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Office of Inspector General
Northeast Region

Audit Report

Food Safety and Inspection Service Oversight of the Recall by Hallmark/Westland Meat Packaging Company

Report No. 24601-10-Hy
September 2009



UNITED STATES DEPARTMENT OF AGRICULTURE

OFFICE OF INSPECTOR GENERAL

Washington D.C. 20250



DATE: September 30, 2009

REPLY TO

ATTN OF: 24601-10-Hy

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: Food Safety and Inspection Service Oversight of the Recall by
Hallmark/Westland Meat Packaging Company

SUMMARY

FSIS needs to improve its process for selecting companies to verify if recalled product is retrieved effectively. During a food recall, FSIS contacts a statistically selected sample of companies to verify that the recalled product is being located and retrieved effectively (i.e., effectiveness checks). FSIS selects the sample from a master list that comprises the recalling company's customers (e.g., wholesalers) and, in turn, their customers (e.g., retailers). Since some companies down the distribution chain cannot accurately identify consignees to whom they may have sold recalled product, FSIS may make its initial selection from the entire customer list so it can immediately start conducting effectiveness checks.¹ Consequently, FSIS' master list and the resulting sample can include companies that did not receive any of the recalled products, and therefore are irrelevant to determining if a recall was effective. FSIS has not developed a process to refine such master lists before selecting samples, or issued nationwide guidance to ensure that inappropriate selections are removed and companies that received recalled product are substituted.

¹ Some establishments are unable to pinpoint when, where, and to whom a particular product or lot was sent because they use non-automated recordkeeping systems—e.g., paper receipts and ledger books. For example, FSIS described an archaic system where bills of sale were kept in a file box in the back of a warehouse. Also, some establishments use old computer software that is no longer compatible with current operating systems and software. In these cases, FSIS typically begins with all the possible destinations (entire customer lists) rather than delaying the recall by sifting through paperwork and translating electronic information to find out precisely where recalled product went. Although imprecise, this procedure is both quick (since most businesses can at least write out lists of their customers) and inclusive (since the resulting lists will contain the recalled product destinations along with other information).

Without these controls, we found that 41 percent of the companies FSIS contacted about Hallmark’s recall—83 of 203—were not useful for determining the recall’s effectiveness. Some did not receive the beef and some did not sell meat at all, while others were out of business. Although the FSIS district office that led the recall initially replaced some companies it knew were either out of business or else did not buy and sell meat, it was not able to identify all of these companies on the master list prior to the start of the effectiveness check process. In addition, it did not replace companies that did not receive recalled product later when conducting its own checks and reviewing other district offices’ work. Our review showed that FSIS conducted effectiveness checks at 66 companies that did not purchase the recalled product, 12 that were not in the business of buying and selling meat, and 5 that were out of business. According to staff from the lead district office, with no guidance on sample substitution² and believing that they were under considerable time pressure³ to finish, they chose not to replace many of the companies determined to be irrelevant during and after the effectiveness check process.

FSIS chose an interval sampling methodology to select companies for effectiveness checks.⁴ We found that the agency weakened its sampling methodology by not consistently applying a constant interval to the universe of companies when selecting companies for effectiveness checks.⁵ In addition, we found that the interval of 47 that FSIS calculated and used excluded 106 companies from the statistical selection because the required sample number was reached before the end of the master list. As a result, FSIS’ conclusion that Hallmark’s recall was successful is not statistically supportable. OIG’s statistician reviewed the FSIS interval sampling methodology and stated that the process would be statistically acceptable if FSIS addressed the concerns identified in this report. Further, unless these issues are addressed, similar questions could arise regarding the process for performing effectiveness checks in future recall situations.

We also verified that FSIS has generally taken appropriate actions in response to recommendations we made in two earlier reports that assessed the agency’s recall procedures and oversight.⁶

FSIS agreed with the recommendations in this report. We have incorporated excerpts from FSIS’ response in the Audit Results section of the report, along with our position, and accepted FSIS’ management decision on each of the recommendations. FSIS’ response is included in the Attachment.

² In a 2006 presentation to the district offices, an FSIS official instructed staff members of district offices to replace a company if it would be closed longer than a few days. However, staff at all three district offices we visited were unaware of any agency guidance on sample substitution.

³ District office staff stated in interviews that they believed they were under pressure to complete the work within short timeframes despite an email from the FSIS Office of Field Operations that emphasized an accurate effectiveness check process rather than a rapid process.

⁴ This methodology relies on sample items being chosen based on a constant interval between sample units on the master list.

⁵ The constant interval was not consistently applied because FSIS replaced 20 companies that were either out of business or did not sell meat with the next company on the master list.

⁶ Our two previous reports were: “FSIS’ Effectiveness Checks for the 2002 Pilgrim’s Pride Recall,” (24601-03-Hy, June 2004) and “FSIS’ Oversight of the 2004 Recall by Quaker Maid Meats, Inc.,” (24601-04-Hy, May 2005).

BACKGROUND

FSIS is the public health agency that ensures that meat, poultry and egg products are safe, wholesome, and properly labeled. In fiscal year 2008, FSIS inspected over 109 billion pounds of meat and poultry carcasses, tested 56,000 raw meat samples for contamination, and verified that companies met food safety standards. If meat, poultry, or egg products are adulterated (in the case of Hallmark, because there was a risk that some cattle might not have received complete and proper inspections as required by law) and have been distributed in commerce, FSIS will ask the responsible company to recall the product. If the company refuses, FSIS has the authority to seize and destroy the product.

In January 2008, the Humane Society released a video that showed Hallmark employees abusing non-ambulatory cattle. In February 2008, FSIS investigated and found that Hallmark repeatedly violated Federal regulations over a 2-year period by slaughtering cattle that were not well enough to stand.⁷ Known as downer cattle, these carry a higher risk of disease than healthy cattle. In April 2009, FSIS amended the Federal meat inspection regulations to require that all downer cattle be condemned.⁸ Prior to this amendment, FSIS veterinarians were allowed to determine, on a case-by-case basis, the disposition of cattle that became disabled after they passed pre-slaughter inspection. However, between February 2006 and February 2008, Hallmark may have slaughtered downer cattle and sold the meat to its customers (e.g., wholesalers) without notifying FSIS' inspectors. Although FSIS determined there was only a remote chance of getting sick from the meat, the agency asked Hallmark to recall all the beef it had distributed during that time because Hallmark did not comply with regulatory inspection requirements and the downers' meat may have been mixed with meat from other cattle (e.g., in ground beef). Hallmark agreed to voluntarily recall over 143 million pounds of beef produced in the previous 2 years—the largest recall in U.S. history.

When a company undertakes a recall, FSIS obtains a list of its customers (e.g., wholesalers) and then contacts the wholesalers to get their lists of customers (e.g., retailers such as grocery stores).⁹ From these, FSIS compiles a master distribution list of potential recipients and selects a sample for Enforcement, Investigation, and Analysis Officers (EIAO) to contact to verify if the recall is effective—i.e., if the product is being located, controlled, and retrieved. FSIS uses interval sampling as its statistical selection methodology, which means that companies are chosen based on a constant interval between them on the master distribution list. For example, FSIS calculated 47 as the appropriate interval for Hallmark's recall, so every 47th company on the agency's master distribution list was to be selected for an effectiveness check.

After selection, FSIS applies critical limits for determining whether a recall is effective. In general, the higher the health risk, the more companies FSIS contacts and the fewer it tolerates with recalled product still available for consumers following a recall (see exhibit A). For example, FSIS assessed Hallmark's recalled beef as having a remote chance to cause illness, and so, from a master list of 9,502, the agency required 200 effectiveness checks with a limit of 12 recipients that could have the product available for consumers. If it found 13 or more, FSIS

⁷ Title 9 Code of Federal Regulations (CFR) 309.3(e).

⁸ Federal Register Volume 74, No. 51, Wednesday, March 18, 2009.

⁹ FSIS Directive 8080.1, Revision 4, Attachment 3, "Recall of Meat and Poultry Products" (Mar. 2, 2006).

would have declared the recall ineffective. Instead, FSIS' effectiveness checks found no companies with the recalled product available. FSIS concluded the recall was effective and closed it in April 2008 with Hallmark having recovered and destroyed 51.7 million pounds of meat.

We conducted two prior audits of FSIS' effectiveness checks and oversight of recalls. In June 2004, we evaluated FSIS' effectiveness checks for the 2002 Pilgrim's Pride poultry recall. In May 2005, we examined FSIS' oversight of the 2004 Quaker Maid Meats beef recall. These audits did not identify the issues we found during this review because, prior to the Pilgrim's Pride audit, FSIS had no process in place for selecting customers to check the effectiveness of a recall.¹⁰ In total, the reports offered seven recommendations that have generally been implemented. For example, in our audit of the Pilgrim's Pride recall, we recommended that FSIS develop a process for selecting customers to check the effectiveness of a recall. FSIS responded by implementing a process for selecting customers based on health risk, and it was this process which FSIS used to evaluate the effectiveness of the Hallmark recall.¹¹ As discussed above, when consumer risk rises, FSIS checks a recall's effectiveness more quickly and with more customers.

OBJECTIVE

We conducted this audit to evaluate FSIS' effectiveness checks of Hallmark's 2008 beef recall. We also assessed whether FSIS had implemented corrective actions in response to recommendations we made in our two prior reports on the agency's recall process.

SCOPE AND METHODOLOGY

To understand and evaluate FSIS' process for conducting effectiveness checks—specifically for the Hallmark recall—we interviewed officials at FSIS' Headquarters in Washington, D.C., and agency officials at 3 of the 13 district offices involved in the company's recall.¹² We also reviewed policies and procedures for conducting a meat recall.¹³ We performed our fieldwork from June through November 2008. Subsequent to this date, however, we continued to work with the OIG statistician to resolve questions regarding FSIS' statistical sampling procedures.

As required by its procedures, FSIS statistically selected 200 potential Hallmark beef recipients from its master list of 9,502 potential recipients. FSIS determined that 20 of the sampled 200 did not receive the beef (either they did not sell or receive the meat during the relevant time period or were out of business). FSIS then selected another 23 companies to replace those who were

¹⁰ The Quaker Maid Meats recall was much smaller in scope and focused primarily on then-recent changes to policy.

¹¹ FSIS classifies the risk from consuming recalled product at three levels. Class I risks have a reasonable probability that consumers may become seriously ill or die. Class II risks (Hallmark's) have a remote probability for illness. Class III risks have no chance of sickness. (See exhibit A.)

¹² We selected three district offices. One of these offices led FSIS' oversight of Hallmark's recall (Alameda, California) and conducted the most effectiveness checks (145). Another office, Denver, Colorado, conducted the second highest number of FSIS' effectiveness checks (19). We selected the third office in Beltsville, Maryland, to provide adequate audit coverage.

¹³ The policies and procedures we reviewed include FSIS Directive 8080.1, Revision 4, Attachment 3, "Recall of Meat and Poultry Products" (March 2, 2006), draft "District Recall Methodology" (July 11, 2005), and FSIS' draft "Recall Methodology for Enforcement Investigations Analysis Officer," (March 24, 2006). These policies and procedures did not address replacing inappropriate sample selections.

irrelevant to determining the recall's success, for a total of 203 to contact.¹⁴ We examined all 203 effectiveness checks to determine if FSIS followed its policies and procedures. We also selected a random sample of 30 effectiveness checks to verify that the information which FSIS obtained was accurate.

In addition, we evaluated FSIS' statistical sampling methodology for effectiveness checks and followed up on FSIS' response to seven recommendations we made in two earlier OIG reports about FSIS' oversight of recalls.

We conducted this performance audit in accordance with generally accepted government auditing standards. These standards require that we plan and perform our audit to obtain sufficient and appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence we obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

AUDIT RESULTS

FSIS' Effectiveness Checks Selection Process Needs Improvement

FSIS needs to improve its process for selecting companies to verify if recalled product is retrieved effectively. FSIS made errors in implementing its statistical methodology for selecting a sample of companies to contact about the effectiveness of Hallmark's recall. Most significantly, 83 of the 203 companies FSIS contacted did not have or did not distribute Hallmark's beef and so were irrelevant for determining the recall's success. In addition, FSIS' master distribution list of potential recipients contained 480 duplicate companies that made it more likely that some businesses would be selected than others.¹⁵ Fundamentally, this occurred because FSIS has not developed a process to eliminate duplicates from its master list before selecting samples, or provided nationwide guidance on replacing inappropriate sample selections. As a result, FSIS' conclusion regarding the success of Hallmark's recall is questionable, and the agency similarly lacks assurance that its conclusions regarding the effectiveness of future recalls will be statistically supportable.

During a food recall, FSIS' policy requires the agency to verify with a statistically selected sample of buyers whether recalled product is being located, controlled, and retrieved. The sample size is based on public health risk as determined by FSIS (see exhibit A). To do this, FSIS first compiles a master list from the recalling company's customers (e.g., wholesalers) and then their customers (e.g., retailers). Since some companies are not able to accurately identify who they sold the recalled product to, FSIS may make its initial selections using the master distribution list (the customer list from the company named in the recall plus the lists maintained by that company's own customers) so that agency officials can immediately begin verifying the

¹⁴ The agency was unable to provide any documents detailing why it added 3 more customers in addition to the required 200 and officials could not recall their basis for the decision.

¹⁵ If a consignee appears on the master distribution list multiple times, that consignee has a higher probability of being selected than does one that is on the master distribution list only one time. That creates a difference in the consignee selection probability that is not accounted for in the underlying methodology taken from a Department of Defense acceptance testing military standard, MILSTD 105E, in which each entity has only one chance of being selected. Even if the consignee does not end up being selected in the sample multiple times, the selection probabilities are distorted. The distortion would persist even if later, after sample selection, the duplicates were removed from the universe.

recall's effectiveness. Consequently, FSIS' master list represents potential product recipients, and can contain duplicates (where two or more companies have the same customer) as well as companies that are out of business, or that did not purchase the recalled product. FSIS has no national guidance about removing duplicates from the master list, or replacing inappropriate members.

In Hallmark's case, FSIS compiled a potential recipient list of 9,502 companies (including 480 duplicates). Based on this number and the agency's determination that there was only a remote health risk from consuming the beef, FSIS statistically selected 200 to contact (see exhibit A). In reviewing the sample, FSIS' staff in the district office leading the recall noticed that 20 of the 200 companies were either out of business, or did not sell meat. They replaced each of the 20 with the next company on the master list.

By doing this after the initial sample selection, FSIS weakened the sample's integrity as an interval sample, which relied on a constant gap of 47 between selected companies. Once FSIS began replacing companies with the next entry on the master list, it altered the interval for the rest of the sample so that 132 selections in total ended up deviating from FSIS' interval. Even if done correctly, we also determined that FSIS' calculated interval excluded 106 companies from statistical selection because the required sample size (200) was reached before the end of the master list.

After replacing the 20 companies that were either out of business or did not sell meat—and then adding 3 others¹⁶—the lead district office split the resulting list of 203 among itself and other district offices nationwide to conduct effectiveness checks according to locality. On their own initiative, a few offices replaced some companies that they found did not buy or sell Hallmark's beef, but most offices did not.¹⁷ Including these replacements, FSIS' district offices found that a total of 83 companies contacted did not have Hallmark's beef: 66 did not buy the beef, 12 were not in the business of buying or selling meat (e.g., a bakery), and 5 were out of business. After all the sampled companies were contacted, the lead office reviewed the district offices' work (effectiveness check forms), but did not have them contact other companies to replace the ones who were out of business or did not purchase the recalled product. FSIS needs to improve its feedback process between the lead district office and the field EIAOs conducting the effectiveness checks when they determine that a company did not receive the recalled product.

When we asked lead district office staff why they initially replaced companies but did not do so later, they explained that they believed they were under considerable pressure to complete the process due to the size of the recall.¹⁸ Since there was no nationwide guidance about replacement, they chose not to require more effectiveness checks. However this decision undercut the statistical viability of FSIS' conclusion that the recall was effective. In effect, only 59 percent of the verifications FSIS conducted were relevant to assessing Hallmark's recall. FSIS should develop guidance to replace inappropriate companies in their sample with companies that received recalled product.

¹⁶ As we discuss in our "Scope and Methodology" section, FSIS was unable to explain why it added 3 more companies after replacing 20.

¹⁷ Three of FSIS' district offices replaced 12 companies that did not buy or sell meat.

¹⁸ District office staff stated in interviews that they believed they were under pressure to complete the work within short timeframes despite an email from the FSIS Office of Field Operations that emphasized an accurate effectiveness check process rather than a rapid process.

In addition to a lack of guidance, FSIS' errors in implementing its statistical selection methodology are also based on not having a statistician monitor the agency's interval sampling. For example, an FSIS official noted that replacements were selected using a method that was intended to keep the sample "random." However, a statistician would have likely noticed that the 20 replacements were not random, and that they disrupted FSIS' interval for the rest of the sample (the 132 deviations noted above). Further a statistician would have insisted that duplicates be removed from the master distribution list before selection as they make it more likely that some businesses will be selected than others.¹⁹ Accordingly, we recommend that FSIS strengthen its oversight of the recall effectiveness process by having a statistician available to oversee both statistical selection and sample replacement if necessary.

FSIS should also have a statistician formally evaluate the appropriateness of interval sampling for effectiveness checks. Interval sampling may be adequate for FSIS' purposes with proper implementation, but the agency has not had a statistician formally evaluate its needs and capabilities in order to determine the most appropriate statistical methodology. Instead, FSIS' policy staff stated that they chose interval sampling for effectiveness checks because this methodology was readily available at no cost to the agency. They asked an FSIS statistician to informally look over their methodology to see if it was acceptable, but not to formally evaluate it against other alternatives.

For example, random sampling gives all members of a list a chance of being selected, unlike FSIS' interval sampling which excluded 106 potential Hallmark beef recipients at the end of the master list. It is also easier to maintain a sample's statistical integrity when replacing members with random sampling, which does not require that a constant interval be maintained during replacement. Further, according to OIG's statistician, random sampling is universally acceptable and better mathematically supported than interval sampling.

We therefore recommend that an FSIS statistician conduct a formal, documented analysis to determine the most suitable sampling methodology for FSIS' effectiveness check process. We also recommend that FSIS formally include a statistician as the agency implements a process to (1) purge the master distribution list of duplicates and any other irrelevant companies before sample selection, and (2) replace inappropriate companies in a way that maintains the sample's statistical integrity. Together, these actions will help provide FSIS with a statistically supportable basis for determining the effectiveness of future recalls.

Recommendation 1

Conduct a formal, documented statistician's analysis to determine and adopt the most suitable statistical methodology for selecting companies to verify a recall's effectiveness. This methodology should include specific instructions for eliminating duplicate product recipients in companies' master distribution lists, and for replacing sampled customers who did not receive recalled products or are out of business.

¹⁹ These statements were based on an assessment by OIG's statistician.

Agency Response

The Office of Data Integration and Food Protection (ODIFP) will assign a statistician to evaluate and strengthen FSIS' statistical methodology for recall effectiveness checks. This review will compare various statistical sampling tools and their potential utility in recall situations. Working with the Office of Policy and Program Development (OPPD), ODIFP then will develop directions for eliminating duplicate product recipients, improving the feedback process to replace inappropriate effectiveness check selections, and achieving desired statistical sample sizes. This analysis will be completed and a final report produced by February 2010. The Directions will then be incorporated into FSIS Directive 8080.1 by OPPD.

OIG Position

We accept FSIS' management decision.

Recommendation 2

Ensure that the statistician's analysis referenced in Recommendation 1 results in a written, nationwide process to be followed by all FSIS field units when conducting recall effectiveness checks.

Agency Response

As stated in the response to recommendation I, OPPD will revise FSIS Directive 8080.1 to incorporate the changes in the recall effectiveness check process developed by ODIFP. OPPD will revise and publish the Directive by April 2010.

OIG Position

We accept FSIS' management decision.

Recommendation 3

Ensure that the process described in Recommendation 2 includes guidance for FSIS field units to use in determining the circumstances under which a statistician needs to be consulted during the recall effectiveness check process. Also, develop plans to ensure that statisticians are available as needed during each recall effectiveness check.

Agency Response

Revisions to FSIS Directive 8080.1 will include guidance for FSIS field units to use in determining the circumstances under which a statistician needs to be consulted during the recall effectiveness check process. Assigned staff from ODIFP with statistical training will be available for statistical assistance. The Directive will also include instructions for contacting assigned staff from ODIFP with statistical training, when necessary. Based on past experience, the need for such consultation should be relatively rare. OPPD will revise and publish the Directive by April 2010.

In a followup telephone contact, FSIS officials clarified that it would be statisticians with PhD's or masters degrees who would be used for the statistical assistance and consultation work.

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.

Exhibit A – Effectiveness Checks Required and Thresholds for Ineffective Recall

Table 1. Recommended timeframes for initiating and reporting verification activities within FSIS

Recall classification	Following the initiation of a recall, FSIS verification activities should begin as soon as possible within a period of:	Following their initiation, FSIS verification activities should be substantially completed within a period of:
<i>Class I</i>	3 days*	10 days
<i>Class II</i>	5 days	12 days
<i>Class III</i>	10 days	17 days

*These denote working days, which may include Saturday and Sunday, depending upon the risk associated with a recalled product.

Table 1 describes, for each Recall classification, when FSIS verification activities should begin and when they should be substantially completed. In a Class I recall there is a health hazard situation where there is a reasonable probability that the use of the product will cause serious, adverse health consequences or death. In a Class II recall there is a health hazard situation where there is a remote probability of adverse health consequences from the use of the product. In a Class III recall there is a situation where the use of the product will not cause adverse health consequences.

Table 2. Effectiveness checks to conduct and critical limits for all Class I recalls involving an illness or outbreak based on epidemiological evidence or with school lunch implications.

Number of Customers	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Customers at which Product was Available to Consumers Exceeds:
1 to 200	All, up to 200	0
201 to 10,000	200	0
10,001 to 35,000	800	1
35,001 to 500,000	800	1
500,001 and over	1,250	2

Table 2 relates to all Class I recalls where there are illnesses, outbreaks, or school lunch implications. It describes, for given numeric ranges of potential customers, how many effectiveness checks FSIS needs to make. It also describes the number of positive results (cases where recalled product was found to be available to consumers) that would lead FSIS to conclude that the recall was ineffective.

Exhibit A – Effectiveness Checks Required and Thresholds for Ineffective Recall

Table 3. Effectiveness checks to conduct and critical limits for Class I recalls when there are **no** illnesses, outbreaks, or school lunch implications.

Number of Customers	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Customers at which Product was Available to Consumers Exceeds:
1 to 20	All, up to 20	0
21 to 150	20	0
151 to 1,200	80	1
1,201 to 2,300	125	2
2,301 to 10,000	200	3
10,001 to 35,000	315	5
35,001 to 150,000	500	8
150,001 to 500,000	800	12
500,001 and over	1250	18

Table 3 relates to Class I recalls when there are no illnesses, outbreaks, or school lunch implications. It describes for given numeric ranges of potential customers, how many effectiveness checks FSIS needs to make. It also describes the number of positive results (cases where recalled product was found to be available to consumers) that would lead FSIS to conclude that the recall was ineffective.

Table 4. Effectiveness checks to conduct and critical limits for Class II recalls or (optionally) for Class III recalls when a firm does not have a Recall Plan.

Number of Customers	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Customers at which Product was Available to Consumers Exceeds:
1 to 5	All, up to 5	0
6 to 25	5	0
26 to 150	20	1
151 to 280	32	2
281 to 500	50	3
501 to 1,200	80	5
1,201 to 2,300	125	8
2,301 to 10,000	200	12
10,001 and over	315	18

Exhibit A – Effectiveness Checks Required and Thresholds for Ineffective Recall

Table 4 relates to Class II recalls or (optionally) Class III recalls when a firm does not have a Recall Plan. It describes, for given numeric ranges of potential customers, how many effectiveness checks FSIS needs to make. It also describes the number of positive results (cases where recalled product was found to be available to consumers) that would lead FSIS to conclude that the recall was ineffective.

Table 5. Effectiveness checks to conduct and critical limits for Class III recalls.

Number of Customers	Number of Effectiveness Checks to Make	Recall Considered Ineffective if the Number of Customers at which Product was Available to Consumers Exceeds:
1 to 8	All, up to 8	1
9 to 50	8	1
51 to 90	13	2
91 to 150	20	3
151 to 280	32	5
281 to 500	50	8
501 to 1,200	80	12
1,201 and over	125	18

Table 5 relates to Class III recalls. It describes, for given ranges of potential customers, how many effectiveness checks FSIS needs to make. It also describes the number of positive results (cases where recalled product was found to be available to consumers) that would lead FSIS to conclude that the recall was ineffective.

The numbers on Tables 2 through 5 are derived from FSIS’ sampling methodology; specifically, Military Standard 105E, “*Sampling Procedures and Tables for Inspection by Attribute.*”

Exhibit B – Agency Response

Exhibit B – Page 1 of 2



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

SEP 18 2009

FROM: Alfred V. Almanza
Administrator

SUBJECT: Office of Inspector General (OIG) Official Draft Report - Food Safety and Inspection Service Oversight of the Recall by Hallmark/Westland Meat Packaging Company (Audit 24601-10-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 has provided responses to the report recommendations.

General Comment

FSIS Directive 8080.1, Revision 5, Attachment 1, Section E, gives District Recalling Officers (DRO) and/or Import Recall Coordinators (IRC) guidance on determining the total number consignees during a recall. FSIS uses a risk-based sampling plan to determine the number of consignees that FSIS program personnel will contact during effectiveness checks. The number of consignees that FSIS will contact depends on the class of the recall and the number and type of consignees that received the recalled product. Although FSIS requests a specific list of the firm's consignees that actually received the recalled product, firms often provide broad customer lists that include all customers of the firm and not just those that may have received the recalled product(s). FSIS is typically not made aware of this until effectiveness checks have commenced and reveal those customers who never actually received the recalled product(s). FSIS must rely on the information provided by the firm. As a result, the efficacy and need to substitute consignees depends greatly upon the accuracy of consignee information provided by the recalling firm. FSIS cannot identify customers that are out of business, did not receive the recalled product, and/or cannot be contacted until after effectiveness checks have commenced. FSIS will improve upon the systematic replacement of these types of customers when they are identified during effectiveness checks by revising the recall methodology.

Recommendation 1:

Conduct a formal, documented statistician's analysis to determine and adopt the most suitable statistical methodology for selecting companies to verify a recall's effectiveness. This methodology should include specific instructions for eliminating duplicate product

recipients in companies' master distribution lists, and for replacing sampled customers who did not receive recalled products or are out of business.

Agency Response:

The Office of Data Integration and Food Protection (ODIFP) will assign a statistician to evaluate and strengthen FSIS' statistical methodology for recall effectiveness checks. This review will compare various statistical sampling tools and their potential utility in recall situations. Working with the Office of Policy and Program Development (OPPD), ODIFP then will develop directions for eliminating duplicate product recipients, improving the feedback process to replace inappropriate effectiveness checks selections, and achieving desired statistical sample sizes. This analysis will be completed and a final report produced by February 2010. The Directions will then be incorporated into FSIS Directive 8080.1 by OPPD.

Estimated Completion Date: February 2010

Recommendation 2:

Ensure that the statistician's analysis referenced in Recommendation No. 1 results in a written, nationwide process to be followed by all FSIS field units when conducting recall effectiveness checks.

Agency Response:

As stated in the response to recommendation 1, OPPD will revise FSIS Directive 8080.1 to incorporate the changes in the recall effectiveness check process developed by ODIFP. OPPD will revise and publish the Directive by April 2010.

Estimated Completion Date: April 2010

Recommendation 3:

Ensure that process described in Recommendation 2 includes guidance for FSIS field units to use in determining the circumstances under which a statistician needs to be consulted during the recall effectiveness checks process. Also, develop plans to ensure that statisticians are available as needed during each recall effectiveness check.

Agency Response:

Revisions to FSIS Directive 8080.1 will include guidance for FSIS field units to use in determining the circumstances under which a statistician needs to be consulted during the recall effectiveness check process. Assigned staff from ODIFP with statistical training will be available for statistical assistance. The Directive will also include instructions for contacting assigned staff from ODIFP with statistical training, when necessary. Based on past experience, the need for such consultation should be relatively rare. OPPD will revise and publish the Directive by April 2010.

Estimated Completion Date: April 2010