U.S. Department of Agriculture

Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Recall Procedures for Adulterated or Contaminated Product

.

Report No. 24601-09-Hy
August 2008

UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250

August 7, 2008

REPLY TO
ATTN OF: 24601-09-Hy

TO: Charles F. Conner
Deputy Secretary

THROUGH: Phyllis K. Fong /s/
Inspector General

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

SUBJECT: Food Safety and Inspection Service Recall Procedures for Adulterated or Contaminated Product

SUMMARY

In response to your memorandum dated October 5, 2007, we performed an audit to determine whether improvements could be made to the Food Safety and Inspection Service's (FSIS) protocols for handling recalls to ensure that accurate information is rapidly obtained and conveyed to the appropriate decision makers.[1] We also evaluated whether FSIS is taking full advantage of its current statutory authorities to address recall situations. We concluded that FSIS has taken strides to strengthen and improve its investigative and recall procedures and took full advantage of its current authority to address recalls, such as the Topps Meat Company (Topps) recall. However, FSIS does not have a science-based sampling protocol in place to collect and analyze a representative quantity of intact[2] samples to submit for testing during an outbreak investigation.

At the time of the recall, there were 5,568 packages (over 11,000 pounds) of product from the same production day at Topps. However, of the 5,568 packages, FSIS collected the only available package of intact product with the identical labeling as the non-intact[3] product from a

[1] On January 29, 2008, we issued a memorandum on "FSIS' Sampling and Testing Procedures for *E. coli* O157:H7" (Audit No. 24601-04-KC).
[2] An intact product is an unopened packaged product.
[3] A non-intact product is a product with opened packaging or a product that has been taken out of its original packaging.

case patient's home to test for *Escherichia coli (E. coli)* O157:H7. This occurred because the agency does not have a protocol in place to collect a representative quantity of intact samples that should be submitted for laboratory analysis during an outbreak investigation. The product collected by FSIS personnel from Topps tested negative for *E. coli* on September 8, 2007. According to FSIS officials, the agency became aware of the additional product at Topps on September 13, 2007. Based on the information available at the time and existing FSIS policy, the agency had no justification for conducting additional tests. As a result, FSIS could not conclude that contamination occurred at the establishment. The lack of additional product testing potentially delayed FSIS' ability to recommend a recall. FSIS ultimately recommended a recall on September 25, 2007, based on a positive test result by a State agency.

As a result of the lessons learned from a number of recalls (including the Topps recall) and FSIS' assessment of recall policies and procedures, the agency has taken strides to strengthen decision making in response to outbreak situations by developing an investigative directive and revising the recall directive. FSIS expects to finalize these directives in September 2008.

FSIS agreed with the Office of Inspector General's (OIG) recommendations; however, the agency had some concerns with parts of the audit and its conclusions. For example, the Topps illness investigation involved multiple products with differing DNA, or deoxyribonucleic acid,[4] fingerprints. The potential source of the contamination involved multiple establishments, some foreign. Since the product obtained from the initial patient was non-intact, it could have been contaminated in a variety of ways (i.e., improper handling by the consumer, cross contamination with produce, etc.). Only one intact same-sized box of product was available at the establishment when FSIS requested that in-plant inspection personnel submit a sample.

In addition, at the time FSIS collected the intact sample on September 5, 2007, the investigation was not an outbreak investigation. It was not until September 10, 2007, that FSIS was first notified that a cluster of 12 *E. coli* O157:H7 case patients had been reported to the Centers for Disease Control and Prevention. It was not until September 21, 2007, that an intact box of Topps ground beef tested positive for *E. coli* O157:H7, and in this case the product that tested positive had an earlier sell by date than that consumed by the initial case patient.

FSIS noted these facts surrounding the investigation only to highlight the uncertainty involved in such an epidemiological investigation, especially during the early stages. We have incorporated excerpts from FSIS' response in the Audit Results section of this report, along with our position, and accepted FSIS' management decision on each of the recommendations. FSIS' response is included in the Attachment.

[4] DNA, or deoxyribonucleic acid, is the genetic material of all cellular organisms and most viruses.

BACKGROUND

As the public health regulatory agency of the U.S. Department of Agriculture (USDA), FSIS is responsible for ensuring that meat and poultry products are safe, wholesome, and properly labeled. When there is reason to believe that product may be adulterated or contaminated, FSIS can request an establishment to voluntarily remove the product from commerce, through a recall. Although recalls are voluntary, FSIS oversees all recall activities actually undertaken by establishments. If an establishment refuses to recall a meat or poultry product, FSIS has legal authority to detain and/or seize those products in commerce.

On September 25, 2007, FSIS announced that Topps, an Elizabeth, New Jersey establishment, voluntarily recalled approximately 332,000 pounds of frozen ground beef products that may have been contaminated with *E. coli* O157:H7. On September 29, 2007, FSIS announced that Topps was expanding the Class I[5] recall to include approximately 21.7 million pounds of frozen ground beef products. These products were produced on various dates between September 25, 2006 and September 25, 2007, and were distributed to food service institutions in the New York metropolitan area and to retail establishments nationwide. The recall was expanded based on an additional positive product sample reported by the New York State Department of Health, reported illnesses, and findings from a food safety assessment[6] conducted by FSIS at the establishment. In October 2007, the establishment ceased all operations.

OBJECTIVE

Our overall objective was to evaluate FSIS' recall procedures for adulterated or contaminated product that has already entered the food distribution chain. Specifically, we (1) evaluated whether any improvements could be made to FSIS' processes for handling recalls to ensure that accurate information is rapidly obtained and conveyed to the appropriate decision makers and (2) evaluated whether FSIS is taking full advantage of its current statutory authorities to address recall situations.

SCOPE AND METHODOLOGY

We performed our audit at FSIS Headquarters in Washington, D.C. Our audit fieldwork was performed from November 2007 to March 2008. To accomplish our objectives, we interviewed the appropriate officials, examined pertinent documentation, and reviewed applicable policies and procedures.

We interviewed FSIS officials to gain an understanding of (1) FSIS' protocols for handling recalls to ensure that accurate information is conveyed to the appropriate decision makers,

[5] A Class I recall is a health-hazard situation where there is a reasonable probability that the use of the product will cause adverse health consequences or death.

[6] A comprehensive food safety assessment considers all food safety aspects that relate to the establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment.

(2) FSIS' current statutory authority, and (3) FSIS' involvement in the Topps recall. We interviewed officials from FSIS' Office of Policy, Program, and Employee Development; Office of Program Evaluation, Enforcement and Review; Office of Field Operations' Recall Management Staff; and Office of Public Health Science's Microbiology Division and the Outbreak Section Eastern Laboratory. In addition, we interviewed State Department of Health officials for Florida and New York, and an official from the Florida State Department of Agriculture.

We analyzed FSIS' draft directive regarding its foodborne illness investigations and proposed revisions to its recall directive. We also examined FSIS' policies and procedures to detain or seize adulterated product found in commerce, collect evidence during an outbreak investigation, work with the States and other Federal agencies during a foodborne illness investigation, and test for *E. coli* at laboratories. We analyzed the chronology of events of FSIS' involvement in the Topps recall for any delays or instances where FSIS procedures were not followed. In addition, we consulted with OIG's Office of Counsel regarding proposed legislation granting FSIS mandatory recall authority and the final proposed rule on the availability of lists of retail consignees during meat and poultry product recalls. Finally, we reviewed the results of FSIS' assessment of its policies and procedures for issuing a public health alert,[7] using epidemiological[8] data, and strengthening the recall directive.

We conducted the audit in accordance with *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.

AUDIT RESULTS

FSIS needs to collect and analyze a more representative sample of intact product during an outbreak investigation to be able to conclude whether contamination occurred at the establishment under investigation. In addition, FSIS has not finalized and implemented its draft directive for investigating foodborne illnesses and its revised directive for handling recalls.

FSIS Should Collect and Analyze a More Representative Sample During an Outbreak Investigation

FSIS does not have a protocol in place to collect a representative quantity of intact samples that should be submitted for laboratory analysis during an outbreak investigation. According to FSIS officials, intact product sampling may not be practical in all cases because of the availability of the product at the time of the investigation. However, at Topps, 5,568 packages (over 11,000 pounds) of product from the same production day were available for sampling. Due to a

[7] Public health alerts provide guidance to consumers and health professionals about the risks of illness associated with an identified pathogen.
[8] Epidemiology is the study of the distribution and causes of disease in a population.

lack of guidance for collecting and analyzing a representative quantity of intact samples, FSIS personnel collected the only package of the 5,568 packages that had the identical labeling as the non-intact product from a case patient's home, which tested negative for *E. coli* on September 8, 2007. As a result, FSIS could not conclude that contamination had occurred at the establishment. The lack of additional product testing potentially delayed the agency's ability to recommend a recall.

On August 31, 2007, FSIS was notified through the Consumer Complaint Monitoring System of an illness possibly linked to Topps hamburger patties. In response, FSIS collected and submitted for testing non-intact product found in the patient's freezer. On September 5, 2007, the laboratory analysis confirmed that 2 of the 13 sub-samples[9] tested positive for *E. coli* O157:H7. FSIS also collected and submitted for testing the one like coded and labeled intact package of product found at the establishment. As noted above, on September 8, 2007, the laboratory reported that all 13 sub-samples from the intact product tested negative for *E. coli* O157:H7.

Due to the lack of a protocol, FSIS did not analyze any of the 5,568 packages of product from the same production day for *E. coli* after FSIS personnel became aware of this product on September 13, 2007.[10] On September 25, 2007, FSIS announced a recall based on a positive *E. coli* test result by a State agency on intact product purchased from a retailer on September 21, 2007.

During an outbreak investigation, FSIS collects and submits for laboratory analysis product samples from the establishment. Investigative sample collection and analysis is an important component of evidence collection during an outbreak investigation. It includes sampling the inventory from establishments engaged in preparation or storage of meat or poultry products. FSIS primarily uses investigative samples to support agency decisions, to take enforcement actions, to support violations of law, and to obtain a ruling in court.[11] A sampling protocol based on established scientific methods would assist FSIS in these efforts. The FSIS directive, however, does not include a protocol for collecting a representative sample of product at the establishment for analysis.

According to FSIS officials, the agency could not conclude that contamination had occurred at Topps since the intact product sample obtained tested negative and there was only one reported illness from a positive non-intact package. Based on this information and the lack of a strong epidemiological case eliminating all possible cross contamination from other sources, the recall committee did not convene to determine the need for a recall. Because *E. coli* is difficult to detect and sporadically present at very low levels, multiple representative samples, if available, should be collected from the establishment and analyzed to provide stronger assurance that *E. coli* is or is not present.

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[9] For outbreak-related samples, FSIS randomly collects 13 sub-samples, each weighing 25 grams, which are representative of the entire product sample.

[10] According to FSIS officials, based on the information available at the time and existing policy, the agency had no justification for conducting additional tests.

[11] FSIS Directive 8010.3, Procedures for Evidence Collection, Safeguarding and Disposal, September 5, 2007.

Recall Procedures

As a result of the lessons learned from a number of recalls (including the Topps recall) and FSIS' assessment of recall policies and procedures, the agency has taken strides to strengthen decision making in response to outbreak situations by developing an investigative directive and revising a recall directive. FSIS expects to finalize these directives in September 2008. Therefore, we could not evaluate their adequacy.

- FSIS developed a draft directive[12] for investigating foodborne illnesses potentially associated with regulated meat. According to the draft directive and FSIS officials, the agency will now consider an entire range of investigative information and use established epidemiologic principles[13] to assess the strength of the association between FSIS–regulated product and the illness. In addition, using epidemiological data to draw conclusions when conducting foodborne illness investigations will allow the agency to respond more timely to recalls.

- FSIS revised the recall directive[14] to reflect changes in agency policy to include revisions to procedures to determine the need for a recall, such as handling recalls from foreign countries, and specific instructions on the conditions under which the agency should issue a public health alert. In addition, FSIS revised recall committee procedures and responsibilities to ensure that accurate information is obtained and conveyed to the appropriate decision makers. For example, the recall directive requires that committee members make every effort to achieve consensus on whether to recommend that the agency request a recall. If a consensus cannot be reached, dissenting members are required to contact their program area Assistant Administrator.

Statutory Authority

Under current law, FSIS may only recommend that an establishment voluntarily remove the product from trade or consumer channels. FSIS may administratively detain the product in the event that an establishment does not voluntarily recall a product. Where appropriate, FSIS may then pursue judicial seizure and legal proceedings in accordance with its directive.[15] A recall is an alternative to FSIS detention or seizure of an adulterated product. We concluded that FSIS took full advantage of its current statutory authorities to address the Topps recall.

According to FSIS officials, only one establishment over the last 8 years disagreed with FSIS' recommendation to recall its product. In a situation like this, FSIS will detain any product found

[12] Draft Foodborne Illness Investigations Directive.
[13] FSIS uses established epidemiologic principles and investigative techniques published by the International Association of Food Protection to determine causal factors of disease outbreaks.
[14] FSIS Directive 8080.1, Revision 5, Recall of Meat and Poultry Products. This revision is currently in draft.
[15] FSIS Directive 8410.1, Revision 4, Detention and Seizure, September 4, 2007. This updated directive did not change FSIS' current authority to detain and seize product.

in commerce that would have been subject to the recall and issue a press release informing the public that product that appears to be adulterated has been shipped and the establishment has refused to recall it.[16] According to FSIS officials, after FSIS issued its press release on the one establishment that disagreed with FSIS' recommendation, the establishment began to recall its product within two days of the public health alert and subsequently completed the recall process.

Final Rule on the Availability of Lists of Retail Consignees

In March 2006, FSIS proposed to amend its regulations to make available to the public a list of the retail consignees of meat and poultry products that have been voluntarily recalled by a Federally-inspected establishment, if product has been distributed to the retail level. This rule will apply only where there is a reasonable probability that the use of the recalled product will cause serious adverse health consequences or death (Class I recalls). FSIS has generally treated distribution lists obtained during recalls as confidential business information. FSIS regulation[17] required disclosure of this information to States and other Federal government agencies through a memorandum of understanding to enable them to verify the removal of the recalled products from commerce. However, State laws prohibit some States from entering into such agreements with USDA. State officials have requested that the distribution list be provided to them without entering into an agreement with USDA, believing that they would be better able to protect the public health by identifying more easily and effectively the product being recalled. Therefore, FSIS believes that this proposal would improve the efficiency of the recall process and address State officials' concerns. FSIS proposed applying the rule to all classes of recalls. However, after evaluating comments to the proposed rule, including those that suggested that it is not necessary to make public retail consignee lists in situations where food safety concerns are minimal, FSIS concluded that it is prudent to modify the rule to apply only to those recalls involving products where there is a reasonable probability that the use of the recalled product will cause serious adverse health consequences or death. The final rule was published on July 17, 2008, and will be effective on August 18, 2008.

FSIS' draft investigative and recall directives are positive actions FSIS has taken to further improve and strengthen its processes for handling outbreak investigations and recalls. FSIS should finalize and implement the new directive for investigating foodborne illnesses and the revised directive for handling recalls.

Recommendation 1

Develop and implement a science-based sampling protocol to collect and analyze a representative sample of product at an establishment to conclude whether contamination occurred there. The protocol should take into consideration the amount of relevant product available for testing.

[16] FSIS Directive 8080.1, Revision 4, Recall of Meat and Poultry Products, May 24, 2004. Revision 5 of this directive is currently in draft.
[17] 9 CFR, Part 390.9 (a) (1), dated April 24, 2002.

Agency Response

FSIS agrees with the recommendation and will develop and implement a science-based sampling protocol to collect a more representative sample of product at an establishment during epidemiological investigations. The protocol will take into consideration the amount of relevant product available for testing. As noted in OIG's January 29, 2008, report to Charles F. Connor on FSIS' sampling and testing programs for *E. coli* O157:H7, regardless of the number of samples tested, the pathogen's existence cannot be detected in all cases nor can the prevalence be determined and projected to the total production in a particular lot or on a given day. However, a sampling protocol for epidemiological investigations will be established that provides a more representative sample. The estimated completion date is September 2008.

OIG Position

We accept FSIS' management decision.

Recommendation 2

Finalize and implement the new directive for investigating foodborne illnesses and the revised directive for handling recalls.

Agency Response

FSIS agrees with the recommendation and will finalize and implement new directives for investigating foodborne illnesses and for handling recalls. As noted in the report, draft procedures were shared with OIG during the course of the audit and these will be finalized. The estimated completion date is September 2008.

OIG Position

We accept FSIS' management decision.

Please follow your internal agency procedures for reporting 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 our staff during our review.

Attachment

United States Department of Agriculture

Food Safety and Inspection Service

Washington, D.C. 20250

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

JUL 22 2008

FROM: Alfred V. Almanza
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report – Food Safety and Inspection Service Recall Procedures for Adulterated or Contaminated Product (Audit 24601-09-Hy)

We appreciate the opportunity to review and comment on this official draft report. The Food Safety and Inspection Service (FSIS) has carefully reviewed the official draft report and accepts both of its recommendations. In addition, FSIS would like to provide a few general comments.

General Comments:
It is important to note that there were several factors that complicated the epidemiological investigation that lead to the September 2007 Topps Meat Company recall of frozen ground beef products potentially contaminated with *E. coli* O157:H7. This particular *E. coli* O157:H7 illness investigation involved multiple products with differing DNA fingerprints. The investigation into identifying the potential source of *E. coli* O157:H7 contamination involved multiple establishments, some foreign. These circumstances made the investigation exceedingly unusual.

The Florida patient had a partially eaten non-intact three-pound box (12 - 1/4 lb patties) of "Topps 100% Pure Ground Beef Patties" with a sell by date of July 12, 2008, from which FSIS had obtained a positive result for *E. coli* O157:H7. Since the product obtained from the patient was non-intact, it could have been contaminated by *E. coli* O157:H7 in a variety of ways (i.e. improper handling by the consumer, cross contamination with produce, etc). With the facts known on September 5, 2007, it was far from certain that contamination occurred at the Topps establishment although it was certainly a possibility, and FSIS reasonably focused its investigation on the identical product (product name, use by date, and size) as that of the Florida patient. Only one unit of such size box was available at the establishment when the District Office, on September 5, 2007, requested that in-plant inspection personnel submit a sample. FSIS collected that sample of identical product and tested 13 sub-samples from the unopened (intact) package for *E. coli* O157:H7, and the results were all negative. These results should not be minimized. In the FSIS microbiological sampling program we consider one sample to be representative of the production lot. If the sample is positive, the entire lot is implicated. If the test is negative, the result is accepted and additional testing is not conducted. As noted above, follow-up testing on the only sample of like-coded product (the same size/weight as the case patient) tested negative.

Given the available facts, and assumptions, known to FSIS on September 5, 2007, FSIS had not yet committed resources to determine what other production at Topps could be microbiologically related to the product consumed by the Florida patient. The District Office was not aware of the availability of other product (specifically, the *two* pound boxes which largely comprised the 5,568 packages) from the same July 12, 2007, production date, until September 13, 2007. It is important to note that even if additional samples had been taken from the two pound boxes of July 12, 2007, production at Topps, there was still the possibility that the additional samples would have tested negative.

At the time FSIS collected the intact sample on September 5, 2007, the investigation was not an outbreak investigation. It wasn't until September 10 that FSIS was first notified that a cluster of 12 *E. coli* O157:H7 case-patients with an indistinguishable Pulsed-Field Gel Electrophoresis (PFGE) pattern combination had been reported to the Centers for Disease Control and Prevention (CDC). The PFGE pattern combination had never been observed before by CDC. Incidentally, all of these cases were clustered in the Northeast and Midwest (Connecticut, Indiana, New Jersey, New York, Ohio and Pennsylvania), none were reported in southern states such as Florida. It wasn't until September 21, 2007, that an intact box of Topps ground beef tested positive for *E. coli* O157:H7, and in this case the product that tested positive had a different sell by date than that consumed by the Florida case patient.

FSIS notes these facts surrounding the investigation only to highlight the uncertainty involved in such an epidemiological investigation, especially during the early stages. A clear and accurate picture of the situation can take time to unfold, and is pieced together from many different sources. Any of the pieces of information presented above (without the benefit of all the other facts surrounding the investigation) could easily be misinterpreted, or could lead one to jump to an erroneous conclusion. FSIS works diligently to ensure epidemiological investigations are conducted thoroughly and in a timely manner to protect the public health.

Responses to Recommendations

Recommendation 1:
Develop and implement a science-based sampling protocol to collect and analyze a representative sample of product at an establishment to conclude whether contamination occurred there. The protocol should take into consideration the amount of relevant product available for testing.

FSIS Response:
FSIS agrees with the recommendation and will develop and implement a science-based sampling protocol to collect a more representative sample of product at an establishment during epidemiological investigations. The protocol will take into consideration the amount of relevant product available for testing. As noted in OIG's January 29, 2008, report to Charles F. Connor on FSIS' sampling and testing programs for *E. coli* O157:H7, regardless of the number of samples tasted, the pathogen's existence cannot be detected in all cases nor can the prevalence be determined and projected to the total production in a particular lot or on a given day. However, a sampling protocol for epidemiological investigations will be established that provides a more representative sample.

Estimated Completion Date: September 2008

Recommendation 2:
Finalize and implement the new directive for investigating foodborne illnesses and the revised directive for handling recalls.

FSIS Response:
FSIS agrees with the recommendation and will finalize and implement new directives for investigating foodborne illnesses and for handling recalls. As noted in your report, draft procedures were shared with OIG during the course of the audit and these will be finalized.

Estimated Completion Date: September 2008