continuous inspection of all egg products processing operations, including those that produce liquid, frozen, and dried egg products. Inspectors at the 83 egg products processing plants nationwide inspect facilities, equipment, and processing operations including pasteurization, product formulation, packaging, labeling, drying, and freezing. In addition, processed egg products are subject to laboratory testing for *Salmonella* before being marketed to the public. Under a 1995 memorandum of agreement with FSIS, AMS is responsible for performing quarterly visits to egg handlers who pack unbroken, consumer-ready shelled eggs to verify that regulatory requirements for labeling and storage temperatures are met. AMS is also responsible for reporting violations to FSIS so that followup actions can be taken. FSIS retains direct responsibility for performing such reviews at all other egg handlers. Ultimately, for both shell eggs and processed egg products, the authority and responsibility for initiating recalls rests with the Food and Drug Administration (FDA).

We found that although FSIS has administered the egg products inspection program for approximately 12 years, agency officials have not yet integrated egg products into their overall management control structure including the science-based Hazard Analysis and Critical Control Point (HACCP) program, even though meat and poultry establishments have operated under HACCP since 1998. In addition, the automated Performance Based Inspection System (PBIS), which both schedules tasks and records inspection results for meat and poultry establishments, has not been extended to egg products processing plants and inspectors still utilize paper records which are stored onsite. FSIS increasingly depends upon PBIS and other Information Technology (IT) systems as part of its oversight and control processes for meat and poultry products, but the new management control processes being developed and implemented are largely dependent upon the availability of electronic records to function. FSIS officials have stated that plans for implementing HACCP have been delayed by changing policies regarding the application of the system to egg processing. Officials stated that the draft proposal to extend HACCP to eggs is under development, but until the clearance process is completed they cannot provide timeframes for implementation. Our reviews at six egg processing plants noted concerns such as potential product adulteration and repeated violations involving the use of restricted eggs (specifically, those that are cracked and leaking, or have foreign materials on

the shells) in egg processing operations. Such conditions, which had not come to the attention of the frontline inspectors for those plants because of the time needed to review inspection records stored on paper, could result in unsafe or unwholesome egg products being marketed to the public. This emphasizes the need to extend HACCP and PBIS to egg products inspections so that this area can be incorporated into FSIS' overall management control structure.

Finally, we found that while FSIS had identified deficiencies in 2003 with Canada's controls over egg product processing plants that exported to the United States, no followup visits had been made since then to verify that corrective actions had been implemented. FSIS officials gave greater priority to the review of meat and poultry establishments, since processed egg products were considered to pose less of a health risk than some meat products due to the use of the pasteurization process. In their last visit, FSIS reviewers found that two Canadian egg product processing plants broke and used eggs that were leaking or had foreign material on their shells.

Our audit found that FSIS' *Salmonella* testing program is generally operating as intended, with plants performing their own tests as part of the *Salmonella* Surveillance Program and making those results available to FSIS inspectors onsite. FSIS also satisfactorily performs its own laboratory tests under the Salmonella Monitoring Program, to provide additional assurance that any contaminated products are either disposed of or re-pasteurized. Also, in our visits to six egg products processing plants, we did not note significant sanitation problems or other deficiencies except as described in the findings.

**Recommendations
In Brief**

We recommended that FSIS develop a plan to incorporate egg product inspection activities into HACCP and its IT systems. We also recommended that once this has been accomplished, FSIS officials conduct trend analyses to identify any serious or widespread deficiencies at egg products processing plants and take appropriate corrective actions. Finally, we recommended that FSIS include egg products processing plants in the next Canadian equivalency review, and in future instances when visits are made to Canadian meat and poultry establishments.

Agency Response

In their response, FSIS officials agreed with the findings and recommendations contained in this report. We have incorporated applicable portions of the response, along with our position, in the Findings and Recommendations section of this report. The agency's response is included in its entirety as exhibit B of this report

OIG Position

We agree with the actions the agency has underway in response to our recommendations. We have reached management decision on all three of the recommendations.

Abbreviations Used in This Report

AMS	Agricultural Marketing Services
CDC	Centers for Disease Control
CFIA	Canadian Food Inspection Agency
EPIA	Egg Products Inspection Act of 1970
FSIS	Food Safety and Inspection Service
FY	Fiscal Year
HACCP	Hazard Analysis and Critical Control Point (System)
IPPS	In-Plant Performance System
IT	Information Technology
NR	Noncompliance Report
OIA	Office of International Affairs
OIG	Office of Inspector General
OPEER	Office of Program Evaluation, Enforcement and Review
PBIS	Performance Based Inspection System
SSOP	Sanitation Standard Operation Procedures
TSC	Technical Service Center
USDA	United States Department of Agriculture

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Background and Objectives

Background

Congress passed the Egg Products Inspection Act (EPIA) in 1970. The EPIA provides for the mandatory continuous inspection of the processing of liquid, frozen, and dried egg products. For the next 25 years, the Poultry Division of the United States Department of Agriculture's (USDA) Agricultural Marketing Service (AMS) inspected egg products to ensure they were wholesome, unadulterated, and properly labeled and packaged to protect the health and welfare of consumers. In May 1995, the Secretary transferred to the Food Safety and Inspection Service (FSIS) the responsibility to conduct inspections at egg and egg product plants.

Eggs and egg products are divided into two separate and distinct areas. The first is consumer-ready shell eggs which are unbroken eggs packaged for sale to the public. These are under FSIS oversight only while in the custody of egg packers or handlers, for the purpose of ensuring that they are being refrigerated at the required temperature and are labeled to show that refrigeration is required. At all other times between laying and retail sale, they are under the jurisdiction of the Food and Drug Administration (FDA). As of fiscal year (FY) 2006, there were 513 egg packers nationwide. The second area involves egg products that are processed at commercial egg processing facilities where the egg shell is broken. These products include whole eggs, yolks, or whites, with or without added ingredients and can be in liquid, frozen, or dried form. There are currently 83 egg product processing plants nationwide. To reduce the risk of *Salmonella*, the EPIA requires that egg products must be pasteurized prior to release into commerce. Based on information from FDA, which has sole authority to order recalls of either shell eggs or processed egg products, there have been eight recalls of processed egg products since 2002. These were all initiated by the plants themselves rather than by FDA. No recalls have taken place for raw, consumer-ready shell eggs. The Centers for Disease Control (CDC) researches diseases affecting human health, including food-borne illnesses. In 1999, CDC coordinated with FDA and FSIS to formulate an Egg Safety Action Plan to identify risks to human health stemming from the consumption of eggs and egg products.

One or more FSIS egg product inspectors are assigned to continuously inspect each of the 83 egg product processing plants nationwide. Inspectors are primarily responsible for inspection of all egg product formulation, pasteurization, packaging, labeling, freezing, and drying. To do this, they use sensory and laboratory testing. Egg and egg product inspectors are responsible for inspection of the facilities, equipment, and methods of processing as well as the product itself. Since 1996, FSIS has been working to develop a Hazard Analysis and Critical Control Point (HACCP) program for egg products. FSIS requires each egg product establishment to conduct

laboratory surveillance testing to detect and prevent the presence of *Salmonella* in egg products marketed to the public. FSIS conducts its own laboratory monitoring program to ensure that the surveillance programs are accomplishing their goal.

At the time of the transfer of inspection responsibilities in 1995, FSIS entered into a memorandum of agreement with AMS under which AMS agreed to continue verifying that temperature and labeling requirements were being met by packers of consumer ready shell eggs as a part of the AMS Shell Egg Surveillance Program. According to an AMS official, there were 513 shell egg packers nationwide in FY 2006. FSIS retains direct responsibility for monitoring compliance with temperature and labeling requirements at egg handlers who are not also packers.

In addition to domestic inspections, any egg products imported into the United States are required to have been inspected under a USDA-approved system. FSIS' Office of International Affairs (OIA) is required to verify that the approved system remains equivalent to USDA standards. Canada is the only country with an approved egg product inspection system, exporting over 16 million pounds of processed egg products to the U.S. in fiscal years 2005 and 2006.

Objectives

Our objective was to evaluate FSIS' monitoring and inspection of egg and egg product processing plants. Specifically, we reviewed the agency's controls designed to ensure that eggs and/or egg products are wholesome, unadulterated, processed under sanitary conditions, stored safely, correctly packaged and properly labeled.

Findings and Recommendations

Section 1. Egg Products Inspection Systems and Procedures Need Updating

Finding 1

FSIS Needs To Develop Electronic Monitoring Systems for Egg Products Inspections

FSIS has not integrated egg product inspections into HACCP or PBIS, even though these systems have been used in meat and poultry inspections for several years. FSIS officials have stated that although they intend to implement these in the future, PBIS will not be extended to egg products until HACCP has been implemented, and this has been delayed by changes in policy that occurred over several years. In addition, processed egg products are considered to be of lower risk than certain meat and poultry products such as raw ground beef because of the requirement for pasteurization, which reduces the risk of public health threats arising from *Salmonella* contamination. However, our reviews at six egg processing plants noted concerns such as potential adulteration affecting over 2 million pounds of product, and repeated violations involving the use of restricted eggs, specifically dirty and leaking eggs, in processing operations. This emphasizes the need for HACCP and PBIS to be applied to egg inspections so that these can be incorporated into FSIS' overall management control structure.

Inspections of eggs and egg products were transferred to FSIS from AMS in 1995, six years after the implementation of the electronic PBIS that both schedules inspections and records inspection results at meat and poultry establishments. In 1998, three years after taking over egg inspections, FSIS modified PBIS to accommodate the requirements of the new science-based HACCP inspection system which began implementation in meat and poultry establishments at that time.

Electronic information technology (IT) systems are critical to FSIS' oversight of inspection operations at meat and poultry establishments. One of the most important of these systems is PBIS, which in addition to assigning inspection tasks for each establishment, also requires that inspectors record the results of their inspections and upload these using personal computers to the agency's central database. Noncompliance Reports (NR's) are also uploaded to the system, making them accessible to FSIS managers and supervisors online. Having such information available makes it possible for agency officials to conduct more efficient reviews to identify corrective actions needed at the establishment, district, or nationwide levels.

In a prior audit report (No. 24601-3-CH, “Use of Food Safety Information Systems”, dated September 2004) we reported that the agency needed to strengthen its management control processes to ensure that this information was being adequately communicated to users at various locations and operating levels. We also cited the need for better trend analyses, particularly of sanitation-related NR’s. FSIS officials concurred with the need for improvements, and in 2006 FSIS implemented AssuranceNet, an online application that monitors agency performance in various activities such as completion of inspection tasks, In-Plant Performance System (IPPS)¹ reviews, and the securing of product samples for microbiological testing. FSIS also created a new position, the district analyst, at each district office to assist managers and frontline supervisors in performing trend analyses and other IT-related functions.

The use of management control systems such as AssuranceNet are dependent upon having inspection records available in an electronic format such as that provided by PBIS. However, unlike FSIS inspectors at meat and poultry establishments, inspectors at egg products processing plants still record their inspection results on paper forms which are stored onsite at each establishment. As a result, these records are not available for review by district analysts or by the Technical Service Center (TSC), which generates various exception reports based on inspection data from meat and poultry establishments.

FSIS Headquarters officials stated that in the future, inspectors at egg products processing plants would use electronic means to record and report inspection results. However, they stated that since the implementation of HACCP necessitated major changes to PBIS at meat and poultry establishments, the agency would not implement PBIS at egg products processing plants until HACCP was in place. FSIS began developing HACCP for egg products in 1996, but delayed implementation when it was decided that HACCP needed to be applied to inspections of consumer-ready shell eggs in addition to processed egg products. This decision was revised again in 2005, when it was determined that HACCP for processed egg products could be implemented independent of an equivalent system for shell eggs. At the time of our audit, FSIS officials stated that a draft proposal to implement HACCP for egg products processed is under development, but until it has completed the clearance process the agency cannot provide timeframes for when it will be implemented.

During our visits to six processed egg products plants under two district offices, we noted five occurrences at three plants that required the

¹ IPPS is a review process that frontline supervisors use to assess the work of in-plant inspection personnel. It is not currently automated, although some IPPS data is input to the AssuranceNet management control system for monitoring purposes.

involvement of the frontline supervisors under FSIS Handbook procedures. At two plants, the inspectors made decisions to release product that was potentially adulterated with foreign materials, without consulting the frontline supervisors as required. Potentially serious sanitation issues occurred over extended time periods at two plants, despite being repeatedly noted by the inspectors, without being referred to the frontline supervisors or district office for further followup and enforcement action. None of the frontline supervisors involved had been previously aware of these situations prior to our audit. Details of the conditions observed are discussed in the following paragraphs.

Release of Potentially Adulterated Products

We found three instances, at two plants, where processed egg products that were potentially adulterated with foreign materials were released into commerce by FSIS inspectors despite the requirement that the inspector place an immediate hold on the product and notify the frontline supervisor as required by the FSIS memorandum, "Adulteration of Egg Products from Identified Extraneous Material," dated October 10, 1997. In each of these instances, the inspectors noted the conditions in their reports of Daily Inspection (FSIS Form PY203, which reflects both inspection activity and deficiencies noted) but made the decision to release the product without consulting the frontline supervisor as required. The conditions we noted were as follows:

At one plant, the inspector noted flaking paint inside a liquid egg packaging machine over a period of 2 weeks, during which time the machine processed over 1.7 million pounds of product. The inspector observed and documented this condition during morning pre-operational inspections, and instructed establishment employees to scrape the flaking paint from the insides of the machine before permitting the company to start daily operations. Despite the possibility that the paint flakes found on 10 out of 11 consecutive mornings had also found their way into the processed egg products, the inspector decided not to hold the product because he felt the chances of product adulteration would be small, and because the paint flakes would have been difficult to find and remove from the product that had already been processed.

On another occasion, the same inspector found pieces of plastic inside a pasteurizing machine during a morning pre-operational check and instructed the establishment employees to re-clean the machine by hand before starting operations. Despite the indication that pieces of plastic might have also gotten into the previous day's production of over 200,000 pounds of liquid eggs, the inspector released the

product. Again, he did so on the grounds that if present, the plastic would be difficult to find and because he believed the possibility of contamination was low.

At a second plant, the inspector observed and documented an instance in which water being sprayed by an establishment employee to clean a catwalk on a tanker truck got into the open tanker during the unloading of 48,000 pounds of liquid egg whites into a storage tank. The inspector informed management that in the future they would need to unhook the tanker before cleaning or the product would be held. In this instance, however, the inspector allowed the product to be processed and shipped without verifying a plant employee's statement that the tanker had already finished unloading or contacting the frontline supervisor for guidance.

We discussed each of these instances with the responsible frontline supervisors, and in each case were told that the supervisor would have disputed the inspectors' decisions and required that the product be held until assurances could be provided that the product was not adulterated. We noted these conditions in our reviews of documents at the plants, but the frontline supervisors had not come across them in their reviews of the paper PY203 reports during supervisory visits. Having these records in a more accessible electronic format would not necessarily have revealed these conditions to the frontline supervisors in time for them to hold the product in these specific instances. However, the use of a system such as PBIS would have increased the chances that a frontline supervisor or a district official would have noted these instances sooner and taken action to ensure that they were not repeated.

Recurring Deficiencies

At two of the six plants we visited (exhibit A), we noted serious, recurring conditions that were repeatedly noted by inspectors on their PY203 forms but which continued to persist. One of these plants averaged 24 deficiencies per month over our 6-month review period that involved "dirty eggs" (with foreign material on the shells) or "leakers" (eggs that are leaking due to cracked shells), as well as an average of 28 other sanitation-related deficiencies. The other plant averaged 13 "dirty egg" and "leaker" deficiencies as well as 66 other sanitation-related deficiencies per month over a 17 month period. FSIS regulations prohibit the use of dirty or leaking eggs in any processed egg product, whether or not it is pasteurized before it leaves the plant. The frontline supervisor had been unaware of these conditions, but as a result of our review one of the plants was issued a letter instructing them to correct the cited conditions.

We did not note other significant sanitation deficiencies during our plant visits, but the above examples illustrate that need for frontline supervisors, district analysts, and other FSIS management officials to have the capability to perform more extensive inspection record reviews than can be accomplished within the limitations of a paper system of recordkeeping. All of the frontline supervisors we interviewed regarding the above instances stated that they had not been aware of the conditions we noted, which came to light only through more extensive record reviews than a frontline supervisor would typically perform. Most frontline supervisors we interviewed stated that when performing IPPS reviews, they generally review only about a week's worth of daily inspection reports due to time constraints whereas our reviews that disclosed the problems covered periods of between 3 and 18 months. In each case, the supervisors stated that they would have taken corrective actions to address the problems, or at least discussed the situations with the inspectors to prevent repetition. Because of the pasteurization process required for all processed egg products, the threat of *Salmonella* outbreaks is reduced. However, this process does not address the problem of adulteration by foreign materials, or issues of product wholesomeness resulting from the use of "dirty eggs" and "leakers." Further, FSIS depends on its inspection process at the egg products processing plants to assure that the pasteurization process is being properly applied. An FDA official informed us that a total of eight recalls have taken place since 2002 involving processed egg products, although in each case these were initiated by the plants themselves rather than by FDA.

FSIS continues to progress in applying IT technology such as the AssuranceNet system to meat and poultry inspections, but egg inspections are still performed and documented in essentially the same manner as when AMS operated the program before the 1995 transition. By entering inspection data into an IT system, FSIS officials can analyze reported deficiencies for trends and use these to identify problems that require corrective actions such as training for inspectors. To provide adequate assurances that only safe and wholesome egg products are marketed to the public, it is important that FSIS update and modernize its monitoring and control systems for egg products to the same standard that is applied to meat and poultry establishments.

Recommendation 1 Incorporate egg product inspection activities into FSIS' IT systems and HACCP, allowing them to interface with the agency's current and planned IT and management control systems.

Agency Response FSIS officials are developing a proposed rule that would require egg product plants to develop and implement HACCP Systems.

They are also developing a new IT system to track domestic inspection activities which will replace PBIS. Until this is completed, they are converting existing reports into electronic formats. This is expected to be completed by June 2008.

OIG Position We accept management decision for this recommendation.

Recommendation 2 Conduct trend analyses to identify any serious or widespread deficiencies at egg products processing plants and take appropriate corrective actions such as training or closer supervision for inspectors.

Agency Response Staff in the Policy Analysis Division will conduct trend analyses to identify any serious or widespread deficiencies at egg products processing plants and take appropriate corrective actions which will begin by March 2008.

OIG Position We accept management decision for this recommendation.

Section 2. Importing of Processed Egg Products

Finding 2

FSIS Does Not Have Adequate Controls Over Imported Egg Products

In a July 2003 review of 37 Canadian slaughter and processing establishments, FSIS representatives noted numerous deficiencies with Canada's inspection system. Deficiencies were also found at four of the six egg products processing plants visited, including "dirty eggs" and "leakers" at two plants, but no followup visits to Canadian egg products processing plants have been made since then. Followup visits were performed at a number of Canadian meat and poultry establishments in 2005, but egg products processing plants were not included despite the fact that at meat and poultry establishments overall the same problems continued to be noted. FSIS officials stated that this was because eggs are considered to be of lower risk than certain meat and poultry products. As a result, there is reduced assurance that these conditions have been corrected with regard to the 10.3 million pounds of processed egg products imported into the United States from Canada in 2005, and the 5.9 million pounds imported in 2006.

FSIS regulations state that egg products can only be imported from countries determined to have an equivalent processing and inspection system. After initial determination of equivalency, a system is to be reviewed as often as deemed necessary to determine if the system remains equivalent.² Currently, Canada is the only country that exports processed egg products to the United States.

In July 2003, FSIS conducted an equivalency review of the Canadian Food Inspection Agency (CFIA) to evaluate its controls over slaughter, processing, and egg product processing plants identified as eligible to export products to the United States. This review disclosed extensive problems in the meat and poultry areas, including a failure to follow HACCP and a lack of daily inspections at some processing establishments. Egg products are not covered under HACCP or Sanitation Standard Operation Procedures (SSOP), so the operations of the six egg products processing plants visited were not evaluated for these. However, the review did raise concerns about sanitation inspections at four of the six plants, including observations that one plant was breaking "dirty eggs" and a second plant was breaking "leakers" as part of their processing operations. Under FSIS regulations, eggs in this condition are not permitted to be used in any processed egg products.

At the end of the review, FSIS received assurances from the Canadian inspection system that all the reported problems noted in 2003 had been

² 9 CFR 590.910 (a)

corrected. When FSIS conducted a followup review in 2005, many of the same conditions reported in 2003 for meat and poultry inspections still persisted. FSIS officials stated that no egg products processing plants were included in the 2005 visits, because the problems noted there in 2003 were not as significant as for the meat and poultry establishments. Also, they stated that eggs are generally considered to be of lower risk than some meat products such as raw ground beef, because of pasteurization.

FSIS officials stated that they have not received any reports of health problems arising from egg products coming out of Canada. The 2003 finding that the use of “dirties” and “leakers” was not being adequately addressed by CFIA at one-third of the plants visited, however, remains a concern. The FSIS report dated July 31, 2003, stated that the cited problems were corrected at the plants at the time of the review. However, the fact that no Canadian egg processing plant has been visited by FSIS in nearly 4 years, as well as the fact that other problems found in 2003 continued to exist in 2005, raises the concern that problems may continue to exist at egg processing plants as well. In August 2006, Canada had 15 egg processing plants.

An official of FSIS’ International Equivalence Staff stated that the next time a review of Canadian plants is conducted, they may include egg plants in their next review of Canadian establishments. However, FSIS does not regularly do equivalency reviews of eggs due to the lower risks involved. This is also due to FSIS’ lack of adequate procedures defining how often the egg inspection area is to be reviewed for a country to maintain equivalence. While we concur that the health risks associated with processed egg products is less than with meat or poultry because of pasteurization, the product wholesomeness issues disclosed earlier should warrant followup within a reasonable timeframe. Therefore, we believe that FSIS officials should ensure that at least some egg processing plants are included in the next scheduled Canadian equivalency review. In addition, FSIS officials should establish reasonable minimum timeframes to review the foreign egg inspection systems for maintaining equivalency.

Recommendation 3 Conduct a followup of egg product processing plants in the next Canadian equivalency review, and in future instances where visits are made to meat and poultry establishments.

Agency Response FSIS officials stated that they conducted an audit of the Canadian Food Inspection Agency in May 2007. The audit included four egg product processing plants, two of which were the plants referenced in the OIG report that had the findings related to breaking of “dirty eggs” and “leakers.” They concluded that the previous issues related to the breaking of ineligible eggs had been effectively addressed and corrected.

FSIS management has agreed that future audits of Canada will include, as part of the establishment component, a representative selection of egg products plants.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We performed audit work at FSIS Headquarters in Washington D.C., at the District 50 Office in Lombard, Illinois, and the District 25 Office in Des Moines, Iowa. Our judgmental selections for our district office visits were based on the number and the variety of egg product processing plants and the proximity to an office of Program Evaluation, Enforcement, and Review (OPEER) regional office. We also judgmentally-selected six egg product plants to visit, three located in Ohio and three located in Iowa. Our plant selection was based on *Salmonella* testing history, proximity of plants to each other, and to ensure that all areas of egg product inspection activities were subject to review. We performed our fieldwork from September 2006 through May 2007.

At FSIS Headquarters, we held discussions with officials from the Office of Public Health and Science (OPHS), the Office of Field Operations, OIA, OPEER, and Office of Policy, Program, and Employee Development. We also conducted interviews with AMS Headquarters and field personnel. We reviewed OIA Canadian Egg equivalency review reports to determine if FSIS had adequately reviewed the international egg inspection area. We reviewed the Pasteurized Egg Products Recognized laboratory client listings to determine if all egg plants conducting *Salmonella* surveillance testing used OPHS recognized labs. We also reviewed AMS' temperature verification records and OPEER's case files to determine if all shell egg plants were visited each quarter and all temperature violations were followed up on.

At two district offices, we interviewed district officials and reviewed egg product handbooks for completeness.

At the six selected egg products processing plants, we interviewed front line supervisors and egg product inspectors, and reviewed documentation to evaluate the egg product inspectors' performance of their prescribed duties. At the plants, we observed operations, and reviewed inspection reports to determine if timely and effective corrective actions were taken for plant level deficiencies. We also reviewed the inspectors' egg products handbooks to determine if they were current.

We interviewed an FDA official to obtain information on recalls of FSIS-inspected egg products. We also interviewed an official from the CDC, and reviewed documentation they provided us, to identify public health risks associated with both shell eggs and processed egg products.

The audit was conducted in accordance with Government Auditing Standards issued by the Comptroller General of the United States.

Exhibit A – Locations Visited

Sites Visited		
FSIS Headquarters Washington D.C.	District 25, Des Moines, IA	Est. #1 (broke eggs, pasteurized and made liquid, frozen, and dried egg products)
		Est. #2 (pasteurized and made liquid, egg products)
		Est. #3 (broke eggs, pasteurized and made liquid, frozen, and dried egg products)
	District 50, Lombard IL	Est. #4 (broke eggs, pasteurized and made liquid, frozen, and dried egg products)
		Est. #5 (broke eggs, pasteurized, and made liquid and frozen egg products)
		Est. #6 (broke eggs)

Exhibit B – Agency Response

Exhibit B – Page 1 of 2



United States
Department of
Agriculture

Food Safety
and Inspection
Service

Washington, D.C.
20250

AUG 15 2007

TO: Robert W. Young
Assistant Inspector General for Audit
Office of Inspector General

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

SUBJECT: Office of Inspector General (OIG) Official Draft Audit Report – Egg Products
Processing Inspection, Report number 24601-08-Ch

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

In addition to the responses to the audit recommendations, FSIS would like to offer additional comments for clarification. OIG has identified three instances where it claims potentially adulterated egg product was released into commerce by FSIS inspection program personnel. In each of these cases, FSIS inspection program personnel made the determination that the product was safe, wholesome and not adulterated before applying the mark of inspection. FSIS will, however, look into these three specific instances and take appropriate action if necessary.

1. Recommendation 1
Incorporate egg product inspection activities into FSIS' IT systems and HACCP, allowing them to interface with the Agency's current and planned IT and management controls systems.

Agency Response

FSIS is in the process of incorporating HACCP into egg product inspection activities and developing a proposed rule that would require egg product plants to develop and implement HACCP Systems.

FSIS is also developing a new IT system to track domestic inspection activities which will replace PBIS. Egg product processing inspection will be tracked within this system. Also, work is almost finished on converting the reports (PY-203 and PY-159, Daily Report on Plant Operations) into full electronic formats. Once completed, FSIS inspection program personnel will be able to save and review their files electronically. FSIS also developing a FSIS Egg Products Non-Compliance Reporting Form.

Exhibit B – Agency Response

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Completion Dates: FSIS intends to complete implementation of electronic reporting by June 2008, and propose the HACCP rule for egg products by March 2008.

2. Recommendation 2
Conduct trend analyses to identify any serious or widespread deficiencies at egg product processing plants and take appropriate corrective actions such as training or closer supervision for inspectors.

Agency Response

The Policy Analysis Division in FSIS/OPPED will conduct trend analyses to identify any serious or widespread deficiencies at egg products processing plants and take appropriate corrective actions.

Completion Date: OPPED/PASD will conduct trend analyses by March 2008.

3. Recommendation 3
Conduct a follow-up of egg product processing plants in the next Canadian equivalency review, and in future instances where visits are made to meat and poultry establishments.

Agency Response

FSIS conducted an audit of the Canadian Food Inspection Agency beginning on May 1, 2007, and concluding on June 6, 2007. The audit included four egg product processing plants, two of which were the plants referenced in the OIG report that had the findings related to breaking of "dirty eggs" and "leakers." The other two egg product processing plants were not part of the 2003 audit. FSIS auditors concluded that the previous issues related to the breaking of ineligible eggs had been effectively addressed and corrected.

FSIS management has agreed that future audits of Canada will include, as part of the establishment component, a representative selection of egg products plants.

Completion Date: FSIS will finalize the May 2007 audit of the Canadian Food Inspection Agency by October 2007.

If you have any questions, please contact William C. Smith, Assistant Administrator, Office of Program Evaluation, Enforcement and Review, at (202) 720-8609.