#19408-A  
Peanut Corporation of America  
14075 Magnolia St.  
Blakely, GA 39823-0448  

By  
EUGENE A. HATFIELD  
Food Safety Auditor  

March 27, 2008  

AIB International  
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RATING

A food safety audit was conducted at this facility on March 27, 2008.

The writer was accompanied throughout the audit by Mr. Danny Kilgore, Operations Manager; and Ms. Annie Bristow, Janitorial and Sanitation Director.

Excellent cooperation was received by the writer, and on some occasions, the items were immediately corrected.

At the conclusion of the audit, a meeting was held to discuss the observations, recommendations, and rating. The meeting was held with Mr. Danny Kilgore, Operations Manager.

Based on the observations made, the information obtained, and the criteria set forth in the *AIB Consolidated Standards for Food Safety*, the overall food safety level of this facility was considered to be:

**SUPERIOR**

(910)

The “serious” or “unsatisfactory” items are shaded, boxed, and bolded in the text of the report. Refer to the definitions in the AIB Consolidated Standards.

The “improvement needed” items are designated in bold type and require prompt attention.

The AIB International states that the report as given herein is to be construed as its findings and recommendations as of the date of this report. The AIB International accepts no responsibility and does not assume any responsibility for the food safety program in effect with (customer). That further AIB International is only making report of the food safety conditions of (customer) as of the date of this report and assumes no responsibility or liability as to whether (customer) carries out the recommendations as contained in this report or does not carry out the recommendations as contained in this report.
RATING ANALYSIS

DATE OF AUDIT: March 27, 2008

TYPE OF AUDIT: Announced

OVERALL RATING: SUPERIOR

ADEQUACY OF FOOD SAFETY PROGRAM  175

PEST CONTROL  195

OPERATIONAL METHODS AND PERSONNEL PRACTICES  175

MAINTENANCE FOR FOOD SAFETY  175

CLEANING PRACTICES  190

TOTAL:  910
## INCIDENCE FREQUENCY REPORT (IFR)

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*TBA = TOTAL ITEMS BY AREA

AP = Adequacy of Food Safety Program  
MS = Maintenance for Food Safety  
PC = Pest Control  
CP = Cleaning Practices  
OP = Operational Methods and Personnel Practices  
UN = Unsatisfactory  
SER = Serious
FACTUAL OBSERVATIONS AND SPECIFIC RECOMMENDATIONS

PLANT OVERVIEW

1. **COM** A current organizational chart dated January 12, 2008, was maintained. The responsibility and authority for ensuring food safety and security, and the facility's compliance with federal, state, governmental, and/or any other appropriate regulatory laws or guidelines were clearly assigned to the Operations Manager. This responsible person remains up to date on regulatory issues and has obtained the required regulatory food security registration dated 11/0/03.

2. **COM** A Food Safety Manual had been developed. This manual included work instructions and/or job descriptions outlining the specific responsibilities of each department manager and employees, a Quality Policy signed by the Company President with a revision date of January 28, 2006, and written policies for the programs listed in the *AIB Consolidated Standards for Food Safety.*

3. **AP** This facility had established a multidisciplinary food safety committee to conduct monthly inspections of the entire plant. Inspections were generally performed by the Operations Manager and/or Janitorial/Sanitation Director. Documentation of the monthly inspections included identified deficiencies, specific assignments, and actual accomplishments. Inspections reviewed included January, 2008, February, 2008, and March, 2008. Follow-up inspections were done to ensure that the items were corrected. In addition, systems and procedures critical to product safety and quality were audited to ensure they were in place, appropriate, and complied with. This audit was performed by the Quality Assurance Manager and Operations Manager annually, most recently on January 12, 2008, by the Operations Manager. Continued attention to items that had the potential to impact product zones was recommended. Items such as the paste room hoist maintenance, cleaning and sealing gaps in vertical support beams, and open ingredient containers in the peanut butter mixing area. (IMPROVEMENT NEEDED)

4. **COM** The facility appeared to maintain an adequate budget and support to maintain the proper and timely acquisition of appropriate tools, materials, equipment, monitoring devices, chemicals, and pest control materials.
5. AP  A Master Cleaning Schedule (MCS) and a daily housekeeping schedule were developed as a formalized, written plan and implemented in this facility. This MCS specified frequency and responsibility. Postcleaning evaluations were conducted. The schedules were documented as current, and the conditions observed in the plant supported the documentation. The schedule included the outside grounds, buildings, drains, and equipment. The schedule was reviewed periodically to ensure that it was still applicable. Continued emphasis on cleaning the edges around the peanut butter pour-up stations and the floor/wall junctions and gaps in the paste room were needed.

6. COM  Detailed, written cleaning procedures were developed and on file for all cleaning tasks in the facility. These procedures included the chemicals, concentrations, tools, and disassembly instructions for equipment at the level needed to facilitate the appropriate sanitation maintenance of the processing and packaging equipment, building areas, and outside grounds. Specific cleaning procedures were developed to prevent cross-contamination amid allergen and non-allergen-containing products.

7. COM  Incoming goods and ingredients received into the facility were inspected according to established written procedures. The incoming goods were checked for damage, cleanliness, and pest activity. The receiving records included date of receipt, carrier, lot number, amount, seal numbers (when applicable), and product and vehicle conditions. Raw materials that contain allergens or are susceptible to mycotoxins, autolysis from temperature abuse, or pathogenic microorganisms were segregated and covered by a separate written procedure with appropriate documentation.

8. COM  Bulk deliveries of liquid materials included a visual inspection both before and after unloading. Verification was conducted that hatch and hose seals matched those listed on the bill of lading to ensure load integrity in transit. The findings were documented.

9. COM  Appropriate specifications were on file for the raw materials, packaging materials, finished products, and intermediate/semiprocessed products. These specifications were detailed to ensure compliance with relevant food safety and legislative requirements. These specifications were periodically reviewed and formally agreed upon with relevant parties.

10. COM  Certificates of analysis and/or supplier guarantees for raw materials, food packaging, and finished products were maintained on file.
11. COM A Hazard Analysis Critical Control Point (HACCP) program had been developed and implemented for all processes and process lines. The program included the following components: Description of the products manufactured and hazards inherent to them, determined through risk assessment; Identification of critical control points (CCPs) and critical limits; Procedures to control the CCPs; Determination of the monitoring frequency for the CCPs and designation of the person(s) responsible for testing; Established and documented deviation procedures; Written verification program, with proper documentation; Documentation of procedures, records of conformance, and corrective actions. This facility had evaluated the processes and procedures and determined that no critical control points were present in the operation. The designated monitoring control points (MCPs) were specified and described. The most recent program reassessment had been performed by the Operations Manager on January 12, 2008.

12. COM The company had established written employee and Good Manufacturing Practices (GMPs) policies. Specific written procedures were on file for providing food safety training to all personnel, including temporary personnel and contractors. Employees also attended monthly food safety meetings that reviewed different aspects of food safety and GMPs. Records of training completion for new employees and annual refresher training documentation were maintained for all personnel. The most recent employee meeting was held on 03/05/08. Items covered included AIB, GMP, hand sanitation, spillage and clean-up. The annual employee training was held in January and February, 2008.

13. COM A written program for evaluating consumer complaints was established at this location. This program included the rapid dissemination of complaint information to all departments responsible for implementing the food safety program. Complaint information was used, where appropriate, to avoid recurrence and implement ongoing improvements to product safety, legality, and quality. Actions appropriate to the seriousness and frequency of the problems identified appeared to be carried out promptly and effectively.

14. COM A written recall program was on file. All finished products were coded. Product traceability was accomplished through the recording of raw material lot numbers on production records, and included source identification for work in progress and rework. Distribution records were maintained to identify the initial point of distribution to facilitate segregation and recall of specific lots. The recall program was tested every six months with appropriate documentation maintained on file. The most recent mock recall was done on January 15, 2008. The incoming peanut lot number tracked was 14675 received on October 18, 2007, from a known supplier. The peanut lot number was used in a number of manufactured products, manufacturing codes for 7 items were provided. The mock recall was completed in two hours and 15 minutes with 100% effectiveness documented.
15. **COM** Written procedures were in place to control nonconforming product, including work in progress, finished product, and returned goods. Corrective actions equal to the seriousness of the risk appeared to be taken. Records were kept of the corrective actions and disposition of the product. The disposition records account for the total quantity of the nonconforming material produced.

16. **COM** A written policy on how to handle regulatory and third party inspections was on file. These procedures included the person(s) delegated to accompany all inspectors and company policies regarding photographs, records, and samples. The most recent regulatory inspection was done by the Georgia Department of Agriculture, Consumer Protection Division, on December 14, 2007. No violations were noted.

17. **COM** A written program to evaluate and select suppliers of goods and services that affect product quality and food safety had been implemented. An approved list of these suppliers was maintained. An approved list of these suppliers dated December 29, 2005, was maintained.

18. **AP** A written policy stating that no glass or brittle plastics were to be used in the facility, except where absolutely necessary, was in place. Included in the policy was a procedure on how to handle any glass breakage in the facility. A list of all essential glass had been developed and was audited on a routine frequency to ensure that any accidental breakage was found and addressed. The most recent audit was done on March 1, 2008. One deficiency was observed during this audit. Additional attention to cracked light covers was recommended.

19. **COM** A formal preventive maintenance program and work order system was in use to prioritize the elements of identified structural, equipment, or utensil maintenance problems that could cause food adulteration. The program listed the equipment and frequency of the work required to keep the equipment and facility well maintained and in good order. A program to ensure that the safety and legality of product were not jeopardized during maintenance operations was implemented at this facility.

20. **COM** This operation had established a formalized program for the control of bacteria, yeast, and mold as required. Records of laboratory analysis and/or environmental sampling were maintained. Environmental samples were sent to an approved, outside laboratory for testing. Finished product testing was determined by customer requirements and could include total plate count, coliforms, E. coli, Salmonella, and Staphylococcus aureus. All microbiological testing would be performed by an approved, outside laboratory. The on-site laboratory was maintained in such a manner as not to jeopardize the safety of product.
A formalized pest control program was established with written procedures outlining the requirements of the program to reduce the potential for product contamination from pest activity or use of materials and/or procedures designed to control pest activity.

Facility management contracted the McCall Services, Inc., Company to provide weekly pest control services for the exterior of the facility and the interior rodent control program. Also, McCall Services, Inc., provided weekly service for the interior insect light traps. A copy of the service agreement that included materials to be used, methods, and precautions was maintained on file. Copies of the current Georgia State Department of Agriculture license with an expiration date of 06/30/09, liability insurance with expiration date of 08/01/08, and current applicator's license with an expiration date of 06/30/09 were maintained on file.

In addition, Adams Pest Control was contracted to perform weekly interior crack and crevice pesticide applications in the facility and offices. Copies of the Georgia State Department of Agriculture license with an expiration date of 06/30/09, liability insurance with expiration date of 03/01/09, and current applicator's license with an expiration date of 06/30/09.

Material Safety Data Sheets (MSDS) and sample labels were maintained on file for all pesticides applied and/or stored on the premises.

A service report was left after each visit by the outside pest control service. These records included the treatments and tasks carried out, documentation of the checks and findings for the pest monitoring devices, descriptions of the current levels of pest activity, and recommendations for actions needed to correct conditions allowing a potential for pest activity. The most recent interior service date was March 25, 2008, the most recent exterior service date was March 26, 2008.

Documentation of all pesticides applied on the premises, including rodenticides, included materials applied, target organism, amount applied, specific area where pesticide was applied, method of application, rate of application or dosage, date and time treated, and applicator's signature. This documentation indicated that the applications were made in accordance with the label directions. A pesticide list was provided. Pesticides used since the previous audit included Generation mini blocks, EPA registration number 7173-218 and Niban Granular Bait, # 64405-2. Entech Fog 5, # 40391-3, was used in the automatic fogging system on-site when needed. This system was operated by facility personnel. The Adams Pest Control pesticide being used for crack and crevice treatment was Bifen I/T, EPA registration # 53883-118.
26. **COM** Schematics depicting the locations of the interior and exterior pest control devices, including 60 mechanical Tin Cat rodent traps, four insect light traps, and 28 bait stations, were maintained on file and appeared current.

27. **PC** Mechanical mousetraps were installed to monitor for rodent activity inside the facility. These traps were properly positioned along walls and beside doors to the outside. The traps were inspected on a weekly basis, and a record was maintained of service and cleaning of each rodent control device. A rodent activity log used to record captures and help direct any necessary corrective actions. The traps randomly examined appeared properly maintained. During the interior inspection, it was noted that several Tin Cats were found to be moved out of position. Employees should be reminded to replace a trap when it is moved due to cleaning or maintenance in order to maintain an effective rodent control program.

28. **COM** Bait stations for rodent control were installed around the exterior perimeter of the facility at appropriate intervals. These stations were tamper resistant, properly positioned, anchored in place, locked, and properly labeled in compliance with regulatory requirements. All stations were serviced at least monthly. Fresh bait had been supplied in the stations randomly examined. The service and results of the checks were documented on plastic punch cards inside each trap and on the pesticide usage sheets provided.

29. **PC** Electronic flying insect light traps (ILT’s) were used in the facility to aid in monitoring insect activity. These traps were more than ten feet (three meters) from exposed product. The traps were scheduled for weekly cleaning in the summer and monthly cleaning in the winter. A record of the service and cleaning of each ILT was maintained, and the activity levels documented. The light tubes were replaced annually and supporting documentation was maintained. The insect light trap located inside the caged ingredient storage room had one light not working and a glue board with many insects on it. The light bulb should be replaced and a new glue board should be installed.

30. **COM** Pheromone lures or traps were not currently in use in this facility.

31. **COM** All pesticides and application equipment used as part of the on-site automatic fogging system were stored in a locked and ventilated room identified with appropriate signage. Materials to control spills or leakage were provided in the storage enclosure. All other pesticides and application equipment were provided by the contract PCOs. No deviations were noted during the facility inspection.

32. **COM** No evidence of rodent or bird activity was noted in or around the facility.

#19408-A-p.9
33. **OP** Eighteen-inch perimeters were generally maintained in all storage areas to provide cleaning and inspection access. Adequate space for cleaning was maintained between rows of stored products. However, several cardboard boxes were stored on the perimeter in the UPS shipping corner and several buckets and containers on the perimeter inside the chemical storage cage. Items stored on the perimeter in the UPS shipping corner and the chemical cage should be elevated to allow inspection and cleaning.

34. **COM** All incoming ingredients and packaging materials were dated on receipt to ease 'first-in, first-out' stock rotation. A formal program was in place to monitor and repalletize raw materials susceptible to stored product pest activity that were in storage for more than four weeks. Ingredients noted included stabilizer, flour salt, and molasses powder.

35. **COM** Materials in storage were adequately segregated to prevent contamination. Segregated storage was provided for allergen containing ingredients, packaging materials, Research and Development items, cleaning and maintenance chemicals, nonconforming stock, and nonproduct related materials, such as parts and equipment.

36. **COM** Metal detection equipment was provided on each product line. The metal detectors were checked regularly throughout the shift using the relevant test pieces for 2.0 mm ferrous, 2.0 mm nonferrous, and 2.0 mm 316 stainless steel. The detectors employed the use of both an alarm and a positive reject mechanism. Rejected material was diverted into a secured container or was removed from the line. Documentation of the checks was maintained. The detectors were checked during the survey and found properly to detect and reject the provided test pieces. It was noted that the case metal detectors did not reject product but used a belt stop as the rejection method. This was due to the size of the container and the loose product involved. The peanut butter metal detector was a flow-thru unit and rejected into a container.

37. **COM** Procedures for corrective actions to respond to any failure of the metal detectors were on file. These included training, isolation, quarantining, and reinspection of all food produced since the last acceptable test of the metal detector.

38. **COM** Company policy required that all employees' cuts and grazes on exposed skin be covered by a company-issued metal detectable metal strip bandage. These bandages were tested on a predetermined frequency through a metal detector and supporting documentation was maintained.

39. **COM** All outside receiving lines or caps for bulk liquid ingredients were locked and identified. The liquid nitrogen tank and receiving line were located inside a locked fence enclosure.
40. COM Accessible and cleanable in-line receiving strainers had been provided for the bulk liquid ingredients. The strainer was examined on a per load basis, and documentation was maintained. The receiving strainer was checked during the survey and found clean and in good condition.

41. COM Adequate hand washing and sanitizing stations were located at appropriate locations and used properly by the employees. "Wash Hands" signs were displayed in the rest rooms, lunchroom, and by sinks and entryways to production areas.

42. COM The washrooms and locker rooms were maintained in an acceptable sanitary condition. The lockers were inspected monthly as a sanitary control, and no open food or drink was allowed.

43. COM A formal allergen program dated January 18, 2005, and reviewed on January 12, 2008, was in place that included written policies and procedures. Effective measures were undertaken to prevent cross contamination amid incompatible materials.

44. COM All shipping vehicles were inspected before loading for cleanliness and structural defects that could jeopardize product integrity, and documentation was maintained. Security seals were provided on and documented for all outbound vehicles.

45. COM Employees observed in the facility were wearing adequate hair and beard restraints. Their clothing and uniforms were clean and well maintained. No evidence of loose or unsecured jewelry was noted.

46. COM No evidence of eating, drinking, or smoking in unauthorized areas was observed. No smoking was allowed except on the exterior of the facility.

47. COM All personal property was stored in appropriate locations defined by company policy.

48. COM Some measures were undertaken to maintain site security. Site security strategies included fencing, controlled gate access at night, parking outside the fenced area, locked doors at night, employee entrance had keypad entry, interior and exterior surveillance cameras, truck seals, employee screening, and awareness and training programs.

49. COM The exterior grounds were adequately maintained to prevent pest harborage. Waste collection containers were located approximately 100 feet behind the facility and spillage was kept to a minimum.
50. COM Fixtures, ducts, and pipes were generally properly installed and maintained to prevent contamination from leaks, condensation, or insulating material.

51. COM Adequate ventilation was provided in the facility. Filters were in place in air make up units. Fans were maintained and operated in a manner to avoid product contamination.

52. COM A calibration program was in place for all regulating and recording controls. This was included as part of the facility Standard Operating Procedures. Accurate Scale Company, also the Georgia Department of Agriculture, Scales and Measures Division, tested the facility scales. The roaster companies, Proctor, AeroGlide, and Pittman oil roasters were used to standardize the roaster control systems. Temperatures were monitored internally to assure proper temperature control.

53. COM Compressed air used in processing was properly filtered, and a program was in place to inspect and replace traps and/or filters.

54. COM Only food grade lubricants were used on food processing machines. These lubricants were fully segregated in a designated location, the maintenance shop.

55. COM Potable water was supplied from an appropriate source, the Blakely City Water System. A program was in place to monitor water quality. The facility had a report from the city based on the Clean Water Act requirements.

56. COM Devices were installed and maintained where appropriate to prevent backflow and/or back siphonage. While the facility did not have in-line back flow prevention devices, anti-siphon devices were observed on faucets located around and inside the facility.

57. COM All fluorescent light tubes, essential glass, and brittle plastic in the facility appeared to be protected from accidental breakage, or were accounted for in the Glass and Brittle Plastics Management Program.

58. COM The floors, walls, and ceilings throughout the plant were generally of sound construction and well maintained. No roof leakage was evident.

59. COM An ongoing housekeeping program was in place throughout the hours of operation so that operational debris was kept to a minimum.
Adequate cleaning equipment and tools were available and stored away from the production areas. During the facility inspection, several wooden-handled utensils were observed, such as scrapers and sweepers. It was recommended that no wooden-handled utensils be used in food production areas due to the possibility of splintering or breakage.

The equipment was cleaned according to the MCS to prevent the development of microorganisms, insects, or foreign material.

Food contact cleaning surfaces and utensils were cleaned often enough to remove food residue and maintain a good cosmetic appearance.

Only cleaning compounds and sanitizers that are authorized for use on food contact surfaces were used for cleaning. The chemical control program consisted of purchasing from approved vendors only. Materials purchased were approved by the sanitation Director or maintenance manager prior to purchase. In addition, chemicals used for cleaning were kept in a locked cage inside the plant warehouse.

The maintenance cleaning practices were found satisfactory. The maintenance debris, tools, and other items generated during maintenance activities were removed from the work area.

This facility had an automated Entech fogging system for fogging the interior of the plant. This system was operated inside a fenced, gated and locked enclosure inside the facility. It was noted that the plant used a pre-operational inspection procedure that included additional cleaning when noted on the inspection checklist. The pre-operational inspector would be notified when fogging had occurred and would require cleaning of product zones prior to releasing the equipment for operation. This general program was documented for review.

No issues were observed on the roof of the facility. All air intakes were properly screened to prevent any pest access into the facility.

A break in the concrete block wall was observed next to dock door 5 on the north exterior wall of the facility. The break in the concrete block should be properly sealed to prevent any possible pest entry or harborage in the block wall.

The paved areas around the facility had been repaired since the previous audit. No issues with standing water or potholes were noted.
69. COM During the exterior inspection, it was noted that the dumpsters used for trash or garbage were located away from the building. The dumpsters were open, but all trash in the dumpsters was being secured inside tied plastic bags. This would prevent possible pest (bird) attraction to the dumpsters.

SUPPORT AREAS

70. COM The employee break room and employee rest rooms were inspected and found to be properly cleaned and maintained.

71. MS In the wash room, a broken plastic light shield was observed. It was noted that all fluorescent lights in the facility were shatter-resistant. However, the broken plastic should be removed to prevent possible fragmentation into the wash room. This was not an open product area.

MAINTENANCE AREAS

72. OP Maintenance areas inspected during the audit were found to be generally clean and maintained. Continued to attention to storing items so that perimeter inspections can be performed was recommended.

WAREHOUSE

73. COM In the warehouse caged area, the insect light trap had a bulb that was not working. Also the glue board had a number of insects trapped. The light bulb should be replaced and the glue board should be replaced to provide an effective insect monitoring program in this storage area.

74. COM The top of the break room was inspected and found to be generally clean and properly maintained.

75. COM The general warehouse storage areas were inspected and found to be properly organized and well maintained. No spillage or torn ingredient containers were observed.
PEANUT BUTTER AND PASTE OPERATIONS

76. OP In the peanut butter mixing operation, several instances of open ingredient containers were observed in the area of the mixer located on the roof of the peanut butter room. Ingredient containers should be closed or secured when not in use in order to prevent possible product contamination due to materials falling into the ingredients being used. (IMPROVEMENT NEEDED)

77. MS In the peanut butter room, the plastic motor fan cover for the blender motor was broken and damaged. While the blender was covered, the plastic cover could fragment and should be replaced.

78. COM In the votator room, the peanut butter transfer piping passageway had loosened and created a gap in the wall seal. In order to prevent any possibility of insect harborage, the wall opening should be re-sealed.

79. CP In the corner by the peanut butter peanut pour-up stations, product residue accumulation was noted on the horizontal beams and in the corner at the floor/wall junction. Several live sawtooth grain beetles were noted in the residue. This area should be thoroughly cleaned and monitored to prevent further buildup and possible insect development.

80. MS In the paste room, the hoist cable had a label located above the peanut hopper that was peeling and could fall into the peanut hopper. The label was immediately removed. Attention should be paid to all items located above open zones. (IMPROVEMENT NEEDED)

81. CP In the northeast corner of the paste room, a gap was noted between vertical roof support beams. This gap had product residue accumulated in the small opening between the beams. A live sawtooth grain beetle was found in the residue. This gap should be thoroughly cleaned to remove all product residue. In addition, it was recommended that the gap be sealed with concrete to remove the gap and provide a cleanable surface.
**Facility And Operating Profile**

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<th>Question/Notes</th>
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| 1  | **Facility and Operations Description:**  
|    | Auditor's Notes:  
|    | The facility, originally built in 1982, is located in a light Industrial area east of Blakely, GA. With a trucking company and nut blanching operation on either side, the facility has a fenced perimeter and a 32,000 square feet building (20,000 production). Operating with 50 employees, there are two producing shifts (roasting on second) over a 5 day schedule. |
| 2  | **Regulatory Inspection Type:**  
|    | FDA, Georgia State Dept. of Agriculture, USDA Vendor Programs |
| 3  | **Products made at this facility:**  
|    | Peanut products |
| 4  | **Products made for the client:**  
|    | Raw, Oil Roast, Dry Roast, Granulated, and Peanut Butter |
| 5  | **What is the average lot size in pounds (coded and identifiable)?**  
|    | 20,000 |
| 6  | **What is the most probable cause of accidental product contamination?**  
|    | Field related items (sticks, stems, rocks) |
| 7  | **The following departments and individuals participated in the audit process:**  
|    | Operations Manager, Danny Kilgore. |

**Section Notes:**
### Score Summary By Section

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<td>Section 7.A - In-Plant Hazardous Materials</td>
<td>100.00%</td>
</tr>
<tr>
<td>Section 8.A - Process Security</td>
<td>98.75%</td>
</tr>
<tr>
<td>Section 9.A - Warehouse and Transportation</td>
<td>91.67%</td>
</tr>
<tr>
<td>Section 10.A - Traceability</td>
<td>100.00%</td>
</tr>
<tr>
<td>Section 11.A - Tamper Evident Packaging</td>
<td>100.00%</td>
</tr>
<tr>
<td>Section 12.A - Crisis Management</td>
<td>90.00%</td>
</tr>
<tr>
<td>Security Audit Average Score:</td>
<td>96.61%</td>
</tr>
</tbody>
</table>

### Category Scoring Guide

- **95-100** = Meet or Exceeds Audit Expectations (Acceptable - Excellent)
- **85-94** = Opportunity For Improvement (Minor)
- **75-84** = Needs Improvement (Major)
- **<75** = Immediate Improvement Needed (Critical)

### Automatic Audit Failure

- Direct Product Contamination.
- Adulterated or Misbranded product.
- Facility was not operating in sanitary condition.
- HACCP System Failure - Plant was producing product that did not meet critical limit(s); appropriate corrective action was not taken; or no HACCP Plan if mandated by regulations.
- Critical Deficiency in any one category.
Overview

Notes from the auditor:
See Notes
This is the first NSF Food Processing and Product Security Audit for the Blakely, GA facility of Peanut Corporation of America. Plant management is shorthanded as they have been without a Quality Assurance Manager since December, 2007. The top management person at the facility, the Operations Manager, has assumed the QA role until a new Quality Manager has been hired. This is a small facility with 50 employees that operates with managers assuming more than their primary role.

The facility has basic security through personnel policies, cameras, key lock doors and fenced perimeter. Product security includes: receiving policies, transport inspections, minor ingredient security and sealed full shipments. Continued periodic security reviews for facility and product are important.

As the findings show, documentation of present programs for consistency and continuity are important. Details for the Recall program, Crisis Management, Allergen management, and sanitation reports are examples.

Management has an understanding of the quality and security needs for a food processing facility, yet, there are details as indicated in the report, that need to be corrected. Primary areas are facility condition, sanitation and pest control, along with documentation of major programs that need attention. Details in the report point out specific findings for correction which can be the basis for daily facility review to determine if similar situations exist. While there were no critical items observed, the potential exists for more serious issues.

Product traceability exercises are conducted twice per year with a review of the process. Changes have been implemented to better identify the use of rework in production and speed up the tracing process. Two tracings conducted this year have been successful during the required time period.

Section Notes:

Non-Compliance Summary

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>Section A /4</td>
<td><strong>Recall Plan and Procedures</strong>&lt;br&gt;A plant specific Recall Plan must be available. The plan must include all necessary contact information. All documentation related to product traceability must be available. A traceability exercise must be conducted at least twice per year.&lt;br&gt;The recall procedure lacks a designated recall coordinator and a public relations spokesperson.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section A /7</td>
<td><strong>Change Management</strong>&lt;br&gt;There must be a policy in place to manage and communicates changes in specifications, policies and procedures in order to maintain continuity and the control of systems.&lt;br&gt;A procedure for change management has not been developed.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section A /10</td>
<td><strong>Crisis and Natural Disaster Management</strong>&lt;br&gt;A crisis management plan must be in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access.&lt;br&gt;A Crisis Management team handles recalls with a documented procedure. There is not a procedure to handle emergencies, natural disasters or other such events.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section B /2</td>
<td><strong>Preliminary HACCP Tasks</strong>&lt;br&gt;A HACCP team must be assembled with team member responsibilities clearly identified. Process flow diagrams outlining each step in the process must be constructed by the HACCP Team and they must perform an on site review to verify its accuracy.&lt;br&gt;There have not been team member responsibilities established or team meetings.</td>
<td>Minor*</td>
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<tr>
<td>Section B /3</td>
<td><strong>Hazard Analysis (HACCP Principle 1)</strong>&lt;br&gt;The HACCP team must prepare a list of all chemical, physical and biological hazards that may occur and conduct a hazard analysis to identify the hazards that are critical and controllable.&lt;br&gt;There is not a documented detail of Hazard Analysis for each of the process steps.</td>
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<tr>
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<tbody>
<tr>
<td>Section C /1</td>
<td><strong>Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management</strong>&lt;br&gt;The plant must demonstrate that the water supply is potable and that potability is maintained at all times. Potability must meet local requirements at a minimum. Water lines and hose drops must be fitted with backflow prevention devices that are tested by a trained inspector at least annually. There can be no dead ends on potable water lines. Hose nozzles must not be submerged in water reservoirs or left laying on the floor. An adequate supply of hot and cold water must be readily available for production, sanitation and handwashing. The facility must have a procedure for handling backed up drains.&lt;br&gt;<strong>Backflow devices are in place yet are not verified on an annual basis</strong></td>
<td>Minor*</td>
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<tr>
<td>Section C /2</td>
<td><strong>Plant Construction and Design</strong>&lt;br&gt;The construction of the facility must be such that it facilitates the production of wholesome product and that it meets the customer and regulatory food safety and quality requirements. Materials must be easily cleanable, floors well drained and drains must have traps and covers. The plant must be designed in a manner appropriate to prevent the contamination of product. A glass and brittle plastic program must be in place.&lt;br&gt;The platform over the two product lines leading to the dry roast swing arm only has “toe” height board around the edges. The floor is chipped near the end of the oil roast line. Tape over a Bin on the mezzanine is fraying. Numerous screw holes are in the metal wall near the Peanut Butter Kettle and in the packaging storeroom. The cloth gasket on the edges at the end of the Dry Roast belt is beginning to fray. Duct tape is used on the seams for the wall panels in the cool room.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section C /3</td>
<td><strong>Plant Condition (Walls, Ceilings, Floors, etc.)</strong>&lt;br&gt;Walls, ceilings and floors must be well maintained, orderly, clean and sealed. No evidence of water leakage, rust or flaking paint. No string, rope, wire or tape used as supports or temporary repairs. Overhead structures must be clean and free of buildup.&lt;br&gt;Numerous screw holes are in the metal wall near the Peanut Butter Kettle and in the packaging storeroom. The cloth gasket on the edges at the end of the Dry Roast belt is beginning to fray. Duct tape is used on the seams for the wall panels in the cool room.</td>
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<td>Minor*</td>
</tr>
<tr>
<td>Section C /7</td>
<td><strong>Equipment Layout, Design and Conditions</strong>&lt;br&gt;Equipment must be designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Product contact surfaces must be constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts.&lt;br&gt;The sweep arm depositing peanuts on a belt is rusty. Clear tape is used to hold a plastic pipe directing granular peanuts to further conveyance.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section C /9</td>
<td><strong>Maintenance Standard (Support of GMPs, Housekeeping, Lubricants</strong>&lt;br&gt;There must be a documented preventative maintenance program that covers the equipment and facilities. Permanent repairs must be made promptly. Food-grade and non-food grade lubricants can not be stored together.&lt;br&gt;No Preventative Maintenance or work order program is documented.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section D /1</td>
<td><strong>Master Sanitation List and Monitoring</strong>&lt;br&gt;There must be a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. There must be scheduled tasks for all cleaning procedures that are monitored and documented.&lt;br&gt;The Master Sanitation List does not cover the process or warehouse areas.</td>
<td>Minor*</td>
</tr>
<tr>
<td>Section D /2</td>
<td><strong>Standard Sanitation Operating Procedures and Monitoring</strong>&lt;br&gt;There must be documented Standard Sanitation Operation Procedures detailing the cleaning methods and frequency of cleaning for all equipment and facility structures. All cleaning and sanitizing must be documented and monitored. Records must be kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a recurrence.&lt;br&gt;<strong>Standard Operating Procedures for cleaning were not available.</strong></td>
<td>Minor*</td>
</tr>
<tr>
<td>Section</td>
<td>Question/Notes</td>
<td>Answer</td>
</tr>
<tr>
<td>---------</td>
<td>-------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------------</td>
<td>--------</td>
</tr>
</tbody>
</table>
| D /4    | **Pre Op Monitoring and Corrective Action**  
A routine documented inspection program must be in place to assess sanitation practices and conditions prior to daily operation. Deficiencies must be noted and corrective actions taken.  
*In a review of the Pre-Op documents for the Dry Roast line for March 2008, there were numerous documents that indicated additional cleaning was needed, yet no corrective action was documented. Also signatures for verification of the Pre-Op monitoring were inconsistent.* | Minor* |
| D /6    | **Operational Housekeeping and Monitoring**  
All areas of the plant must be kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials must be accumulated in identified containers and disposed of properly. Floor drains must be kept clean, odor free and covered. No tool storage or materials on top of equipment, electrical boxes or window ledges.  
*A fan in the Peanut Butter packaging area had dusty blades and grill. A wrench and scraper were stored on a shelf over the processing line. Per the management, the white buckets are to be used for edible materials and red buckets for inedible materials. Observations indicate the white and red buckets are both used for trash and inedible materials.* | Minor* |
| D /8    | **RTE Sanitation and Corrective Action**  
Employees working in Ready to Eat (RTE) areas must take additional precautions to protect product from microbiological cross contamination. Personnel handling RTE food must wear sanitary gloves.  
*Outer clothing in Ready-To-Eat processing areas is to be dedicated to that area. Note the conditions indicated in C.4.* | Minor* |
| E /1    | **Documented and Specific Pest Control Program**  
There must be a pest management program in place that is overseen by a licensed Pest Control Operator (PCO). Site maps for all traps and bait stations, documentation of services, Material Safety Data Sheet (MSDS), the PCO applicators license and letter of insurance must be current and on file.  
*Non-certified personnel are applying pesticides (herbicide Round-Up / Honcho Plus).* | Minor* |
| E /4    | **Pest Tight Doors and Entrance Closures**  
All doors must be tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., to provide easy access to pests.  
*Dock doors (3 and 4) and personnel doors (SE corner of building and at Bulk Peanut Butter loading) did not have a good seal.* | Minor* |
| E /5    | **Secure Storage and Documentation of Pest Related Chemicals**  
If pest related chemicals are stored on site, they must be stored in a secured location with limited access. An up to date inventory log of chemicals must be maintained. Containers must be destroyed once empty. Safety precautions for storage of pest related chemicals must be available.  
*There was a container of herbicide unsecured on an outside table.* | Minor* |
| E /6    | **Storage and Handling Policies and Practices**  
There must be established procedures to assure that ingredients and supplies do not become a source of contamination. Receiving areas and storage locations must be maintained in a clean and sanitary manner. All ingredients and supplies must be held under conditions necessary to maintain product integrity.  
*Condensation from an air conditioner is draining to the floor of the secured ingredient area.* | Minor* |
| G /6    | **Allergen and Sensitive Ingredient Controls**  
In facilities where allergens or sensitive ingredients are present, there must be detailed procedures to prevent the contamination of other products. Products containing allergens must be labeled as required by regulations.  
*A detailed documented allergen program for production and training is needed since there are different allergenic ingredients potentially used in addition to the primary peanut products.* | Minor* |
### Section A  Administration and Regulatory Compliance

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Food Safety, Quality and Food Defense Organization and Responsibilities</strong>&lt;br&gt;There must be a plant management organization chart that shows the reporting structure of the plant operating departments. The chart must clearly show the reporting relationship of the Quality Manager.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td><strong>Food Safety, Quality and Food Defense Policies and Procedures</strong>&lt;br&gt;There must be policies and procedures that address relevant food safety, quality and security requirements for the receiving, handling, manufacturing and shipping of product. The expectations should be defined through product and process specifications, testing procedures, sampling programs and accept/reject criteria.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Specific Training Goals and Programs for Management and Operating Personnel</strong>&lt;br&gt;Documents must be available to demonstrate management’s commitment to a planned training program for both management and food production personnel. The plan must include training of all new employees and refresher training for all current employees on a regular basis.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Recall Plan and Procedures</strong>&lt;br&gt;A plant specific Recall Plan must be available. The plan must include all necessary contact information. All documentation related to product traceability must be available. A traceability exercise must be conducted at least twice per year. <strong>The recall procedure lacks a designated recall coordinator and a public relations spokesperson.</strong></td>
<td>Minor*</td>
</tr>
<tr>
<td>5</td>
<td><strong>Regulatory Compliance</strong>&lt;br&gt;The facility must maintain a file of regulatory actions, visits, reports or other notifications received from any regulatory agency. Written responses with appropriate corrective actions must be documented. A log of samples submitted for pathogen, antibiotic or environmental testing must be maintained.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td><strong>Document and Records Management</strong>&lt;br&gt;A document control policy must be in place that covers all aspects of creating, storing and disposing of documents.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td><strong>Change Management</strong>&lt;br&gt;There must be a policy in place to manage and communicates changes in specifications, policies and procedures in order to maintain continuity and the control of systems. <strong>A procedure for change management has not been developed.</strong></td>
<td>Minor*</td>
</tr>
<tr>
<td>8</td>
<td><strong>Documentation to Track Effectiveness of Policies</strong>&lt;br&gt;Management reviews must take place to evaluate the level of conformance to operational policies.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td><strong>Management Awareness and Commitment to Food Safety, Quality &amp; Food Defense</strong>&lt;br&gt;Management must be committed to food safety and quality. There active support should be shown through training programs, auditing for compliance to policies and provision of corrective actions.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td><strong>Crisis and Natural Disaster Management</strong>&lt;br&gt;A crisis management plan must be in place that defines emergency procedures, outlines the crisis team members and provides key contacts with 24/7 access. <strong>A Crisis Management team handles recalls with a documented procedure. There is not a procedure to handle emergencies, natural disasters or other such events.</strong></td>
<td>Minor*</td>
</tr>
<tr>
<td>11</td>
<td><strong>Customer/Consumer Complaints (Policies, Follow Up and Response)</strong>&lt;br&gt;There must be a customer complaint program in place that addresses responsibilities, response time and corrective actions based on the investigation of a complaint.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

- The recall procedure lacks a designated recall coordinator and a public relations spokesperson.
- A procedure for change management has not been developed.
- A Crisis Management team handles recalls with a documented procedure. There is not a procedure to handle emergencies, natural disasters or other such events.

### Section B  HACCP Management

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Prerequisite Programs</strong>&lt;br&gt;Prerequisite programs must be well developed, documented and monitored.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
### Section B  HACCP Management

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
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</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>Preliminary HACCP Tasks</td>
<td>Minor*</td>
</tr>
<tr>
<td></td>
<td>A HACCP team must be assembled with team member responsibilities clearly identified. Process flow diagrams outlining each step in the process must be constructed by the HACCP Team and they must perform an on site review to verify its accuracy. <strong>There have not been team member responsibilities established or team meetings.</strong></td>
<td></td>
</tr>
<tr>
<td>3</td>
<td>Hazard Analysis (HACCP Principle 1)</td>
<td>Minor*</td>
</tr>
<tr>
<td></td>
<td>The HACCP team must prepare a list of all chemical, physical and biological hazards that may occur and conduct a hazard analysis to identify the hazards that are critical and controllable. <strong>There is not a documented detail of Hazard Analysis for each of the process steps.</strong></td>
<td></td>
</tr>
<tr>
<td>4</td>
<td>Critical Control Points (HACCP Principle 2)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Documentation for determining a step or process as a CCP or not, must be clearly explained. Meetings must be conducted on a regular basis by the HACCP team to review any changes in the process that might affect the CCP determination. <strong>No Critical Control Points have been established.</strong></td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>Critical Limits (HACCP Principle 3)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Control measures identifying operating and critical limits must be established and for each CCP. All critical limits must be measurable. Process capabilities must be documented to establish that CCP limits are compatible with the plant process and that limits are attainable. <strong>No Critical Control Points have been established, for which to develop critical limits.</strong></td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>CCP Monitoring (HACCP Principle 4)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>CCP monitoring procedures must be conducted at a frequency sufficient enough to detect any loss of control. The data must be evaluated by those empowered to implement corrective actions and must be documented on HACCP records. <strong>No monitoring has been established since no Critical Control Points have been established.</strong></td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>Corrective Actions (HACCP Principle 5)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Corrective actions must be developed for each CCP including instructions with the necessary actions to take to secure product and bring the CCP under control in the event a critical limit is exceeded. <strong>No corrective actions have been established since no Critical Control Points have been established.</strong></td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Verification and Validation (HACCP Principle 6)</td>
<td>N/A</td>
</tr>
<tr>
<td></td>
<td>Documentation must be available confirming the HACCP plan is scientifically and technically sound. The documentation should also confirm that all hazards have been identified and CCPs are effective and valid. Validation of the plan must be performed and documented on an annual basis. <strong>No verification of CCP monitoring has been established.</strong></td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Documentation and Record Keeping (HACCP Principle 7)</td>
<td>Acceptable</td>
</tr>
<tr>
<td></td>
<td>HACCP procedures must be documented with detailed corrective actions and product dispositions. Final records must be in ink, signed by the appropriate personnel and without missing data or blanks. Records must be securely stored and easily retrievable. <strong>The HACCP Plan has been reviewed and documented on an annual basis.</strong></td>
<td></td>
</tr>
</tbody>
</table>

**Section notes:** A HACCP program even if voluntary has a specific format such as a detailed Hazard Analysis based on items that include chemical, physical, biological hazards of a process flow chart. The consideration of a CCP can be based on current scientific studies (temperatures of similar processes) or existing regulatory statements (FDA documents for metal detection).

### Section C  Facilities and Equipment

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<td>1</td>
<td>Potable Water, Ice, Backflow Prevention, Steam and Waste Water Management</td>
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### Section C  Facilities and Equipment

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<tr>
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<td><strong>Plant Construction and Design</strong>&lt;br&gt;The construction of the facility must be such that it facilitates the production of wholesome product and that it meets the customer and regulatory food safety and quality requirements. Materials must be easily cleanable, floors well drained and drains must have traps and covers. The plant must be designed in a manner appropriate to prevent the contamination of product. A glass and brittle plastic program must be in place. <strong>The platform over the two product lines leading to the dry roast swing arm only has &quot;toe&quot; height board around the edges. The floor is chipped near the end of the oil roast line. Tape over a Bin on the mezzanine is fraying.</strong></td>
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<td>4</td>
<td><strong>Ready To Eat (RTE) Operational Areas</strong>&lt;br&gt;Ready to Eat areas must be separated and effectively isolated from other operations. Filtered air supplies must provide a positive room air pressure and filters must be routinely inspected and maintained for maximum efficiency. <strong>The plant air flow is negative bringing outside air into an area where Ready-To-Eat products that have already been through a kill step are exposed to the plant environment.</strong></td>
<td>Minor*</td>
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<tr>
<td>5</td>
<td><strong>Employee Support Facilities</strong>&lt;br&gt;The cafeteria, locker room and toilet facilities must be adequately sized, physically separated from food production areas and maintained in a sanitary condition. Toilet facilities must be well ventilated, doors must be self-closing and can not open directly into the production areas. Signs must be clearly posted in locker rooms, toilet facilities and at entrances to work areas reminding employees to wash and sanitize their hands before starting work and when leaving toilet facilities.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td><strong>Handwashing Facilities</strong>&lt;br&gt;Hand washing facilities must be provided in locker rooms, toilet facilities and at entrances to work areas. They must be adequate in size, quickly deliver tempered water and maintained with hand soap and single service towels. Hands-free activated faucets must be available in and adjacent to processing areas.</td>
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<td>7</td>
<td><strong>Equipment Layout, Design and Conditions</strong>&lt;br&gt;Equipment must be designed, installed and maintained in a manner that provides a safe, wholesome and quality product with easy access for cleaning and sanitizing. Product contact surfaces must be constructed with materials that are smooth, impervious, non-toxic, non-absorbent and corrosion resistant with appropriate covers and no metal-to-metal contact between moving parts. <strong>The sweep arm depositing peanuts on a belt is rusty. Clear tape is used to hold a plastic pipe directing granular peanuts to further conveyance.</strong></td>
<td>Minor*</td>
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<tr>
<td>8</td>
<td><strong>Plant Lighting and Protection</strong>&lt;br&gt;Adequate illumination must be provided and lighting must be protected from breakage and possible contamination. Light fixtures must be maintained clean, free of cracks, dust or other materials that could cause contamination.</td>
<td>Acceptable</td>
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<td>9</td>
<td><strong>Maintenance Standard (Support of GMPs, Housekeeping, Lubricants</strong>&lt;br&gt;There must be a documented preventative maintenance program that covers the equipment and facilities. Permanent repairs must be made promptly. Food-grade and non-food grade lubricants can not be stored together.&lt;br&gt;<strong>No Preventative Maintenance or work order program is documented.</strong></td>
<td>Minor*</td>
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#### Section notes:
Peanut products as produced at this facility are a direct consumable product without further treatment by the consumer. Considerations as a Ready-To-Eat Product need to be kept in mind for the production and storage environment.
## Section D  Sanitation, Housekeeping and Hygiene

<table>
<thead>
<tr>
<th>No</th>
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<th>Answer</th>
</tr>
</thead>
</table>
| 1  | **Master Sanitation List and Monitoring**  
There must be a documented cleaning procedure for operational areas, equipment, warehouse, storage, maintenance, employee support areas and other plant areas. There must be scheduled tasks for all cleaning procedures that are monitored and documented.  
*The Master Sanitation List does not cover the process or warehouse areas.* | Minor*  |
| 2  | **Standard Sanitation Operating Procedures and Monitoring**  
There must be documented Standard Sanitation Operating Procedures detailing the cleaning methods and frequency of cleaning for all equipment and facility structures. All cleaning and sanitizing must be documented and monitored. Records must be kept of all deficiencies found and the corrective action that is taken to bring the equipment into a sanitary condition and prevent a reoccurrence.  
*Standard Operating Procedures for cleaning were not available.* | Minor*  |
| 3  | **Cleaning Chemical and Sanitizer Control**  
There must be procedures that specify the proper dilution of chemicals and/or sanitizers. All chemical containers must be properly labeled and used for their intended purpose only. Chemicals must be securely stored during periods of non-use. | Acceptable |
| 4  | **Pre Op Monitoring and Corrective Action**  
A routine documented inspection program must be in place to assess sanitation practices and conditions prior to daily operation. Deficiencies must be noted and corrective actions taken.  
*In a review of the Pre-Op documents for the Dry Roast line for March 2008, there were numerous documents that indicated additional cleaning was needed, yet no corrective action was documented. Also signatories for verification of the Pre-Op monitoring were inconsistent.* | Minor*  |
| 5  | **Verification of Cleaning Effectiveness**  
The effectiveness of the sanitation program must be monitored visually prior to production and supplemented with an objective measurement at a frequency that demonstrates effectiveness. | Acceptable |
| 6  | **Operational Housekeeping and Monitoring**  
All areas of the plant must be kept clean, orderly and free from accumulation of litter. Garbage, trash and waste materials must be accumulated in identified containers and disposed of properly. Floor drains must be kept clean, odor free and covered. No tool storage or materials on top of equipment, electrical boxes or window ledges.  
*A fan in the Peanut Butter packaging area had dusty blades and grill. A wrench and scraper were stored on a shelf over the processing line. Per the management, the white buckets are to be used for edible materials and red buckets for inedible materials. Observations indicate the white and red buckets are both used for trash and inedible materials.* | Minor*  |
| 7  | **Personal Hygiene and Good Manufacturing Practices**  
There must be a dress code that is enforced for everyone entering the facility. Employees must wear clean clothing and shoes appropriate for the working conditions. Hair restraints must be worn in all processing and warehouse areas. Employees working in production areas must not wear fake fingernails, fingernail polish, jewelry, rings, or watches, etc. Employees cannot work in food processing areas if they have a communicable illness, or open sores. Employees must wash their hands before starting work and any time necessary to avoid product contamination. If gloves are worn, they must be intact, with no holes, and kept clean. There must be a means to avoid contamination of outer clothing when using the toilet facilities. Eating, drinking or using tobacco products must not be permitted except in designated areas. | Acceptable |
| 8  | **RTE Sanitation and Corrective Action**  
Employees working in Ready to Eat (RTE) areas must take additional precautions to protect product from microbiological cross contamination. Personnel handling RTE food must wear sanitary gloves.  
*Outer clothing in Ready-To-Eat processing areas is to be dedicated to that area. Note the conditions indicated in C.4.* | Minor*  |
| 9  | **GMP Self Inspections and Corrective Actions**  
Internal GMP self-inspections must be conducted to verify compliance to policies and to evaluate the effectiveness of the policies. Follow-up audit activities must be conducted to record the effectiveness of corrective actions for deficiencies and repeat items. | Acceptable |

**Section notes:**

## Section E  Rodent and Pest Control Management
### Section E  Rodent and Pest Control Management

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Documented and Specific Pest Control Program</strong>&lt;br&gt;There must be a pest management program in place that is overseen by a licensed Pest Control Operator (PCO). Site maps for all traps and bait stations, documentation of services, Material Safety Data Sheet (MSDS), the PCO applicators license and letter of insurance must be current and on file. Non-certified personnel are applying pesticides (herbicide Round-Up / Honcho Plus).</td>
<td>Minor*</td>
</tr>
<tr>
<td>2</td>
<td><strong>Outside Premises Management (Grounds, Waste Disposal Areas)</strong>&lt;br&gt;The buildings exterior and grounds must be well maintained and free from pest harborages. Adequate trash and waste disposal facilities must be available and the premises must be free from standing water that could attract pests.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Inside Premises Management</strong>&lt;br&gt;Interior conditions must be orderly, clean throughout and allow for easy access and evaluation along walls. Control measures must be used at distances from food or food contact surfaces to avoid any potential for contamination. Trapping devices must be in proper working condition and no bait stations can be used inside the plant or warehouse.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Pest Tight Doors and Entrance Closures</strong>&lt;br&gt;All doors must be tight closing and no exterior holes/cracks in walls, pipe chase, vent openings, windows, etc., to provide easy access to pests. Dock doors (3 and 4) and personnel doors (SE corner of building and at Bulk Peanut Butter loading) did not have a good seal.</td>
<td>Minor*</td>
</tr>
<tr>
<td>5</td>
<td><strong>Secure Storage and Documentation of Pest Related Chemicals</strong>&lt;br&gt;If pest related chemicals are stored on site, they must be stored in a secured location with limited access. An up to date inventory log of chemicals must be maintained. Containers must be destroyed once empty. Safety precautions for storage of pest related chemicals must be available. There was a container of herbicide unsecured on an outside table.</td>
<td>Minor*</td>
</tr>
<tr>
<td>6</td>
<td><strong>Activity Reports Detailed with Corrective Actions</strong>&lt;br&gt;Activity reports must be available with specific details about all pest activity observed. Recommended corrective actions should be included on the reports as well as details about the chemicals used in response to the observed activity. Activity reports must be signed by the PCO and by a designated plant representative. All deficiencies require documented corrective action.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

- Non-certified personnel are applying pesticides (herbicide Round-Up / Honcho Plus).
- Dock doors (3 and 4) and personnel doors (SE corner of building and at Bulk Peanut Butter loading) did not have a good seal.
- There was a container of herbicide unsecured on an outside table.

### Section F  Receiving and Inventory Control

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Incoming Vehicle Review and Documentation</strong>&lt;br&gt;There must be a written inspection program that describes acceptable and/or unacceptable conditions for all inbound carriers. All inbound carriers must be inspected for food safety, quality and security related concerns at the time of receiving.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td><strong>Specific Receiving Policies with Inspection and Acceptance Plans</strong>&lt;br&gt;All ingredients and supplies must be purchased from approved vendors. Current specifications for purchased ingredients and supplies must be available. Incoming materials and ingredients must be inspected for damage, contamination and other unacceptable conditions as described by the receiving policy. Records must be maintained along with supplier codes for lot traceability.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Release Criteria for Ingredients</strong>&lt;br&gt;All ingredients must be maintained in a secure fashion and released for use against a defined approval program. An inventory management system must be in place to assure proper rotation.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Storage and Handling Policies and Practices</strong>&lt;br&gt;There must be established procedures to assure that ingredients and supplies do not become a source of contamination. Receiving areas and storage locations must be maintained in a clean and sanitary manner. All ingredients and supplies must be held under conditions necessary to maintain product integrity. Condensation from an air conditioner is draining to the floor of the secured ingredient area.</td>
<td>Minor*</td>
</tr>
<tr>
<td>5</td>
<td><strong>Bulk Receiving Systems Sanitation and Monitoring</strong>&lt;br&gt;Bulk ingredient handling and storage equipment must be maintained in a sanitary and secure manner. The cleaning procedures and frequencies must be documented.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
### Section F  Receiving and Inventory Control

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
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</thead>
<tbody>
<tr>
<td>6</td>
<td><strong>Restricted and/or Sensitive Ingredient Control, Including Chemical Compounds</strong>&lt;br&gt;All restricted or sensitive ingredients, potentially toxic chemicals and allergenic materials must be maintained under strict control and stored separately to minimize the potential for accidental product contamination.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

A detailed documented allergen program for production and training is needed since there are different allergenic ingredients potentially used in addition to the primary peanut products.

### Section G  Process and Product Evaluation

<table>
<thead>
<tr>
<th>No</th>
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</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Process Control and Documentation Procedures</strong>&lt;br&gt;There must be established process control procedures to assure products meet all food safety requirements. In-process ingredients and products must be adequately protected and properly labeled with date and lot number.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td><strong>Specification and Formulation Control and Accuracy</strong>&lt;br&gt;Records must be available that demonstrate compliance to product formulations and finished product specifications. Test protocols and frequencies must be followed as identified in the specification. Production records must be maintained for twelve months beyond product shelf life.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Routine Calibration of Operational Equipment and Measuring Devices (such as thermometers, scales, flow meters, counters, metal detectors, etc.)</strong>&lt;br&gt;Key process control devices must be calibrated by an outside contractor at least annually. All devices must also be monitored internally at a frequency adequate to verify accuracy during day to day usage. Corrective actions must be documented when measuring devices are found to be out of calibration.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Foreign Material Control</strong>&lt;br&gt;All finished product must be scanned through an instrument calibrated to identify and separate contaminated product. There must be a written procedure describing the maintenance, set-up and verification tests of detector systems with documentation to show the procedures are being followed. The cause for any rejection must be recorded on a calibration/test log.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td><strong>Application of Statistical Control</strong>&lt;br&gt;Statistical control must be used to determine the capability of the process equipment and the setting of critical limits for critical control points.</td>
<td>N/A</td>
</tr>
<tr>
<td>6</td>
<td><strong>Allergen and Sensitive Ingredient Controls</strong>&lt;br&gt;In facilities where allergens or sensitive ingredients are present, there must be detailed procedures to prevent the contamination of other products. Products containing allergens must be labeled as required by regulations. A detailed documented allergen program for production and training is needed since there are different allergenic ingredients potentially used in addition to the primary peanut products.</td>
<td>Minor*</td>
</tr>
<tr>
<td>7</td>
<td><strong>Documentation Showing Product Meets Specifications</strong>&lt;br&gt;Records must be maintained to assure that the appropriate product attributes were evaluated and that the results were consistent over time.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td><strong>Rework and Carryover Products</strong>&lt;br&gt;There must be a documented procedure for managing rework and carry over products. Rework must be traceable to its original production and to finished product. Production dates and original lot numbers must be carried forward in production documents. Rework and carry-over must be kept to a minimum and used promptly at the first opportunity. There must be a routine and documented &quot;clean break&quot; in the rework/carryover cycle.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td><strong>Analytical Records Management</strong>&lt;br&gt;Established systems must be used to properly store and retrieve analytical information, documents, reports, records, etc.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

Established systems must be used to properly store and retrieve analytical information, documents, reports, records, etc.
### Section H  Packaging and Labeling

<table>
<thead>
<tr>
<th>No</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Label Accuracy and Regulatory Compliance</strong>&lt;br&gt;There must be procedures in place to assure products are labeled properly and that the labels meet regulatory requirements.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td><strong>Documented Net Weight or Count Compliance Policy and Performance</strong>&lt;br&gt;Plants must have a documented policy for net weight, liquid contents or product count to verify compliance to label requirements and/or specifications.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Clear Manufacturing Codes on Individual and Cased Product</strong>&lt;br&gt;All product must have a code date that is of such size, color and contrast to afford easy legibility at a reasonable distance. Each individual sell unit must have a production or lot code. Packages within the sell unit must have a lot code. The individual package code dates and the case codes dates must be the same.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Package Integrity and Function for Distribution</strong>&lt;br&gt;All packaging must be designed and assembled to provide protection for the product from environmental and shipping conditions. Verification of proper sealing and closure of the packaging must be conducted.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td><strong>Label Security and Obsolete Label Controls</strong>&lt;br&gt;There must be a written plan in place to prevent the use of unauthorized or incorrect labels.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td><strong>Tamper Evident Packaging</strong>&lt;br&gt;Tamper evident packaging must be used and a documented monitoring program must be in place.</td>
<td>Acceptable</td>
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</tbody>
</table>

### Section I  Storage and Shipping

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<thead>
<tr>
<th>No</th>
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<th>Answer</th>
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</thead>
<tbody>
<tr>
<td>1</td>
<td><strong>Warehouse and Finished Product Management</strong>&lt;br&gt;Warehouse conditions must be maintained in a manner to assure product integrity. Finished product and packaging materials must be held separated and away from chemicals. Product not &quot;cleared&quot; for shipment must be clearly identified and stored in a location where it is not likely to be shipped in error.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td><strong>Retained and Returned Products</strong>&lt;br&gt;There must be documented procedures requiring identification, secured segregation, documentation, evaluation, disposition and reconciliation of non-conforming retained and returned products that is placed on hold. Returned products must be placed on hold immediately, designated areas must be established for retained and returned products and an inventory log must be maintained showing current product on hold and the disposition of all released product with proper authorization.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td><strong>Storage Facility and Dock Maintenance</strong>&lt;br&gt;Warehouse storage areas must be clean and orderly and have adequate space around the periphery for access, inspection and cleaning. Items must be stored off the floor, floors and walls must be in good condition and emergency doors must be tight fitting. Shipping docks, dock plates and levelers must be clean and kept orderly.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td><strong>Transport Condition</strong>&lt;br&gt;There must be written procedures for acceptable carrier conditions available to shipping personnel. Outbound trailers must be inspected and results must be documented. No product can be loaded into unacceptable carriers. When non-dedicated carriers are used, trailer logs must be assessed to determine if unacceptable materials had been present.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td><strong>Release Authorization to Ship Product</strong>&lt;br&gt;Release authorization must be required before any product is shipped.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td><strong>Product Traceability</strong>&lt;br&gt;Procedures must be established to effectively trace specific lots of ingredients, food contact packaging and finished products through the shipping and distribution channels. Traceability exercises must be conducted at least twice per year to the first level of distribution. Management assessments of each traceability exercise must be conducted. The most recent traceability exercise must demonstrated a 99.5% to 105% level of accountability within 4 hours.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

*During the audit, a traceability exercise was conducted on a by-product and its use in a Peanut Butter product. The exercise traced 100% of the resulting finished product in 5 minutes. An earlier tracing in January, 2008, was also successful in 2 hours and 15 minutes.*
### Section I  Storage and Shipping

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**Section notes:**

### Section J  Analytical Records and Laboratory Support

<table>
<thead>
<tr>
<th>No</th>
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<th>Answer</th>
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</table>
| 1  | Laboratory Facility and Staffing  
Laboratories must be adequately equipped and staffed to provide the essential technical support. Lab staff qualifications must be documented, toxic supplies must be securely stored and properly labeled and the laboratory must be clean, orderly and well lit. | Acceptable |
| 2  | Laboratory Procedures and Documentation  
Laboratory procedures must be documented, authorized and dated. Testing procedures must be based on recognized and approved procedures and documentation of all testing must be available. | Acceptable |
| 3  | Laboratory Equipment Calibration  
Calibration records must be maintained for all laboratory balances and test equipment for calibrations performed by a certifying company as well as all internal calibration check. | Acceptable |
| 4  | Analytical Accuracy Verification  
Documented evidence must be available that demonstrates laboratory test results are accurate and reliable. | Acceptable |

**Section notes:**  
JL and Dibel Labs are used as contract labs for microbiological testing.

### Section K  Food Defense

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
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</table>
| 1  | Management  
A risk assessment must be conducted by an established Food Defense team to evaluate all vulnerabilities and risks that exist in the facilities process. A documented Food Defense program must be in place. The facility must have a registration number from the applicable regulatory agency and unusual occurrences must be documented and assessed by management. | Acceptable |
| 2  | Human Element  
All individuals entering the facility must show proof of identification. A screening program must be in place for all employees. Temporary employees must be fully supervised at all times. Contractors and visitors must be required to show identification and sign in and out. Visitors must be accompanied while in the facility. A current roster of employees and work assignments must be maintained and employees must be prohibited from bringing personal items into processing areas. There must be a program in place to train Food Defense rules at the facility with documentation for each individual. | Acceptable |
| 3  | Facility  
Procedures must be in place to address access to and from the plant grounds and facility. A schematic of the facility and outside grounds must be available that identifies all entrances into the building, accesses to the roof and sensitive areas. Access to sensitive areas and utilities must be restricted. There must be a documented process for issuing, tracking and retrieving keys, identification badges and passes for the buildings and for secure areas. | Acceptable |
| 4  | Operations  
The facility must be evaluated for vulnerability to sabotage with documented procedures developed to address areas of concern. Non-employee drivers and delivery personnel must have a designated waiting areas. Trucks and/or trailers must be inspected before unloading. There must be a procedure for the receipt of damaged product. Vehicles must be kept secured when not in use and after loading is completed. Seal numbers must be recorded. | Acceptable |

**Section notes:**

### Section 2.A  Awareness

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Audit #: Visit #: 156233 - 116355  
789 Dixboro Road, Ann Arbor, Michigan 48105-9723 USA 1-800-NSF-MARK (734)-769-8010 www.nsf.org
### Section 2.A Awareness

<table>
<thead>
<tr>
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<tbody>
<tr>
<td>1</td>
<td>Product Security Review team designated by management with written responsibilities. A production team consisting of the Operations Manager, 4 department managers and the Quality Assurance Manager. In this small facility, this group, also acts as Product Security Team. Responsibilities need to be documented for each title or person in the Team.</td>
<td>Minor</td>
</tr>
<tr>
<td>2</td>
<td>Policies and procedures organized and maintained as controlled documents.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Team meets at least quarterly to review compliance to policies and procedures. Through daily staff meetings, the Team includes security issues on the agenda and logs the details the Production Managers log book.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td>All elements of process from ingredients through to finished product shipping have been evaluated for potential malicious product tampering.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td>Product Security program is effectively communicated to suppliers, customers and employees. Verification is documented. For employees there are training sessions, supplier contracts and customer surveys that include security information.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section Notes:**

- A production team consisting of the Operations Manager, 4 department managers and the Quality Assurance Manager. In this small facility, this group, also acts as Product Security Team. Responsibilities need to be documented for each title or person in the Team.
- Through daily staff meetings, the Team includes security issues on the agenda and logs the details the Production Managers log book.
- For employees there are training sessions, supplier contracts and customer surveys that include security information.
- Critical processing areas with respect to product security have been identified, and access is limited to designated employees.

### Section 3.A Employees, Contractors and Visitors

<table>
<thead>
<tr>
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</thead>
<tbody>
<tr>
<td>1</td>
<td>Employee applications contain full personal, employment and legal history of applicant.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td>A current roster of employees is maintained, including their current work assignments.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>All employees have a photo identification issued by the facility, and this ID is used to gain entrance. In this small facility, personal recognition is used as identification by managers and supervisors. Facility access is by key-coded doorways including the employee entrance.</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>Critical processing areas with respect to product security have been identified, and access is limited to designated employees. Critical areas such as minor ingredients and sanitation chemicals are accessed by designated employees.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td>Personal items and/or containers are not brought into the operating areas by employees.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td>The plant has an employee termination process which includes immediate escort from the facility and the accounting for plant issued identification, keys, etc.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>The plant has a documented process for managing Product Security issues with temporary employees in the same manner as with permanent employees. A hiring is conducted through a temporary agency for background and drug testing as well as a probationary period. Orientation and periodic training is provided to all temporary and full time employees.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Plant has a documented policy for management of contractors, which includes method to ID contractor's employees, and a sign-in log. Contractors receive the same training as employees in addition to sign in and are escorted.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>Contractors have an ID badge or other designation and are signed in and out of the plant. Contractors are escorted while in the facility.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td>Tool boxes and other containers undergo inspection as contractors enter the plant each day. No toolbox or containers are inspected.</td>
<td>Unacceptable</td>
</tr>
<tr>
<td>11</td>
<td>The plant has a documented process for managing all visitors, which includes verification of ID and a sign-in process. There is sign in process for all visitors with escort. No ID verification was conducted for the auditor.</td>
<td>Minor</td>
</tr>
<tr>
<td>12</td>
<td>Visitors are always accompanied by a designated plant employee.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>13</td>
<td>Visitor vehicles are subject to inspection. License information is logged. Visitor vehicles do not enter the fenced area of the physical building.</td>
<td>NA</td>
</tr>
</tbody>
</table>
There is documented evidence the visitor log is reviewed each day to insure all visitors have signed out. This is inconsistent since there are few visitors.

Plant has documented training elements focusing on security guidelines, suspicious activities and criminal consequences.

Policies address authorized access to grounds, plant, manufacturing and storage areas. A Bio-Security and visitor policy are in effect.

All entrances have individual authorization controls—electronic or by individual ID. All entrances to the building are key coded with limited employee authority. Key codes are changed each month.

The plant must have a documented process for issuing keys for the building and for secure areas:
- Secure key system that is resistant to unauthorized copying of keys
- Complete listing of all issued keys
- Process for changing all keyed systems as needed.
An issuance of numbered keys is documented.

All employees have photo ID badge. Personal recognition is used for employee entry so no badges are issued.

Photo ID badges have electronic scan strips to control access to specific areas of facility and document arrival and departure. Personal recognition is used for employee entry so no badges are issued.

Emergency exits are alarmed and verified.

Employees access is restricted to assigned areas of the plant.

Water source, private or municipal is securely protected and access strictly controlled.

Spice & condiment weighing and batching area secured and access controlled.

Bulk mixing & storage areas secured.

Evening, weekend, holiday security for ingredient areas.

TV monitoring or controlled access of minimally supervised areas.

Plant grounds are fenced and provide perimeter security.

Outside facility and grounds are illuminated.

Plant must have a documented supplier management procedure which addresses issues of Product Security.

Plant is aware of significant changes with ingredient suppliers, including change of management, ownership, labor disputes, etc.

Shipping trailers, bulk trailers/cars or containers are sealed, and the plant documents seal numbers and compares the numbers to supplier shipping manifests.

Bulk shipping containers have records of previous hauls, cleaning and inspections.

Incoming shipping vehicles are thoroughly inspected, and this inspection is documented by the plant.
### Section 5.A Ingredient Safety

<table>
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</thead>
<tbody>
<tr>
<td>6</td>
<td>Incoming goods undergo inspection to assure general wholesomeness and packaging integrity.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>The plant has a policy that addresses the handling of ingredients or packaging materials that have damaged packaging.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Lot identification procedures are followed.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>There are separate storage areas for food and non-food items.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td>Bulk tanks are secured by locked hatches or rooms.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>11</td>
<td>Packaging storage areas are controlled and secured.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>12</td>
<td>Labeling security controls to prevent unauthorized usage of labels and procedures for timely isolation and destruction of obsolete labels. Labels are produced as needed at the production line.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>13</td>
<td>Access to storage areas is limited to authorized personnel.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>14</td>
<td>The plant has a procedure for managing damaged or returned ingredients or packaging, or for damaged Work-in-Process.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>15</td>
<td>No opened ingredients are stored in warehouse areas.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>16</td>
<td>Ingredient packages that are opened are placed in closed top plastic containers for additional holding in a secured area of the warehouse.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>16</td>
<td>Policy to address risk of imported ingredients.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

Labels are produced as needed at the production line.

Ingredient packages that are opened are placed in closed top plastic containers for additional holding in a secured area of the warehouse.

The water source is municipal and water test results are provided.

The water source is municipal.

No water storage tanks are used.

No boiler is used at this facility.

MSDS are available for all chemicals used for water and boiler treatment.

No boiler is used at this facility.

Chemical levels in boiler water are monitored.

No boiler is used at this facility.

Boiler additives are on the approved list (NSF).

No boiler is used at this facility.
### Section 6.A Utilities

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>13</td>
<td>Chemicals and containers for boiler chemicals are secured. No boiler is used at this facility.</td>
<td>NA</td>
</tr>
</tbody>
</table>

**Section notes:**

No boiler is used at this facility.

### Section 7.A In-Plant Hazardous Materials

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>The laboratory maintains a current inventory of all laboratory chemicals and solvents. Only physical testing is conducting with no chemicals involved.</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>MSDS are available for all laboratory chemicals. Only physical testing is conducting with no chemicals involved.</td>
<td>NA</td>
</tr>
<tr>
<td>3</td>
<td>All stored laboratory chemicals are secured. Only physical testing is conducting with no chemicals involved.</td>
<td>NA</td>
</tr>
<tr>
<td>4</td>
<td>Access to the laboratory is restricted to authorized personnel.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td>Culture wastes from the microbiological laboratory are autoclaved. No microbiological testing is conducted at this facility.</td>
<td>NA</td>
</tr>
<tr>
<td>6</td>
<td>Glass containers are not allowed on the factory floor.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>The laboratory has a procedure for controlling broken glass. The laboratory uses a disposable plastic dish for peanut butter testing in the lab. These dishes are enclosed in packaging when entering the lab for use or leaving the lab after usage.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Mercury-in-glass thermometers are inventoried, and kept inside the laboratory. No mercury-in-glass thermometers are inside the plant or laboratory.</td>
<td>NA</td>
</tr>
<tr>
<td>9</td>
<td>Cleaning chemicals are stored in locked areas, and inventories are maintained.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td>MSDS are maintained for cleaning janitorial chemicals.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>11</td>
<td>CIP systems are isolated from production piping during plant operations. No CIP system exists at the facility.</td>
<td>NA</td>
</tr>
<tr>
<td>12</td>
<td>Lubricants should have approval for incidental contacts with food. (NSF Listing)</td>
<td>Acceptable</td>
</tr>
<tr>
<td>13</td>
<td>MSDS are maintained for all maintenance chemicals and solvents.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>14</td>
<td>Scrap in the maintenance shop is regularly discarded.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>15</td>
<td>Access to the maintenance shop is restricted to authorized personnel.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>16</td>
<td>Pest control chemicals are either stored off-site by a contracted PCO, or stored in a locked, isolated room if managed by in-house PCO’s.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>17</td>
<td>Rodenticides or pesticides are not used in plant operating areas.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>18</td>
<td>Exterior bait stations are secured to the ground or wall, and are locked or sealed.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>19</td>
<td>Trapped pests are immediately disposed.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>20</td>
<td>MSDS are maintained for pest control chemicals.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>21</td>
<td>A plant employee accompanies the contracted PCO on their rounds.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

No CIP system exists at the facility.

### Section 8.A Process Security

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Computer security programs for processing controls, formulation and ingredient management. No computer system is used for process control or formulation or ingredient management.</td>
<td>NA</td>
</tr>
<tr>
<td>2</td>
<td>Only the ingredients in the product recipe should be staged in the blending area.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Containers, implements and tools shall be clean before the start of operations.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td>All ingredients are properly identified.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
### Section 8.A Process Security

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>5</td>
<td>Small tools, such as scoops, scrapers, knives, etc. shall be inventoried and accounted for at the end of the shift. No documentation is established as to small tool accountability.</td>
<td>Minor</td>
</tr>
<tr>
<td>6</td>
<td>Sifters and in-line screens should be used for all applicable granular or liquid ingredients. This equipment is used during batch preparation.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>Equipment, such as dicers, grinders, mixers, etc. shall be inspected for condition, and this inspection documented, prior to use and after use. This is part of the Pre-Op inspection at the beginning of each shift.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>All unusual events during the production shift are documented. Events are noted in the plant manager's log.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>The spice and condiment preparation area should be secure with access restricted to assigned employees. This area should be locked when not attended. Seasoning are kept locked until use in the secured ingredient area with only limited key issuance.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td>All formulated spice mixes shall be identified.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>11</td>
<td>Screens shall be used to sieve spice ingredients where appropriate.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>12</td>
<td>All unusual events in the spice preparatory area during the production shift are documented. Events are noted in the plant manager's log.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>13</td>
<td>Storage tanks in the production area must have lids, and must be inspected before use.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>14</td>
<td>CIP systems on tanks must be disconnected prior to production. No CIP systems are used at this facility.</td>
<td>NA</td>
</tr>
<tr>
<td>15</td>
<td>Storage tanks in remote locations should be alarmed and/or locked. No storage bins or tanks are in remote locations.</td>
<td>NA</td>
</tr>
<tr>
<td>16</td>
<td>In the filling and packaging areas, metal detectors, magnets, screens/sieves should be applied as appropriate. Both magnets and metal detectors are used in the process as appropriate.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>17</td>
<td>Pumps, conveyors and filling/depositing/packaging equipment must be inspected prior to use and at the end of the shift, and this inspection documented. Equipment checks are conducted each shift.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>18</td>
<td>All unusual events in the filling area during the production shift are documented. Events are noted in the plant manager's log.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>19</td>
<td>Empty containers should be effectively cleaned and protected by covers during transit to filling and prior to closing.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>20</td>
<td>In the processing, freezing, drying, cooking, pasteurizing step, the registered process is posted at the processing step controls. There are no registered processes.</td>
<td>NA</td>
</tr>
<tr>
<td>21</td>
<td>Authorized operators are identified by license, certification or other plant designation. There are no registered processes for operator license or certification.</td>
<td>NA</td>
</tr>
<tr>
<td>22</td>
<td>Production processing records must be reviewed by responsible management at the prescribed frequency.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>23</td>
<td>Controllers for critical process factors must be locked. These are located in locked cabinets with key codes locks for limited access.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>24</td>
<td>Critical instruments must be calibrated at the designated frequency.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>25</td>
<td>Post processing controls must be identified in plant procedures.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>26</td>
<td>Controls must be in place to prevent unauthorized switching or change of processing systems.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>27</td>
<td>Labeling controls must effectively prevent the mis-labeling of products. Labels are applied as printed on the production line.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>28</td>
<td>All unusual events in the processing area during the production shift must be documented. Events are noted in the plant manager's log.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
Section 8.A Process Security

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>29</td>
<td>Documented control of rework, carry-over ingredients and product must be available.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

Section notes:

Section 9.A Warehouse and Transportation

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Clear policy defining authorized access to warehouse for ingredients &amp; finished product.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td>Non-employees (truck drivers) limited to office or designated area only. No access to warehouse or plant. Drivers only enter with escort.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Clear policy defining acceptable condition of ingredient packaging and integrity.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td>No damaged containers accepted if product is exposed to contamination.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td>Policy addressing damage to ingredients after receiving-- must be handled immediately.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td>Product not in original unopened package should not be stored in warehouse.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>Returns, rework &amp; withheld clearly marked in designated area. Individual pallets clearly marked.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Weekly accounting for all returns, rework &amp; withheld. This is conducted daily.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>Transport evaluated for condition</td>
<td>Acceptable</td>
</tr>
<tr>
<td>10</td>
<td>Transport evaluated for temperature maintenance. Most products are shipped in ambient conditions. Temperature conditions are evaluated per customer requests.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>11</td>
<td>Procedures for transport companies covering driver ID, changes, stops, seal authentication, breakdowns and recognizing and reporting suspicious activities.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>12</td>
<td>Documented procedures for maintaining equivalent security at all outside warehouse facilities. No documented procedures have been established.</td>
<td>Unacceptable</td>
</tr>
</tbody>
</table>

Section notes:

Section 10.A Traceability

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>All ingredients assigned individual lot numbers with vendor lot or batch numbers identified.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td>Bulk ingredients traceable by lot with no commingling of lots.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Packaging lot numbers documented for each lot.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>4</td>
<td>Individual container units clearly identified with lot numbers and time or sequence.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>5</td>
<td>Shipping case units clearly identified with lot numbers and time or sequence.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td>Damaged, destroyed, reworked or sample cases of finished product documented.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>Daily accounting and balance of cases produced vs. cases to warehouse, destroyed, reworked, withheld or sampled.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Inclusion of records of production irregularities or unusual events (glass breakage).</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>Mock recalls through distribution system semi-annually.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

Section notes:

Section 11.A Tamper Evident Packaging

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Risk assessment document addressing product and its packaging. This is conducted when packaging changes are contemplated.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>
**Section 11.A Tamper Evident Packaging**

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>2</td>
<td>If used, effective monitoring programs in place to assure proper application. This is verified by QA personnel.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>3</td>
<td>Tamper evident review of ingredient packaging and containers-- bulk materials, drums, pallets. During receiving, the packaging is reviewed with rejection of torn or opened containers.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

**Section 12.A Crisis Management**

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Crisis Management team identified with responsibility in writing. This exists as the Recall Team for which responsibilities are defined.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>2</td>
<td>Crisis management procedures cover food security, recalls, emergency and disaster possibilities. For areas other than recalls, procedures need to be developed.</td>
<td>Minor</td>
</tr>
<tr>
<td>3</td>
<td>Team members have specific training and protocol procedures to address each crisis. For areas other than recalls, training needs to be conducted.</td>
<td>Minor</td>
</tr>
<tr>
<td>4</td>
<td>Crisis management policies and procedures reviewed with team members semi-annually. For areas other than recalls, reviews need to be conducted.</td>
<td>Minor</td>
</tr>
<tr>
<td>5</td>
<td>Current contact lists for all team members, regulatory contacts, clients, suppliers, corporate &amp; other key. As per the Recall procedures.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>6</td>
<td>Current contact list available to responsible personnel on all shifts, weekends &amp; holidays.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>7</td>
<td>Recall plan tested to assure 99.5 % recovery within 4 hours quarterly. During the audit, a traceability exercise was conducted on a by-product and its use in a Peanut Butter product. The exercise traced 100% of the resulting finished product in 5 minutes. An earlier tracing in January, 2008, was also successful in 2 hours and 15 minutes.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>8</td>
<td>Plan to isolate and remove potentially compromised material and restore security to manufacturing process to facilitate timely return to safe production of wholesome product.</td>
<td>Acceptable</td>
</tr>
<tr>
<td>9</td>
<td>Plan requires review by QA or food safety group prior to resumption of activities following incident.</td>
<td>Acceptable</td>
</tr>
</tbody>
</table>

**Section notes:**

**Section 1.A Ingredients of Concern**

<table>
<thead>
<tr>
<th>No</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>1</td>
<td>Does the plant use or store Peanuts or Peanut Products?</td>
<td>Yes</td>
</tr>
<tr>
<td>2</td>
<td>Does the plant use or store Tree Nuts?</td>
<td>Yes</td>
</tr>
<tr>
<td>3</td>
<td>Does the plant use or store Crustacea?</td>
<td>No</td>
</tr>
<tr>
<td>4</td>
<td>Does the plant use or store Fish?</td>
<td>No</td>
</tr>
<tr>
<td>5</td>
<td>Does the plant use or store Egg or Egg Products?</td>
<td>No</td>
</tr>
<tr>
<td>6</td>
<td>Does the plant use or store Milk or Milk Products? Ranch flavor, Nacho Cheese flavor</td>
<td>Yes</td>
</tr>
<tr>
<td>7</td>
<td>Does the plant use or store Soybean or Soy Products? Soy Oil</td>
<td>Yes</td>
</tr>
<tr>
<td>8</td>
<td>Does the plant use or store Wheat, Corn (Maize) or Related Grains?</td>
<td>No</td>
</tr>
<tr>
<td>9</td>
<td>Does the plant use or store Mollusks?</td>
<td>No</td>
</tr>
<tr>
<td>10</td>
<td>Does the plant use or store Seeds?</td>
<td>No</td>
</tr>
</tbody>
</table>
### Section 1.A Ingredients of Concern

<table>
<thead>
<tr>
<th>No.</th>
<th>Question/Notes</th>
<th>Answer</th>
</tr>
</thead>
<tbody>
<tr>
<td>11</td>
<td>Does the plant use or store Cottonseed Products? Cottonseed Oil</td>
<td>Yes</td>
</tr>
<tr>
<td>12</td>
<td>Does the plant use or store Legumes?</td>
<td>No</td>
</tr>
<tr>
<td>13</td>
<td>Does the plant use or store Sulfites?</td>
<td>No</td>
</tr>
<tr>
<td>14</td>
<td>Does the plant use or store FD&amp;C Yellow #5 or #6?</td>
<td>No</td>
</tr>
</tbody>
</table>
| 15  | Does the plant use or store Monosodium Glutamate, Autolyzed yeast, Hydrolyzed protein?  
Spice contains Torula yeast | Yes     |
| 16  | Does the plant use or store Meat?                                              | No     |
| 17  | Does the plant use or store Poultry?                                           | No     |

**Section notes:**

The information contained in this report is privileged and confidential. This report shall not be reproduced, except in its entirety, without the written approval of NSF Cook & Thurber.

* Represents Non Compliances.

If you have any questions about this report, please contact your NSF Project Manager, Betty Teasdale, at 734-913-5767 or bteasdale@nsf.org.
Draft Audit Report

Auditor: WAYNE H. BERKNER

Tidewater Blanching
160 County Street

Suffolk       VA       23439
Scores:

- Adequacy of Program: 200
- Pest Control: 200
- Operational Methods: 200
- Maintenance: 180
- Cleaning Practices: 200

Total Score: 980

Rating: Superior
A food safety audit was conducted at this facility on December 14, 2004. The writer was accompanied throughout the audit by

Excellent cooperation was received by the writer, and on some occasions, the items were immediately corrected.

At the conclusion of the audit, a meeting was held to discuss the observations, recommendations, and rating. A draft copy of the report was left at the plant.

Based on the observations made, the information obtained, and the criteria set forth in the AIB Consolidated Standards for Food Safety, the overall food safety level of this facility was considered to be:

Superior
980

The AIB International states that the report as given herein is to be construed as its findings and recommendations as of the date of this report. The AIB International accepts no responsibility and does not assume any responsibility for the food safety program in effect with (customer). That further AIB International is only making report of the food safety conditions of (customer) as of the date of this report and assumes no responsibility or liability as to whether (customer) carries out the recommendations as contained in this report or does not carry out the recommendations as contained in this report.
Westland/Hallmark Foods, LLC
13677 Yorba Avenue
Chino, California

HACCP Consulting Group, L.L.C.
4022 Nicholas Court
Fairfax, VA 22033

November 16, 2007

Conducted By:
John Miller
Vice President
Please understand that the analysis, statements, recommendations, advice, or suggestions provided in this report are based on scientific literature and wide industry acceptance. Neither the analysis, statements, recommendations, advice, nor suggestions provided shall be construed as a guarantee to prevent damage, spoilage loss, accidents, or injury resulting from their use. Furthermore, the use of analysis, statements, recommendations, advice, or suggestions included in this report is not an assurance that a person or organizations is proficient in their use as included. The use of analysis, statements, recommendations, advice, or suggestions included in this report is not to be construed as taking any responsibility for damage, spoilage, loss, accident, or injury resulting from such use. Nor are the analysis, statements, recommendations, advice, or suggestions to be construed as assuring current or future compliance with either US, Food and Drug (FDA) or USDA, Food Safety and Inspection Service (FSIS) regulations as The HACCP Consulting Group (HCG), L.L.C., has no control over what actions are taken by the client based on the content of this report.
REVIEW SUMMARY

On November 13 and 14, 2007 an on-site assessment was performed at Westland/Hallmark Foods, LLC, hereafter WHMC, Federal Establishment 336, located at 13677 Yorba Avenue, Chino, California by the HACCP Consulting Group (HCG), L.L.C. The review was performed at the request of Westland/Hallmark Foods Management. The focus of the review was to ensure that Establishment 336 continues to be in compliance with the regulatory requirements of Code of Federal Regulations 9, specifically parts 310.22, 313, 416 and 417 as well as the company's written programs. The results of the review are as follows:

OVERVIEW

Westland/Hallmark slaughters and fabricates approximately 500 beef animals per day on one production shift. The beef cattle that are slaughtered and fabricated are from domestic stock only and the company maintains documentation to support the origin of the animals. The company is an approved supplier to the Federal School Lunch Program. As such the company is subject to ongoing audits by AMS. WHMC has in place a well developed Quality Management System that includes Training Programs for employees, Prerequisite programs to support the Food Safety System through ongoing internal company audits, and procedures for monitoring the systems that are in place. Management uses the monitoring results to track and identify trends in the facility that may impact upon the safety and quality of the products.

HUMANE HANDLING PROCEDURES

WHMC has a well designed Humane Handling Program in place to ensure that live animals that are received for slaughter and fabrication are treated in a manner conducive to the tenets of established humane handling practices. The program is designed using guidelines developed by Dr. Temple Grandin of Colorado State University. Live animal haulers that bring cattle to the facility are required to read WHMC rules for unloading animals. Their understanding of the requirements is documented by the company. In addition, all plant employees that work with live animals are provided with training in Humane Handling practices. During a review of the live animal unloading and holding pen practices, the animals were unloaded properly with a minimum amount of stress, placed in holding pens that were clean, and provided with sufficient water. There was no evidence of crowding and minimal vocalizing by the cattle. The pens, including fencing, appeared to be in good repair. The company inspects the pens on a daily basis to ensure that the enclosures remain in good repair and do not have any obstructions or other deficiencies that could cause harm to the animals. The results of the review are documented.
WHMC has a written procedure for ongoing maintenance of the stun guns. Each stun gun is identified, inspected daily, and replaced if they are not operating properly. The personnel performing stunning of cattle are trained and monitored during slaughter operations. Results of the monitoring are recorded.

**SPECIFIED RISK MATERIALS**

All animals slaughtered and fabricated by WHMC are considered to be thirty months of age or more. As such all parts of the animal that are considered to be SRMs are removed during processing and disposed of. The company has an intensive written procedure for removal and handling of these materials. The lone exception to the procedure is one consignee that receives beef arm chucks under seal from WHMC and bones them under their own in house procedures. A “Chain of Custody” is maintained for these products during transfer from WHMC to the consignee.

All products that are fabricated in the plant are beef that is slaughtered in the facility with the exception of Beef Plates that are purchased from an outside domestic source. That product is fabricated on a dedicated line, identified throughout the processing and packaging, and is not commingled with any other product in the plant. WHMC fabricates product in the boning department in lots of 60 carcasses. The product from each lot is provided with a separate identity throughout processing, packaging, and shipment. In addition, there is a physical time break in the process between lots to preclude any possibility of commingling product from different lots. This allows WHMC to maintain positive product identity if the need should arise.

**MICROBIOLOGICAL TESTING**

Each Combo of Beef Trim is tested at the end of the Fabrication process using N=60 method of sample collection. The product is sampled for TPC, *coliforms*, *Listeria spp.*, *Salmonella*, and *Escherichia coli O157:H7*. The company testing results that were reviewed were all negative for E. coli and extremely low for non pathogenic organisms.

In addition, WHMC has an environmental testing program in place. The various areas of the facility are mapped and color coded for sampling purposes. The results are recorded and graphed on computer for tracking of any positive results. Employee hand tools, garments, and food contact surface equipment is sampled both during pre-operational inspection and during operations. All of the company results that were reviewed showed that the sanitation program is extremely effective. The fabrication department contact surfaces are scrapped and sanitized at mid shift break and showed very low microbiological organism levels.
The company samples one carcass for each 300 animals slaughtered for generic E. coli, Biotype 1 to comply with 9 Code of Federal Regulations (CFR) part 310.25. The sample results have been very good.

SANITATION STANDARD OPERATING PROCEDURES (SSOP)

Slaughter Preoperational Walk Thru

During a pre-op walk thru, the reviewer observed plant employees inspecting equipment and setting up various equipment. The facilities and equipment were clean and employees appeared to have a thorough understanding of sanitation requirements. No deficiencies were observed.

Fabrication SSOP Pre-Operational Walk Thru

Plant employees charged with performing the pre-op inspection in the fabrication department were using proper techniques when inspecting the equipment. Although they were already conducting the inspection and setting up the department for processing, the contact surfaces and surrounding areas of the department appeared to be clean. The employees were using proper handling techniques from a sanitary standpoint when placing product totes and other hand equipment in their respective areas.

HACCP SYSTEM

The HACCP plans are well designed, thorough, and reflect the processes in the plant's operation. The process steps in the flow charts accurately depict the steps in the Hazard Analyses. The Hazard analyses reflect well thought out reasoning and address product flow in the respective operations as they are identified on the flow charts. In addition the plans reflect a well grounded and thorough working knowledge of the principles of HACCP by the plant's food safety team.

WHMC has two validated Critical Control Points (CCP) in the HACCP system. The first CCP is application of Lactic Acid. The acid is applied via a cabinet system at solution strength of up to 5 percent. The other design parameters are a solution temperature of 140 degrees Fahrenheit and pressure of 40 pounds per square inch.
The second CCP is Zero Tolerance. A trained company Quality Control Employee selects 3 carcass sides each hour during production and examines them for identifiable contaminants, fecal, ingesta, or milk.

In addition, lactic acid is also applied to cheek, head and weasand meat and other variety meat items that are harvested during the slaughter process.

WHMC’s HACCP plan includes a temperature CCP of carcass surface (44.6 F) in the holding cooler and the fabrication process.

The company employees other processing aids to help ensure the safety of the food products. They utilize three steam vacuum stations in the slaughter process as well as a hot water rinse cabinet that sprays hot water at a temperature of 195 degrees Fahrenheit on each carcass for 12 seconds. One of the three steam vacuums is located at pre-evisceration followed by a pre-evisceration lactic acid spray. Although studies have shown that this helps to reduce bacteria on carcass surfaces, it is not a validated intervention in the HACCP plan. During observation of the slaughter process, the reviewer noted that the person operating the steam vacuum on the lower carcass surfaces was not completely vacuum the lower neck area and front shank areas of the carcasses. Plant management immediately reacted to the observation and instructed the plant employee on proper vacuum techniques.

As a further aid, the company applies Inspexx to each carcass side during carcass breaking process. The acid is applied at a solution rate of two hundred parts per million to the entire surface of each carcass. During the review, the employee applying the inspexx was not applying the material to the upper hock area of every carcass. Plant management immediately provided instruction to the person performing the process.

To further emphasize good manufacturing practices or Best Practices, WHMC has an extensive training program for all employees in the facility. Employees working in the slaughter process are trained in animal handling techniques such as proper sterilization of hand tools, including use of a two knife system when making various cuts in the process as well as effective routine cleaning of hands and garments to preclude cross contamination of carcasses.

CONCLUSIONS:

Based on observations gleaned during the review, it is evident that Westland/Hallmark Meat Company has a sound food safety system that goes well above and beyond that which would normally be expected or required from a regulatory standpoint. The company management is rightfully proud of their food safety system and willingly shared information and their internal programs with the HCG.
If you have any questions, please feel free to contact me at: 916-996-0285

Sincerely,

John H. Miller VP
HACCP Consulting Group, L.L.C.
9346 Winding River Way
Elk Grove, California 95624

Attachment:
Attached is a list of the programs associated with the plant's Quality Management System (QMS)

QUALITY MANAGEMENT SYSTEM
CONTINUOUS IMPROVEMENT OBJECTIVES

A Quality Management System (QMS) has been developed to ensure that the high quality products that are produced and supported by their HACCP, SSOP's, Prerequisite Programs and GMP's are consistently achieved, by evaluating each program and their supporting sub-categories as a cohesive and supporting unit. WHMC has been able to monitor and improve their general operations by ongoing and documented planned improvements.

WHMC is able to prepare, execute and augment their operations by reviewing monthly internal GMP audit reports, pre-operational, operational and maintenance logs. In-house audits are used as a proactive tool to monitor, correct and assign improvements to noted deficiencies/deviations as well as plant operations, programs, employee practices and the physical condition of the facility. Committee members review pertinent collective documents which results with planning, creating and implementing documented corrective actions including applicable preventive measures in order to prevent reoccurrences.

A quorum has been established and applied to the QMS members for individual responsibility and accountability in order to ensure that total and consistent conformity is met. Copies of each audit, including noted
deviations, planned corrective actions, and completed corrective actions are forwarded to pertinent Department Personnel as well as upper management. All generated audits are filed in chronological order for any needed future references.

The entire facility is reviewed on a monthly basis or sooner if needed. Plant audits involve facility walkthroughs, reviewing specific areas such as; the integrity of the each buildings infrastructure with regards to sanitation, applicable daily QC documents, equipment maintenance, humane handling and worker practices.

Reviews by committee members of past documented audits, including pertinent pre-operational and operational deficiencies, and Non-compliance records cited by the USDA are conducted. In addition Committee Members collectively and accurately measure deviations that were corrected at set time tables as well as the most recent deviations that were noted during each post audit. All corrected areas are individually reviewed and verified in a series of planned documented plant meetings.

The monitoring of their food safety systems is of the utmost importance. QC personnel who are assigned to monitor, record and review records are trained on an annual basis or sooner if needed. This training includes the following categories:

- Basics of HACCP, SSOP, GMP's & Pre-requisite Programs
- Monitoring of CCPs as prescribed by the HACCP System, (Including scientifically established critical limits);
- Corrective Action(s) procedures in the event that critical limits have not been met.(Which includes corrective action plan(s), (Form 417.3 FSIS/USDA)
- Procedures and records of calibration;
- HACCP documents are consistently signed and dated;
- Verification of HACCP, SSOP & Prerequisite Systems which is kept for a minimum of one (1) year;
- Pre-operational Sanitation Checklist;
- Daily Pre-operational Sanitation Deficiency Report;
- Operational Sanitation Checklist;
- Daily Operational Sanitation Deficiency Report;
- Hooks For Laborers;
- Personal Hygiene Log;
- Temperature Checklist of Sterilizers;
- Lactic Acid Solution Monitoring Report;
- Inspexx 200 Solution Monitoring Report;
- Quad DS Solution Monitoring Report;
- Quad DS Solution Mix – Hand Held Sprayers – Monitoring Form;
- Inspexx 200 Solution Mix – Hand Held Sprayers – Monitoring Form;
- Quad DS Floor Sprayer Report;
- Daily Calibration Check & Verification;
- Production Report for Harvesting, (Zero Tolerance, Lactic Acid Intervention, Product Temperature Stage)
- Production Report For Raw Not Ground Meat Products (Product Temperature Stage Monitoring);
- Production Report For Raw Not Ground Beef Products, (HACCP);
- Mid-Shift Wet Clean-Up;
- Meat CO2 Injector Monitoring Checklist;
- Storage Cooler Ambient Temperature Monitoring;
- De-boning Cooler Ambient Temperature Monitoring;
- Monitoring of SRM’s;
- Government/Commercial On-Line Inspection of Boneless Beef;
- Daily Pre-Shipment Sanitation Cargo Bay Inspection;

The areas that are evaluated by Committee members are;

- HACCP, (Awareness concerning revisions, etc.)
- SSOP’s, (Awareness concerning revisions, etc.)
- Pre-Requisite Program
- GMPs, (Pest Control, Employee Practices)
- Plant Defense Program
- Exterior Audit Results (Dry storage & VersaCold exterior freezer)
- Microbiological Training/Test results/Evaluations, (In-house & Out-house)
- Recall Exercises
- Product Integrity Control/Continual Improvement
- Return Product Control
- Cold Chain Management of Storage Product Control
- Dry Storage Control, (Including Material Rotations, Guarantee’s, etc.)
- BSE Control Points
- Animal Welfare Controls
New Employee Orientation & Human Resources, (Job Safety Analysis & Descriptions)
Plant Sanitation Reviews/Correspondence/Hazardous Communication/Working with Chemicals Training
Business Emergency Contingency Plan
Preventive Maintenance, (Including Protocols for Trucks & Trailers, Trailer Failure, New Equipment, General Construction)
Facilities and Practices, (Storage coolers, fabrication, grinding, harvest floor)
Pest Control Evaluation with Orkin
Customer Complaints
Employee Practices/Training, (harvest, fabrication & grinding)
Exterior areas, (Trash, Cardboard)

QMSC COMMITTEE MEMBERS

Stan Mendell, WMC, Plant Manager
Pablo Salas, HMC, Plant Manager, Harvest
Tony Cuevas, WMC Quality Assurance, De-boning
Gustavo Manzo, HMC, Supervisor, Harvest
Martin Laguna, Quality Assurance, Harvest
Henry Wong, Grinding Manager
Martin Gonzalez, Quality Assurance, Grinding
Tony Gonzalez, Shipping & Receiving Supervisor
Tony Padilla, Plant Maintenance Lead Supervisor
Steve Sayer, Principle

In the event of a 3rd party audit the QMSC would meet to evaluate plant conditions and practices. Noted deviations will be documented with a planned corrective action list created. Specific assigned roles to procure applicable documents involve:

Harvest CCP’s
De-boning CCP’s
Grinding CCP’s
HACCP Program
SSOP Program
GMP Programs
Prerequisite Program
Animal Welfare Program
Assignment for corrections would be developed and assigned to all applicable documentation listed above. Revised procedures will be noted for accuracy and compliance since the last documented audit. Final audit results were used for among other areas, Employee Training, Planned Improvement Program, Continuous Improvement, Employee Safety Committee, and USDA Weekly Exit Meetings.
Animal Welfare Audit

BEEF*

for:

Westland Meat Co/Hallmark Meat Packing: Chino, CA

Report Date
November 21, 2007

Audit by
Stacy Riggs
Silliker, Inc.

*Criteria for this audit are based on "Recommended Animal Handling Guidelines and audit Guide, 2007 edition" published by the American Meat Institute Foundation.

This audit report sets forth Silliker, Inc. ("Silliker") findings and recommendations as of the date herein. Silliker shall not assume any responsibility for the programs and/or facility being audited nor for events or actions occurring prior or subsequent to this audit. Silliker shall not endorse, and hereby expressly disclaims, any liability related to the client carrying out Silliker's recommendations, if any, contained in this report.

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## ANIMAL WELFARE AUDIT: BEEF

| Company Name: Parent Company: | Westland Meat Company/Hallmark Packing Company | Audit Date: | November 21, 2007 |
| Plant Address: | 13677 Yorba Avenue Chino, CA 91710 | Start & End Time: | 8:00am - 12:00pm |
| Primary Contact: | Steve Sayer | Silliker Auditor: | Stacy Riggs 903-243-3101 |
| Email: | steve_sayer_westland@yahoo.com | Telephone: | 909-590-3340 |
| USDA est #: | 336 | Fax: | 909-590-3320 |
| Pass/Fail: | Pass | Line Speed: | 50 head/hour |

**Was religious slaughter performed during the audit?** No

**Was conventional slaughter performed during the audit?** Yes

### AUDIT SUMMARY - ANIMAL SURVEY

<table>
<thead>
<tr>
<th>AMI Core Criteria</th>
<th>Passing Score</th>
<th>Score</th>
</tr>
</thead>
<tbody>
<tr>
<td>Electric Prodding</td>
<td>25% or less prodded</td>
<td>6%</td>
</tr>
<tr>
<td>Vocalization</td>
<td>3% or less (conventional) 5% or less (ritual or with use of head holder)</td>
<td>0%</td>
</tr>
<tr>
<td>Slips and Falls</td>
<td>Truck unload - 1% or less falls 3% or less slips In plant - 1% or less falls 3% or less slips</td>
<td>0% 0% 0% 0%</td>
</tr>
<tr>
<td>Stunning Accuracy</td>
<td>95% or greater accuracy</td>
<td>97.8%</td>
</tr>
<tr>
<td>Bleed Rail Insensibility</td>
<td>100% Insensible</td>
<td>0%</td>
</tr>
<tr>
<td>Access to water</td>
<td>Yes, water provided</td>
<td>Yes</td>
</tr>
<tr>
<td>Willful acts of Abuse</td>
<td>No willful acts of abuse</td>
<td>No</td>
</tr>
</tbody>
</table>

**Auditor Signature:** Stacy Riggs 903-243-3101; stacy.riggs@silliker.com

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.
# AUDIT SUMMARY

<table>
<thead>
<tr>
<th>Category</th>
<th>Possible Points</th>
<th>Actual Points</th>
<th>Percentage</th>
</tr>
</thead>
<tbody>
<tr>
<td>I. Livestock Receiving</td>
<td>25</td>
<td>25</td>
<td>100</td>
</tr>
<tr>
<td>II. Livestock Condition</td>
<td>10</td>
<td>10</td>
<td>100</td>
</tr>
<tr>
<td>III. Handling and Holding</td>
<td>45</td>
<td>45</td>
<td>100</td>
</tr>
<tr>
<td>IIII. Observations</td>
<td>30</td>
<td>26</td>
<td>86.7</td>
</tr>
<tr>
<td>Total</td>
<td>110</td>
<td>106</td>
<td>96.4</td>
</tr>
</tbody>
</table>

*Items in bold and caps are automatic failure questions if a "1" is scored by auditor.*
Summary of Audit Findings
Critical / Major Areas (Questions scoring a 1 or 2):

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.
<table>
<thead>
<tr>
<th></th>
<th>A. Livestock Receiving</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Company provides written expectations for humane handling to transporters. Guidelines must be posted or delivered to transporters. (1 element)</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>Trailer should be cleaned regularly to prevent heavy accumulation of feces. Manure should not surpass hooves. Trailers must have slip resistant floors and no potential injury points (broken glass, sharp metal edges, etc.) (3 elements)</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>Ramps and unloading area should be slip resistant with no accumulated manure or standing water. There are no potential injury points (broken gates, sharp metal edges, etc.) in unloading areas. (3 elements)</td>
<td>5</td>
</tr>
<tr>
<td>4.</td>
<td>The plant should discourage use of electric prods during unloading of animals. Less than 5% of animals should be electrically prodded. (1 element)</td>
<td>5</td>
</tr>
<tr>
<td>5.</td>
<td>Animals that have become non-ambulatory in transport are handled humanely and per company's established procedures. Auditor verifies that procedures require stunning of animal prior to being physically removing from trailer or transport vehicle. (Reason for this verification is it is very unlikely auditor will be able to visually verify an animal being stunned on a transport vehicle.) (2 elements)</td>
<td>5</td>
</tr>
</tbody>
</table>

**Possible Points** 25  
**Actual Points** 25  

Comments

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.
<table>
<thead>
<tr>
<th>2.0</th>
<th>A. Livestock Condition</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>Facility has an established procedure for animals that become non-ambulatory after ante-mortem inspection. Procedure includes stunning animal prior to dragging it from pens, chutes, or ramps. (2 elements)</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>Any dead-on-arrivals (DOAs) carcasses should be staged out of public view. The facility must keep track of DOAs. (2 elements)</td>
<td>5</td>
</tr>
</tbody>
</table>

Possible Points 10
Actual Points 10

Comments

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.
### A. Handling and Holding

<table>
<thead>
<tr>
<th>Item</th>
<th>Description</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1.</td>
<td>All pens should have slip resistant floors and be cleaned or bedded daily. Manure should not surpass the hoof of the animal, and standing water should not be present. Crowd pen, chutes, restrainer, and knock box areas have slip resistant floors. (Verify maintenance records are being maintained.)</td>
<td>5</td>
</tr>
<tr>
<td>2.</td>
<td>Pens, chutes, restrainer area, and knock box should be in good repair with no potential injury points (broken gates, sharp metal edges, broken concrete, etc.) present. There are no potential distractions present or observed in the pens, chutes, restrainer, or knock box area. Distractions could include poor design, poor lighting/shadows, out of place objects, voices/noise, debris, etc. Solid sides should be present on crowd pen and chute sides to prevent distractions.</td>
<td>5</td>
</tr>
<tr>
<td>3.</td>
<td>There is a preventative maintenance program in place for the stunning equipment. There must be back-up stunning equipment in the stunning area. Stunning equipment must also be available to the receiving area for downers on trailers and in pens.</td>
<td>5</td>
</tr>
<tr>
<td>4.</td>
<td>Plant must have an Emergency Livestock Management Plan. The plan should address potential risks and actions for insuring animal welfare, based on geographic location and climate. The plan should be reviewed at least annually.</td>
<td>5</td>
</tr>
<tr>
<td>5.</td>
<td>Holding pens must not be overstocked. Animals should have ease of mobility. Crowd pen should be stocked less than 3/4 full. Crowd pen gate should not be used to push animals.</td>
<td>5</td>
</tr>
<tr>
<td>6.</td>
<td>All holding pens must have unrestricted access to potable water. Troughs should be regularly cleaned and water cannot be frozen. Animals must have access to feed if held for over 24 hours.</td>
<td>5</td>
</tr>
<tr>
<td>7.</td>
<td>The company's training program must reflect procedures and policies for receiving livestock, condition of livestock, holding and handling, and stunning. Retraining should be done at least annually. Records of training must be maintained.</td>
<td>5</td>
</tr>
<tr>
<td>8.</td>
<td>Company performs animal welfare self-audits at least weekly. Records of the self-audits are maintained. Consistent deviations or observations must have corrective actions completed with timelines. The observations of insensibility, stunning accuracy, electric prod usage, vocalization, and slips and falls must be included in the self-audits conducted.</td>
<td>5</td>
</tr>
<tr>
<td>9.</td>
<td>ANY WILLFUL ACT OF ABUSE IS GROUNDS FOR AUTOMATIC AUDIT FAILURE. 1) DRAGGING A CONSCIOUS, NON-AMBULATORY ANIMAL; 2) PURPOSEFUL SLAMMING OF GATES OF LIVESTOCK; 3) PURPOSEFUL DRIVING OF LIVESTOCK ON TOP OF ONE ANOTHER; 4) HITTING OR BEATING AN ANIMAL.</td>
<td>5</td>
</tr>
</tbody>
</table>

**Possible Points** 45  
**Actual Points** 45
### 4.0 A. Observations

<table>
<thead>
<tr>
<th>Item</th>
<th>Rating</th>
</tr>
</thead>
<tbody>
<tr>
<td>1. SLIPS AND FALLS- UNLOADING: DETERMINE THE NUMBER OF SLIPS AND FALLS DURING UNLOADING AND RECORD PROBABLE CAUSES if any are observed. Count the number of cattle that slip or fall during unloading. In large plants unloading should be continuously observed until 100 animals from three different vehicles are scored. An equal number of animals from each deck should be scored. Vehicles should be scored in the order of arrival at the unloading ramp. In small plants where vehicles are not continuously unloaded, a single vehicle should be scored. If no vehicle arrives, the score sheet is marked unloading not observed. A SLIP IS RECORDED WHEN A PORTION OF THE LEG, OTHER THAN THE FOOT TOUCHES THE GROUND, OR A FOOT LOSES CONTACT WITH THE GROUND IN A NON-WALKING MANNER. A FALL IS RECORDED WHEN AN ANIMAL LOSES AN UPRIGHT POSITION SUDDENLY AND A PART OF THE BODY OTHER THAN THE LIMBS TOUCHES THE GROUND. EXCELLENT = NO SLIPS OR FALLS = 5; ACCEPTABLE = 3% OR LESS SLIPPING OR 1% OR LESS FALLS = 3; NOT ACCEPTABLE = GREATER THAN 1% FALLS OR GREATER THAN 3% SLIPS= 1</td>
<td>5</td>
</tr>
<tr>
<td>2. SLIPS AND FALLS- STUNNING CHUTE AREAS: DETERMINE THE NUMBER OF SLIPS AND FALLS DURING HANDLING IN ANY OF THE FOLLOWING LOCATIONS: CROWD PEN, SINGLE FILE CHUTE, BARNs, ALLEYS OR STUNNING BOX. Score a minimum of 50 animals in large plants. A SLIP IS RECORDED WHEN A KNEE OR HOCK TOUCHES THE FLOOR. IN CATTLE STUN BOXES AND THE SINGLE FILE CHUTE, A SLIP SHOULD BE RECORDED IF THE ANIMAL BECOMES AGITATED DUE TO multiple SHORT SLIPS. A FALL IS RECORDED IF THE BODY TOUCHES THE FLOOR. EXCELLENT = NO SLIPS OR FALLS = 5; ACCEPTABLE = 3% OR LESS SLIPPING OR 1% OR LESS FALLS = 3; NOT ACCEPTABLE = GREATER THAN 1% FALLS OR GREATER THAN 3% SLIPS= 1</td>
<td>5</td>
</tr>
<tr>
<td>3. USE OF ELECTRIC PRODS FROM CROWD PEN TO RESTRAINER /KNOCK BOX: MONITOR THE PERCENTAGE OF 100 CATTLE PRODDED WITH AN ELECTRIC PROD AT THE RESTRAINTER ENTRANCE. Facilities with two or more single file chutes should be audited, so there is an even distribution of animals observed among all of the single file chutes. If multiple employees are using prods, score 100 animals passing by each employee. Add the percentages together to determine the final score. Note whether or not a prod was used for each animal and the apparent reason for prod use in the comments. ELECTRIC PRODS SHoulD ONLY BE USED WHEN NECESSARY. ELECTRIC PRODS AND ANY OTHER OBJECTS SHALL NOT BE USED ON SENSITIVE AREAS (FACE, ANUS AND GENITAL). ELECTRIC PRODS SHOULD NOT BE USED IN HOLDING AREA OR CROWD PEN. EXCELLENT = 5% OR LESS PRODDED = 5; ACCEPTABLE = 25% OR LESS PRODDED = 3; NOT ACCEPTABLE = GREATER THAN 25% PRODDED = 1</td>
<td>3</td>
</tr>
<tr>
<td>4. VOCALIZATION: MONITOR THE NUMBER OF CATTLE THAT VOCALIZE (PROVOKED BY STRESS OR AGITATION) IN THE CROWD PEN, LEAD-UP CHUTE STUNNING BOX OR RESTRAINER. SCORE A MINIMUM OF 100 ANIMALS IN LARGE PLANTS AND 50 OR AT LEAST ONE HOUR OF PRODUCTION IN SMALLER PLANTS. VOCALIZING ANIMALS IN THE CROWD PEN AND LEAD-UP CHUTE ARE SCORED DURING ACTIVE HANDLING. SCORE AN ANIMAL AS A VOCALIZER, IF IT MAKES ANY AUDIBLE VOCALIZATION. Determine cause for animals that are vocalizing and include in comments. AMI GUIDELINES DEFINE ACCEPTABLE VOCALIZATION AS UP TO 3% FOR CONVENTIONAL SLAUGHTER AND UP TO 5% IN KOSHER OR HALAL OPERATIONS OR ANY OPERATION USING A HEAD HOLDER. EXCELLENT = LESS THAN 1% VOCALIZATION = 5; ACCEPTABLE = 3% or less (conventional) or 5% or less (ritual or with use of head holder) VOCALIZATION = 3; NOT ACCEPTABLE = GREATER THAN 3% (CONVENTIONAL) OR 5% VOCALIZATION (RITUAL OF WITH USE OF A HEAD HOLDER = 1</td>
<td>5</td>
</tr>
</tbody>
</table>

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.

SILLIKER Inc.
900 Maple Road, HOMEWOOD, IL 60430/TEL +1(708)957-7878/FAX +1(708)957-8405
rev. 2 10/2007
A. Observations

5. STUNNING ACCURACY (CONVENTIONAL ONLY): PLANNED DOUBLE KNOCKING IS PROHIBITED. IF A NON-PENETRATING CAPTIVE BOLT IS USED, THE ANIMALS SHOULD BE BLED PROMPTLY BUT NO LONGER THAN 60 SECONDS AFTER STUNNING TO AVOID RETURN TO SENSIBILTIY. THE FIRST SHOT MUST RENDER THE ANIMAL INSENSIBLE. SCORq 100 CATTLE IN PLANTS WITH LINE SPEEDS GREATER THAN 100 CATTLE PER HOUR. FIFTY CATTLE OR AT LEAST ONE HOUR OF PRODUCTION SHOULD BE AUDITED IN SLOWER PLANTS PROCESSING FEWER THAN 100 HEAD PER HOUR. RECORD PERCENTAGE OF ANIMALS THAT WERE STUNNED TWICE AND PROBABLE CAUSES AND INCLUDE IN COMMENTS. Auditor is to list stunning method used in comments. EXCELLENT = 99-100% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 5; ACCEPTABLE = 95-98% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 3; NOT ACCEPTABLE = LESS THAN 95% INSTANTLY RENDERED INSENSIBLE WITH 1 SHOT = 1

6. BLEED RAIL INSENSIBILITY SURVEY: ANY SENSIBLE ANIMAL ON THE BLEED RAIL CONSTITUTES AN AUTOMATIC AUDIT FAILURE. SCORE A MINIMUM OF 100 ANIMALS IN LARGE PLANTS. FIFTY CATTLE OR AT LEAST ONE HOUR OF PRODUCTION SHOULD BE AUDITED IN SLOWER PLANTS PROCESSING FEWER THAN 100 HEADS PER HOUR. IT IS CRITICAL THAT ANIMALS SHOWING SIGNS OF A RETURN TO SENSIBILITY BE RESTUNNED IMMEDIATELY. THERE IS ZERO TOLERANCE FOR BEGINNING ANY PROCEDURES LIKE SKINNING THE HEAD OR LEG REMOVAL ON ANY ANIMAL THAT SHOWS SIGNS OF A RETURN TO SENSIBILITY; however, it is important to complete the audit and note observations about insensitivity. Insensitivity is characterized by a floppy head, straight tongue hanging out, no righting reflex, eyes are in a blank stare (no eye tracking), no natural blinks occurring. EXCELLENT = 100% INSENSIBLE = 5; NOT ACCEPTABLE = LESS THAN 100% INSENSIBLE = 1

Comments

3. Observed three head out of the 50 head observed, prodded, while being moved from the crowd pens to the knock box. Use of electric pod = 6 %

5. Observed one head (#7) double-knocked, out of the 45 head observed knocked during a one hour period. Stunning accuracy = 97.8 %

Items in bold and caps are automatic failure questions if a "1" is scored by auditor.
To: Steve Mendell, President  
Westland/Hallmark Meat Company  
13677 Yorba Avenue  
Chino, CA 91710

From: V E Coiner DVM  
Meat Consultant

February 1, 2008

Thank you for asking me to visit your official establishment and provide you with my independent review.

I retired from supervisory positions in USDA’s Food Safety and Inspection Service in 1997. I worked for FSIS for 26 years in many parts of the U.S., starting as a Vet Medical Officer at a slaughter plant. Since retirement, I advise and counsel meat firms and provide my independent views based on my substantial experience.

Steve, I have reviewed the records and programs you have at your plant; which Steve Sayer has in place at your plant and these are the best I have ever seen in any plant.

You have excellent records of all of your training programs and ongoing training of all employees.

Your plant has passed numerous audits on humane handling of animals in this plant in the year of 2007 and has no failures; which you should to be very proud of.

You have no failures of E-coli and Salmonella samples; which again shows you have an excellent control over all the harvesting and processing in this plant.

I have also gone through the AM pens and slaughter floor and I see a few windows of opportunities or enhancements, which as we discussed should be initiated at your plant.

(1) You need to hire an employee to monitor the handling of all the livestock full-time.
(2) You should eliminate all weak animals from entering your plant premises. I have talked to Donnie Hallmark. You need to make the dairymen and cattle buyers aware of this.
(3) You also need to place a hasp and FSIS seal on the old downer door as a further enhancement to prevent any possible way of allowing a weak animal to enter the slaughter floor.

Again, I would like to commend you and all of your employees for the fine job they have been doing at this plant to produce an excellent product for consumer.

If I can be of any assistance to you in the future please call me anytime at 208-373-0669 or 208-863-3399.
### GEORGIA DEPARTMENT OF AGRICULTURE

Consumer Protection Division
19 Martin Luther King Jr. Drive Room 306
Atlanta, Georgia 30334

---

**FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS**

<table>
<thead>
<tr>
<th>Compliance Status</th>
<th>COS</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Supervision</td>
<td></td>
<td></td>
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<tr>
<td>Person in charge present, demonstrates knowledge, and performs duties</td>
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<tr>
<td>Management awareness; policy present</td>
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<tr>
<td>Proper use of reporting, restriction &amp; exclusion</td>
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<tr>
<td>Good Hygienic Practices</td>
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<td></td>
<td></td>
<td></td>
</tr>
<tr>
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<tr>
<td></td>
<td></td>
<td></td>
</tr>
<tr>
<td>Adequate hand washing facilities supplied &amp; accessible</td>
<td></td>
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<tr>
<td>4</td>
<td>Proper eating, tasting, drinking, or tobacco use</td>
<td></td>
</tr>
<tr>
<td>5</td>
<td>No discharge from eyes, nose, and mouth</td>
<td></td>
</tr>
<tr>
<td>6</td>
<td>Hands clean and properly washed</td>
<td></td>
</tr>
<tr>
<td>7</td>
<td>No bare hand contact with ready-to-eat foods or approved alternate method followed</td>
<td></td>
</tr>
<tr>
<td>8</td>
<td>Adequate hand washing facilities supplied &amp; accessible</td>
<td></td>
</tr>
<tr>
<td>9</td>
<td>Food obtained from approved source</td>
<td></td>
</tr>
<tr>
<td>10</td>
<td>Food received at proper temperature</td>
<td></td>
</tr>
<tr>
<td>11</td>
<td>Food in good condition, safe, and unadulterated</td>
<td></td>
</tr>
<tr>
<td>12</td>
<td>Required records available: shell stock tags, parasite destruction</td>
<td></td>
</tr>
<tr>
<td>13</td>
<td>Food separated and protected</td>
<td></td>
</tr>
<tr>
<td>14</td>
<td>Food-contact surfaces: cleaned &amp; sanitized</td>
<td></td>
</tr>
<tr>
<td>15</td>
<td>Proper disposition of returned, previously served, reconditioned, and unsafe food</td>
<td></td>
</tr>
</tbody>
</table>

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### GOOD RETAIL PRACTICES

Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.

<table>
<thead>
<tr>
<th>Compliance Status</th>
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<tbody>
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<td>Safe Food &amp; Water</td>
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<td></td>
</tr>
<tr>
<td>Transportation of Food</td>
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<td></td>
</tr>
<tr>
<td>Water and ice from approved source</td>
<td></td>
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</tr>
<tr>
<td>Variance obtained for specialized processing methods</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper cooling methods used, adequate equipment for temperature control</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Plant food properly cooked for hot holding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Approved thawing methods used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Thermometers provided and accurate</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food Identification</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Food properly labeled; original container</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Insects, rodents, and animals not present</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Contamination prevented during food preparation, storage &amp; display</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Personal cleanliness</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Wiping cloths; properly used and stored</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Washing fruits and vegetables</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

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**Compliance Status**

<table>
<thead>
<tr>
<th>Compliance Status</th>
<th>COS</th>
<th>R</th>
</tr>
</thead>
<tbody>
<tr>
<td>Potentially Hazardous Food (Time/Temperature Control for Safety Food)</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper cooking time and temperatures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper reheating procedures for hot holding</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper cooling time and temperatures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Proper hot holding temperatures</td>
<td></td>
<td></td>
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<tr>
<td>Proper cold holding temperatures</td>
<td></td>
<td></td>
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<tr>
<td>Proper date marking and disposition</td>
<td></td>
<td></td>
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<tr>
<td>Time as a public health control: procedures &amp; records</td>
<td></td>
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</tr>
<tr>
<td>Consumer Advisory</td>
<td></td>
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<td>Consumer advisory provided for raw or undercooked foods</td>
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<tr>
<td>Enforcement Tactics</td>
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<tr>
<td>Withhold from safe issued/ Equipment Rejected/ Food Destruction</td>
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<tr>
<td>Chemical</td>
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<td></td>
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<tr>
<td>Food additives: approved and properly used</td>
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<td></td>
</tr>
<tr>
<td>Toxic substances properly identified, stored, used</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Conformance with Approved Procedures</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Compliance with variance, specialized process, and HACCP plan</td>
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</tr>
</tbody>
</table>

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Risk factors are improper practices or procedures identified as the most prevalent contributing factors of foodborne illness or injury. Public Health Interventions are control measures to prevent foodborne illness or injury.

---

**Person in Charge (Signature)**

**Inspector (Signature)**

Date: 10/23/2008
Establishment: PEANUT CORPORATION OF AMERICA  

Address: 14075 MAGNOLIA ST  
City/State: BLAKELY, GA  
Zip Code: 39823-1881  
Telephone: (229) 723-3411

Establishment #: 037234  
Permit Holder: Peanut Corporation of America  
Purpose of Inspection: Regular  
Est. Type: Regular  
Risk Category: Regular

<table>
<thead>
<tr>
<th>Economic Issues</th>
<th>#/s</th>
<th>Area</th>
<th>Equipment</th>
<th>Reason For Rejection</th>
</tr>
</thead>
<tbody>
<tr>
<td>55. Scales Checked</td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>56. Packages Weighted</td>
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<tr>
<td>57. Scanner Verification</td>
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<tr>
<td>58. Eggs Inspected</td>
<td></td>
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<tr>
<td>59. Out of Date Foods</td>
<td>0</td>
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<td></td>
</tr>
<tr>
<td>60. False Advertising</td>
<td></td>
<td></td>
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</tr>
<tr>
<td>81. Product Evaluation</td>
<td></td>
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</table>

**ECONOMIC AND TEMPERATURE OBSERVATIONS**

<table>
<thead>
<tr>
<th>Economic Issues</th>
<th>#/s</th>
<th>Item/Location</th>
<th>Temp</th>
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</tr>
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<tbody>
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</tr>
</tbody>
</table>

**OBSERVATIONS AND CORRECTIVE ACTIONS**

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Violation of Code</th>
<th>Remarks</th>
</tr>
</thead>
<tbody>
<tr>
<td>46</td>
<td>[40-7-1-.31(6)]</td>
<td>Totes returned from Boca Grande 3245 North Berkeley Lake Rd. Duluth GA 30096, are intended for reuse by this customer. Photographs taken of these totes show butter left on them as well as a black buildup. A liner is placed inside of totes prior to filling. Totes removed. Today is the first attempt at refilling these totes. Practice will be suspended. Corrected On-Site. New Violation.</td>
</tr>
<tr>
<td>53</td>
<td>[40-7-1-.67(1, 2)]</td>
<td>Mildew and possibly some static dust on ceiling of butter storage room. New Violation. Correct By: 11/05/2008</td>
</tr>
</tbody>
</table>

Remarks: History: FDA with Beard 06-10-08 CURRENT: Signed by Sam Lightsey.

Person in Charge (Signature):  
Date: 10/23/2008

Inspector (Signature): Donna Adams (48270102)  
Date: 10/23/2008
GEORGIA DEPARTMENT OF AGRICULTURE
Consumer Protection Division
19 Martin Luther King Jr. Drive Room 306
Atlanta, Georgia 30334

Consumer Protection Field Forces
Capitol Square, Room 306
Atlanta, Georgia, 30334

Establishment
PEANUT CORPORATION OF
AMERICA
Address
14075 MAGNOLIA ST
City/State
BLAKELY, GA
Zip Code
30823-1881
Telephone
(229) 723-3411

Establishment # 037234
Permit Holder
Peanut Corporation of America
Purpose of Inspection
Regular

FOODBORNE ILLNESS RISK FACTORS AND PUBLIC HEALTH INTERVENTIONS

Compliance Status

Supervision
1 IN Person in charge present, demonstrates knowledge, and performs duties

Employee Health
2 IN Management awareness; policy present
3 IN Proper use of reporting, restriction & exclusion

Good Hygienic Practices
4 IN Proper eating, tasting, drinking, or tobacco use
5 IN No discharge from eyes, nose, and mouth

Control of Hands as a Vehicle of Contamination
6 IN Hands clean and properly washed
7 IN No bare hand contact with ready-to-eat foods or approved alternate method properly followed
8 IN Adequate hand washing facilities supplied & accessible

Approved Source
9 IN Food obtained from approved source
10 IN Food received at proper temperature
11 IN Food in good condition, safe, and unadulterated
12 IN Required records available: shell stock tags, parasite destruction

Protection from Contamination
13 IN Food separated and protected
14 IN Food-contact surfaces: cleaned & sanitized
15 IN Proper disposition of returned, previously served, reconditioned, and unsafe food

Food Temperature Control
31 IN Proper cooling methods used; adequate equipment for temperature control
32 IN Plant food properly cooked for hot holding
33 IN Approved thawing methods used
34 IN Thermometers provided and accurate

Food Identification
35 IN Food properly labeled; original container

Compliance Status

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29 IN Water and ice from approved source
30 IN Variance obtained for specialized processing methods

Food Temperature Control
31 IN Proper cooling methods used; adequate equipment for temperature control
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Prevention of Food Contamination
36 IN Insects, rodents, and animals not present
37 IN Contamination prevented during food preparation, storage & display
38 IN Personal cleanliness
39 IN Wiping clothes: properly used and stored
40 IN Washing fruits and vegetables

Compliance Status

Potentialy Hazardous Food (Time/Temperature Control for Safety Food)
16 IN Proper cooking time and temperatures
17 IN Proper reheating procedures for hot holding
18 IN Proper cooling time and temperatures
19 IN Proper hot holding temperatures
20 IN Proper cold holding temperatures
21 IN Proper date marking and disposition
22 IN Time as a public health control: procedures & records

Consumer Advisory
23 IN Consumer advisory provided for raw or undercooked foods

Enforcement Tactics
24 IN Withhold from sale issued / Equipment Rejected / Food Destruction

Chemical
25 IN Food additives: approved and properly used
26 IN Toxic substances properly identified, stored, used

Conformance with Approved Procedures
27 IN Compliance with variance, specialized process, and HACCP plan

Compliance Status

GOOD RETAIL PRACTICES

Good Retail Practices are preventative measures to control the addition of pathogens, chemicals, and physical objects into foods.

Compliance Status

Safe Food & Water
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Compliance Status

Proper Use of Utensils
41 OUT In-use utensils: properly stored
42 IN Utensils, equipment and linens: properly stored, dried, handled
43 IN Single-use/single-service articles: properly stored, used
44 IN Gloves used properly

Utensils, Equipment and Vending
45 OUT Food and nonfood-contact surfaces cleanable, properly designed, constructed, and used
46 IN Warewashing facilities: installed, maintained, used; test strips
47 IN Nonfood-contact surfaces clean

Physical Facilities
48 IN Hot and cold water available; adequate pressure
49 IN Plumbing installed; proper backflow devices
50 IN Sewage and waste water properly disposed
51 IN Toilet facilities: properly constructed, supplied, cleaned
52 IN Garbage/refuse properly disposed; facilities maintained
53 IN Physical facilities installed, maintained, and clean
54 OUT Adequate ventilation and lighting; designated areas used

Person in Charge (Signature) Donna Adams
Date: 06/10/2008

Inspector (Signature) Donna Adams (48270102)
Date: 06/10/2008
### Economic and Temperature Observations

<table>
<thead>
<tr>
<th>Economic Issues</th>
<th>#’s</th>
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<tr>
<td>61. Product Evaluation</td>
<td></td>
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</tr>
</tbody>
</table>

### Observations and Corrective Actions

<table>
<thead>
<tr>
<th>Item Number</th>
<th>Violations cited in this report must be corrected within the time frames below.</th>
</tr>
</thead>
<tbody>
<tr>
<td>41</td>
<td>Violation of Code: [40-7-1-.14(2)] Scraper for final bulk tank after metal detector (fill bulk tank) is stored over reject product. Scraper was not covered, no cleaning schedule. Plant mgr covered product with throw-away plastic bags. Scraper will be rotated and washed hourly. Corrected On-Site. New Violation.</td>
</tr>
<tr>
<td>45</td>
<td>Violation of Code: [40-7-1-.28(1)] Possible metal flakes from metal scrubber which is used to clean outside of equipment. Clean, properly stored wiping cloths to be used for clean up. Corrected On-Site. New Violation.</td>
</tr>
<tr>
<td>54</td>
<td>Violation of Code: [40-7-1-.67(4)] Dust buildup on fan in butter room. New Violation. Correct By: 06/11/2008</td>
</tr>
</tbody>
</table>

Remarks

No violation 12-14-07. CURRENT: FDA with Beard, routine. Investigation as per FDA request.

---

Person in Charge (Signature): [Signature]

Date: 06/10/2008

Inspector (Signature): Donna Adams (48270102)

Date: 06/10/2008
This document lists observations made by the FDA representative(s) during the inspection of your facility. They are inspectional observations, and do not represent a final Agency determination regarding your compliance. If you have an objection regarding an observation, or have implemented, or plan to implement, corrective action in response to an observation, you may discuss the objection or action with the FDA representative(s) during the inspection or submit this information to FDA at the address above. If you have any questions, please contact FDA at the phone number and address above.

DURING AN INSPECTION OF YOUR FIRM WE OBSERVED:

OBSERVATION 1

Failure to manufacture foods under conditions and controls necessary to minimize the potential for growth of microorganisms and contamination.

Specifically, the firm's private laboratory microbiological testing found the following:

Salmonella Typhimurium: Peanut paste under lot # 8278 was found contaminated with Salmonella Typhimurium by private laboratory testing conducted by the firm. After the firm retested the product and received a negative status, the firm shipped 10 lb. of the product in interstate commerce. Additionally, this peanut paste was manufactured on 9/26/08 from 10 lb. totes of roasted peanuts received on 9/25/08. The lots of roasted peanuts received on 9/25/08 were also used to produce the following products that were also shipped in interstate commerce: (b)(4) totes were used to manufacture peanut butter under lot # 8276, one tote was used to manufacture peanut butter under lot # 8277 and (b)(4) under lot # 8277.

Creamy Stabilized Peanut Butter, manufactured on 8/11/08 (producing both lots #8220 and #8224), tested positive for Salmonella by (b)(4) received this PCA sample for these lots on 8/12/08 and issued a report of positive results on 8/27/08. The isolate from this sample was sent to (b)(4) and was confirmed as Salmonella Anatum. The firm then had this lot retested at both (b)(4) and (b)(4) with both labs finding negative results. However, PCA had already shipped into interstate commerce the following: An 8/15/08 shipment of (b)(4) lbs. (invoice #0107013) creamy stabilized peanut butter under lot #8220 went to (b)(4).

Lot #8258, Peanut Meal and Medium Chopped Peanuts, manufactured on 9/24/08, tested positive for Salmonella by (b)(4) and received this PCA sample on 9/25/08 and issued a report of the positive results on 10/6/08. This sample was confirmed by (b)(4) as Salmonella Anatum. However, PCA had already shipped into interstate commerce the following lots before lab results were known: On 9/24/08 a shipment of (b)(4) lbs. (invoice #302583) of peanut meal under

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lot #8268 to (b)(4). On 9/25/08 a shipment of (b)(4) lbs. (invoice #1057536) medium chopped granules under lot #8268 went to (b)(4). 

Lot #8168, Medium Chopped Peanuts and Peanut Meal, manufactured on 6/16/08 tested positive for Salmonella by (b)(4). This firm resubmitted a sample to (b)(4) on 6/21/08 with a report issued on 6/23/08 as negative. This firm had shipped the following product into interstate commerce prior to receiving the sample results on 6/23/08: A shipment on 6/18/08 of (b)(4) lbs. (invoice #662837) of peanut meal under lot #8169 went to (b)(4). On 6/20/08 this firm shipped approximately (b)(4) lbs. (invoice #61108) of peanut meal under lot #8169 to (b)(4). 

Lot #8161A, Small Chopped Peanuts, manufactured on 6/10/08, testing positive for Salmonella by (b)(4). This firm resubmitted a sample to (b)(4) on 6/11/08 which was found to be negative per a report issued 6/21/08. PCA had already shipped product from lot #8161A in interstate commerce before the positive results were known on 6/16/08. On 6/19/08 a shipment of approximately (b)(4) lbs. (invoice #MB6408) of small chopped peanuts under lot #8161 went to (b)(4). On 6/13/08 a shipment of (b)(4) lbs. (invoice #11114-3) of small chopped peanuts under lot #8161 went to (b)(4). 

Lot #8028, Peanut Paste, manufactured on 1/26/08 tested positive for Salmonella by (b)(4). However, also on 1/26/08 PCA shipped (b)(4) lbs. (invoice #4503605302) of peanut paste under lot #8028 to (b)(4). 

Salmonella (no strain identified): Medium Chopped Granules manufactured on January 24, 2008 under lot #8024 tested positive for Salmonella by a private laboratory. After the firm retested the product and received a negative status, the product was shipped in interstate commerce. 

Lot #7206, Small Chopped Peanut Granules, manufactured on or around 7/25/07, tested positive for Salmonella by (b)(4) received the PCA sample on 7/25/07 and issued a report of the positive results on 7/30/07. PCA had already shipped approximately (b)(4) lbs (invoice #736434-001) of small chopped peanuts under lot #7206 to (b)(4) on 7/27/07 before the lab results were obtained. 

Lot #7192A, Small Chopped Peanuts, manufactured on 7/11/07, tested positive for Salmonella by (b)(4) received the PCA sample for this lot on 7/12/07 and issued a report of the positive Salmonella results on 7/18/07. Two more samples of this lot were submitted to both (b)(4) and (b)(4) on 7/19/07. The (b)(4) follow-up sample of this lot submitted on 7/18/07 was classified negative on 7/19/07. The (b)(4) follow-up sample of this lot was classified negative on 7/19/07.

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DATE ISSUED: 02/05/2009
Lot #7192B, Medium Chopped Peanuts, manufactured on 7/9/07, tested positive for Salmonella by
(b)(4). PCAs received two PCA samples for lot #7190B on 7/10/07 and 7/12/07. Both samples were positive with the lab
reports issued on 7/16/07 and 7/18/07 respectively. The following shipments were released into interstate commerce before the
final lab results were obtained. On 7/11/07 a (b)(4) lb. shipment of medium chopped peanuts (invoice #10086) under lot
#7190 went to (b)(4). On 7/12/07 a (b)(4) lb. shipment of medium chopped peanuts (invoice #18049-30) under lot
#7190 went to (b)(4). On 7/13/07 a (b)(4) lb. shipment of medium chopped peanuts (invoice #31810) under lot #7190 went to
(b)(4). Additionally, the firm made the following shipments on or after the positive Salmonella results were obtained. On 7/18/07 a shipment of
(b)(4) lbs. of medium chopped peanuts (invoice #23917) under lot #7190 went to (b)(4) and on 7/24/07 a shipment of approximately
(b)(4) lbs. of medium chopped peanuts (invoice #10872-2) under lot #7190 went to (b)(4).

Lot #7190 B19-JR, Oil-Roasted Salted Jumbo Peanuts manufactured on 7/9/07 tested positive for Salmonella by
(b)(4). PCAs received the PCA sample for this lot on 7/13/07 and issued a report of the positive results on 7/16/07. On 7/12/07 PCA submitted a second sample to the (b)(4) labs of the same lot (7190 B19-JR) and received a negative status for Salmonella on 7/16/07. The following shipments were released by PCA into interstate commerce before final lab results were known. A 7/10/07 shipment of (b)(4) lbs. (invoice #12131) oil roasted jumbo peanuts under lot #7190 went to (b)(4). A 7/12/07 shipment of (b)(4) lbs. (invoice #21357) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4). A 7/13/07 shipment of approximately (b)(4) lbs. (invoice #21358) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4). A 7/13/07 shipment of approximately (b)(4) lbs. (invoice #11463) oil roasted salted jumbo peanuts under lot #7190 went to (b)(4).

Lot #7157, Small Chopped Peanut Granules, manufactured on 6/7/07, tested positive for Salmonella by
(b)(4). PCAs received the PCA sample on 6/7/07 and issued a report of the positive results on 6/13/07. However, PCA had already shipped (b)(4) lbs (invoice #721676-001) of small chopped peanuts under lot #7157 to (b)(4) on 6/7/07 before the lab results were obtained.
OBSERVATION 2

Failure to maintain equipment, containers and utensils used to convey, hold, and store food in a manner that protects against contamination.

Specifically, the peanut paste line was not cleaned after the Salmonella Typhimurium was isolated from the peanut paste manufactured on September 26, 2008 (lot # 8278). The firm continued to manufacture peanut paste in this system from 9/26/08 to the beginning of this inspection on 1/9/09. (b)(4) lots of peanut paste have been manufactured on this line between 9/26/08 and 1/9/09.

There are no records to document the cleaning of the peanut paste line after Salmonella was detected in peanut paste manufactured on January 25, 2008 (lot # 8028). The firm continued to manufacture peanut paste in this system.
OBSERVATION 3

Failure to perform mechanical manufacturing steps so as to protect food against contamination.

Specifically, this firm recognizes the roasting step as the control point for eliminating microbiological contamination in raw materials. However, this firm has not established the effectiveness of the temperature, volume, or belt speed specific to this roaster to assure it is adequate as a kill step for pathogenic bacteria. Additionally, the firm's records of the roaster's temperature are inadequate in that dates have been left off of several circular recording charts. For example, in August 2008 three days of recording charts were not dated; in September 2008 two recording charts were not dated; in October 2008 six charts were not dated; in November 2008 24 days of recording charts were not dated; and in December 2008 and January 2009 no temperature recording charts were dated.

OBSERVATION 4

Failure to store finished food under conditions that would protect against microbial contamination.

Specifically, on 1/9/09 (b)(4) lb. totes of raw peanuts were observed to be stored directly next to (b)(4) lb. totes of finished, roasted peanuts in the firm's production/packaging room. The totes of finished product included the following: Honey Roasted Peanuts under lot # 8339; Dry Roasted Peanuts under lot # 9002; Peanut Meal under lot # 9005; and Dark Roasted Peanuts (paste line) under lot # 9009. The totes of raw peanuts were all under lot # 40147. On 1/26/09, an additional (b)(4) lb. tote of raw peanuts under lot # 16195-08 was observed to be stored in the production/packaging room along with the same lots of finished goods listed above. It was visually difficult to discern which of these totes were finished products and which were raw products.

The above totes of finished product were stored within 15 feet of a floor crack where an environmental swab was collected on 1/10/09 and found positive for Salmonella Senftenberg.

Also, one environmental swab collected on 1/10/09 from the finished product cooler floor (beside the south wall) was found positive for Salmonella Mbandaka. The swab location was within 3 feet of pallets of finished product.

Mold was observed growing on the ceiling and walls in the firm's cooler used for finished product storage. In addition, water stains were observed running down from the cooling unit fans in the cooler. On 1/10/09, pallets of finished product were stored directly beneath this unit.
OBSERVATION 5

The plant is not constructed in such a manner as to allow ceilings to be kept in good repair.

Specifically, on 1/10/09 there were open gaps observed as large as 1/2" x 2 1/2 feet at the air conditioner intakes located in the roof of the firm. Water stains were also observed on the ceiling around the air conditioner intakes. Additionally, there were water stains and streaks located on the edges of the skylights where rain water has been leaking into the firm. All of these openings were located in the production/packaging room. Totes of finished, roasted product and a roasted nut packaging line are located directly underneath these areas.

OBSERVATION 6

The design of equipment and utensils fails to preclude the adulteration of food with contaminants.

Specifically, a felt material is present on the final roller at the roaster's discharge. This material cannot be adequately cleaned or sanitized.

Also, the rework kettle in the peanut butter room had openings (2" x 3") at the top exposing the peanut butter to open conditions.

OBSERVATION 7

Proper precautions to protect food and food-contact surfaces from contamination with microorganisms cannot be taken because of deficiencies in plant construction and design.

Specifically, the firm is not equipped with a ventilation system to prevent cross-contamination by providing a negative room pressure in the facility. A negative room pressure would direct air flow from the finished product areas into the negative pressure room (raw peanut receipt and staging area), ensuring that contaminated air does not escape to other parts of the facility.

The raw peanut receipt/staging area, peanut paste tanker line, peanut roasters, and the peanut granule line are housed in the same open room with no segregation. In addition, the honey roasted peanuts, considered to be finished product, are filled into
boxes utilizing a hopper in the "kitchen area", this location is where the raw peanuts enter the roaster, again no segregation.

Raw peanuts are filled into boxes utilizing a hopper located in the Production/Packaging room. This hopper is positioned above the packaging line for the small party packs of roasted peanuts. There is no segregation of raw and finished product in this area.

OBSERVATION 8

Devices and fixtures are not designed and constructed to protect against recontamination of clean, sanitized hands.

Specifically, the sink located in the peanut butter room is used interchangeably as a point for cleaning hands and utensils and for washing out mops.

OBSERVATION 9

-Failure to conduct cleaning and sanitizing operations for utensils and equipment in a manner that protects against contamination of food.

Specifically, on 1/12/09 a build-up of product residue was observed on grinders, hoppers, and support beams on the peanut paste tanker line. Also, pieces of the yellow and black caution sign on the mill were flaking off into the catch pan for product under the mill.

On 1/9/09, the dry ingredient staging area above the peanut butter room was dirty with a heavy build-up of different powdery ingredients on all exposed surfaces. This is an open area of the ceiling located directly above the dry ingredient hopper and ribbon mixer.

On 1/9/09, a mesh-type conveyor was observed to be stored in the firm's equipment/utensil wash room, which was used as a catch-all storage area for buckets, stainless steel pipes, removable pumps, removable Y-spouts, and floor mats. The insides and end rollers of this conveyor were covered with a slimy, black-brown residue. Additionally, the bottom sections of the wash room walls had areas of mold.
DEPARTMENT OF HEALTH AND HUMAN SERVICES
FOOD AND DRUG ADMINISTRATION

DATE OF INSPECTION
01/09/2009 - 02/05/2009

FIRM NAME
Peanut Corporation Of America

STREET ADDRESS
14075 Magnolia St.

CITY, STATE, ZIP CODE
Blakely, GA 39823-1881

TYPE OF ESTABLISHMENT INSPECTED
Peanut Roaster/Peanut Butter and Paste Manufacturer

OBSERVATION 10

Effective measures are not being taken to protect against the contamination of food on the premises by pests.

Specifically, on 1/9/09 a live roach and several dead roaches were observed in the firm's wash room. This wash room is adjacent to the production/packaging area.

Also, the bumper pads used for sealing the trailers against the bay doors were inadequate in that openings of 6 inches or more were observed along the sides and tops of the trailers. These trailers, containing raw or roasted product in totes, can be left backed up to the bay doors for 5-7 days allowing these openings to exist.

DATES OF INSPECTION:
01/09/2009(Fri), 01/12/2009(Mon), 01/13/2009(Tue), 01/14/2009(Wed), 01/15/2009(Thu), 01/16/2009(Fri), 01/19/2009(Mon), 01/20/2009(Tue), 01/21/2009(Wed), 01/22/2009(Thu), 01/23/2009(Fri), 01/26/2009(Mon), 01/27/2009(Tue), 02/03/2009(Thu)

AMENDED

Janet R. Gray, Investigator
Darcy E. Brillhart, Microbiologist
Sandra J. Gaul, Investigator
Robert F. Neifigan, Investigator
Lesley K. Satterwhite, Microbiologist
Theresa L. Stewart, Investigator

DATE ISSUED
02/05/2009
Audit Report

Evaluation of FSIS Management Controls Over Pre-Slaughter Activities

Report No. 24601-0007-KC
November 2008
This report presents the results of our audit concerning management controls over pre-slaughter activities. Included is our assessment, based on the information available at the time our work was performed, of the events that took place at Hallmark-Westland Meat Packing Company in the fall of 2007. Your response to the official draft report, dated November 20, 2008, is included as exhibit D. Excerpts of the response, along with the Office of Inspector General’s position, are incorporated into the Findings and Recommendations section of the report. Based on your responses, we were able to reach management decisions on all of the report’s 25 recommendations. Please follow your agency’s internal procedures in forwarding documentation for final action to the Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staff during this audit.
Executive Summary
Evaluation of FSIS Management Controls Over Pre-Slaughter Activities
(Audit Report 24601-7-KC)

Results in Brief
On January 30, 2008, the Humane Society of the United States (HSUS) released videos to the public that documented the egregious abuse of cattle awaiting slaughter at the Hallmark-Westland Meat Packing Company (hereafter referred to as Hallmark) in Chino, California. These abuses, which took place in the fall of 2007, included electric shocks, spray from high-pressure water hoses, and the ramming of cattle with a forklift. The abuses were committed by employees of the establishment in an apparent attempt to force non-ambulatory cattle to rise for slaughter. On February 1, 2008, Hallmark voluntarily ceased operations pending investigation by the U.S. Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) into the alleged abuses.

FSIS determined, as part of its own investigation, that Hallmark employees violated the ban on slaughter of non-ambulatory disabled (“downer”) cattle by failing to notify the FSIS Public Health Veterinarian (PHV) when animals became non-ambulatory after having passed ante-mortem inspection. “Downer” animals are known to be at high risk for bovine spongiform encephalopathies (BSE). Therefore, it is critical that they be carefully examined before slaughter (ante-mortem) and then, if appropriate, condemned. Currently, an animal that becomes non-ambulatory after ante-mortem inspection may only be slaughtered if the PHV determines through re-examination that its condition is due to an acute injury, such as a broken leg. On February 4, 2008, FSIS issued a Notice of Suspension to Hallmark for its failure to maintain and implement controls to prevent the inhumane handling and slaughter of animals.

On February 17, 2008, Hallmark announced that it was voluntarily recalling approximately 143 million pounds of raw and frozen beef products. This recall, the largest recall to date, was designated as Class II due to the establishment’s noncompliance with regulatory requirements and the remote possibility that the beef being recalled could cause adverse health effects if consumed. In public testimony USDA officials reinforced their determination that the recall occurred because the establishment did not comply with regulatory inspection requirements, not due to food safety concerns. To mitigate public concerns that downers may have entered the

1 Title 9 Code of Federal Regulation (C.F.R.) 309.3 (e).
2 BSE, widely referred to as “mad cow disease,” is a chronic degenerative disease of the central nervous system of cattle. BSE belongs to the family of diseases known as transmissible spongiform encephalopathies (TSE), which include scrapie in sheep and goats, chronic wasting disease (CWD) in deer and elk, and Cruetzfeldt-Jakob disease (CJD) in humans.
3 In May 2008, the Secretary announced plans for a total ban on the slaughter of cows too sick or weak to stand. A proposed rule to implement such a ban was published for public comment on August 27, 2008.
4 Class I recall involves a health hazard situation where there is a reasonable probability that eating the food will cause health problems or death.
food supply, USDA officials cited three other interlocking safeguards that protect the public even if other safeguards, such as ante-mortem inspection, should fail; these safeguards are the removal of Specified Risk Materials (SRM), BSE surveillance testing, and the feed ban. Under the Federal Meat Inspection Act (FMIA), if an establishment does not present animals for ante-mortem inspection, FSIS is unable to determine that animals are fit for slaughter as human food, and therefore cannot permit the carcasses to be marked as “inspected and passed.”

The release of the videos by HSUS led Congress, USDA, and the public to question how such events could have occurred at a slaughter establishment that was under inspection by FSIS. FSIS inspection personnel are charged with enforcing the requirements of the Humane Methods of Slaughter Act, the FMIA, and the Poultry Products Inspection Act. FSIS inspects all meat, poultry, and processed egg products sold in interstate commerce to ensure that they meet U.S. food safety standards.

At the request of the Secretary of Agriculture, the Office of Inspector General (OIG) is leading the Department’s criminal investigation into potential violations of the FMIA. The investigation is ongoing, and OIG Investigations is working cooperatively with FSIS’ Office of Program Evaluation, Enforcement, and Review (OPEER) and other law enforcement agencies, as well as coordinating these efforts with the U.S. Department of Justice. At the conclusion of the investigation, a report of investigative findings will be issued to the appropriate USDA officials.

This audit was conducted to determine what inspection controls and/or processes may have broken down at Hallmark, and whether the events that took place there are isolated or systemic. To make that assessment, we evaluated the adequacy of FSIS’ pre-slaughter controls at 10 other slaughter establishments which, like Hallmark, slaughter culled cows. We also evaluated the effectiveness of FSIS’ controls over the removal of SRMs from cattle, as well as inspector-generated samples for residue testing. Because of the ongoing investigation, our assessment of what happened at Hallmark is limited by the information we have to date. Also, since Hallmark has ceased operations, we could not observe and validate FSIS’ oversight and verification of that establishment’s food safety systems. Therefore, we made

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5 Title 9 C.F.R. 310.22(a) defines SRMs as: 1) the brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column, and dorsal root ganglia of cattle 30 months of age or older, and 2) the tonsils and distal ileum of all cattle.

6 In 1997, the Food and Drug Administration implemented a mandatory feed ban that prohibits feeding most mammalian protein to ruminants, including cattle. This rule was strengthened in a final rule published April 25, 2008.


9 Cows are culled from a herd for reasons such as unsatisfactory milk production or reproductive failure, a weak condition or old age, or when the cost to feed does not guarantee a profit from feeding.

10 Although all cows may be subject to residue testing, culled dairy cows are particularly likely to have been administered antibiotics and other drugs because of their age and physical condition.
our assessment as to what happened at Hallmark through interviews and review of available records, where possible.

We determined that there were deliberate actions\textsuperscript{11} by Hallmark personnel\textsuperscript{12} to bypass required inspections, as well as noncompliance with required inspection procedures by FSIS in-plant staff. Supervisory and other management controls did not detect and/or prevent these incidents. Although we found varying degrees of noncompliance and/or inconsistent implementation of required inspection procedures by FSIS inspectors in the other cull establishments reviewed during the audit, nothing came to our attention to indicate that unsuitable animals were passed for slaughter at these establishments. In addition, there was no single underlying reason why the noncompliances occurred. Therefore, we concluded that the events that occurred at Hallmark were not a systemic failure of the inspection processes/system as designed by FSIS. However, we did determine that management controls designed to provide oversight of the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to minimize the chance that events such as those at Hallmark could happen in the future. The observations made during this audit and conclusions reached are limited to cull slaughter operations, which are inherently higher risk due to the health and age of the animals slaughtered.

We did not observe any systemic inhumane handling incidents at the 10 establishments visited during this audit, nor did anything come to our attention that would lead us to believe any were occurring when we were not there. However, we concluded that there is an inherent vulnerability that humane handling violations can occur and not be detected by FSIS inspectors because FSIS does not provide continuous surveillance of all operating areas within a slaughter establishment at all times. Further, animals slaughtered at cull slaughter establishments, like Hallmark, are in a generally weak physical condition, which increases the risk that humane handling violations can occur as establishment employees attempt to move the animals from the unloading areas to the holding pens to slaughter. At Hallmark, egregious humane handling violations occurred when its employees attempted to move non-ambulatory cattle. In response to the events at Hallmark, on August 27, 2008, USDA announced a proposed rule to ban the slaughter of all cattle that become non-ambulatory disabled after passing ante-mortem inspection; these animals would be condemned and properly disposed of rather than slaughtered.

In addition to implementing the proposed ban on non-ambulatory cattle, and establishing appropriate oversight to ensure compliance at slaughter establishments, FSIS can also strengthen management controls and improve

\textsuperscript{11} Because of the ongoing criminal investigation, no further information can be provided in this report.

\textsuperscript{12} The San Bernardino County District Attorney in California filed animal cruelty charges against two former Hallmark employees; both were convicted.
its oversight of its inspection staff. FSIS must take action to demonstrate that the various compensating controls it has in place over its pre-slaughter inspection processes are consistently understood and implemented by its inspection and management staff. We noted the following concerns.

**Sufficiency and Competency of Inspection Resources**

- FSIS cannot demonstrate that the resources assigned to its offline inspection activities are sufficient to adequately perform the tasks assigned. At Hallmark, and at each of the other 10 slaughter establishments we visited, we noted inspection noncompliances of varying types and degree. The reasons for these noncompliances varied, but at three establishments, in addition to Hallmark, the PHVs stated they took shortcuts in ante-mortem inspection activities in order to complete all assigned tasks. Although we observed no adverse impact at the 10 cull slaughter establishments reviewed, such noncompliances can facilitate attempts to bypass inspection processes, as was the case at Hallmark.

- We cannot assess the reasonableness of the supervisory span of control assigned to frontline supervisors (FLS) because FSIS cannot provide supportable work measurement assumptions. The FLS is assigned a circuit of establishments for supervision and oversight and represents the first level of supervision above the in-plant level. The FLS at Hallmark, as well as the FLSs at 7 of the 10 establishments reviewed, were not aware of common practices used by in-plant inspection staff that did not meet FSIS requirements. Therefore, we concluded that FSIS needs to develop a supportable, risk-based methodology for assigning its inspection staff, and re-assess the adequacy and effectiveness of its supervisory span of control.

- FSIS does not have a formal, structured developmental program and system in place to ensure that all of its inspection and supervisory staff receive both formal and on-the-job training to demonstrate that they possess the competencies essential for its mission-critical functions. Since FSIS’ inspection staff is directly involved in ensuring the safety of the food supply, we believe a structured program of continuing education, certified each year, would provide the organizational control needed to demonstrate a knowledgeable and qualified workforce.

**Management Controls**

- FSIS has a management control structure in place that should have identified and/or mitigated the problems disclosed at Hallmark, as well as those we identified at the establishments visited during the
audit. FSIS management, however, did not detect the inconsistent application and/or noncompliance with required inspection procedures that occurred at Hallmark, or at the establishments visited during the audit. FSIS needs to more fully utilize its management information systems to monitor compliance with its inspection requirements, as well as to obtain early alerts of potential problems.

We reported limitations with FSIS’ management control systems in a prior audit, Report 24601-07-Hy, *Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments*, dated December 2007. FSIS is in the process of re-aligning its systems in a Public Health Information System (PHIS) to better integrate and consolidate numerous applications that collect information to provide mission critical support. In addition, FSIS is continuing to enhance and implement systems designed to provide management oversight of the public health activities of its inspection workforce. We concluded that these control systems should be strengthened to minimize the potential for events such as those that occurred at Hallmark to happen in the future.

**SRM Verification Activities**

- FSIS cannot effectively demonstrate that its verification of establishment controls and written procedures for the removal, segregation, and disposition of SRMs is adequate to detect noncompliance. FSIS’ information systems do not provide information to document the verification of each establishment’s controls, nor do they readily provide data for analysis to detect trends of noncompliance or to identify areas where more in-plant oversight is needed. During our establishment visits, we observed that FSIS was verifying the removal of SRMs from each carcass that passed through the slaughter process. However, we found that inspectors did not always detect or consistently document noncompliances with SRM control requirements.

We believe FSIS needs to strengthen its overall management controls and oversight processes to provide reasonable assurance that the compensating controls FSIS has put in place for pre-slaughter inspection activities and SRM verification activities are consistently and fully implemented by its inspection staff.
Recommendations

In Brief

FSIS needs to reassess the inhumane handling risks associated with cull slaughter establishments and determine if more frequent or in-depth reviews need to be conducted. Also, FSIS should establish a process to analyze available data for anomalies or variances in both establishment and inspector performance that could require additional followup by district management.

FSIS needs to develop a supportable, risk-based methodology for determining the inspection resources needed at each establishment and its appropriate supervisory structure. We also recommend that a structured training and development program, with a continuing education component, be developed for both its inspection and management resources. Further, supervisory and management oversight of in-plant performance needs to be strengthened to ensure that on-site evaluations are thorough and are conducted at the required frequencies.

We have also made numerous recommendations for FSIS to strengthen its pre-slaughter inspection processes and compensating controls over the movement and tracking of animals from ante-mortem inspection, to slaughter, and/or through proper disposal, residue testing procedures, and SRM verification activities.

Agency Response

FSIS agreed with the report’s 25 recommendations. We have incorporated the FSIS response in the Findings and Recommendations section of this report, along with the OIG position. FSIS’ response to the draft report is included in its entirety as exhibit D.

OIG Position

Based on FSIS’ response, we were able to reach management decisions on the report’s 25 recommendations.
<table>
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<th>Abbreviation</th>
<th>Description</th>
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<tr>
<td>BSE</td>
<td>Bovine Spongiform Encephalopathy</td>
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<td>CSI</td>
<td>Consumer Safety Inspector</td>
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<td>DVMS</td>
<td>District Veterinary Medical Specialist</td>
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<td>eADRs</td>
<td>Electronic Animal Disposition Reporting System</td>
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<td>EARO</td>
<td>Executive Assistant for Regulatory Operations</td>
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<td>Enforcement Investigations and Analysis Officer</td>
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<td>Environmental Protection Agency</td>
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<td>FAST</td>
<td>Fast Antimicrobial Screening Test</td>
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<td>OIG</td>
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Background and Objectives

Background

The Food Safety and Inspection Service (FSIS) is the public health regulatory agency of the U.S. Department of Agriculture (USDA). As such, the agency protects consumers by ensuring that meat, poultry, and processed egg products are safe, wholesome, and accurately labeled. Under the Federal Meat Inspection Act (FMIA) and Poultry Products Inspection Act, FSIS inspects all meat, poultry, and processed eggs sold in interstate commerce to ensure that it meets U.S. food safety standards. FSIS is responsible for verifying that slaughter and processing establishments implement food safety systems that comply with Pathogen Reduction and Hazard Analysis and Critical Control (HACCP) standards. HACCP requires that all significant hazards with the products and production environment be identified and controlled. FSIS is also responsible for enforcing the Humane Methods of Slaughter Act (HMSA); its inspectors verify the humane treatment of livestock in slaughter establishments.

FSIS employs about 7,800 in-plant inspectors at about 6,200 Federally-inspected establishments; of these, 632 slaughter cattle. FSIS employs public health veterinarians (PHV), food inspectors (FI), and consumer safety inspectors (CSI) who are responsible for inspecting animals prior to slaughter, as well as carcasses after slaughter, to ensure the meat is safe for human consumption. The CSI performs in a relief or trouble-shooting in-plant inspection capacity but is primarily responsible for conducting regulatory oversight activities inside establishments relating to sanitation performance standards, sanitation operating procedures, pathogen reduction verification procedures, and other food security verification procedures. The CSI and PHV both observe animal handling and the slaughter process to ensure compliance with HMSA. In 2004, FSIS implemented the Humane Activities Tracking System (HATS) to document the time spent by FSIS inspection personnel in verifying that humane handling slaughter requirements are met.

FSIS regulations require that all livestock offered for slaughter at an official establishment be examined on the day of and before slaughter. Livestock are inspected before slaughter (ante-mortem), resulting in one of three possible outcomes: 1) passed for slaughter; 2) “suspect,” which requires further inspection by a PHV post-mortem; or 3) condemnation. Both suspect and condemned animals must have metal identification tags placed in an ear and be properly tracked (disposition documented) in official inspection records. Post-mortem inspection is performed on a carcass-by-carcass basis in the

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13 In 2000, FSIS completed implementation of the Pathogen Reduction and HACCP system, which required meat and poultry processing and slaughter establishments to identify critical points in the production chain where food safety hazards could be controlled, reduced, or eliminated (process control).
15 Of these, 103 establishments primarily slaughter cull cattle. These figures are based on FSIS 2007 slaughter data.
16 Title 9 C.F.R. 309.1 (a).
slaughter area after the animal has been humanely stunned and bled. Inspectors look for signs of disease or pathological conditions that would render the carcass (or parts of it) unwholesome or otherwise unfit for human consumption. USDA implemented a number of regulatory actions to reduce the likelihood that high-risk tissues would enter the human food supply. Non-ambulatory disabled or downer cattle have been banned from the food supply because these animals have been determined to be at high risk for bovine spongiform encephalopathy (BSE). USDA currently allows the slaughter of animals that become non-ambulatory because of an acute injury after passing ante-mortem inspection, but only if the PHV re-examines the animal and determines it is acceptable for slaughter.\textsuperscript{17} On August 27, 2008, USDA announced a proposed rule to impose a complete ban on the slaughter of cattle that become non-ambulatory after initial inspection by FSIS. Under the proposed rule, all cattle that are non-ambulatory disabled at any time prior to slaughter will be condemned and properly disposed of.

In 2004, FSIS declared certain beef tissues and products to be specified risk materials (SRM) and banned these products from the human food supply.\textsuperscript{18} The brain, skull, eyes, trigeminal ganglia, spinal cord, vertebral column (excluding the vertebrae of the tail, the transverse processes of the thoracic and lumbar vertebrae, and the wings of the sacrum), and dorsal root ganglia of cattle 30 months of age and older are considered SRMs, as well as the tonsils and distal ileum of the small intestine of all cattle, regardless of age.\textsuperscript{19} Establishments are required to control or prevent these SRMs from entering the food supply.\textsuperscript{20} Establishments that process cattle both under and over 30 months of age must segregate the banned materials and ensure the slaughter equipment is properly cleaned after animals 30 months and older are processed.\textsuperscript{21} Carcasses containing SRMs can be processed and shipped to other establishments for further processing, provided that proper controls are established to ensure that all SRMs are removed by these “downstream processors”\textsuperscript{22} before they are marketed for consumption.

FSIS administers the National Residue Program (NRP) in cooperation with the Environmental Protection Agency (EPA) and the Department of Health and Human Services, Food and Drug Administration (FDA) to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and processed egg products.\textsuperscript{23} FSIS began administering the NRP in 1967 and follows FDA and EPA guidance on residue monitoring and tolerance action levels.

\textsuperscript{17} Title 9 C.F.R. 309.3 (e).
\textsuperscript{18} Title 9 C.F.R. 310.22.
\textsuperscript{19} Title 9 C.F.R. 310.22 (a).
\textsuperscript{20} Title 9 C.F.R. 310.22 (b) and (c).
\textsuperscript{21} Title 9 C.F.R. 310.22 (f).
\textsuperscript{22} Title 9 C.F.R. 310.22 (g).
\textsuperscript{23} FSIS regulations are published in Title 9 C.F.R., Chapter III. FSIS personnel collect samples at inspected establishments and analyze samples at FSIS laboratories for residues. FDA and EPA have statutory authority for establishing residue tolerances or action levels under the Federal Food Drug and Cosmetic Act, and through the Federal Insecticide, Fungicide and Rodenticide Act (as modified by the Food Quality Protection Act), respectively.
FSIS inspectors sample livestock carcasses and parts under the NRP’s Domestic Sampling Plan, which is comprised of two component sampling plans. Under the first of these, the Scheduled Sampling Plan, FSIS inspectors collect random samples of healthy-appearing carcasses that have been passed for consumption to determine the exposure assessment or the prevalence of residues in the national food supply. FSIS also schedules exploratory assessments to investigate or target certain types of animals or residues for ongoing or previous exposures.

A second component of the NRP is Inspector-Generated Sampling. Inspectors judgmentally select a carcass for sampling based on several factors, including (a) signs or symptoms observed in the live animal, (b) pathological conditions or abnormalities of the carcass and/or its associated viscera, (c) previous known residue violations by the animal’s owner, (d) the animal’s herd history, or (e) the fact that an animal is identified as a “high risk” type, such as bob veal or show animals. When the inspector collects a judgmental sample, he/she is to retain (or, if necessary, condemn) the carcass and perform an in-plant screening test called FAST (Fast Antimicrobial Screening Test) on swabs from the kidney, which determines if residues of antibiotics or sulfonamides possibly exist in the sample. If a FAST test has a positive indication of residue, inspection staff forward the related carcass samples to FSIS laboratories for confirmation and further analysis of potential residues or other contaminants.

FSIS reports the laboratory test results in the Laboratory Electronic Application for Results Notification (LEARN) system. Inspectors use LEARN for condemnation instructions if violative residue levels are found in the samples of those carcasses or parts that were retained pending test results. A sample is considered a violation when a residue is detected exceeding an FDA or EPA established tolerance or action level. If a violative level of residue is found, FSIS notifies FDA of the violation and assists in obtaining the names of producers or other parties involved in offering contaminated animals for slaughter. FDA has jurisdiction over residues on the farm and performs any necessary followup or enforcement actions with violators.

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24 Viscera are the internal organs of the animal.
25 Cattle marketed at up to 3 weeks in age, or up to 150 pounds in weight.
26 Sulfonamides are prescription animal drugs used as antibiotics to treat conditions such as bacterial pneumonia, foot rot, and acute mastitis.
Objectives

This audit was conducted to determine what inspection controls and/or processes may have broken down and whether the events at Hallmark are isolated or systemic. We evaluated the adequacy of FSIS’ pre-slaughter controls and determined whether improvements are needed to identify and prevent similar incidents from occurring elsewhere. We also evaluated the effectiveness of FSIS’ controls over the removal of SRMs from cattle, as well as FSIS’ inspector-generated sampling program for residues at cull cow establishments.
Findings and Recommendations
Section 1. No Systemic Failure of Inspection Processes, but Management Controls Can Be Strengthened to Mitigate Future Occurrences

The events at Hallmark are the subject of an ongoing criminal investigation. Therefore, our assessment of what happened is limited to the information that is available to date. However, through investigative analyses of Humane Society of the United States (HSUS) videos, review of inspection and slaughter documentation, and interviews with managers and employees of Hallmark, as well as FSIS inspection and supervisory personnel, we concluded that there were deliberate actions on the part of Hallmark personnel to bypass inspection processes required by Federal regulations. In addition, the FSIS Public Health Veterinarian (PHV) and other inspection personnel assigned to Hallmark did not always perform their inspection duties as required. These noncompliances, which were not detected or prevented by FSIS’ management and supervisory controls, may have facilitated the attempts by Hallmark employees to bypass required inspection processes. Information presently available to us indicates that one non-ambulatory animal was slaughtered by Hallmark; the disposition of its carcass, however, is still under investigation.

Although we found varying degrees of noncompliance and/or inconsistent implementation of required inspection procedures by FSIS personnel at the other 10 cull slaughter establishments we visited during the audit, nothing came to our attention to indicate that unsuitable animals were passed for slaughter. The noncompliances we observed at these 10 establishments were attributable to a number of different reasons, and we did not observe any single underlying factor that caused them to occur. Therefore, we concluded that the events that occurred at Hallmark were not a systemic failure of the inspection processes/system, as designed, by FSIS. However, we did determine that management controls designed to provide oversight over the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to mitigate the chance that events such as those that occurred at Hallmark can happen in the future.

27 Because of the ongoing criminal investigation, no further information can be provided in this report.
28 The San Bernardino County District Attorney filed animal cruelty charges against two former Hallmark employees; both were convicted.
29 Title 9 C.F.R. 309.1 (a).
Finding 1
Deliberate Actions and Inspection Control Breakdowns Contributed to the Regulatory Violations at Hallmark

HUMANE HANDLING

Is Hallmark Representative of Other FSIS-Inspected Slaughter Establishments?

During 2007, there were about 632 Federally-inspected establishments nationwide that slaughtered cattle. The majority slaughter primarily younger fat cattle. Hallmark, however, is representative of another group of 103 establishments that slaughter primarily cull cows. These are often "spent" dairy cows that have been sold off by their dairies when they can no longer produce milk in sufficient quantities to make them profitable. Because of their age and use, dairy cull cows tend to be in poorer physical condition than fat cattle.

Although FSIS regulations and directives generally do not distinguish between establishments that slaughter fat cattle and those that slaughter cull cows, we believe the risks are greater at cull cow establishment – both in terms of potential animal abuse and food safety issues. This is because cull cows are (1) more likely to have pathological conditions that would render them unfit for use as human food; (2) in generally weaker physical condition, which increases the risk of inhumane handling by slaughter establishment employees as they attempt to move them from the unloading areas to the holding pens to slaughter; and (3) more likely to have been administered antibiotics or other drugs before arrival at the slaughter establishment, thus increasing the risk that they will contain violative levels of residues.

Because of these higher risk factors, we chose 10 cull slaughter establishments to visit as part of our audit, all of which were from a group of 49 establishments that, according to FSIS data, slaughtered the greatest number of cull cows during calendar year 2007. Of these, four slaughtered cull cows exclusively, while six slaughtered both cull cows and fat cattle. Details of our findings at these 10 establishments are discussed in sections 2 and 3 of this report.

30 A class of beef cattle of any age but usually greater than 1 year, judged ready for slaughter to provide prime cuts of beef.
31 In 2007, FSIS data show that over 50 percent of cattle slaughtered at these establishments were cull cows.
The 10 establishments we visited, like Hallmark, slaughtered cull cows. During our visits, we did not observe any systemic inhumane handling incidents nor did anything come to our attention that would lead us to believe any were occurring when we were not there. However, we did note that an inherent vulnerability exists that such violations can occur and not be detected because FSIS does not have sufficient staffing levels to provide continuous surveillance of all operating areas within and around a slaughter establishment at all times.

Further, many slaughter establishments (including Hallmark) receive and unload animals from transport vehicles after business hours, as well as on weekends. When interviewed after the release of the HSUS videos, the PHV at Hallmark stated that he had asked permission to make unannounced humane handling visits to Hallmark after working hours. However, FSIS policy is that permission must be granted by an employee’s supervisor for off-hour visits. In this case, the PHV stated that the request was disapproved because of potential liability issues.32

On March 10, 2008, FSIS issued two notices to strengthen its oversight of humane handling compliance. One of these reinforced an existing notice that required inspection personnel to conduct verification activities randomly throughout their tour of duty. The other required inspectors to increase the time they spend verifying humane handling regulatory requirements by at least 50 percent for a 2-month period.

We concluded, therefore, that there was no evidence of systemic humane handling violations at any of the 10 establishments we visited. However, because of the limitations in FSIS’ monitoring capabilities, there is an inherent vulnerability that such violations can occur and not be detected.

FSIS regulations, directives and notices33 state that if a noncompliance with humane handling requirements has occurred - even one in which the inspector has not observed animals actually being injured or abused - FSIS personnel are to document the noncompliance on FSIS Form 5400-4, Noncompliance Record (NR), and verify that the establishment takes the necessary corrective actions. If corrective actions are not taken in response to an NR, or if the inspector sees an animal being injured or treated inhumanely, FSIS is to take progressively stronger actions, such as shutting down the noncompliant portion of an establishment pending the completion of corrective actions, or requiring that an abused animal be immediately euthanized. If the observed inhumane treatment is of an egregious nature, FSIS must impose a suspension action.34

32 To date, no evidence has been disclosed to indicate that the animal handling abuses at Hallmark took place after working hours.
34 Directive 6900.2, while specifying corrective actions to be taken in cases of egregious violations, did not define an “egregious violation.” Notice 12-05, dated February 18, 2005, however, addressed this need. Under this guidance, situations of active abuse such as those documented at Hallmark would be classified as egregious and would require that a suspension action be initiated.
At Hallmark, between December 2004 and February 2008, we found no evidence that in-plant inspectors wrote NRs or took suspension actions for humane handling violations. However, FSIS personnel acknowledged at least two incidents of humane handling violations that occurred during this period, both of which involved active abuse of animals. The inspectors did not write an NR or pursue any other enforcement actions; only verbal directions were provided to establishment personnel to discontinue the action or practice in question. The inspectors did not believe an NR was necessary because the specific incident was immediately resolved. We verified that both the PHV and CSI at Hallmark received training in humane handling requirements, and we further verified that this training covered the required enforcement actions under Directive 6900.2. Thus, we must conclude that both of these employees were aware of the requirements; however, we have no information beyond the statements they made as to why they failed to follow them.

In December 2005, prior to the Hallmark incidents in 2007, the District Veterinary Medical Specialist (DVMS) visited Hallmark for a humane handling verification review and issued a report documenting noncompliances with the facility, animal access to water, excessive prodding, and stunning effectiveness. The DVMS report stated that 100 animals were observed being driven into the stunning area; 33 were prodded with an electric prod, 21 of which were prodded between 2 and 3 times. According to the DVMS’ report, the majority of this activity took place in the chute leading to the stunning box. The DVMS noted at least two design features of the chute that could have caused animals to balk and not move. An NR was issued as a result of the DVMS review and Hallmark was required to correct the noncompliances identified.

We believe the degree of excessive prodding of animals by Hallmark employees during the DVMS review should have raised questions as to why humane handling noncompliances had not been previously identified by the inspectors because (1) these actions were taken despite the presence of the DVMS, and (2) they may have been at least partly related to ongoing structural issues with the chute. However, there is no record that any such inquiry was made by FSIS managers. A subsequent review by the DVMS in May 2007 reported that corrective actions were taken on the prior review findings and no further noncompliances were identified at that time.
In addition to the DVMS’ findings, NR data recorded in the Performance Based Inspection System (PBIS) might have also provided a warning that inspectors at Hallmark were not identifying humane handling violations. The following table shows the NRs written for humane handling violations as a percent of total NRs written from January 2006 through January 2008.

<table>
<thead>
<tr>
<th>Humane Handling NRs</th>
<th>All NRs</th>
</tr>
</thead>
<tbody>
<tr>
<td>No. Establishments</td>
<td>No. NRs (2)</td>
</tr>
<tr>
<td>All Slaughter</td>
<td>346</td>
</tr>
<tr>
<td>Top 49 Cull Establishments</td>
<td>38</td>
</tr>
<tr>
<td>10 Establishments Reviewed</td>
<td>8</td>
</tr>
<tr>
<td>Hallmark (1)</td>
<td>1</td>
</tr>
</tbody>
</table>

(1) Hallmark is one of the top 49 cull slaughter establishments.
(2) Humane handling violations were noted in 3.1% of all NRs written; 2.9% written for the top 49 cull establishments; and 2.5% of the 10 establishments reviewed. Of the top 49 cull establishments, 11 (22 percent) including Hallmark had no NRs written for humane handling.

As illustrated in the table, the top 49 cull slaughter establishments were over 50 percent more likely than slaughter establishments in general to have NRs written for humane handling violations. The cull slaughter establishments also averaged about 4 humane handling NRs per establishment, as compared to an overall average of only about 2.5 per establishment. Hallmark’s unusual lack of an NR history in the humane handling area, in conjunction with the DVMS’ 2005 report, should have indicated the need to further examine the humane handling oversight activities at this establishment.

The abuses at Hallmark appeared to take place predominately during working hours, when FSIS personnel were on duty at the establishment.\(^\text{35}\) Office of Inspector General (OIG) Investigations’ analysis of the HSUS videos showed that abuses took place in the unloading areas, the pens, and between the pen and slaughter areas. FSIS personnel have access to all of these areas; however, they cannot monitor all of them at any one particular time. As a result, there is an inherent vulnerability that such violations could occur and not be detected.

At the time the HSUS videos were recorded, Hallmark slaughtered about 500 animals each day and had approximately 147 employees engaged in various aspects of slaughter and processing operations. FSIS had five inspectors onsite – one PHV, one CSI, and three FIs. The FIs performed “online” duties during slaughter operations, which meant that they were required to monitor their specific stations on the slaughter line on a continuous basis; they would not be able to observe humane handling violations in the “offline” areas.

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\(^{35}\) Based on information made available to us from the ongoing investigation, these were the only times the HSUS reporter would have been in a position to record the videos.
The PHV and CSI performed offline duties which included, but were not limited to, humane handling inspections. The PHV’s duties also included performing ante-mortem and post-mortem inspections, and supervision of the other inspection staff. The CSI’s responsibilities also included performing numerous verification inspection tasks required under HACCP, as well as functioning in a relief online inspector capacity. Both the PHV and CSI recorded they performed humane handling inspections in the Humane Handling Activities Tracking System (HATS). The CSI at Hallmark also provided inspection oversight at the processing operation at Hallmark-Westland Meat Packing Company. The CSI estimated he spent equal time at each facility.

At the time the recorded abuses took place, Hallmark did not have a video monitoring system in place. Although our information indicates that such a system was in process of being installed before the establishment ceased operations, there is no assurance that this would have prevented animal abuses from occurring. Three of the 10 establishments we visited during the audit had video monitoring, but FSIS inspectors were not given access to these systems. At one of the establishments, its management stated they would not allow FSIS access even if requested. There are currently no regulations in place that require FSIS be granted access to establishment video surveillance systems. Therefore, we have no information to make an assessment as to the effectiveness of video monitoring in preventing inhumane treatment of animals.

FSIS Directive 6900.2, Humane Handling and Slaughter of Livestock, provides the requirements for verifying the humane handling and slaughter of livestock. Its provisions include the requirements that (1) the driving of livestock from unloading ramps to holding pens and from holding pens to the stunning area shall be done with a minimum of excitement and discomfort to the animals; and (2) electric prods, canvas slappers, or other implements employed to drive animals shall be used as little as possible in order to minimize excitement and injury. Any use of implements which, in the opinion of the inspector, is excessive, is prohibited. In addition to ensuring that each establishment has facilities to protect animals from inclement weather and animals have access to water, inspectors are required to verify that animals are handled humanely at the time they are presented for ante-mortem inspection. The directive requires that inspectors write NRs when humane handling violations are observed, even in cases (such as those involving structural deficiencies) where animals have not actually been injured.

Were Inspection Staff Knowledgeable of the Requirements of the Humane Handling Slaughter Act?

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Westland Meat Packing Company was a processing establishment that was co-located with Hallmark and owned by the manager of Hallmark.
Both the PHV and CSI at Hallmark received training in humane handling. We reviewed the training modules and found that they appeared sufficiently comprehensive in terms of both the requirements and enforcement actions required, should humane handling violations be observed. Nevertheless, the inspectors did not take the proper actions when they observed violations. Neither the PHV nor CSI believed they should write an NR if an observed violation was immediately resolved. This apparently included at least two instances of egregious abuse; in one of these cases the PHV instructed the establishment to immediately euthanize the animal.

At Hallmark and at the 10 establishments we visited, all 19 PHVs assigned to those establishments received training in humane handling requirements. This topic is included as part of FSIS’ Public Health Veterinarian training, a 9-week course that each PHV must complete before beginning duties in that position. All 18 CSIs also received training, either as part of Basic Livestock Slaughter Inspection training or from an online humane handling training module. These employees are the ones most likely to encounter animal abuse situations, if they occur, because of their assigned duties.

Of the 66 FIs assigned to the 10 establishments we visited, 27 (41 percent) had not received the Basic Livestock Slaughter Inspection training, which would have also provided them with humane handling training. FSIS also provides online training in Humane Handling, but only 5 (8 percent) of the 66 FIs had taken this training. Although these employees generally perform “online” duties and may not encounter humane handling situations on a routine basis, we did find that FIs are sometimes called upon to perform ante-mortem inspections, where such training would be needed.

We concluded, therefore, that based on their training, PHVs and CSIs should possess the necessary knowledge to identify and enforce humane handling requirements. However, this does not extend to the FIs, who may, or may not, be assigned offline oversight duties. The events at Hallmark demonstrate there is no assurance that even a properly trained employee will identify and report humane handling violations. FSIS has other management controls, however, that should identify noncompliance by their inspectors. In the case of Hallmark, these controls broke down. The DVMS review, as well as oversight reviews by the frontline supervisors (FLS), 37 indicate that FSIS failed to respond to indicators that in-plant inspectors may not have been identifying and/or reporting humane handling violations.

37 See Finding 2 for our conclusions regarding the FLS’ supervisory span of control.
What Pre-Slaughter Procedures Were Not Followed at Hallmark? If Followed, Could These Have Provided Adequate Control Over the Movement of Animals to Slaughter?

The ante-mortem inspection procedure, if implemented as specified in FSIS Directive 6100.1\(^{38}\) and associated training, can provide reasonable assurance that diseased animals unfit for slaughter are not entering the food supply. The directive requires that before livestock can be offered for slaughter, they must be presented for ante-mortem inspection. FSIS inspectors are to observe the animals both at rest and in motion for abnormalities and signs of disease or health conditions that would make them unfit for slaughter. For each animal inspected, the ante-mortem process will result in one of three possible outcomes. The animal will be either: 1) passed for slaughter; 2) marked as “suspect” for additional examination by a PHV after slaughter; or 3) condemned and immediately disposed of. “Suspect” animals are those whose condition - as observed ante-mortem - indicates the need for further examination of the animals’ carcasses and organs at post-mortem.\(^{39}\) Suspect animals are required to be identified using a metal tag placed in the ear and be segregated from other animals and slaughtered separately. Only if the post-mortem examination satisfies the PHV as to an animal’s condition can the carcass enter the food chain. FSIS Form 6150-1, Identification Tag, Ante-Mortem, is to accompany the animal until it is either passed at post-mortem inspection or condemned as unfit.

At Hallmark, the PHV stated that he did not fill out the 6150-1 forms himself, but rather delegated this responsibility to Hallmark employees. Further, he stated that he did not require the use of the metal ear tags to identify suspect animals because it saved time not to use them. He instructed Hallmark employees to notify him when suspect animals reached the point where post-mortem inspection would be conducted so that he could make a final determination on them. These practices essentially created an “honor system” in which the inspector relied on Hallmark employees to identify suspect animals moving to, and through, slaughter. This weakened control was further exacerbated by the fact that the PHV sometimes designated entire pens of animals as suspect, depending on the supplier of the animals. This practice, when followed, would have sent large numbers\(^{40}\) of suspect animals moving to slaughter without proper identification.

The PHV also stated that establishment employees were delegated the responsibility of filling out condemnation forms on animals that were to be euthanized because of their condition. FSIS inspection personnel were not observing the denaturing\(^{41}\) and destruction of condemned animals. FSIS

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39 Post-mortem inspection occurs in the slaughter area after the animal has been humanely stunned and bled. Inspectors look for signs of disease or pathological conditions that would render a carcass or part unwholesome or otherwise unfit for human consumption.
40 An individual pen at Hallmark could contain over 30 animals.
41 9 C.F.R. § 314.3, Disposition of Condemned Products at Official Establishments Having No Tanking Facilities, defines denaturing as the application by injection, or other means, of carbolic acid, cresylic disinfectant, or other specified chemicals to render the meat unusable.
regulations require that condemned products or carcasses be destroyed in the presence of an inspector by incineration, or else be denatured to prevent them from re-entering the food chain.

Another control specified in Directive 6100.1 requires inspectors to verify that the slaughter establishment has an animal identification system that accurately identifies each animal and establishes that inspection personnel have performed ante-mortem inspection on each animal. Although no specific requirements are stated beyond this, the directive cites the pen card as one example of such an identification system. Pen cards are establishment records that identify the number of cattle in each pen presented to the PHV for ante-mortem inspection. At Hallmark, as well as the other establishments we visited, the PHV’s signature on a pen card was intended to serve as evidence that the animals in the pen associated with that particular card had received ante-mortem inspection. Although there is no evidence to indicate that the PHV at Hallmark ever signed pen cards in cases where he had not performed ante-mortem inspection, there is an increased risk that animals may not have been properly controlled for slaughter if proper identification is not made of suspect and condemned animals.

In January 2004, the General Accountability Office (GAO) issued a report on FSIS’ implementation of the HMSA. GAO found that because of incomplete and inconsistent inspection records, it was difficult to determine the frequency, scope, and severity of humane handling slaughter violations. They also found that because guidance was not clear, enforcement actions in response to violations were inconsistent. GAO reported that because of the lack of information on how much time inspectors spend on verifying compliance with the HMSA, it was difficult to determine whether the number of inspectors was adequate.

In response, FSIS incorporated humane handling violation codes in the electronic PBIS and developed guidance to clarify when an NR should be written and when enforcement actions should be taken for repetitive violations. FSIS also developed HATS to track the time inspectors spend on verifying compliance. Further, Notice 12-05, dated February 18, 2005, and reinforced by Notice 16-08, dated March 10, 2008, now provides FSIS employees with examples of what constitutes an egregious abuse for enforcement purposes.

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42 Title 9 C.F.R. 314.3.
44 At Hallmark, the PHV did in most cases sign the pen cards. Our review of the pen cards for the period September 2007 through January 2008 showed that of 224 pen cards, 5 were not signed by the PHV. However, we have no information to validate that the PHV counted the animals in each pen to ensure the accuracy of the pen cards; the PHV stated he reviewed the pen cards for accuracy.
45 GAO-04-247, Humane Methods of Slaughter Act, USDA Has Addressed Some Problems but Still Faces Enforcement Challenges.
GAO also recommended in its 2004 report that once FSIS developed a mechanism to identify the level of effort that inspectors were currently devoting to humane handling and slaughter activities, the agency also needed to develop criteria for determining the level of inspection resources that are appropriate based on establishment size, configuration, and history of compliance. However, FSIS has not developed adequate criteria for making the most effective use of its inspection resources based on HATS data. For instance, DVMS reviews are performed at the same frequency at all establishments, despite the greater risk of abuse (also cited in the 2004 GAO report) at cull slaughter establishments. In addition, FSIS has not addressed the concern that was heightened by the release of the HSUS videos – that its inspectors are not deployed to continuously monitor all areas where establishment employees could potentially be abusing sick or weak animals to move them to slaughter.

Conclusion

We have concluded that FSIS needs to re-assess its resources at cull cow establishments, so that informed decisions can be made as to the levels of staffing needed to prevent future incidents, such as those at Hallmark. Although we concluded that the events at Hallmark were not a systemic failure of the inspection processes/system, as designed, at the other cull establishments reviewed, management controls to demonstrate the sufficiency and competency of its personnel resources can be strengthened (see Finding 2). Also, we determined that FSIS’ management controls were ineffective in disclosing the “shortcuts” taken by the PHV at Hallmark (see Finding 2 and section 2 of this report for a discussion of our review of the ante-mortem processes at the 10 establishments we visited during the audit).

Recommendation 1

Require that DVMS reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments’ humane handling activities. Also, establish controls to ensure that DVMS review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

Agency Response

In the response to the official draft, FSIS agreed to issue a new directive by February 2009 that would provide DVMSs with additional guidance related to their reviews. This guidance will require each DVMS, before conducting a Humane Handling Verification visit, to review the results of the prior DVMS review as well as NRs, Memoranda of Information, and suspensions for the preceding 6 months. While at an establishment, each DVMS will discuss with in-plant inspection personnel any issues of concern that have been noted, including any which have been discussed with the establishment’s management which did not rise to the level of a noncompliance. Also through
discussion, the DVMS will ascertain the knowledge base of the FSIS in-plant inspection staff. This information will be provided in a written document to the district manager and deputy district managers, who will in turn share it with the applicable frontline supervisor to address performance issues.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 2**

Reassess the humane handling risks associated with cull slaughter establishments, and determine whether DVMS reviews should be conducted on a more frequent basis at those establishments.

**Agency Response**

The Office of Food Defense and Emergency Response’s Data Analysis and Integration Group (OFDER/DAIG) will complete an analysis of noncompliance rates for humane handling procedures at dairy cow establishments as compared to rates at establishments that slaughter other market classes of adult cattle. The analysis will be completed by August 2009 and provided to Office of Field Operations (OFO) for final determination. In addition, the new directive (see Recommendation 1) that will be provided to the DVMSs could result in more frequent Humane Handling Verification visits.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 3**

Establish a process to analyze PBIS data for anomalies or variances in both slaughter establishment and inspector performance that could require additional followup by district management.

**Agency Response**

OFDER/DAIG will develop a quarterly humane handling alert, based on a review of establishment noncompliance data, that can be used by OFO management to identify anomalies or variances in slaughter establishment noncompliance or inspector performance that could require additional follow-up by district management. The process will be established by January 2009 and the first alert will be distributed in March 2009.
OIG Position

We accept FSIS’ management decision.

Recommendation 4

Determine whether FSIS-controlled in-plant video monitoring would be beneficial in preventing and detecting animal abuses at cull cow slaughter establishments.

Agency Response

In their response, agency officials stated that FSIS-controlled video cameras would not provide the definitive data needed to support enforcement of humane handling requirements, as compared to the direct, ongoing and random verification of establishment handling and slaughter practices that FSIS uses. For example, video footage might not reveal whether an animal was conscious during a certain point in the slaughter process. However, they agreed that the use of cameras to monitor humane handling compliance could be useful to the establishments themselves in deterring and detecting animal abuses, particularly if an establishment has implemented a systematic approach to meeting the humane handling and slaughter requirements.

FSIS has authority to access establishments’ video records under the Federal Meat Inspection Act, specifically 21 U.S.C. 642, and FSIS has enforced access to video records when these were used to meet certain aspects of HACCP and Sanitation Standards Operating Procedures (SSOP) requirements. FSIS will issue Compliance Guidelines for Using Video Records to industry for designing, maintaining, and validating their video systems so that video records are trustworthy, accurate, and a true representation of the process. An accompanying FSIS directive will clarify FSIS inspection personnel’s access to and verification of establishment video records. Both the guidelines and the directive will be issued by March 2009.

OIG Position

We accept FSIS’ management decision.
Finding 2

Management Controls Were Not Effective in Detecting Inconsistent Application and/or Noncompliance With Required Inspection Procedures

FSIS has a management control structure in place that should have identified and/or mitigated FSIS personnel noncompliances with required inspection procedures that occurred at Hallmark, as well as those that we observed at the other 10 establishments during this audit (see section 2). We concluded that management controls designed to provide oversight over the inspection processes, as well as organizational controls to demonstrate the sufficiency and competency of its personnel resources, can be strengthened to minimize the potential for these events from happening in the future.

Prior audits\(^{46}\) have reported concerns with FSIS’ management controls and information technology (IT) systems that generate the data necessary to provide proper oversight and management of inspection operations. FSIS has, in recent years, made significant strides in designing and developing a management control structure that will allow better monitoring by officials at the Headquarters and district office levels than was previously possible. FSIS is re-aligning its systems into the Public Health Information System (PHIS) to better integrate and consolidate its numerous applications that collect information used to provide mission critical support for inspection, surveillance, enforcement, scheduling, modeling, and analysis. PHIS is being developed, in part, to predict hazards and vulnerabilities, communicate or report analysis results, and target resources to prevent or mitigate the risk of food-borne illness and threats to the food supply. PHIS is not scheduled for full implementation until the second half of fiscal year 2009.

FSIS implemented the In-Plant Performance System (IPPS)\(^{47}\) and AssuranceNet\(^{48}\) as a means of providing management oversight of the public health activities of FSIS inspection personnel. These systems, in addition to various food safety and district management reviews, are important components in the implementation of an effective management control structure; they provide valuable performance data to supervisors and higher-level managers. However, FSIS is still in the process of fully and effectively enhancing and implementing these systems.

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\(^{47}\) IPPS was implemented in October 2002. IPPS is a tool used by supervisors to assess the work of non-supervisory in-plant inspection personnel. The IPPS review process provides a framework and guidelines for supervisors to use in evaluating employee performance.

FSIS has staffing models/standards to demonstrate that resources assigned to online and CSI functions are adequate to fulfill their required duties and responsibilities. However, there are no staffing models to identify the number of PHVs needed for ante-mortem and post-mortem inspection functions, as well as other offline inspection tasks.

FSIS regulations provide guidelines for maintaining online inspection staffing based on line speed. The Inspector-In-Charge (IIC) has the authority to require the establishment to reduce line speeds where, in his/her judgment, inspection procedures cannot be adequately performed. CSIs, who perform HACCP verification activities, are assigned based on a model called MAW, Method of Assigning Work. MAW was developed in 2003/2004 and replaced prior work measurement standards developed in the 1960’s. The MAW is based on the number of tasks assigned by the PBIS and an annualized estimate of the time needed to perform these tasks (including administrative time associated with the task). MAW’s staffing model, however, does not take into consideration the type of slaughter establishment (i.e., fat or cull cattle) or the number of animals slaughtered.

For ante-mortem inspection and other offline functions (pre-slaughter and humane handling activities), no staffing models and/or standards exist. FSIS officials stated that it is up to the district managers to decide – within the limitations of the authorized resources for each district – how each establishment should be staffed based on the conditions at the establishment. An FSIS Human Resource official stated that one factor district managers should use to assign PHVs is the number of cattle requiring veterinary disposition; he would expect a cull slaughter establishment to need more PHV time because they would suspect more cattle.

At Hallmark, there was one PHV and one CSI. The FLS informed us that prior to 1998, there were two PHVs assigned to the establishment. The PHV stated that he took “shortcuts” in the ante-mortem process to save time, and stated that he had complained in the past about lack of staffing.

At each of the other 10 slaughter establishments we visited, we noted inspection noncompliances of varying types and degree (see section 2). The reasons for these noncompliances also varied, but at three establishments, the PHVs admitted they took shortcuts in inspection activities in order to complete all tasks. One of these establishments had a vacant PHV position; therefore, one PHV was providing inspection coverage that, in the past, had been performed by two.

49 The scope of this audit was limited to pre-slaughter activities; this audit did not review or analyze the basis for these standards.
50 Title 9 C.F.R. 310.1.
Without a risk-based, supportable methodology for assigning its inspection staff, FSIS cannot demonstrate that the resources assigned to its offline inspection activities are sufficient to adequately perform the tasks assigned.

The reasonableness of the span of control assigned to FLSs cannot be assessed because FSIS cannot provide supportable work measurement assumptions. Therefore, we cannot determine whether FSIS assigns adequate supervisory oversight to in-plant inspection activities. We found that the FLS responsible for Hallmark, as well as the FLSs at 7 of the 10 establishments reviewed, were not aware of common practices used by in-plant inspection staff that did not meet FSIS requirements (see section 2). Therefore, we concluded that oversight of in-plant operations is adversely impacted by the supervisory span of control assigned to the frontline supervisor.

FSIS assigns each FLS a circuit of establishments for supervision and oversight. The circuit represents the first level of supervision above the in-plant level. The FLS is responsible for managing, coordinating, and supervising the inspection and enforcement activities at each assigned establishment through a subordinate supervisory structure. The FLS’ duties include, but are not limited to: overseeing and coordinating the review, implementation, and assessment of in-plant inspection programs; determining the adequacy of inspection resources; ensuring the comprehensive analysis of corrective actions to resolve noncompliances; managing and implementing program and organizational changes; utilizing FSIS information systems and other analytical records to oversee establishment compliance with HACCP and other regulatory requirements; providing oversight of food safety assessments and in-depth verification compliance reviews; ensuring proper implementation of sampling initiatives; and utilizing IPPS to guide, direct and assess the overall performance of non-supervisory inspection personnel. This position is an interdisciplinary position that is classifiable as either a Supervisory Veterinary Medical Officer or a Supervisory Consumer Safety Officer.

In 1990 (prior to implementation of HACCP), FSIS updated its 1984 circuit maintenance guidelines. Circuits were assigned based on a “structured workload” of 13 to 15 supervisory workdays a month, to include allowances for travel between establishments. Two supervisory days per month were provided for establishments with three or more inspectors on each of two shifts.

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51 Frontline supervisors oversee the in-plant inspection activities within each circuit in a district. They generally report to a deputy district manager.
53 It was expected that the remainder of the month would be spent on administrative and other duties not related to direct in-plant supervision.
FSIS officials recognized that these guidelines needed to be updated, and in December 2005 published a “Frontline Supervisor Study” based on input from 91 percent of the agency’s 156 FLSs on-board at that time. The purpose of the study was to obtain input on the importance of the FLS’s responsibilities, the time allocated to them, what the FLSs felt was needed to better fulfill their responsibilities, as well as their thoughts on the role of the FLS in the future. Some of the concerns identified by the FLSs were as follows.

- They were responsible for too many direct reports and too many establishments which made it difficult for them to conduct quality IPPS reviews and to perform their management control activities.

- Some FLSs had double the workload and responsibilities for long periods (sometimes 1-2 years) because of vacancies.

- Circuits that covered large geographical areas made it difficult to conduct IPPS reviews.

- Some FLSs found it difficult to allocate time for training because of their workload.

At Hallmark, the FLS was not aware of the inspection practices that were not being followed. At the time of our audit, this FLS was responsible for 60 establishments and 17 employees who reported directly to him (direct reports). FLSs for 2 of the establishments we reviewed were responsible for 2 circuits representing 69 and 88 establishments, and 31 and 28 direct reports, respectively. Both of these assignments were temporary, and were due to vacancies in other circuits; however, two other FLSs in our sample covered over 50 establishments each, and two had a comparable or larger number of direct reports as the Hallmark FLS. We question whether the FLS can provide an adequate level of oversight with such a wide supervisory span of control.

In August 2008, FSIS issued a draft revision to its Circuit Maintenance Guidelines. The supervisory workload of the circuit remained at 13 to 15 workdays a month, while the standards specified for a circuit were set as 45 establishments and 16 direct reports. Circuit workloads were based on computed allowances for supervision, the number of establishments, and travel on a monthly average basis of 20.5 workdays. The computation allows an average of 29 minutes for an establishment, regardless of shift, type, or size, and .5 day for each direct report. According to FSIS Headquarters

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54 An FLS’ direct report would generally include any employee who is not directly supervised by another in-plant FSIS supervisor such as an IIC or Supervisory Public Health Veterinarian.

55 These guidelines do not specify what work an FLS is expected to perform on any given visit to an establishment. According to one district manager, a typical visit might include a review of NRs, a walk through of all or part of the facility, discussions with the IIC, and performance of any needed IPPS reviews.
officials we interviewed, the determination of how many establishments and direct reports a FLS should have, as well as the amount of time allocated, is not documented through formal studies. Rather, these guidelines are based on the judgment of the officials who drafted the guidelines, and on-going discussions with FSIS field personnel. In the absence of a documented methodology to support its work measurement assumptions, we cannot determine whether FSIS assigns adequate supervisory oversight to in-plant inspection activities.

The following table illustrates the span of control assigned to the FLS who was assigned to Hallmark and the 10 establishments reviewed.

<table>
<thead>
<tr>
<th>Establishment</th>
<th>No. of Establishments</th>
<th>Direct Reports</th>
<th>FLS Not Previously Aware of Conditions Disclosed by Audit</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hallmark</td>
<td>60</td>
<td>17</td>
<td>Yes</td>
</tr>
<tr>
<td>Establishment 1</td>
<td>88</td>
<td>28</td>
<td>Yes&lt;sup&gt;56&lt;/sup&gt;</td>
</tr>
<tr>
<td>Establishment 2</td>
<td>69</td>
<td>31</td>
<td>Yes&lt;sup&gt;57&lt;/sup&gt;</td>
</tr>
<tr>
<td>Establishment 3</td>
<td>54</td>
<td>19</td>
<td>No</td>
</tr>
<tr>
<td>Establishment 4</td>
<td>14</td>
<td>16</td>
<td>No</td>
</tr>
<tr>
<td>Establishment 5</td>
<td>53</td>
<td>16</td>
<td>Yes</td>
</tr>
<tr>
<td>Establishment 6</td>
<td>44</td>
<td>16</td>
<td>No</td>
</tr>
<tr>
<td>Establishment 7</td>
<td>29</td>
<td>14</td>
<td>Yes</td>
</tr>
<tr>
<td>Establishment 8</td>
<td>25</td>
<td>15</td>
<td>Yes&lt;sup&gt;58&lt;/sup&gt;</td>
</tr>
<tr>
<td>Establishment 9</td>
<td>14</td>
<td>11</td>
<td>Yes</td>
</tr>
<tr>
<td>Establishment 10</td>
<td>24</td>
<td>17</td>
<td>Yes</td>
</tr>
</tbody>
</table>

At 7 of the 10 establishments visited, the FLSs were not aware of some or all of the conditions we noted. Based on discussions with the FLSs, we concluded that they were not aware of the conditions we noted because of the number of establishments they oversaw and their inability to spend sufficient time at each establishment.<sup>59</sup>

The revised Circuit Maintenance Guidelines Directive has not been formally issued, and its effect on the structure of circuits nationwide cannot yet be assessed because we have not been provided the support and methodology for the assumptions used in the staffing guidelines. However, we did note the following when comparing the draft guidelines to the existing circuit structures for Hallmark and the 10 establishments reviewed during this audit.

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<sup>56</sup> Due to a vacancy in another circuit, this FLS was assigned oversight over 2 circuits for a period of 6 months at the time of our audit.

<sup>57</sup> Due to a vacancy in another circuit, this FLS was assigned oversight over 2 circuits for a period of 6 weeks at the time of our audit.

<sup>58</sup> The circuit for this establishment did not have an FLS at the time of our audit; the deputy district manager was providing supervision until the position could be filled.

<sup>59</sup> There are no guidelines describing the specific amount of time an FLS should spend at an establishment on any given visit.
• The FLS for Hallmark exceeded both the recommended numbers of establishments and direct reports provided by the draft guidelines.

• At 7 of the 10 establishments we visited, we noted that the FLSs had not been aware of conditions that we noted, a situation we attributed at least in part to the FLS’ supervisory span of control. Of these, three exceeded the recommended number of establishments in the draft directive while three exceeded the recommended direct reports.\(^{60}\)

We concluded that supervision and oversight at Hallmark was not adequate to prevent or detect the inspection deficiencies identified to date. This was clearly evident by the IPPS reviews of the PHV; these reviews did not identify deficiencies in his work. In addition, we concluded that supervision and oversight of inspection operations can be strengthened by re-assessing supervisory span of control.

As noted previously, FSIS has made significant strides in the development of an overall management control system through the use of IPPS and AssuranceNet. These systems should have notified FSIS managers of potential problems at Hallmark. However, there are inherent limitations in both systems, as designed, because they depend heavily on reliable, in-plant observations by FSIS’ in-plant inspectors and the FLS.

The IPPS system is a tool for supervisors to assess the work of non-supervisory inspection personnel. The IPPS review process provides a framework and guidelines for supervisors to use in evaluating employee performance; it also allows higher-level supervisors at the district and Headquarters levels to review and evaluate the adequacy of the performance assessments. The IPPS reviews performed by the FLS at Hallmark – particularly those documenting the performance of the PHV – should have disclosed the fact that required procedures for ante-mortem inspection were not being followed.

In an interview following the release of the HSUS videos, the FLS who oversaw Hallmark stated that he had not been aware of the noncompliant practices being followed by the PHV, such as allowing establishment employees to fill out required paperwork or the suspecting of entire pens of animals. Therefore, these problems were not reflected in his IPPS review of the PHV.\(^{61}\)

\(^{60}\) We did not assess the number of indirect reports at these establishments because we were not aware, at the time of fieldwork, this would be one of the measurement criteria in the draft guidelines.

\(^{61}\) The investigation is still ongoing, and we do not have complete information as to why the FLS did not become aware of these issues. However, based on interviews taken as part of the investigation, the FLS noted that some of his onsite reviews were very limited. He cited the number of establishments he was responsible for as one contributing factor.
The AssuranceNet system is the second and broader component of FSIS’ management control process. This system tracks and monitors the performance of FSIS personnel in several key functional areas related to food safety and security; each functional area contains one or more monitored performance measure in which current performance is measured against predetermined thresholds. For instance, AssuranceNet monitors whether district management teams\textsuperscript{62} are reviewing at least 10 percent of the IPPS reviews performed within their districts each year; at least 1 percent of these must be done on-site, by accompanying the FLS or other supervisor.

AssuranceNet is primarily designed to monitor performance trends at the circuit level and higher. We reported limitations with FSIS’ management control systems in a prior audit, Report 24601-07-Hy, \textit{Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments}, dated December 2007. In that audit, we reported that AssuranceNet was not used to review the performance of individual establishments unless the entire circuit failed to meet a particular performance measure. We recommended that FSIS provide guidance to its management officials to view performance data down to the establishment level, as well as the circuits and districts. In response, FSIS issued new guidance\textsuperscript{63} for managers to use in reviewing AssuranceNet’s performance indicators. However, the new guidance still characterizes AssuranceNet as a monitoring tool at the circuit level and higher; managers are only expected to “drill down” to individual establishments when issues are identified at the circuit level.

The effectiveness of both systems can be reduced if district management teams\textsuperscript{64} do not ensure that IPPS reviews are being adequately performed. AssuranceNet data for the period July 1, 2007, through August 28, 2008, showed that only 6 of 15 districts had met or exceeded their targets for reviewing 10 percent of the completed IPPS reviews. Of the remaining nine districts, five completed half or fewer of the required reviews.\textsuperscript{65} Also, district management teams in 3 of 15 districts had not performed the required onsite reviews during the performance of IPPS reviews at establishments.\textsuperscript{66} Of our six sampled districts, we found that only one met its 10 percent review requirement, with three completing fewer than half. Two districts had not completed any onsite reviews with the FLSs. If these reviews are not performed, FSIS district managers cannot assure that FLSs are providing the proper oversight of in-plant inspectors.

\textsuperscript{62} The district management team consists of the district manager and the deputy district managers.
\textsuperscript{63} FSIS Notice 19-08, issued on March 26, 2008.
\textsuperscript{64} For AssuranceNet purposes the district management team in each district is composed of the district manager and the deputy district managers.
\textsuperscript{65} In 2008, FSIS extended the end of its rating cycle from June 30 to September 30 to meet the Departmental requirement for all USDA employees to be on the same rating cycle; for this year, therefore, the rating period was not yet complete.
\textsuperscript{66} This includes the district where Hallmark is located.
In fiscal year 2001, Congress provided funds to establish 17 District Veterinary Medical Specialist (DVMS) positions dedicated to the oversight of compliance with the Humane Methods of Slaughter Act (HMSA). About 75 percent of the DVMS’ time is to be spent on field reviews and correlations, which include visiting slaughter establishments to observe humane handling practices. If violations are observed, the DVMS may recommend that the inspector write NRs or administer suspensions.

A DVMS review was performed at Hallmark in December 2005, more than 2 years before the release of the HSUS videos. The DVMS report documented serious offenses and recommended an NR be written by the PHV. However, there is no evidence in the report that the DVMS ever questioned why such activities had not been previously identified by the PHV or CSI (see Finding 1 for a further discussion of this problem). FSIS needs to establish a control to ensure that DVMS reviews are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

FSIS offers a variety of training courses, both formal classroom and online, to develop the competencies of its inspection staff. PHVs are required to take a 9-week PHV course before they can assume that position in the field. CSIs are provided Food Safety Regulatory Essentials (FSRE) training that covers HACCP oversight duties. FIs are given Slaughter Inspection Training that includes, among other subjects, training on humane handling requirements and ante-mortem inspection. Other training is available online to inspectors through AgLearn, including three courses that deal with SRMs and the removal of SRMs from carcasses.

FSIS, however, does not have a formal, structured developmental program in place to demonstrate and ensure that all of its employees receive both formal and on-the-job training. Since FSIS’ inspection staff is directly involved in ensuring the safety of the food supply, we believe a structured program of continuing education, certified each year, would provide the organizational control needed to demonstrate a knowledgeable and qualified workforce.

FSIS training requirements are not clearly defined in FSIS’ written policy or directives. FSIS Directive 4338.1, dated March 4, 2004, Training as a Condition of Employment, requires that the PHV, CSI, and Enforcement Investigations and Analysis Officer (EIAO) receive training within one year of entry into their positions. However, the type of training the CSI is to receive is not specified, and the FI position is not covered in the directive. Although FSIS has a system in place to track the training each employee

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67 USDA’s online training system.  
68 The EIAO serves as a consumer safety officer and conducts onsite food safety and other verification activities, as well as investigations and analysis for administrative and civil enforcement matters.
receives, there is no requirement in place for managers to validate and certify that all mandatory training has, in fact, been received.

FSIS Headquarters officials stated that FIs should receive Slaughter Inspection Training during the first year of their employment. According to FSIS officials, this training would, among other things, give them the basic knowledge for performing ante-mortem inspections. However, of the 66 FIs that had been assigned to Hallmark and the 10 establishments we visited during our audit, only 39 (59 percent) had ever taken this training. Although the PHV at Hallmark did not allow FIs to perform ante-mortem inspection, the PHVs at four of the other establishments we visited did.

We noted similar concerns regarding the training provided for the removal of SRMs from carcasses of cattle over 30 months of age. Although FSIS officials stated that they attempt to provide each PHV and offline inspector with one of the SRM courses available online from AgLearn, we found that 7 of 18 CSIs did not have this training.

FSIS officials stated that an important component of their overall training program is the on-the-job training provided by the PHV and/or IIC in each establishment. However, no formal program has been developed for demonstrating what specific on-the-job training should be provided, nor are PHVs required to maintain any specific documentation of the training provided.

Given the critical public health mission of FSIS, we believe that FSIS needs to strengthen its human capital management by establishing a structured training and development program, with strong organizational controls, to demonstrate the competency of its workforce in fulfilling its mission. These organizational controls should be comparable to the continuing education requirements for other technical and scientific professions.

**Recommendation 5**

Develop a documented, supportable methodology for assigning in-plant inspection staff for offline inspection activities, including a basis for assignment at different types of plants.

**Agency Response**

Concurrent with the effort to strengthen its public health infrastructure through the development of PHIS, FSIS is planning changes to its offline inspection personnel work. Models are being designed to estimate time, procedures, and frequency of tasks required by establishment shift. These are inclusive offline work assignments that include ante-mortem and post-
mortem inspection responsibilities. Testing of the new method of offline inspection is scheduled for the spring of 2009, and the work assignment assumptions used to develop the models will also be available at that time. FSIS expects to implement this process by June 2009.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 6**

Reassess and support the methodology used to establish the supervisory span of control for frontline supervisors.

**Agency Response**

FSIS officials stated that the primary objective of revising the Circuit Maintenance Guidelines was to provide agency managers with key parameters to use in determining the optimum numbers of FLS positions based on the number of establishments, employees, and travel within a district. They stated that the directive implementing the guidelines was not an attempt to develop a work measurement instrument for the FLS position, nor could it determine the absolute span of control of the FLS position due to the highly variable nature of their work. Revising the Circuit Maintenance Directive created 17 additional circuits; this resulted in fewer establishments per circuit, fewer direct and indirect reporting lines to the FLSs, and reduced travel time.

They stated that the increase in the total number of FLS positions will provide management with the opportunity to strengthen management controls over in-plant inspection activities, including the application of HACCP programs, and allow for more routine on-site reviews of in-plant operations and ongoing assessments of inspection data generated at the in-plant level. The new Circuit Maintenance Guidelines Directive was completed in September 2008, and FSIS will fully implement the directive during the second quarter of FY 2009. Further, FSIS will perform an assessment of the new guidelines by the end of March 2010 to determine, among other things, the impact of the reduction of the FLS span of control.

**OIG Position**

We accept FSIS’ management decision.
Recommendation 7

Strengthen human capital management by establishing a structured training and development program, with strong organizational controls, to demonstrate the competency of the inspection workforce in fulfilling its mission.

Agency Response

FSIS will establish policies and procedures to ensure that all mission critical occupational groups (FLS, PHV, CSI, Program Investigator, Import Inspector, and Food Inspector) receive formal, entry level on-the-job or classroom training based on their job description, performance standards, and agency policies and procedures within 1 year or sooner of starting their positions. Further, FSIS will require that inspection program personnel recertify this training annually. These policies and procedures will be implemented in a directive or notice to be issued by September 2009.

In the interim, to ensure that inspection program personnel demonstrate the appropriate level of competency, the IPPS Supervisory Guide has been modified to include explicit instructions to conduct an IPPS assessment to observe and evaluate the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible. The guidelines provide a “work method” to ensure that supervisors ask the right questions and observe the inspection personnel on every aspect of their jobs. These observations are required to be documented in the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken and perform a follow-up IPPS review within 60 days. The draft IPPS Supervisory Guide is out for comment with the districts and FLSs, and FSIS plans to issue the revised guideline by December 2008.

OIG Position

We accept FSIS’ management decision.

Recommendation 8

Strengthen management controls to ensure that district management teams are performing on-site evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should be increased.
Agency Response

FSIS officials stated that 4 of the 15 districts had not met the requirement for reviewing 10 percent of IPPS assessments performed during the last rating cycle, while one district had not met the 1 percent standard for onsite reviews of IPPS assessments. They stated also that during the summer of 2008 district analysts had received training to allow them to make more effective use of the custom reports available through AssuranceNet. These reports allow the districts to see what percentage of IPPS reviews they have performed overall, as well as broken down by circuit so that they can better monitor and target their efforts throughout each rating cycle. Also, the AssuranceNet system was enhanced during the summer of 2008 to allow district management teams to see which IPPS assessments have generated followup due to deficiencies identified by the rating supervisors. Following the next IPPS cycle, an assessment will be performed on these improvements to determine whether they resulted in the districts meeting the required IPPS frequencies. A report will be prepared of the results of this assessment. This is expected to be completed in November 2009.

OIG Position

We accept FSIS’ management decision.
Section 2. FSIS Pre-Slaughter Activities

Under the FMIA and FSIS regulations and directives, FSIS inspectors are required to examine and inspect all livestock before slaughter. The purpose of this process, called ante-mortem inspection, is to ensure that animals accepted for slaughter are only those that are healthy, without non-violative levels of chemical and drug residues, and otherwise suitable for conversion into safe, wholesome products. This part of the overall inspection process is critical because certain animal health conditions\(^{69}\) can only be assessed while animals are still alive. If performed properly, ante-mortem inspections can be expected to remove obviously diseased animals from the food supply prior to slaughter and to identify animals that require a more extensive post-mortem examination by an FSIS veterinarian.

Thus, if an establishment fails to present animals for ante-mortem inspection, or if these inspections are not carried out in accordance with FSIS directives\(^{70}\) a vital safeguard to prevent diseased or otherwise unfit cattle from entering the food chain may be compromised; this was one of the related concerns raised about the egregious humane handling incidents at Hallmark.

Finding 3

Inspectors Did Not Comply With Required Inspection Procedures and/or Used Inconsistent Methods in Performing Ante-Mortem Inspections

Our reviews at 10 cull slaughter establishments found varying degrees of noncompliance and/or inconsistent implementation of required ante-mortem inspection procedures. While nothing came to our attention to indicate that unsuitable animals were being passed for slaughter at these establishments, some of the practices we observed would reduce the level of assurance that unsuitable animals would be detected and effectively controlled for proper disposition. In our visits, we found that 8 of the 10 establishments were not following required accountability procedures designed to ensure that only animals that had passed ante-mortem inspection are slaughtered. In addition, at 5 establishments we questioned the adequacy of the practices used in the ante-mortem inspection process itself. The observations made during this audit, and the conclusions reached, are limited to operations that slaughter cull cows since these animals are of higher risk for pathological conditions and the presence of drug residues.

\(^{69}\) Conditions of the central nervous system can only be detected when the animal is alive.

Management controls designed to provide proper oversight of the inspection process, as well as organizational controls to demonstrate the sufficiency and competency of the inspection staff, were not sufficient to identify and enforce compliance. In at least two cases, the inspectors did not follow required procedures because they felt the conditions at their establishments allowed for deviations. This was particularly true at smaller establishments, where inspection personnel believed they could visually track and monitor individual animals through the ante-mortem inspection and slaughter processes. In one instance, the PHV stated that there was insufficient time or personnel to perform ante-mortem inspection in the manner required by Directive 6100.1; in others, the inspectors cited limitations or restrictions resulting from the physical layout of the slaughter establishments. FSIS supervisory personnel were either unaware of these situations or did not believe they were problems that needed to be corrected. The concerns we noted in the ante-mortem inspection procedures at the 10 cull establishments are described below.

Inadequate Tracking of Animals

At five establishments, FSIS inspectors allowed establishment employees to control the required accountability process that is designed to provide assurance that only animals that have received ante-mortem inspection are allowed to go to slaughter. Directive 6100.1 requires FSIS inspectors to verify that slaughter establishments have animal identification systems in place to identify each animal, and ensure that ante-mortem inspection is performed on each animal.

The directive does not provide specifics on the required animal identification systems, but does cite the “pen card” system as an example. Under this method, each pen of animals presented for ante-mortem inspection is accompanied by a pen card which, at minimum, lists the number and type of animals being presented. At the discretion of individual establishments, other information such as owner identification can be included. The signature of the FSIS PHV on a pen card is used to provide evidence that the associated pen of animals has received ante-mortem inspection.

Inspectors did not effectively use the pen cards or other techniques to ensure that all animals moved to slaughter receive ante-mortem inspections. Specifically, we noted the following.

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71 One of the 10 establishments we visited used an equivalent form called a drive sheet, which combined information from multiple pens of animals rather than separating them on individual cards.
At three of the five establishments, inspectors did not verify that the number of animals shown on each pen card reflected the number of animals being presented for ante-mortem inspection and passed for slaughter. As noted in Finding 1, inaccurate data on pen cards could potentially be used by establishment employees to bypass the accountability system and move uninspected animals to slaughter.

At four of the five establishments, inspectors did not, even on a periodic basis, reconcile the pen cards to establishment slaughter records to ensure that the number of animals slaughtered did not exceed the number on which ante-mortem inspection had been performed. Since FSIS, in its training, recommends that PHVs maintain pen cards for one week, the only record remaining to document the number of animals passing ante-mortem inspection and approved for slaughter are the establishment slaughter records. Therefore, reconciliation of this accountability system by the inspector is a critical control.

At one establishment, the inspector simply pre-signed blank pen cards and provided these to establishment personnel for later use. When interviewed, the inspector claimed not to have understood the purpose or significance of these cards.

The failure to properly control, verify, and reconcile animals approved for slaughter could potentially facilitate deliberate acts to bypass inspection processes.

Ante-mortem inspection procedures were either incorrectly or inconsistently implemented at 5 of the 10 establishments we visited. Animals were not always observed both at rest and in motion, nor were they always observed individually. Inspection personnel attributed their actions to either a lack of sufficient time or personnel to conduct the inspection procedures as required, or to limitations in the physical structure and layout of the establishments.

At three establishments, inspectors did not always observe cattle both at rest and in motion, as required, when performing ante-mortem inspection. FSIS training materials state that certain abnormal signs, such as labored breathing, are easier to detect while the animals are at rest. However, other abnormalities, such as lameness, may not be detected until the animals are in motion. Either of these conditions are potential signs that animals may be suffering from pathological conditions, violative drug residue levels, or central nervous system conditions, which would require that they be either condemned and immediately euthanized, or else designated as “U.S. Suspect”...
so that their fitness for human consumption can be evaluated during post-mortem examination.

We noted inconsistent practices for viewing animals on both sides during ante-mortem inspection. At three establishments, inspectors did not observe both sides of the animal. Although regulations do not require in-motion inspection from both sides, this procedure is taught to new inspectors as the proper method of inspection. FSIS training materials citing this procedure are available to the public from FSIS’ website. Observation of both sides of the animal is important at establishments that slaughter older cattle that are more susceptible to disease.

FSIS Headquarters officials stated that there is no requirement, nor is it necessary, to view the animals on both sides. However, inspectors at 7 of the 10 establishments we visited were, in fact, viewing both sides of the animals during ante-mortem inspection. Our discussions with a representative of the World Organization for Animal Health, Office International des Epizooties (OIE), disclosed that while there are no specific guidelines for observing animals from both sides during ante-mortem inspection, OIE considers it preferable to view animals from both sides for a more complete examination in regards to clinical conditions that may be visible from only one side of the animal. We also consulted two independent experts, who believed that viewing both sides of an animal was important for identifying eye tumors, abscesses, open cuts or other wounds that might not be apparent at post-mortem.

At four establishments, inspectors did not observe the animals individually. Instead, animals moved past the inspector concurrently in rows or groups of three to four animals deep, effectively obscuring the observation of potential injuries and abnormalities of each animal. Inspection personnel cited a variety of reasons for not observing the animals individually, such as lack of time or because they did not believe it was required. Although FSIS Directive 6100.1 does not specifically require the individual inspection of each animal, FSIS training materials state that inspection personnel should direct the establishment to move all of the animals slowly and individually so inspection personnel can identify any abnormalities. We discussed this issue with experts in veterinary medicine, whose opinions were that in order to identify animal maladies during ante-mortem inspection, it is important that animals be viewed on an individual basis.

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75 OIE (also referred to as the World Organization for Animal Health) is an international animal health organization based in France that has developed the Terrestrial Animal Health Code which contains guidelines for use by importing and exporting countries to avoid the transfer of agents pathogenic for animals or humans, while avoiding unjustified sanitary barriers.
<table>
<thead>
<tr>
<th>Suspect Animals Not Properly Identified or Segregated for Slaughter</th>
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<tbody>
<tr>
<td>FSIS requires that animals exhibiting signs of disease during ante-mortem inspection be segregated for further examination by a PHV. Regulations require that animals identified as “U.S. Suspect” be identified with a serially numbered ear tag and be slaughtered separately from healthy animals.76</td>
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At six establishments, however, we noted that inspectors did not properly use ear tags to identify suspect or condemned77 animals. The PHV at one establishment considered ear tags to be inhumane, while two others told us they visually tracked the animals. Two other PHVs used alternate systems that did not include ear tags,78 and one PHV did not feel they were necessary because he considered every animal “suspect.” At four establishments, inspectors were not using the required FSIS Form 6150-1 to document animals designated as suspect; two of these were also not using Form 6150-1 to document when animals became non-ambulatory in the chute. The FLSs were not aware FSIS procedures were not being followed; in at least one instance, however, the FLS was aware of the situation but allowed the PHV to continue this practice. Without proper tagging of suspect and condemned animals, there is reduced assurance that inspectors are properly identifying and tracking the animals through the inspection and slaughter processes.

At two of these establishments, we also observed that suspect animals were not set apart and slaughtered separately from other healthy animals as required by regulations. At both establishments we identified issues with other aspects of the control systems designed to properly identify and control the movement of suspect animals. Inspectors at both establishments were not using ear tags to identify suspects, nor were they performing a reconciliation to slaughter records. The FLSs for these establishments stated they were not aware of these noncompliances because they had responsibility for more than one circuit and had not been able to spend significant time at any one establishment.

<table>
<thead>
<tr>
<th>Non-Veterinarians Have Performed Ante-Mortem Inspection Without Formal Training or Direct Supervision</th>
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<tbody>
<tr>
<td>Information published by FSIS states that the PHV is either performing or verifying ante-mortem inspection on every animal.79 However, this is not an FSIS requirement. In our visits to 10 cull cow slaughter establishments, we observed that the PHVs at 7 establishments allowed the CSI and/or FI to perform ante-mortem inspections on either a regular or occasional basis. We found that while the PHVs at these seven establishments always performed follow-up examinations of animals the inspectors recommended be either suspected or condemned, no such check was performed on animals that had been passed for slaughter. FSIS does not have a system in place to reliably</td>
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76 Title 9 C.F.R., Part 309, Ante-Mortem Inspection (309.2(n) and 309.18 (a)), issued January 2008.
77 Title 9 C.F.R 309.18(c) requires that animals classified as “condemned” be identified with a serially numbered ear tag.
78 At one establishment, the PHV attached the FSIS Form 6150-1 Identification Tag, directly to the pen card until the animal was slaughtered; after slaughter, the tag was attached to the tongue. At another establishment, the PHV used a U.S. Retained Tag, in lieu of a suspect ear tag. Neither of these methods complies with Directive 6100.1 and increase the risk that suspect carcasses may be misidentified at post-mortem inspection.
demonstrate that these non-veterinary employees have either the training or knowledge to perform ante-mortem inspections.

FSIS procedures are not specific as to the level of supervision that a PHV should exercise over non-veterinarian inspectors during ante-mortem inspections. FSIS Headquarters officials stated that it is an acceptable practice to leave the determination as to who can conduct ante-mortem inspection to the individual PHV. They stated that non-veterinarians can be trained to identify signs that indicate an animal’s possible unfitness for slaughter. These signs are taught as part of FSIS’ Basic Livestock Slaughter Inspection training, which FSIS officials stated that they attempt to provide to all newly-hired food safety inspectors during their first year on the job. Further, the PHV is responsible for assuring that their subordinate inspectors are adequately trained to perform ante-mortem inspection. The PHVs we interviewed stated that as long as the inspector had proper on-the-job training, they did not have to be physically present when the inspector conducts ante-mortem inspection.

Based on our observations, however, we question whether even a fully trained non-veterinary inspector can be expected to identify clinical signs that might warrant further examination. For example, the PHV at one establishment stated that cows with retained fetal membranes may have a metritis condition and should be designated as “suspect” animals. This would require further examination by a PHV at both ante-mortem and post-mortem inspection. However, we observed that the CSI at this establishment passed three such animals for slaughter without further examination by the PHV. Discussions with FSIS personnel and a review of disposition guidelines revealed that a number of factors would have to be considered when determining whether to pass such an animal for slaughter. The guidelines provide for consideration of factors such as discharges, temperature, and other clinical signs. We question whether an inspector without veterinary training can make such determinations. At another establishment, the PHV allowed an entry-level FI, who had been on the job four months, to perform ante-mortem inspection without formal training. The on-the-job training was not documented but we were informed by the FI that his training encompassed “hands-on observations and review of photographs.”

In addition, FSIS could not demonstrate that all of its employees who performed ante-mortem inspection had received the required formal training. Although all 18 CSIs at the 10 plants we visited had received formal training, this was not the case for 10 of the 25 FIs, at 2 of the 4 establishments where the PHVs assigned FIs ante-mortem inspection responsibilities. FSIS officials stated that formal training was of less importance in an employee’s development than on-the-job training provided by the PHV. However, there is

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80 Bacterial infection of the uterine tract.
81 At the other 6 establishments of the 10 in our sample, the PHVs or CSIs performed all ante-mortem inspections.
no evidence or system that documents either the type or extent of training given to each employee by the PHV. Also, there is no structured training program that documents and certifies that non-veterinary employees are being trained in a consistent manner (See section 1 for a discussion on this necessary organizational control).

Ante-mortem inspection is a critical part of FSIS’ overall system of controls to prevent unfit animals from being slaughtered for human food. Adequate controls must be established and implemented to ensure that ante-mortem inspections: (1) are being performed on every animal that goes to slaughter; (2) comply with the procedures required under FSIS directives; and (3) are either performed by trained veterinarians, or by properly-trained inspectors.

**Recommendation 9**

Strengthen and clarify the requirements for in-plant inspection personnel to assess the adequacy of each establishment’s animal identification system. In addition, strengthen FSIS guidance requiring the use of ear tags to identify suspected and condemned animals.

**Agency Response**

FSIS is writing a new notice pertaining to verification of an establishment’s identification records and to reconciling livestock numbers between ante-mortem and slaughter. The notice will clarify that the establishment is responsible for providing livestock data to inspection program personnel when requesting ante-mortem inspection. It will also explain that inspection program personnel are to verify this data when performing ante-mortem inspections, as well as the verification method to be used. In April 2009, FSIS will revise and reissue FSIS Directive 6100.1 (Ante-Mortem Livestock Inspection) to permanently capture the content of the new notice. The directive will also provide clarified tagging instructions for livestock that is determined to be U.S. Suspect or U.S. Condemned.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 10**

Require inspectors to verify the accuracy of the animal counts on pen cards and drive sheets, and reconcile these to establishment slaughter records.
Agency Response

FSIS is writing a new notice pertaining to verification of an establishment’s identification records and the reconciliation of livestock numbers between ante-mortem and slaughter. This notice will clarify that the establishment is responsible for providing livestock data to inspection program personnel when requesting ante-mortem inspection. The notice will explain that inspection program personnel are to verify the establishment’s data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. The notice is expected to be issued in December 2008, and will be incorporated into Directive 6100.1 in April 2009.

OIG Position

We accept FSIS’ management decision.

Recommendation 11

Strengthen existing guidance for inspectors to observe animals both at rest and in motion during ante-mortem inspection.

Agency Response

FSIS will revise and reissue FSIS Directive 6100.1, Ante-Mortem Livestock Inspection, to clarify that inspection program personnel are to observe animals both at rest and in motion during ante-mortem inspection. The revised directive is expected to be issued in April 2009.

OIG Position

We accept FSIS’ management decision.

Recommendation 12

Implement controls to ensure that each non-veterinary inspector has received necessary training, both formal and informal, before performing ante-mortem inspections.

Agency Response

On September 10, 2008, FSIS implemented a structured on-the-job (OJT) training program for all food inspectors and other non-veterinary inspectors performing ante-mortem inspections. The new OJT program is one of six modules contained in the 2008 Interim Employee Development Guide which
provides resources to supervisors and trainers to aid in their training efforts in the first phase of a new inspector’s career. The module contains several topics for which new inspectors must demonstrate basic proficiency, including Sanitation and SSOPs, and ante-mortem and post-mortem inspection. The module also includes forms which both the inspector and the supervisor/trainer must initial when the inspector has attained basic proficiency on each subject. The supervisor/trainer is required to add comments on each form reflecting both the inspector’s strengths and weaknesses, and include their plan for improving any deficiencies in knowledge and/or execution. When all subjects in the module are completed, the forms are to be submitted to the district office so that formal classroom training can be scheduled.

Newly hired inspectors will be required to complete the classroom training in a timely manner, within 1 year of entering on duty. FSIS will also require that these inspectors recertify this training annually. To ensure that inspection program personnel have received the necessary training, OFDER/DAIG will conduct quarterly analyses of this training data and provide a report to the Office of Outreach, Education, and Employee Training and to the districts so that they can follow up on any instance where required training has not been received. The first report that will include a status of inspection program personnel who have received the structured OJT will be completed by September 2009.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 13**

Develop procedures to require PHVs to verify, at least on a periodic basis, that non-veterinary inspectors perform ante-mortem inspections in accordance with FSIS directives. Also, ensure that such observations are documented.

**Agency Response**

FSIS officials stated that they have made improvements to the IPPS Supervisory Guidelines that will result in better accountability for carrying out ante-mortem and other inspection activities. The new guidelines will contain explicit instructions for conducting IPPS assessments to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible, and to observe their performance of inspection and verification procedures. The guideline will incorporate a “work method” to ensure that supervisors ask the right questions and that they observe the performance of the inspection personnel on every aspect of their jobs,
including ante-mortem inspections. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure that remedial action is taken such as correlation or re-training, and to perform a follow-up within 60 days. The revised IPPS Supervisory Guidelines are currently out in draft, and FSIS expects to issue them in December 2008.

**OIG Position**

We accept FSIS’ management decision.

<table>
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<tr>
<th>Finding 4</th>
<th>FSIS Needs to Strengthen Controls Over Secondary Entrances to Prevent the Potential Slaughter of Unfit Animals</th>
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Eight of the 10 establishments we visited had usable, secondary access points (commonly called downer doors) to the establishments’ slaughter areas, of which only three were secured under FSIS lock. Such entrances could, if not adequately monitored by FSIS, facilitate the movement of non-ambulatory or uninspected animals to enter the slaughter areas without FSIS’ knowledge. Prior to 2004, establishments could use these special access areas to bring in animals for slaughter that were too weak to walk through the regular serpentine chutes to the stunning boxes. FSIS’ ban of the slaughter of non-ambulatory animals made these structural features either obsolete or else usable only in very limited circumstances. However, FSIS has no policy in place for determining how, or if, these areas should be controlled.  

We also noted that 4 of 10 establishments had winches above the primary stunning box that were not under FSIS lock. These winches could be used to drag non-ambulatory cattle into the establishment. These secondary entrances and winches were generally not observable from FSIS’ online inspection stations, and could serve as routes into the slaughter areas that could potentially bypass FSIS inspection. The lack of adequate animal accountability systems (see Finding 3) further increases the risk that such entry points can be misused, if not properly controlled.

In some instances, these doors and other facilities are needed as part of the slaughter process. For example, secondary stunning boxes might be used on healthy, ambulatory animals that cannot fit through the serpentine chute because of their size or other factors (e.g., longhorn cattle). However, controls should be put into place to ensure the establishment cannot easily move animals into the processing areas that potentially may not have passed inspection. FSIS has the authority to require that establishments only use

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82 At Hallmark, such a secondary access area was padlocked; we could not determine when this occurred.
83 Two establishments had both an unsecured winch and an unsecured downer door.
facilities and equipment that are essential to inspections.\textsuperscript{84} FSIS can control secondary entrances and related work areas and equipment through the use of FSIS-controlled locks at all times when the doors or other facilities are not being used by the establishment.

As a result of our reviews, FSIS inspectors at one of the cited establishments informed us that they would implement this practice and affix locks to the establishments’ secondary access door to ensure that they could only be used under FSIS supervision. We believe that FSIS needs to require that, at all establishments, these doors and other facilities be secured and maintained under FSIS control to ensure that they are used only under FSIS supervision.

**Recommendation 14**

Require that secondary entrances to slaughter areas, stunning boxes, and winches not used as part of establishments’ normal slaughter operation be placed under FSIS control to ensure that they can be used only under the supervision of inspection personnel.

**Agency Response**

FSIS officials stated that the agency does not have statutory or regulatory authority to require that secondary entrances and equipment be placed under FSIS control. However, FSIS does recognize the need to ensure that these entrances and pieces of equipment are not used in violation of the statutes or regulations. By May 2009, FSIS will either issue a new FSIS notice or revise FSIS Directive 6900.1 Revision 1, “Humane Handling of Disabled Livestock,” to clarify that inspection program personnel, through ongoing verification activities, are to ensure that secondary entrances and equipment are not used by official establishments to adulterate product, create unsanitary conditions, handle livestock inhumanely, or to violate the statutes or regulations in any other way. The issuance will instruct inspection program personnel to take regulatory control or other actions if official establishments misuse secondary entrances or equipment in such a manner.

**OIG Position**

We accept FSIS’ management decision.

\textsuperscript{84} Title 9 C.F.R. 305.3 and Title 9 C.F.R. 307.2
Finding 5  Effectiveness of Inspector-Generated Residue Testing as Part of the Ante-Mortem Inspection Process Needs to Be Re-Assessed

FSIS administers the National Residue Program (NRP) in cooperation with EPA and FDA to control veterinary drug, pesticide, and environmental contaminant residues in meat, poultry, and processed egg products. The NRP encompasses two domestic sampling programs. One, Scheduled Sampling, tests randomly-sampled cattle that exhibit no signs of illness to determine the exposure assessment or the prevalence of residues in the national food supply. The other, Inspector-Generated Sampling, involves a rapid, in-plant screening test called FAST (Fast Antimicrobial Screening Test) on any carcass that, based on herd history, ante-mortem, or post-mortem inspection findings, there is reason to believe may have an illegal drug residue.\textsuperscript{85} Cull cows, because of their age and general weakened health condition, have a higher risk for violative\textsuperscript{86} residues than fat cattle.

FSIS publishes a Repeat Violator List as a means to assist in-plant inspectors in the identification of problem producers who repeatedly offer animals with violative residues for slaughter. If violative results occur, the PHV is to condemn the carcass and/or parts.

At Hallmark, we identified concerns with the implementation of the NRP. Through interviews with inspection staff conducted during the on-going investigation, we determined that the process for sampling for residues was not being followed, nor were test samples properly controlled. We also found these same noncompliances at 6 of the 10 additional cull slaughter establishments visited. Although required procedures were not followed, we were able to confirm that carcasses and/or parts identified as violative by inspector-generated samples at these six establishments were properly condemned and disposed of.

However, we did identify additional concerns with the design and implementation of the NRP that are outside the scope of this audit. Therefore, we will conduct a more in-depth review of the effectiveness of the NRP in a future audit effort.\textsuperscript{87} This report is limited to a review of the process for obtaining and testing inspector-generated samples, as well as the management controls associated with this segment of the NRP.

\textsuperscript{86} FSIS uses guidance from FDA and EPA for residue monitoring and tolerance action levels.
\textsuperscript{87} This review was begun as part of the current audit, and will continue following issuance of this report.
At 8 of the 10 establishments visited, inspection personnel (inspectors and PHVs) did not use herd history to select animals for residue testing. Inspectors at two establishments relied solely on the establishment to inform them when animals from a past violator arrived for slaughter. FSIS has not provided clear direction on how to use repeat violator information as a basis for testing, nor did we find any monitoring of compliance with this program by FSIS. PHVs told us that it is difficult and too time consuming to check the data on manual pen or drive cards for repeat violators. In addition, the farm source of the herd is not usually documented when cattle are purchased through an auction facility. As a result, there is reduced assurance that meat products have been sufficiently tested for violative levels of residues from those producers determined to be most at risk.

FSIS has not developed a process to monitor FAST test results, either to identify issues that need corrective action or to determine how the testing program itself might be improved. District officials do not have access to FAST test data in a usable format to facilitate oversight of the NRP.

For recordkeeping purposes, FSIS in-plant inspection personnel record the results of each sample test (whether positive or negative) on the 3-part FAST Worksheet. Once the worksheet (which has space for test results from 25 samples) is completed, the original is sent to the FSIS Financial Processing Center and a copy to the district office. The Financial Processing Center enters the information from the FAST Worksheet into a database, which is transmitted to FSIS Headquarters. We found, however, that this data may not always be complete. Staff at the Financial Processing Center stated that data from the FAST Worksheets are not entered when: (1) the establishment identification number is not included; (2) the data are not readable; or (3) the information is from the prior fiscal period. We found no evidence that followup was made to obtain clarification on the data reported.

The automated FAST test residue information is not shared with district offices, nor are all district officials even aware of its existence. An official with the FSIS Office of the Chief Information Officer (OCIO), which receives the data in Headquarters, stated that while their offices can run reports for the districts from the database upon request, there is no process in place to distribute it to the district offices on a recurring basis. We found three instances in which district offices were manually entering FAST test data into their own databases. One district, for instance, was attempting to use the data in conjunction with Electronic Animal Disposition Reporting System (eADRS) to determine what pathologies indicated a greater need for residue testing; another was attempting to assess the overall effectiveness of the agency’s residue testing. In interviews, officials at one district stated that they were not aware that this data already existed in electronic format. Officials at

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FSIS Directives 10.800.1 and 10.220.3 state that herd history and prior residue violations are two of many factors that PHVs can take into consideration when selecting animals for in-plant testing.
another, however, stated that they had attempted to obtain the data from FSIS’ Financial Processing Center but were not given access. We believe that to efficiently utilize this information, FSIS needs to implement an ongoing process to analyze FAST test results to monitor trends and to identify the need for enforcement action.

We also noted that because there are insufficient guidelines as to the extent of FAST testing a PHV in any given establishment should perform, the levels of testing varied greatly between even similar establishments. For example, we reviewed FAST test information maintained by the PHVs at two of our sampled establishments that had very similar operations and found significant variations in their testing programs. Establishment 1 and 6 received most of their cattle for slaughter from the same sources, and slaughtered 648,364 and 712,040 head of cattle, respectively, between January 2006 and April 2008. However, Establishment 1 performed 1,607 FAST tests and found 25 violations while Establishment 6 performed at least 41,837 FAST tests with 550 violations. In contrast to both of these, Establishment 10 performed no FAST tests at all for a period of more than 1 year, a fact that was not noted by the district office.

The analysis of FAST results can provide a basis for monitoring and verifying the effectiveness of residue testing performed by individual establishments. Without such analyses by the district offices or higher management levels, there is reduced assurance that the inspector-generated testing programs are being carried out in the most effective manner; or, as in the case of Establishment 10, are being carried out at all.

At six establishments (see exhibit B), inspectors did not adequately maintain custody of test samples. At four establishments, inspectors allowed establishment staff to obtain FSIS samples from carcasses or the associated viscera. At one establishment we observed establishment staff collecting tissues, placing the tissues and a USDA retain tag in clear plastic bags, inserting a swab into the kidney, tying the sample bags together, and placing the sample bags into a bucket located at an FSIS station. At three establishments, inspection personnel left test samples unsecured. For example, at one establishment, kidney and liver samples were placed on trays, tagged, and placed into a cooler that was not locked or under FSIS control. The inspectors stated that samples are often kept in the cooler overnight for testing the following day. Establishment staff has access to the cooler, and could easily tamper with, or switch, the samples. The district manager agreed that the samples should have been better safeguarded, and stated that they would need to discuss this issue at the district level.

Inspectors Did Not Follow Custody Requirements for Test Samples

89 Viscera are the internal organs of an animal.
FSIS directives state that agency personnel are to collect tissue samples from slaughtered animals for residue testing and maintain adequate security over them until they can be shipped to the laboratory. The directive requires that inspection program personnel collect tissue samples every time there is reason to suspect that a violative residue is present.  

FSIS requirements for securing test samples are clear, and FSIS needs to monitor compliance with these requirements. However, the requirements for collecting samples were less clear and could be misinterpreted. We believe these need to be clarified to prevent the use of non-FSIS personnel to perform this function.

**Recommendation 15**

Develop specific guidance and procedures for in-plant FSIS personnel to use herd history as a basis for performing residue tests.

**Agency Response**

FSIS receives a weekly report from USDA’s National Information Technology Center that identifies establishments that have purchased, on more than one occasion, animals from the same supplier that have violative residues as confirmed by FSIS laboratories. Currently, upon receipt of this report, FSIS Headquarters notifies the district offices about these establishments through the shared Outlook residue mailbox files. By December 2008, FSIS will issue a notice instructing the district offices to inform all IICs (and their FLSs) at establishments known to have purchased livestock from repeat violators about new violations involving the violating firms. The notice will advise inspection program personnel about their responsibilities when they are informed that an establishment has repeatedly purchased animals from the same supplier with violative levels of residues. The notice will also give instructions to PHVs regarding additional residue sampling if an establishment continues to purchase livestock from these suppliers.

**OIG Position**

We accept FSIS’ management decision.

**Recommendation 16**

Develop a process that provides on-going monitoring and analysis of inspector-generated residue sampling. Initiate follow-up actions when there are variances in inspector performance and/or residue test results.

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Agency Response

FSIS will implement the eSample system by June 2009 which, among other things, will be used to collect FAST or other rapid test results used in inspector generated sampling. The eSample database will eliminate any duties that FSIS’ Office of Management currently has related to the collection of these test results at the Federal Processing Center in Urbandale, IA.

The Office of Public Health and Science (OPHS) Residue Branch will analyze data from eSample and the eADRS to include production volumes (number of head slaughtered), number of in-plant screening tests conducted and test results, both positive and negative, for each establishment on a quarterly basis. OPHS has identified and will implement the following parameters as part of this process: 1) select and monitor in-plant screening tests with acceptable sensitivity and low specificity (close to tolerance and low numbers of “false” positives); 2) improve inspector generated sampling criteria; and 3) establish uniform in-plant sampling between establishments. The estimated completion date for the first analysis is August 2009. Once the data are analyzed, OPHS will provide OFO and other FSIS program managers with a report indicating any discrepancies in in-plant screening testing procedures so that appropriate action can be taken.

OIG Position

We accept FSIS’ management decision.

Recommendation 17

Clarify the written requirements for the collection of test samples. In addition, strengthen monitoring to ensure that inspectors properly safeguard samples against possible tampering.
Agency Response

FSIS has selected a new in-plant residue test screening method to be used by inspectors in all slaughter establishments. By April 2009, FSIS will draft a directive to provide instructions to field personnel regarding comprehensive criteria for performing in-plant residue screen tests (herd history, current health of animal presented for inspection, etc.). The directive will also provide directions on how to collect and submit samples to ensure sample integrity and how to secure samples onsite prior to their submission to the FSIS laboratories. To further ensure that inspectors are fully aware of the protocol for shipping samples, FSIS will link the new directive to the current FSIS Directive 7355.1, Revision 2, “Use of Sample Seals for Laboratory Samples and Other Applications.”

OIG Position

We accept FSIS’ management decision.
Section 3. Specified Risk Materials

To mitigate public concerns that downer cattle from Hallmark or other slaughter establishments can enter the food supply, FSIS cited four interlocking safeguards that would protect the public health even if other controls to prevent unfit animals from being slaughtered should fail. These are the feed ban, BSE surveillance testing, the prohibition of non-ambulatory or disabled “downer” animals from the food supply, and the removal of Specified Risk Materials (SRMs) from cattle at the time of slaughter. USDA requires the removal of SRMs because these tissues have been identified as vectors for BSE. Beef slaughter and processing facilities are required to incorporate controls for handling such materials into their food safety systems. FSIS provided interim guidance for controlling SRMs in January 2004, and published a final SRM rule on July 13, 2007. In addition to affirming the interim rule, the final rule added regulations for monitoring the removal of SRMs by downstream processors.

Under these requirements, establishments must remove specified parts such as tonsils and distal ileum from the carcass of each animal. Establishments must also have procedures in place to ensure that carcasses of younger animals are not cross-contaminated with SRMs from older animals, and also to ensure that unused parts containing SRMs are destroyed or denatured to prevent their possible re-use. Because of the importance which USDA places on the SRM removal process, and because cull establishments such as Hallmark predominately slaughter older animals (over 30 months old) for which SRM removal is most critical, we reviewed the effectiveness of FSIS’ controls over SRM removal at the 10 establishments we visited.

During our establishment visits, we observed FSIS’ methods of providing oversight of the SRM removal process and verified that FSIS inspectors were, in fact, observing the removal of SRMs from each carcass that passed through the slaughter process. However, we noted several areas where we believe FSIS can strengthen its management controls to ensure adequate oversight and enforcement of SRM requirements. These areas are described below.

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91 The Food and Drug Administration has primary responsibility for preventing the introduction of BSE from animal feed.
92 SRM controls can be incorporated in either HACCP, SSOP, or pre-requisite plans.
93 An establishment that does not slaughter, but receives carcasses from a slaughter establishment for further processing.
94 For animals over 30 months of age, additional parts are classified as SRMs. These include the brain, eyes, and vertebral column.
Finding 6  FSIS Needs To Strengthen Its Monitoring of the Effectiveness of SRM Intervention Procedures

In recent years, FSIS has made significant strides in the development of management control processes to accumulate and analyze food safety data and to strengthen the agency’s monitoring of food safety activities. However, despite the level of importance that agency officials attribute to removing SRMs from the food supply and in preventing the contamination of edible carcasses and parts, FSIS’ management control systems provide little information for oversight of these activities. We found that neither PBIS, AssuranceNet, nor IPPS are currently designed to provide managers at the Headquarters and district office levels with data to detect trends of noncompliance or to identify areas where more in-plant oversight is needed. In addition, we noted that managers are not always using all available data as part of their monitoring efforts. As a result, FSIS cannot effectively demonstrate that its verification of establishment controls and written procedures for the removal, segregation, and disposition of SRMs is adequate to detect noncompliance.

FSIS’ overall management control structure depends upon several key systems to provide managers with information to monitor the performance of food safety operations in slaughter establishments. These systems include:

- PBIS, which assigns inspection tasks in support of HACCP, and which records both the performance of those tasks and the extent of noncompliance at each establishment;
- IPPS, which provides a framework and guidelines for supervisors to use in evaluating the performance of non-supervisory employees; and
- AssuranceNet, which uses data from PBIS, IPPS, and other sources to track and monitor the performance of FSIS inspectors in several key functional areas.

OIG identified the need for FSIS to strengthen these management control systems in several prior audits.\(^95\) We also raised concerns relating to the monitoring and control of SRMs in an audit issued in January 2006.\(^96\) Although FSIS has implemented corrective actions in response to our recommendations, we found that additional actions are needed as described below.

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\(^95\) These audits include 24601-3-Ch, Use of Information Technology Systems, issued in September 2004; 24601-6-Ch, In-Plant Performance Systems, issued in March 2006; and 24601-7-Hy, Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Processing Establishments, issued in December 2007.

The inspection tasks conducted by FSIS inspectors are partly assigned by PBIS. PBIS creates a list of tasks each morning that direct the inspectors to review different aspects of an establishment’s operation. The system has codes that may include SRM handling procedures and practices, but nothing that specifically directs the inspectors to examine them. Instead, an inspector can choose to examine another part of the establishment’s operation that falls within the general inspection task category. We previously reported that because of the lack of any specific PBIS tasks relating to SRMs, and because all of the establishments we reviewed elected to incorporate their SRM procedures into pre-requisite plans rather than into HACCP, we could not determine the extent to which this area was being monitored or evaluate the effectiveness of FSIS’ controls over SRM removal.

In our previous audit, we recommended that FSIS establish specific tasks within PBIS to verify SRM control procedures. FSIS proposed, and OIG accepted, an alternative action to facilitate more comprehensive searches of PBIS data through the use of dropdown menus (see next topic).

In our current audit, 8 of the 10 cull slaughter establishments we visited elected to place their SRM control procedures in pre-requisite plans. Inspectors at the establishments we visited stated that they performed the necessary SRM procedures, but could not provide documentation of what was done. Although we did not observe any SRMs entering the food supply, FSIS officials cannot demonstrate that the level of its inspection efforts for SRMs is adequate.

In response to our previous audit, FSIS enhanced PBIS by adding a dropdown menu of keywords and regulatory citations. The dropdown menu allows inspection personnel to select from a list of regulatory citations and choose the appropriate provisions to describe the types of noncompliance that could be found while performing a given PBIS verification procedure. However, work performed as part of a more recent OIG audit disclosed that over 50 percent of the SRM-related NRs did not cite the appropriate provisions of Title 9 C.F.R. 310.22 that would allow noncompliances to be readily identified by reviewers, such as by Executive Assistants for Regulatory Operations (EARO) or district analysts. We found, during this audit, that while most inspection personnel were aware of the dropdown menu, many stated they did not use it when documenting SRM noncompliances because they lacked knowledge and experience in dealing with this particular type of noncompliance.

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98 Pre-requisite programs are practices and conditions needed prior to and during the implementation of HACCP. They are often facility-wide programs rather than process or product-specific.
100 The EAROs are the next level of management above the district level. Each district manager reports to one of the three EAROs.
District officials we interviewed during the current audit stated that although they are able to access NRs through PBIS, their ability to analyze them is limited. In some cases, district officials stated that they did not know how to perform keyword searches; others cited the difficulty in searching technical terms that may be spelled in various ways by in-plant inspectors in the NR narratives. This limitation, combined with the lack of regulatory citations on the NRs themselves, make it difficult to identify which NRs are SRM-related without a lengthy manual review. All of the officials we interviewed stated that they were not performing such reviews.

FSIS has not enhanced PBIS to facilitate the monitoring of SRM control compliance due to the current focus on developing the replacement PHIS system. However, without some type of district-level monitoring of SRM-related NRs, district managers and other officials cannot determine whether in-plant inspection staffs are adequately monitoring and enforcing SRM requirements. When implementing PHIS, FSIS officials need to ensure that NRs for SRMs can be readily accessed and analyzed by managers in the same manner that NRs for other types of violations presently can be.

We also noted that FSIS inspectors at the establishments we visited were not always writing NRs, even when they observed violations. This problem, if not corrected, can also limit managers’ awareness of the true extent these violations are occurring. This condition is discussed in Finding 7.

Although the district offices reviewed were not performing analyses of SRM-related NRs, the Office of Food Defense and Emergency Response (OFDER) was performing such analyses on a monthly basis and compiling this data into a monthly SRM Noncompliance Report. Because of the system limitations previously noted, OFDER officials stated that a significant manual review effort is needed to produce these reports. For example, use of keyword searches allowed FSIS to identify about 240 NRs that appeared to be SRM-related out of a total of 7,800 NRs written in December 2007. However, each of the 240 had to be read manually to identify the 23 NRs that, in OFDER’s assessment, actually represented SRM noncompliances.

We reviewed the SRM Noncompliance Reports from January 2007 forward, and found that they contained valuable information that could have been used for monitoring at the district level. For example, one report showed that in March 2008, FSIS issued 55 SRM-related NRs compared to only 35 in the previous month. This report also identified the fact that 51 percent of the NRs

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101 One difficulty in performing keyword searches for SRM-related NRs – as noted by the Office of Food Defense and Emergency Response – is the probability that technical terms such as *distal ileum* and *dorsal-root ganglia* can be misspelled by those who enter the NRs.

102 For example, when performing keyword searches, OFDER uses 75 different keywords that represent known misspellings of technical terms.

103 This office, created in 2002, coordinates and manages all homeland security activities within FSIS. Its function is to ensure that policy makers, scientists, field staff, and management are prepared to prevent and respond to any food security threat.
Management Control Systems Are Not Designed to Monitor SRM Compliance

(28 of 55) related to deficiencies in establishments’ HACCP systems. It would be reasonable to conclude that had this information been disseminated to the districts, district managers could have increased monitoring of establishments’ systems relevant to the removal and control of SRMs.

However, district managers are not provided these reports. Instead, under the policy of the Office of Field Operations, these reports are reviewed by the EAROs. We interviewed two of the three EAROs, and were told that they do not review these reports. One stated that they are waiting for the development of PHIS, since the new system is expected to generate reports and perform trend analysis.

As noted in Finding 2, much of FSIS’ efforts in the area of management controls have been directed to the development of AssuranceNet and IPPS. Both of these systems were referenced in FSIS’ response to OIG’s most recent audit that reported SRM issues. FSIS, in its response to that audit, stated that its multi-layered management control system (AssuranceNet) would address SRM controls in its performance measures for HACCP procedures and control of condemned and inedible material. FSIS stated that these performance measures would be integrated with system design control functions via Food Safety Assessments (FSA) and IPPS. We agree that both AssuranceNet and IPPS provide some information in this area. However, neither provides distinct data on inspectors’ performance in SRM verification activities for managers to assess on a district or nationwide basis.

The Supervisory Guide for IPPS references validation of SRM controls, in that it instructs the FLS to determine the PHV’s knowledge of how each establishment is controlling SRMs. However, we found that the IPPS rating forms for PHVs, CSIs, and FIs do not contain any performance element specifically related to SRM verification activities. As a result, reviewing officials such as district managers or EAROs cannot determine how, or whether, a supervisor has addressed an employee’s performance in this area, as required for other performance elements.

We also noted that AssuranceNet, which FSIS officials use to monitor performance in various food safety areas, does not contain any performance elements specifically related to SRM verification activities. In January 2006, before the system was implemented, FSIS stated that AssuranceNet would include “performance measures for HACCP procedures and control of condemned and inedible material that would encompass verification of an establishment’s control of SRMs.” We found that AssuranceNet does monitor completion of certain PBIS tasks, as well as an element that monitors whether


105 FSAs are FSIS district-level reviews to assess the design and validity of an establishment’s HACCP plan, SSOPs, and pre-requisite plans. They are generally conducted by an EIAO.
“100 percent of condemned animals and inedible product (are) identified and properly disposed of.” However, these elements encompass a much broader range of activities than SRM removals, and do not provide any specific information on the effectiveness of SRM removals and interventions. This is particularly true since AssuranceNet is primarily designed to monitor trends at the circuit level and higher, rather than at individual establishments.

Given the importance placed upon SRM removal and intervention as a means of protecting the public even in instances where other FSIS controls may fail - as at Hallmark - FSIS needs to demonstrate that it provides an appropriate level of monitoring through the agency’s management control systems. We have been advised that this may partly be addressed by the new PHIS system when it becomes operational. However, managers will still need to have sufficient data to ensure that tasks necessary to verify SRM controls and interventions are being accomplished as intended.

**Recommendation 18**

Develop processes, as part of the new PHIS system, to verify that inspectors are regularly performing SRM-related tasks as part of their inspection duties. Incorporate features in PHIS that will allow managers to track and evaluate the extent to which such tasks are being performed at the establishment, circuit, and district levels.

**Agency Response**

The PHIS, currently being developed, will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel perform HACCP verifications at beef plants and verify that establishments handle SRMs in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification and for responding to apparent anomalies. As PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track whether tasks are performed and that the appropriate regulatory requirements are verified as required. This feature will apply to all regulatory requirements, not only those related to SRMs. PHIS will be in full production readiness by March 2010.
OIG Position

We accept FSIS’ management decision.

Recommendation 19

Implement procedures for district offices to monitor and analyze SRM-related NRs as part of the agency’s overall management control process. Provide district-level users access to all information, including OFDER’s monthly exception reports.

Agency Response

FSIS will modify PBIS by adding a drop down menu that will provide the districts with a tool to sort and search all NRs by regulatory citations. This will enable them to monitor and analyze specific SRM-related NRs. This proposed PBIS modification is an interim measure pending PHIS implementation. In addition, OFDER/DAIG prepares quarterly exception reports that are distributed to Office of Policy, Program and Employee Development (OPPD) and OFO. The EAROs will share these reports with each corresponding district. Information contained in these reports will provide each district with data for correlation purposes, and they can further use such information and data to follow up on particular issues of concern. FSIS will provide the districts with guidance in the form of an FSIS directive or notice that will explain how and what to do with both the PBIS data and OFDER’s report to monitor and analyze SRM-related NRs as part of the agency’s overall management control process. The modifications to PBIS will be made and the FSIS directive or notice will be published by March 2009.

OIG Position

We accept FSIS’ management decision.

Recommendation 20

Add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure that these are adequately monitored both at the district and Headquarters levels.

Agency Response

FSIS believes that general performance elements and measures are the most effective approach to ensure that inspection personnel understand the broad concepts and thought processes they are to use in performing their verification activities, regardless of the pathogen or adulterant in question. However, agency officials agreed that FSIS should provide specific guidance
to supervisors on how to assess employees’ knowledge and performance of those verification activities with reference to specific hazards, like SRMs or *E. coli* O157:H7, as they apply to the inspector’s assignment. The revised IPPS Supervisory Guidelines will provide specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs. The sections dealing with HACCP verifications, SSOP verifications, and pre-requisite program verifications specifically direct the supervisor on how to assess the employee’s knowledge and proficiency in carrying out verifications of SRM control activities. This is expected to facilitate supervisors in assessing the performance of in-plant inspection personnel in their verification of SRM controls, as well as other performance areas.

PHIS will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. This data will be available to OFO supervisory personnel for them to track and ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification frequencies and for responding to variations in frequency. As PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track the performance of tasks and to assure that the appropriate regulatory requirements are verified as required. These features will apply to all regulatory requirements, not just SRMs. PHIS will be in full production readiness by March 2010.

**OIG Position**

We accept FSIS’ management decision.

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**Finding 7**

**FSIS Inspectors Did Not Always Detect or Document Noncompliance With SRM Regulations**

Inspectors at 5 of the 10 establishments we reviewed did not detect instances of noncompliance with FSIS requirements for the removal and disposition of SRMs (see exhibit C). The deficiencies we noted included establishment pre-requisite plans that did not contain required SRM procedures, and the failure of establishment employees to follow in-plant intervention procedures or to ensure that SRMs were being removed from products shipped to other processing establishments. This occurred, in part, because FSIS inspectors misinterpreted applicable regulations and directives. In some cases, we noted that FSIS inspectors had not received up-to-date training on SRM requirements. Finally, we noted that inspectors at three of these establishments were reluctant to write NRs even after the noncompliances had been noted by the auditors. If FSIS in-plant inspectors do not detect such
noncompliances, or do not document them with NRs, the ability of FSIS to demonstrate the effectiveness of SRM removal and intervention processes is greatly reduced.

In August 2007, FSIS issued a notice that directed inspection personnel at slaughter establishments to conduct awareness meetings with establishment management. These meetings were to (1) make establishment managers aware of changes to regulatory requirements for handling SRMs, (2) advise management that because changes might affect the establishment hazard analysis or alter the critical control points they should reassess the adequacy of their HACCP plan, and (3) ask them specific questions that their controls and procedures would be expected to address. Beginning October 1, 2007, inspectors were to use FSIS Directive 6100.4, Verification Instructions Related to SRMs to verify that the establishment’s plans had incorporated the appropriate controls and procedures.

However, at two establishments, we found that the pre-requisite plans did not address the requirements of 9 CFR 310.22 and Directive 6100.4, which state that any slaughter establishment which ships carcasses containing SRMs to “downstream” processing establishments must (1) assure that the carcasses are accompanied by documentation stating that the SRMs must be removed, and (2) maintain documentation to show that the downstream establishment has received the carcasses and has certified to the subsequent removal and disposition of the SRMs. In both of these cases, FSIS personnel had documentation that the awareness meetings had been held as required by Notice 56-07. However, in one case the PHV misinterpreted the directive’s requirements, stating that he believed it sufficient that the processing establishment’s own SRM plan required their removal. In the other case, the inspectors stated they understood the requirement but had failed to notice that the pre-requisite plan did not contain the required controls. In both cases, the PHVs had received training on SRMs; however, this training took place before the training modules were updated to reflect the requirements for shipments to downstream processors.

At one of these two establishments, an FSA conducted in April 2008 also failed to disclose that the establishment’s pre-requisite plan did not address the requirements for transporting carcasses containing SRMs. The district manager stated that because of the way FSA reports are formatted, the district officials who reviewed the report could not determine the extent to which SRM procedures had been covered. She noted that the FSA did not concentrate on SRM-related issues, but rather on HACCP compliance in general.

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107 We reported this in audit 24601-7-Hy, Issues Impacting the Development of Risk-Based Inspection at Meat and Poultry Establishments. Until July 2008, FSAs were presented in an inconsistent, text-based format that did not allow FSIS managers to fully analyze the results of the FSAs.
At one establishment we visited, an investigation by FSIS OPEER disclosed that the establishment had not been properly removing the tonsils from market heads that it began shipping in 2003. Establishment personnel stated that at that time, the PHV instructed them in the method for tonsil removal. They continued using that method until a State inspector in Iowa discovered tonsil material during a routine inspection of cattle heads shipped by the establishment in 2008. Continuous review by FSIS inspection personnel during the previous 4 years, however, failed to identify this deficiency. The establishment issued a voluntary recall of over 400,000 pounds of product - about half of the cattle heads it shipped since 2003. Because the PHV who initially instructed establishment employees in tonsil removal was no longer with the agency, we could not validate that incorrect instructions were given to the establishment. The current PHV and FLS stated that they had not monitored tonsil removal sufficiently to have discovered that the establishment failed to remove all SRMs. We noted that both the CSI and the FLS received training in SRM tonsil removal after this noncompliance at this establishment had been disclosed.

Title 9 C.F.R. 310.22 and FSIS Directive 6100.4 require that precautions be taken when establishments slaughter cattle of mixed ages (over-and-under 30 months of age) to prevent cross-contamination by SRMs. If establishments do not segregate the carcasses and parts from the older and younger cattle, FSIS inspectors are required to verify that the establishment is either using dedicated equipment for each age group to cut through the SRMs, or cleaning and sanitizing the equipment before it is again used on carcasses or parts from cattle under 30 months old. However, at two establishments we found that these requirements were not being followed.

Establishment 1’s pre-requisite plan called for cattle, following the initial splitting of the carcass in the slaughter area,\textsuperscript{108} to be processed in order of their age with all cattle under 30 months of age being processed on any given day before any of the over-30-month cattle. Under this plan, it would have been unnecessary to either use dedicated equipment or to break down and clean the saws and other equipment until the next day’s slaughter operations began. However, we found that by the time the carcasses reached the processing area, they had been graded by USDA Agriculture Marketing Service; and from that point forward, the establishment first grouped the carcasses by USDA grade (e.g., USDA Prime, Choice, or Select) for further processing, and only then by age. Under this system, an over-30-month old carcass of one grade would be sawed before an under-30-month carcass in the next grade-grouping. Because it was not specified in the pre-requisite plan, the establishment did not break down and clean the equipment during this process (although each saw had a low-pressure “sanitizer” spray installed).

\textsuperscript{108} In the slaughter area, the establishment’s pre-requisite plan called for the use of dedicated equipment for sawing under-and-over 30-month-old carcasses, and we found the establishment to be in compliance with that requirement.
The FLS was not aware that this had been occurring, while the Supervisory Public Health Veterinarian stated that this would not warrant writing an NR because there were no “visible SRMs” on the equipment. During the audit, establishment management agreed to change their pre-requisite plan to “rinse and sanitize” the equipment. Although we observed establishment employees actually breaking down the equipment for cleaning during our visit, the FLS stated that the pre-requisite plan – even as revised – did not specifically require anything beyond the “continuous sanitation” provided by the sanitation sprayers attached to the saws.

FSIS Headquarters officials also agreed that an NR was unnecessary because they believed the sanitizer spray was sufficient to address the problem. We do not agree with this position because the establishment was not following its own pre-requisite plan, and this alone should have generated an NR.

We observed a similar situation at Establishment 10 where its employees used a single set of knives for removing the heads from carcasses of mixed ages. In addition, the establishment was using a single split saw to cut through the vertebral columns of these carcasses; and although establishment employees sprayed off the saw when switching from older carcasses back to under-30-month old carcasses, they did not break down the equipment and remove all visible debris as required by their pre-requisite plan. FSIS had not been aware that this was occurring, and agreed that the establishment was out of compliance. The PHV immediately dealt with the issue and the FLS stated a meeting would be held with establishment management to address the issue regarding the knives. The establishment took immediate corrective actions. However, FSIS again determined that an NR would not be written for the noncompliance.

We also observed that at Establishment 1, the automatic denaturant system did not disperse denaturant in sufficient amounts to ensure that inedible materials – including SRMs – were clearly identified as being inedible. This system should spread denaturant evenly across the inedible material and be readily visible. However, during our visit, the denaturant was barely visible. FSIS agreed that the system malfunctioned, but stated that the system appeared to be functioning properly the last time they had checked. Title 9 C.F.R. part 314.3 states that denaturant must be deposited in all portions of the carcass or product to the extent necessary to preclude its use for food purposes. The PHV agreed with this following our discussion, and wrote an NR to document the noncompliance.

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109 We noted – as we found at Establishment 10 – that there was a buildup of material inside the closed saw casing. Unlike at Establishment 10, however, the PHV and FLS did not believe this qualified as “visible SRMs.”
During the audit, when we pointed out apparent SRM noncompliances, FSIS inconsistently issued regulatory citations (NRs). We attributed this to an inadequate understanding of SRM requirements, which in turn indicates a need for additional training. For instance, Establishment 3 and 4 both had deficiencies in their pre-requisite plans that resulted in similar noncompliances regarding the shipping and tracking of carcasses that contained SRMs. At Establishment 4, the PHV agreed with our assessment and immediately wrote an NR. At Establishment 3, however, the CSI stated that he believed the establishment had “met the intent” of Directive 6100.4 and refused to write an NR. He was subsequently overruled by the district manager, who stated that an NR would be written.110

At Establishment 2, which was located in another district, we found that although the establishment’s pre-requisite plan was in compliance, it was not being followed. In this case, although the establishment was properly identifying the shipped carcasses as containing SRMs, they were not ensuring that downstream processors provided the required certifications that the SRMs had been removed. FSIS inspectors were not aware of the noncompliance before the audit, but did issue an NR when we notified them as to what we found. However, we were subsequently notified by the district office that the NR had been rescinded. An FSIS Headquarters official stated that the establishment was generally following their written procedure and the OIG finding represented only a “minor variation,” despite the fact that nearly half of the downstream shipments we reviewed (23 of 43 shipments, involving over 540,000 pounds of product shipped) did not contain the required certification. The FLS for this establishment stated, however, during our visit that any deviation from an establishment’s written plan would justify an NR.

Establishment 3 and 4 were both in the same district; and while both ultimately took equivalent enforcement action, in one case this only came about through the intervention of the district office. However, despite the fact that an FSA had recently been performed at Establishment 4, the district office only became aware of the deficiencies in the establishments’ pre-requisite plans as a result of our audit. Establishment 2 was in another district, which took a markedly different position on the enforcement of a situation similar to that found at the other two establishments. We believe that such inconsistencies further highlight the need for more effective management controls and training.

110 FSIS Directive 6100.4 requires, among other provisions, that when an establishment ships meat products containing SRMs to other establishments for additional processing, the shipping establishment must obtain written certifications from the processors that the SRMs have been removed before the products are marketed. Neither of these two establishments reflected this in their pre-requisite plans; therefore, the required procedures were not being followed.
At Establishment 4, we also noted that FSIS inspectors did not require the establishment to obtain age verification documentation for animals it slaughtered. Although the establishment’s normal practice was to consider all animals as over 30 months of age, it also occasionally slaughtered under-30-month-old animals for one of its buyers. We found that the establishment did not comply with its pre-requisite plan, which required age verification of under-30-month old animals. The inspectors at this establishment disagreed with the need to write an NR, stating that “the establishment treated all animals as over 30 months of age, so aging is not necessary.” District officials, when they became aware of the situation, instructed the PHV to write an NR.

As noted above, we found that Establishment 1 and 10 were not following their pre-requisite plans in that they cut and/or sawed carcasses of mixed ages but did not use dedicated equipment for each group or clean and sanitize the saws when switching from older to younger cattle. However, neither of these noncompliances resulted in inspectors writing an NR. Establishment 10 took corrective actions, including the requirement that the saws be actually broken down and cleaned rather than simply sprayed – a process which had left visible SRMs in the enclosed areas of the saw casings. However, no NR was written. An FSIS official stated that these issues “did not deal with deviations from critical control points within the HACCP plan.” However, Directive 6100.4 requires that FSIS inspection personnel issue an NR in any instance where the establishment has failed to develop and implement procedures that comply with 9 C.F.R. 310.22. Although Establishment 10’s procedures were in compliance with the regulation, their implementation clearly was not. As a result, we believe an NR should have been issued.

Likewise, at Establishment 1, FSIS declined to write an NR on the basis that the low-pressure sprayers on the saws – a measure that the establishment’s revised pre-requisite plan referred to as “rinsing and sanitizing” – met the requirements of Directive 6100.4. This action appeared inconsistent with the actions taken at Establishment 10, since in both cases a buildup of material was noted inside the closed saw casings. In any case, the presence of the sprayer did not change the fact that Establishment 1 mixed the age groups when sawing carcasses, which clearly violated the controls specified in its pre-requisite plan.

We discussed these issues with two of the four EAROs, and asked how, or if, they monitored the effectiveness of SRM verification activities. One stated that SRM controls are primarily monitored through the FSAs, and that they review some – but not all – of these. The other EARO stated that they do not have a large role in monitoring SRM compliance because this is done at the establishment level. Moreover, they do not have major concerns about SRMs because they see relatively few NRs being written on these issues.
The noncompliances we observed at 5 of the 10 establishments visited occurred for various reasons. In some cases, we noted that the PHVs did not have up-to-date training on SRM issues – the training record for the PHV at Establishment 2, for instance, did not list any SRM training at all. However, it is uncertain whether lack of formal training can explain why in-plant personnel were not aware of ongoing noncompliance, or did not recognize them as such. However, we believe that the conditions noted during this audit support the need for greater management control over SRM verification activities. We question how EAROs can effectively use FSAs as the primary tool to monitor compliance with SRM requirements. Also, we believe the EARO’s lack of concern regarding SRM noncompliance because “relatively few NRs are written” may be questionable because, as disclosed during the audit, there is inconsistent interpretation as to when NRs should be written. Without documentation that there has been noncompliance, FSIS has no means to assess risk and monitor trends in compliance with SRM control and interventions.

Thus, under the current management control structure, there is reduced assurance that district offices can become aware of situations that require their intervention; the same would apply to the EAROs who supervise them. Without adequate monitoring tools, FSIS may not become aware of situations that require intervention until these reach a stage that requires a recall or other enforcement action.

**Recommendation 21**

Provide specific guidance to FSIS personnel at all slaughter establishments to verify that HACCP, SOP, and pre-requisite plans are in compliance with FSIS regulations and directives. Ensure that this covers key provisions that each establishment’s plans must address. Further, require the Inspector-in-Charge (IIC) at each establishment to certify completion of this review to the district office.

**Agency Response**

FSIS will issue an FSIS notice or revise Directives 6100.2, “Post-Mortem Livestock Inspection,” and 6100.4, “Verification Instructions Related to Specified Risk Materials,” to require the IIC at each slaughter establishment to verify that his or her staff has reviewed the regulatory requirements and verification instructions in the directives relative to SRM controls and the establishment’s HACCP, Sanitation SOP, and prerequisite programs. These issuances will contain a reporting or notification process that captures whether the IIC at the establishment completes the review. The new instructions will be issued by April 2009.
OIG Position

We accept FSIS’ management decision.

Recommendation 22

Incorporate steps in future FSAs to verify that establishments’ HACCP, SOP, and pre-requisite plans are in compliance with FSIS regulations and directives regarding SRMs.

Agency Response

FSIS agreed that it was necessary to incorporate mechanisms into the FSA process to ensure compliance with SRM requirements, and has modified the FSA documentation to include these requirements. As part of the PHIS data infrastructure enhancement initiative, the FSA documentation process has been improved to a question and answer format and includes an SRM section within the 03J meat slaughter FSA tool. These questions lead the EIAO to verify that slaughter establishments are complying with 9 CFR 310.22. These FSA tools already are in use and related training continues.

Over 300 EIAOs, EIAO-trained PHVs, case specialists, deputy district managers, and district managers were trained during the summer of 2008 in the use of these tools as part of the Advanced EIAO training course. The tools have been incorporated into the basic EIAO training course, and FSIS plans to conduct 3 more Advanced EIAO training courses starting in January 2009 for the remaining EIAO-trained PHVs and district office personnel. Training is expected to be completed by May 2009.

OIG Position

We accept FSIS’ management decision.

Recommendation 23

Implement procedures to require that, as part of their supervisory visits, FLSs provide ongoing oversight to FSIS inspectors in their SRM-related inspection duties.

Agency Response

As noted earlier, FSIS has made improvements to the IPPS Supervisory Guidelines that will result in better accountability for carrying out SRM-related and other inspection activities. The new guidelines will contain explicit instructions for conducting IPPS assessments and testing the knowledge of in-plant inspection personnel on the policies and procedures for
which they are responsible, as well as how to observe their performance of inspection and verification procedures. The guideline provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform verification of an establishment’s SRM controls correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session. FSIS plans to issue the revised guideline in December 2008.

OIG Position

We accept FSIS’ management decision.

Recommendation 24

Strengthen guidance to clarify when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment prerequisite plans.

Agency Response

FSIS will issue a new notice by March 2009 that clarifies when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment prerequisite plans.

OIG Position

We accept FSIS’ management decision.

Recommendation 25

Assess the level of training needed by both FLSs and in-plant inspectors on SRM verification responsibilities, and develop controls to ensure that such training is provided in a timely manner.

Agency Response

FSIS will ensure that all FLSs, as well as in-plant inspectors and PHVs performing SRM verification, complete the updated SRM training course in AgLearn. To ensure appropriate inspection personnel receive needed training, OFDER/DAIG will conduct quarterly analyses of the training data and
provide a report to the Office of Outreach, Employee Education, and Training and the districts so that they can follow up with those inspection personnel that have not received needed training. FSIS estimates that all appropriate inspection personnel will receive this training by April 2009.

**OIG Position**

We accept FSIS’ management decision.
Scope and Methodology

We performed our audit at FSIS Headquarters in Washington, D.C., 6 FSIS district offices, and 10 cull cattle slaughter establishments between March and June 2008. To accomplish our objectives, we interviewed responsible FSIS personnel and establishment employees who worked at Hallmark-Westland Meat Packing Company (Hallmark) in Chino, California, as well as reviewed pertinent establishment and FSIS records gathered for OIG’s criminal investigation into potential violations of the Federal Meat Inspection Act. The investigation is ongoing and OIG Investigations is working cooperatively with FSIS OPEER and other law enforcement agencies, as well as coordinating their efforts with the U.S. Department of Justice. The purpose of our involvement in selected aspects of the investigation was to determine what inspection controls or processes may have broken down at Hallmark that allowed the egregious humane handling violations to occur.

Hallmark slaughtered cull cows. We concluded that establishments that slaughter cull cows are a higher risk for potential humane handling concerns because of the condition, age, and health of the animals slaughtered. Therefore, we limited the scope of this audit to FSIS pre-slaughter activities at cull slaughter operations to determine whether the conditions or abuses that occurred at Hallmark were isolated or systemic. Because this is an ongoing investigation, the audit is limited by the information we have to date.

During the audit, we interviewed appropriate FSIS officials, reviewed files, procedures, and operations related to FSIS’ performance of and oversight over, pre-slaughter activities. We observed ante-mortem inspections, as well as FSIS’ oversight over the accountability of animals moving from ante-mortem inspection to slaughter. We examined post-mortem controls over the monitoring and removal of SRMs and evaluated compliance with inspector-generated residue sampling and testing procedures. Our review covered current slaughter operations and we examined prior inspection and slaughter records (calendar years 2006 and 2007), as necessary.

FSIS Headquarters and Field Offices

At FSIS Headquarters, we determined the responsibilities of the following offices as they relate to pre-slaughter activities, SRMs, and residue sampling and testing:

- Program Evaluation, Enforcement and Review—assesses FSIS program functions and operations;
• Field Operations—manages the national program of inspection and enforcement activities;

• Policy and Program Development—develops and makes recommendations concerning all domestic policy;

• Public Health Science—provides scientific analysis, advice, data, and recommendations regarding matters involving public health and science;

• Office of Outreach, Employee Education and Training—provides education resources and technical support; and

• Office of Management—provides a full range of administrative and support services.

We obtained and analyzed data covering the period January 2006 through April 2008 from FSIS’ automated data and reporting systems (PBIS), Electronic Animal Disposition Reporting System (eADRS), Residue Violation Information System (RVIS), related to ante-mortem inspection, control of SRMs, and residue sampling and testing, and HATS. We also evaluated management use of PBIS, eADRS and/or HATS to monitor inspection operations and evaluated whether FSIS used these data to effectively monitor and supervise inspection activities.

We performed audit work at the following six FSIS district offices. They were selected because they provide management oversight of the 10 slaughter establishments included in this audit.

• Alameda, California
• Des Moines, Iowa
• Lawrence, Kansas
• Philadelphia, Pennsylvania
• Dallas, Texas
• Madison, Wisconsin

We visited the FSIS Financial Processing Center in Urbandale, Iowa, to gain familiarity and understanding of time and attendance reporting requirements for inspection personnel, and policies and procedures for entering FAST test screening results into the automated system for recording these results.

During our audit field work, we also visited the Midwestern and Western FSIS laboratories in St. Louis, Missouri, and Alameda, California, respectively, to evaluate their roles and responsibilities regarding the residue sampling and testing program. At the laboratories, we interviewed laboratory
officials and staff regarding residue testing policies and laboratory procedures, and observed sample processing at the laboratories.

**Slaughter Establishments**

We selected 10 of the top 49 establishments that slaughter cull cows. We considered such factors as 2007 slaughter statistics, geographic representation, relative establishment size, and participation in Government feeding programs. These animals would generally be over 30-months old and be subject to full compliance with SRM requirements. Four of the establishments reviewed supplied product to five processors who provided 59.7 percent of processed beef used in the National School Lunch Program.

We made unannounced visits to these establishments, observed pre-slaughter inspection operations, and held discussions with establishment officials, FSIS PHVs, front-line supervisors, and inspectors to obtain an understanding of their responsibilities and to become familiar with the establishments’ operations. We observed FSIS’ ante-mortem inspections and post-mortem inspection practices relating to SRM removal and residue testing. We interviewed in-plant inspectors and PHVs, obtained records/documentation to support the procedures for the identification, handling, removal, segregation, and disposal of SRMs. We interviewed FSIS personnel, and obtained and reviewed documentation used in support of the inspection operations reviewed, including tracking the identification of suspected residue animals through the FAST test screening process and residue sample collection at the establishments.

We also reviewed the establishments’ NRs to identify SRM violations, and food safety assessments and reports of humane handling verification visits to determine whether any of the conditions identified during the audit were previously identified by FSIS.

To accomplish our audit objectives, we:

- Identified and reviewed laws, regulations, policies, and procedures related to humane handling, residue testing, SRMs, and pre-slaughter and post-mortem inspection requirements;
- Obtained and reviewed performance reports prepared by the establishment or 3rd parties for its monitoring or supervision activities of pre-slaughter/humane handling operations where available;
- Evaluated FSIS controls/processes that are to provide oversight and monitoring of inspection operations;
• Evaluated the effectiveness of management controls FSIS put into place in response to our prior audit recommendations. Specifically, how FSIS management verifies inspectors are in compliance with SRM control procedures and identifies trends in NRs through the use of PBIS enhancements, IPPS, and AssuranceNet reviews;

• Obtained FSIS’ procedures (staffing models/standards) used to assign inspection resources and supervisory levels for oversight at slaughter establishments;

• Evaluated FSIS’ organization control over the development and training of its inspection resources; and

• Contacted various international experts, academia, and other knowledgeable industry individuals, as necessary.

We conducted this performance 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 based on our audit objectives.
## Exhibit A – Pre-Slaughter Inspection Issues

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>ESTABLISHMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>No documentation of suspect animals at ante-mortem inspection.</td>
<td>X X X X X</td>
</tr>
<tr>
<td>Ante-mortem inspections were performed by non-veterinarians outside the immediate supervision of a PHV.</td>
<td>X X X X X X X</td>
</tr>
<tr>
<td>Food inspectors performing ante-mortem inspection did not have required formal training.</td>
<td>X X</td>
</tr>
<tr>
<td>Animals were not observed both in motion and at rest during ante-mortem inspection.</td>
<td>X X X X X X</td>
</tr>
<tr>
<td>Animals were viewed in groups rather than individually during ante-mortem.</td>
<td>X X X X</td>
</tr>
<tr>
<td>Animals were not viewed from both sides during ante-mortem.</td>
<td>X X</td>
</tr>
<tr>
<td>Ear tags were not used to identify suspect animals.</td>
<td>X X X X X X</td>
</tr>
<tr>
<td>Ear tags were not used to identify condemned animals.</td>
<td>X X</td>
</tr>
<tr>
<td>No reconciliation of animal counts per pen cards to establishment slaughter records.</td>
<td>X X X</td>
</tr>
<tr>
<td>Accuracy of pen cards not verified through actual counts of animals in pens.</td>
<td>X X X X</td>
</tr>
<tr>
<td>PHV pre-signed pen cards before performing ante-mortem inspection.</td>
<td>X X</td>
</tr>
<tr>
<td>Suspect animals were not slaughtered separately from other animals.</td>
<td>X X X</td>
</tr>
<tr>
<td>Disposition of animals that become non-ambulatory after ante-mortem inspection not adequately documented.</td>
<td>X X</td>
</tr>
<tr>
<td>Downer doors, winches, and additional knock-sites not under FSIS lock.</td>
<td>X X X X X X X</td>
</tr>
</tbody>
</table>

111 For Hallmark, we have no information in this area.
## Exhibit B – Residue Testing Issues

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>ESTABLISHMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>Inspector-generated residue testing were not based on herd history.</td>
<td>Hallmark 1 2 3 4 5 6 7 8 9 10</td>
</tr>
<tr>
<td>Establishment personnel delegated responsibility for collecting test samples.</td>
<td>X</td>
</tr>
<tr>
<td>Test samples were not adequately secured while at establishments.</td>
<td>X</td>
</tr>
<tr>
<td>FSIS depended upon establishment personnel for notification when animals were received from known violators.</td>
<td>X</td>
</tr>
</tbody>
</table>
### Exhibit C – Specified Risk Material Issues

<table>
<thead>
<tr>
<th>ISSUES</th>
<th>ESTABLISHMENTS</th>
</tr>
</thead>
<tbody>
<tr>
<td>FSIS did not ensure that establishments adequately reassessed their HACCP System for SRM control.</td>
<td>X X</td>
</tr>
<tr>
<td>Establishments did not follow pre-requisite plans for shipping to downstream processors.</td>
<td>X</td>
</tr>
<tr>
<td>Establishments did not properly carry out SRM removal.</td>
<td></td>
</tr>
<tr>
<td>Establishments did not use dedicated or properly cleaned equipment when cutting products that contained SRMs.</td>
<td>X</td>
</tr>
<tr>
<td>FSIS did not take enforcement actions on SRM violations.</td>
<td>X^{112} X^{113} X^{114}</td>
</tr>
</tbody>
</table>

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112 FSIS Headquarters officials stated that an NR was unnecessary because they believed the sanitizer spray was sufficient to address the problem.

113 In-plant inspection personnel did issue an NR when we notified them as to what we found. However, we were subsequently notified by the district office that the NR had been rescinded. An FSIS Headquarters official stated that the establishment was generally following their written procedure and the OIG finding represented only a “minor variation.”

114 In-plant inspection personnel disagreed with the deficiency. However, the district office agreed and directed the in-plant personnel to write an NR.

115 In-plant inspection personnel did not write an NR because they concluded the cited deficiency did not represent a violation of a critical control point.
Exhibit D – Agency Response to the Draft Report

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

FROM: Alfred V. Almanza
      Administrator


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 OIG’s recommendations.

Responses to Recommendations

Recommendation 1:
Require that DVMS reviews evaluate the effectiveness of in-plant FSIS personnel in overseeing slaughter establishments’ humane handling activities. Also, establish controls to ensure that DVMS review results are correlated with prior reported violations to determine whether inspection processes need to be reassessed or other administrative actions taken.

FSIS Response:
FSIS will issue a new Directive providing District Veterinary Medical Specialists (DVMSs) with additional guidance related to their reviews. DVMSs will be instructed to review data for the past six months, to include any noncompliance records (NRs), Memoranda of Information, and suspensions and to also review the previous Humane Handling Verification visit results prior to conducting their Humane Handling Verification visit. While at the plant the DVMS will engage all in-plant inspection program personnel in a discussion regarding any issues of concern noted by the in-plant inspection program personnel and any discussions that took place with establishment management regarding issues that did not rise to the level of a noncompliance, but that may be of concern. Based on the observations and the assessment any appropriate administrative action could be taken.

During the Humane Handling Verification visits the DVMSs will engage the in-plant inspection program personnel in a discussion to ascertain their knowledge base. This information will then be provided in a written document to the District Manager and Deputy District Managers who in turn will share it with the appropriate Frontline
Exhibit D — Agency Response to the Draft Report

Supervisor (FLS) to address performance issues. While at the plant, if the DVMS determines in-plant inspection personnel have a knowledge deficiency, the DVMS will provide the appropriate information. In addition, if there are indications that in-plant inspection program personnel are not adequately monitoring conditions based on the observations, the District Manager and Deputy District Managers will also be apprised of the issue in order to facilitate performance correction by the appropriate supervisor. The FSIS Directive containing the additional DVMS guidance will be published by February 2009.

Estimated Completion Date:
February 2009

Recommendation 2:
Reassess the humane handling risks associated with cull slaughter establishments, and determine whether DVMS reviews should be conducted on a more frequent basis at those establishments.

FSIS Response:
The Office of Food Defense and Emergency Response’s Data Analysis and Integration Group (OFDER/DAIG) will complete an analysis of noncompliance rates for humane handling procedures at dairy cow establishments as compared to rates at establishments that slaughter other market classes of adult cattle. The analysis will be completed by August 2009, and provided to the Office of Field Operations (OFO) for final determination.

Also, the DVMSs will be given additional guidance in the form of an FSIS Directive to monitor all humane handling noncompliance, establishment corrective actions and other findings as brought forward by inspection personnel, which could result in more frequent Humane Handling Verification visits.

Estimated Completion Date:
August 2009

Recommendation 3:
Establish a process to analyze PBIS data for anomalies or variances in both slaughter establishment and inspector performance that could require additional followup by district management.

FSIS Response:
OFDER/DAIG will develop a quarterly humane handling alert based on a review of establishment noncompliance data. The quarterly alert can be used by OFO management to identify anomalies or variances in slaughter establishment noncompliance or inspector performance that could require additional follow-up by District management. The process will be established by January 2009 and the first alert will be distributed in March 2009.
Estimated Completion Date:
March 2009

Recommendation 4:
Determine whether FSIS-controlled in-plant video monitoring would be beneficial in preventing and detecting animal abuses at cull cow slaughter establishments.

FSIS Response:
FSIS has determined that FSIS-controlled video cameras would not provide the definitive data needed to support enforcement of humane handling requirements, as compared to the direct, ongoing and random verification of establishment handling and slaughter practices that FSIS uses. For example, video footage would not likely provide definitive evidence of whether an animal was conscious at a certain point during the slaughter process. And, reliance by inspection program personnel on video for verification or enforcement could lead unscrupulous establishments or establishment employees to regularly mishandle livestock outside of the camera’s view.

That being said, industry use of video cameras to monitor humane handling compliance, such as monitoring of employee humane handling actions in holding pens, can be useful to the establishments themselves in deterring and detecting animal abuses. This is especially true if the establishment has implemented a systematic approach to meeting the humane handling and slaughter requirements, as FSIS recommended in a 2004 Federal Register Notice (69 FR 54625). FSIS has authority to access establishments’ video records under the Federal Meat Inspection Act, specifically 21 U.S.C. 642. FSIS has enforced access to video records when the video was used to meet certain aspects of HACCP and SSOP requirements.

FSIS will issue Compliance Guidelines for Using Video Records to industry for designing, maintaining and validating their video system so that the video records are trustworthy, accurate and a true representation of the process. An accompanying FSIS Directive will clarify FSIS inspection personnel access to and verification of establishment video records. Both documents will be issued by March 2009.

Estimated Completion Date:
March 2009

Recommendation 5:
Develop a documented, supportable methodology for assigning in-plant inspection staff for off-line inspection activities, including a basis for assignment at different types of plants.

FSIS Response:
The Agency is currently developing the Public Health Information System (PHIS), an effort to strengthen its public health data infrastructure as part of the ongoing effort to improve food safety and food defense. Concurrently, the Agency is planning changes to off-line inspection personnel work. Models are being designed to estimate time,
Recommendation 6:
Reassess and support the methodology used to establish the supervisory span of control for frontline supervisors.

FSIS Response:
The FLS positions have primary oversight of inspection and enforcement activities at the in-plant level. The primary focus of the FLS position is to protect the public health through coordination and supervision of Consumer Safety Inspectors or subordinate in-plant supervisory personnel. The subordinate supervisory personnel provide technical and administrative supervision of in-plant inspection employees who conduct inspections and enforcement activities at slaughter and processing establishments.

The FLS position was not designed to provide daily supervision to each subordinate assigned within the circuit boundaries; instead, the FLS develops goals, explains policies, and delegates daily supervisory tasks to in-plant supervisors. The FLS independently plans, develops, and carries out their supervisory and technical responsibilities.

In 2005, the Program Evaluation and Improvement Staff of the Office of Program Evaluation, Enforcement and Review conducted a study of the FLS position on behalf of OFO. The study recommended increasing the number of FLS positions to enable a greater leadership role in its food safety and food defense mission. An OFO task group comprised of FLSs, District Managers, and Program Analysts reviewed the study and selected key recommendations from the study for future implementation under FSIS Directive 1010.2, Revision 2, Circuit Maintenance Guidelines.

The primary objective of revising the Circuit Maintenance Guidelines was to provide Agency managers with key parameters to use to determine the optimum number of FLS positions based on the number of plants, employees, and travel within a district. The Directive was not an attempt to develop a work measurement instrument for the FLS position, nor can it determine the absolute span of control of the FLS position due, in part, to the highly variable nature of their work. Revising the Circuit Maintenance Directive created seventeen new circuits bringing the total number of circuits to 175. Additional impact of the revised Circuit Maintenance Guidelines includes:
• Fewer establishments per circuit: on average the number of plants per circuit decreased from 37 to 34 – each circuit will have fewer than 45 establishments.

• Fewer direct reporting lines to the FLS: on average the number of direct reports decreased from 20 to 15 – each FLS will have fewer than 16 direct reports.

• Fewer indirect reporting lines: on average the number of indirect reports will decrease from 33 to 32 – each FLS will have fewer than 55 indirect reports.

• Reduce the amount of travel for FLS: on average the FLS travel reduced from 1.8 travel days to 1.6 travel days.

Implementing the new Circuit Maintenance Guidelines will increase the total number of FLS positions, thereby reducing the span of control of FLS positions. Increasing the number of FLS positions will provide management with the opportunity to strengthen management controls over in-plant inspection activities including the application of HACCP programs. More FLS positions allow for more routine on-site reviews of in-plant operations and ongoing assessments of inspection data generated at the in-plant level. The new Circuit Maintenance Guidelines Directive was completed in September 2008. FSIS will fully implement the Directive during the second quarter of FY 2009. Further, FSIS will perform an assessment of these new guidelines by the end of the first quarter, 2010, to determine, among other things, the impact of the reduction of the FLS span of control.

Estimated Completion Date:
March 2010

Recommendation 7:
Strengthen human capital management by establishing a structured training and development program, with strong organizational controls, to demonstrate the competency of the inspection workforce in fulfilling its mission.

FSIS Response:
FSIS will establish policies and procedures to ensure that all mission critical occupational groups (Food Inspector, Consumer Safety Inspector, Public Health Veterinarian, Frontline Supervisor, Program Investigator, Import Inspector) receive formal, entry level on the job, or classroom training based on their job description, performance standards, and Agency policies and procedures within one year of coming on board in the position, and sooner when possible (e.g., within the first 3-6 months). Further, FSIS will require that inspection program personnel recertify this training annually. These policies and procedures will be implemented and described in an FSIS Directive or Notice to be issued by September 2009.

In the interim before the implementation of the new policies and procedures, to ensure inspection program personnel demonstrate the appropriate level of competency, the In-Plant Performance System (IPPS) Supervisory Guideline has been modified to include
Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline by December 2008.

Estimated Completion Date:
September 2009

Recommendation 8:
Strengthen management controls to ensure that district management teams are performing on-site evaluations of IPPS reviews at the minimum frequency required by AssuranceNet. In addition, evaluate whether the frequency of these reviews should increased.

FSIS Response:
During this past IPPS cycle, four of the fifteen Districts fell below the 10% requirement for reviewing IPPS assessments documented by FLSs and in-plant supervisors- these Districts ranged from 5% to 7% IPPS assessments reviewed. All but one of the fifteen Districts met or exceeded the 1% performance standard for conducting on-site evaluations of the IPPS assessments reviewed by the District management team. However, the District that did not meet the 1% requirement did conduct onsite evaluations of IPPS in three of its eight circuits.

A few recent developments will assist the Districts to better monitor their own progress in meeting these requirements in the future. This last summer, the District Analysts were trained to more effectively use the custom reports in AssuranceNet. These reports allow the Districts to see what percentage of reviews they have performed overall, as well as broken down by circuit so that they can better monitor and target their efforts more efficiently throughout the rating cycle. This reporting allows them to monitor the performance of their FLS personnel in reviewing subordinate supervisors’ performance of IPPS assessments, as well. In addition, the AssuranceNet system was also enhanced during the summer to allow District management teams to see which IPPS assessments have generated follow-up due to deficiencies identified by the supervisor performing the IPPS assessment. This enhances the ability of the District to focus on IPPS assessments on which weaknesses have been identified and to ensure that effective follow-up is accomplished by subordinate supervisory levels. Following the next IPPS cycle, an assessment will be performed on these improvements to determine whether they resulted in the Districts meeting the required IPPS frequencies. A report will be prepared of the results of this assessment.
Estimated Completion Date:
November 2009

Recommendation 9:
Strengthen and clarify the requirements for in-plant inspection personnel to assess the adequacy of each establishment’s animal identification system. In addition, strengthen FSIS guidance requiring the use of ear tags to identify suspected and condemned animals.

FSIS Response:
FSIS is writing a new FSIS Notice pertaining to verification of an establishment’s identification records and reconciling livestock numbers between ante-mortem and slaughter. This Notice is expected to be issued in December 2008. The Notice will clarify that the establishment is responsible for providing livestock data (that identify livestock) to inspection program personnel when requesting ante-mortem inspection. It also will explain that inspection program personnel are to verify the establishment’s data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. In April 2009, FSIS will revise and reissue FSIS Directive 6100.1 (“Ante-Mortem Livestock Inspection”) to permanently capture the content of the December 2008 FSIS Notice. This Directive will also provide clarified tagging instructions for livestock that have been determined to be a US Suspect or US Condemned animal.

Estimated Completion Date:
April 2009

Recommendation 10:
Require inspectors to verify the accuracy of the animal counts on pen cards and drive sheets, and reconcile these to establishment slaughter records.

FSIS Response:
FSIS is writing a new FSIS Notice pertaining to verification of an establishment’s identification records and reconciling livestock numbers between ante-mortem and slaughter. This Notice will clarify that the establishment is responsible for providing livestock data (that identify livestock) to inspection program personnel when requesting ante-mortem inspection. This Notice will explain that inspection program personnel are to verify the establishment’s data when performing ante-mortem inspection as well as the verification method to be used. After livestock have passed this verification process during ante-mortem inspection, they may be moved to slaughter. This Notice is expected to be issued in December 2008.

Estimated Completion Date:
December 2008
Recommendation 11:
Strengthen existing guidance for inspectors to observe animals both at rest and in motion during ante-mortem inspection.

FSIS Response:
FSIS will revise and reissue FSIS Directive 6100.1 ("Ante-Mortem Livestock Inspection") to clarify that inspection program personnel are to observe animals both at rest and in motion during ante-mortem inspection. The revised Directive is expected to issue in April 2009.

Estimated Completion Date:
April 2009

Recommendation 12:
Implement controls to ensure that each non-veterinary inspector has received necessary training, both formal and informal, before performing ante-mortem inspection.

FSIS Response:
FSIS has implemented and will continue a structured on-the-job (OJT) training program for all Food Inspectors (FIs) and other non-veterinary inspectors performing ante-mortem inspection. The structured OJT training, which was implemented on September 10, 2008, is one of six modules contained in the 2008 Interim Employee Development Guide (IEDG) which provides resources to supervisors and trainers to aid in their training efforts in the first phase of a new inspector’s career. The structured OJT module contains several topics for which new inspectors must demonstrate basic proficiency. These topics include the following: Sanitation and SSOPs, Ante-mortem and Post-mortem inspection, Good Commercial Practices, HACCP overview, Food Safety Standard (Fecal) Overview, Condemned/Inedible, and Food Defense Overview. The structured OJT module includes forms that both the new inspector and supervisor/trainer must initial when the inspector has attained basic proficiency on each subject. The supervisor/trainer must then add written comments on each of the forms reflecting both the inspector’s strengths and weaknesses in the particular core competency or subject matter. The comments must also include their plan to improve on deficiencies in both knowledge and/or execution for that competency. When all of the subjects in the structured OJT module have been completed, the signed forms must be submitted to the District Office so that the District can track each new inspector through the training and to ensure the completion of the structured OJT module is recorded in the inspector’s learning history. Once the forms are submitted to the District, generally within two to four weeks of starting OJT, the inspector is ready for the Center for Learning’s Formal Classroom Training. Newly hired inspector’s will be required to complete the formal classroom training course in a timely manner, typically within one year of entering on duty.

Further, FSIS will require that these inspection program personnel recertify this training annually. To ensure that appropriate inspection personnel have received the necessary training, OFDER/DAIG will conduct quarterly analysis of this training data for inspection program personnel and provide a report to the Office of Outreach, Education and Employee Training (OOEET) and the Districts so that they can follow-up with those
Exhibit D – Agency Response to the Draft Report

Veterinary inspectors perform ante-mortem inspections in accordance with FSIS directives. Also, ensure that such observations are documented.

FSIS Response:
This verification is already part of the IPPS system. However, FSIS has made some improvements to the IPPS Supervisory Guideline that will result in better accountability for carrying out the ante-mortem and other inspection activities. The Agency has revised the Guideline to change it from a document that largely outlined regulatory requirements and the contents of Directives and Notices to a document with explicit instructions for how to conduct an IPPS assessment to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible, as well as how to observe their performance of inspection and verification procedures. The Guideline provides a "work method" to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform ante-mortem procedures correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session. The draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline in December 2008.

Estimated Completion Date:
December 2008

Recommendation 14:
Require that secondary entrances to slaughter areas, stunning boxes, and winches not used as part of establishments normal slaughter operation be placed under FSIS control to ensure that they can be used only under the supervision of inspection personnel.

FSIS Response:
FSIS does not have statutory or regulatory authority to require that secondary entrances and equipment be placed under FSIS control in general. However, FSIS does recognize the need to ensure that these entrances and pieces of equipment are not used in violation of the statutes or regulations. By May 2009, FSIS will either issue a new FSIS Notice or revise FSIS Directive 6900.1 Revision 1, "Humane Handling of Disabled Livestock," to clarify that inspection program personnel, through ongoing verification activities, are to
Recommendation 15:
Develop specific guidance and procedures for in-plant FSIS personnel to use herd history as a basis for performing residue tests.

FSIS Response:
FSIS receives a weekly report on residue violators from USDA's National Information Technology Center. This report identifies establishments that have purchased, on more than one occasion, animals with violative residues, as confirmed by FSIS laboratories, and from the same supplier. Upon receipt of the report, FSIS headquarters currently notifies the District Offices about these establishments through the shared “Outlook residue mailbox files.”

By December 2008, the Agency will issue an FSIS Notice to instruct District Offices to inform all ICCs (and their FLSS) at establishments known to have purchased livestock from repeat residue violators about new violations involving the violating firms. The Notice will advise inspection program personnel at these establishments about their responsibilities when they are informed that an establishment repeatedly (more than once) has purchased from the same supplier animals with violative levels of residues. Among other things, the Notice will give instructions to PHVs regarding additional residue sampling if an establishment continues to purchase livestock from a supplier with repeat residue violations.

Estimated Completion Date:
December 2008

Recommendation 16:
Develop a process that provides on-going monitoring and analysis of inspector-generated residue sampling. Initiate follow-up actions when there are variances in inspector performance and/or residue test results.

FSIS Response:
FSIS will implement the eSample system by June 2009. Among other things, this system will be used to collect Fast Antimicrobial Screen Test (FAST) results or other rapid test results used in inspector generated sampling. The eSample database will eliminate any duties Office of Management currently has related to the collection of these test results at the Federal Processing Center in Urbandale, IA.
The Office of Public Health Science (OPHS), Residue Branch, will analyze data from eSample and the Electronic Animal Disposition Reporting System (eADRS) to include production volumes (number of head slaughtered), number of in-plant screening tests conducted and test results, both positive and negative, for each establishment on a quarterly basis. OPHS has identified and will implement the following parameters as part of this process: 1) select and monitor in-plant screening tests with acceptable sensitivity and low specificity (close to tolerance and low numbers of “false” positives), 2) improve inspector generated sampling criteria, and 3) establish uniform in-plant sampling between establishments. The estimated completion date for the first analysis is August 2009. Once the data are analyzed, OPHS will provide OFO and other FSIS program managers with a report indicating any discrepancies in in-plant screening testing procedures so that appropriate action can be taken.

**Estimated Completion Date:**
August 2009

**Recommendation 17:**
Clarify the written requirements for the collection of test samples. In addition, strengthen monitoring to ensure that inspectors properly safeguard samples against possible tampering.

**FSIS Response:**
FSIS has selected a new in-plant residue test screening method to be used by inspectors in all slaughter establishments. By April 2009, FSIS will draft an FSIS Directive to provide instructions to field personnel regarding comprehensive criteria for performing in-plant residue screen tests (herd history, current health of animal presented for inspection, etc.). The Directive also will provide directions on how to collect and submit samples to ensure sample integrity and, specifically in response to OIG concerns, how to secure samples onsite prior to submission to FSIS labs. To further ensure that inspectors are fully aware of the protocol for shipping samples, FSIS will link the new Directive (once it is posted to the FSIS Web site) to the current FSIS Directive 7355.1, Revision 2, “Use of Sample Seals for Laboratory Samples and Other Applications.”

**Estimated Completion Date:**
April 2009

**Recommendation 18:**
Develop processes, as part of the new PHIS system, to verify that inspectors are regularly performing SRM-related tasks as part of their inspection duties. Incorporate features in PHIS that will allow managers to track and evaluate the extent to which such tasks are being performed at the establishment, circuit, and district levels.

**FSIS Response:**
The PHIS, currently being developed, will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel
Perform HACCP verifications at beef plants and verify that establishments handle specified risk material (SRM) in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification frequencies and for responding to variations in frequency. As the PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track that tasks are performed and that the appropriate regulatory requirements are verified as required. This feature will apply to all regulatory requirements, not only those related to SRMs. The PHIS will be in full production readiness by March 2010.

**Estimated Completion Date:**
March 2010

**Recommendation 19:**
Implement procedures for district offices to monitor and analyze SRM-related NRs as part of the agency’s overall management control process. Provide district-level users access to all information, including OFDER’s monthly exception reports.

**FSIS Response:**
FSIS will modify PBIS by adding a drop down menu that will provide the Districts with a tool to sort and search all NRs by regulatory citations. This will enable them to monitor and analyze specific SRM-related NRs (i.e., those not in compliance with 9 CFR 310.22). This proposed PBIS modification is an interim measure pending PHIS implementation. In addition, OFDER/DAIG prepares quarterly exception reports that are distributed to OPPD and OFO. These reports will be shared by the Executive Associates for Regulatory Operations (EAROs) with each corresponding district. Information contained in these reports will provide each District with data for correlation purposes. Districts may further use such information and data to follow-up on particular issues of concern. FSIS will provide the Districts with guidance in the form of an FSIS Directive or Notice that will explain how and what to do with both the PBIS data and OFDER’s report to monitor and analyze SRM-related NRs as part of the Agency’s overall management control process. The modifications to PBIS will be made and the FSIS Directive or Notice will publish by March 2009.

**Estimated Completion Date:**
March 2009

**Recommendation 20:**
Add specific fields to both AssuranceNet and IPPS for SRM-related activities and develop processes to ensure that these are adequately monitored both at the district and Headquarters levels.
The revised IPPS Supervisory Guideline provides specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs. The sections dealing with HACCP verifications, SSOP verifications and prerequisite program verifications specifically direct the supervisor on how to assess the employee's knowledge and proficiency in carrying out verification of SRM control activities. The instructions are set up in this manner because establishments may incorporate their SRM controls into the HACCP plan, SSOP or prerequisite program. For example, if the supervisor is assessing the performance of an inspector conducting HACCP verification activities and the SRM controls are in the establishment HACCP plan, the supervisor evaluates the employee's knowledge and execution of verifications concerning SRM regulatory requirements when evaluating the HACCP verification activity. The Draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. The revised Guideline should issue in December 2008.

Also, the PHIS currently being developed will have features that require inspection personnel to record which specific regulatory requirements are verified each time they are performed, even if noncompliance is not found. For example, when inspection personnel perform HACCP verifications at beef plants and verify that establishments handle SRM in accordance with their plans and regulatory requirements, the regulatory requirements that inspection personnel verified will be recorded in the PHIS database. The data will be available to OFO supervisory personnel for them to track to ensure that inspectors are performing such verifications at the specified frequencies. PHIS policy and training will include guidelines for monitoring SRM verification frequencies and for responding to variations in frequency.

As the PHIS is developed, the system of management controls will be restructured to allow managers at all OFO levels to track that tasks are performed and that the appropriate regulatory requirements are verified as required. In line with the Agency's preference for general performance elements and because its management controls are not designed to track performance of individual inspection program personnel, this feature will apply to all regulatory requirements, not only those related to SRMs. That is, while the new system of management controls will reflect PHIS features, it likely will not contain a management control specific to SRM verification. The PHIS will be in full production readiness by March 2010.
Estimated Completion Date:
March 2010

Recommendation 21:
Provide specific guidance to FSIS personnel at all slaughter establishments to verify that HACCP, SOP, and pre-requisite plans are in compliance with FSIS regulations and directives. Ensure that this covers key provisions that each establishment’s plans must address. Further, require the Inspector-in-Charge (IIC) at each establishment to certify completion of this review to the district offices.

FSIS Response:
FSIS will issue an FSIS Notice or revise Directives 6100.2, “Post-Mortem Livestock Inspection,” and 6100.4, “Verification Instructions Related to Specified Risk Materials,” to require the IIC at each slaughter establishment to verify that his or her staff has reviewed the regulatory requirements and verification instructions in the directives relative to SRM controls and the establishment’s HACCP, Sanitation SOP and prerequisite programs. These issuances will contain a reporting or notification process that captures whether the IIC at the establishment completes the review. The new instructions will be issued by April 2009.

Estimated Completion Date:
April 2009

Recommendation 22:
Incorporate steps in future FSAs to verify that establishments’ HACCP, SOP, and pre-requisite plans are in compliance with FSIS regulations and directives regarding SRMs.

FSIS Response:
FSIS agrees that it is necessary to incorporate mechanisms into the FSA process to ensure compliance with SRM requirements and has modified the FSA documentation to include these requirements. As part of the PHIS data infrastructure enhancement initiative, the FSA documentation process has been improved to a question and answer format and includes an SRM section within the 03J meat slaughter FSA tool. These pointed questions lead the EIAO to verify that slaughter establishments are complying with 9 CFR 310.22. These FSA tools already are in use and related training continues.

Over 300 EIAOs, EIAO-trained PHVs, case specialists, Deputy District Managers, and District Managers were trained during the summer of 2008 in the use of these tools as part of the Advanced EIAO training course. The tools have been incorporated into the basic EIAO training course also and the FSIS plans to conduct 3 more Advanced EIAO training courses starting in January 2009 for the remaining EIAO trained PHVs and district office personnel. Training is expected to be completed by May 2009.

Estimated Completion Date:
May 2009
Recommendation 23:
Implement procedures to require that, as part of their supervisory visits, FLSs provide ongoing oversight to FSIS inspectors in their SRM-related inspection duties.

FSIS Response:
FSIS has made some improvements to the IPPS Supervisory Guideline that will result in better accountability for carrying out the SRM-related and other inspection activities. The Agency has revised the Guideline to change it from a document that largely outlined regulatory requirements and the contents of Directives and Notices to a document with explicit instructions for how to conduct an IPPS assessment to test the knowledge of in-plant inspection personnel on the policies and procedures for which they are responsible, as well as how to observe their performance of inspection and verification procedures. The Guideline provides a “work method” to ensure that the supervisors ask the right questions and observe the performance of the inspection personnel on every aspect of their jobs, including whether inspection personnel perform verification of establishment's SRM controls correctly. These observations are required to be documented on the IPPS report in AssuranceNet. If supervisors find deficient performance, they are to ensure remedial action is taken, i.e., correlation, re-training, and to perform a follow-up IPPS within 60 days and document their observations during that follow-up session.

FLSs do not provide daily supervision to each subordinate assigned within the circuit boundaries; instead, the FLS develops goals, explains policies, and delegates daily supervisory tasks to in-plant supervisors. FLSs do, however, conduct some IPPS assessments, e.g., for non-supervisory inspection program personnel assigned to processing establishments within a circuit. To the extent they conduct IPPS assessments, FLSs would use the revised IPPS Supervisory Guide which provides specific instructions to supervisors for determining the knowledge and proficiency of their inspection personnel on various aspects of their jobs, including verification of SRM controls. The draft IPPS Supervisory Guideline is currently out for comment with the Districts and Frontline Supervisors. FSIS plans to issue the revised Guideline in December 2008.

Estimated Completion Date:
December 2008

Recommendation 24:
Strengthen guidance to clarify when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans.

FSIS Response:
FSIS will issue a new FSIS Notice that clarifies when NRs should be written for noncompliance with controls for the removal, segregation, and disposal of SRMs, including noncompliance with controls specified in establishment pre-requisite plans. This new Notice is expected to be issued by March 2009.
Estimated Completion Date:
March 2009

Recommendation 25:
Assess the level of training needed by both FLSs and in-plant inspectors on SRM verification responsibilities, and develop controls to ensure that such training is provided in a timely manner.

FSIS Response:
FSIS will ensure that all FLSs and in-plant inspectors and PHVs performing SRM verification complete the updated SRM training course in AgLearn. To ensure appropriate inspection personnel receive needed training, OFDER/DAIG will conduct quarterly analysis of the training data and provide a report to OOEFT and the Districts so that they can follow-up with those inspection personnel that have not received needed training. The Agency estimates that all appropriate inspection personnel will receive this training by April 2009.

Estimated Completion Date:
April 2009
Informational copies of this draft report have been distributed to:

Administrator, FSIS  
   Attn: Agency Liaison Officer  (20)
Government Accountability Office  (1)
Office of Management and Budget  (1)
Office of the Chief Financial Officer
   Director, Planning and Accountability Division  (1)
The recent outbreak and product recalls associated with peanuts and peanut products exposed significant vulnerabilities in the supply chain, vulnerabilities that exist from farm to table and across a broad spectrum of food types.

In order to restore consumer confidence and more effectively manage the risks associated with food safety and quality in the supply chain, significant reforms will be necessary. Advances in science and an overhaul of the regulatory agencies alone will not solve the problem. The companies that have the most to lose when things go wrong must take the initiative to develop far more rigorous solutions to protect their customers and their brands.

These observations are insights gained from 17 years of work in the food safety and quality assurance field. There are gaps that exist in many areas of food safety and quality assurance in corporate America and, for that matter, the world, so these comments are not specific to any particular entity or industry segment.

- That there was another large, multi-state outbreak was not in the least bit surprising. Industry, government, the public and the media have a tendency to overreact, responding disproportionately to a single event: *E. coli* in lettuce, *Salmonella*-tainted jalapeno peppers. Botulism in carrot juice. *E.coli* contaminated ground beef. These specific incidents are indicative of larger issues and the inherent risks in the supply chain. We must think more strategically and develop fully integrated, industry and enterprise level compliance management systems for managing supply chain food safety and quality.

- The reality is that certain levels of physical and pathogenic contamination in raw materials are to be expected. Companies must develop sophisticated processes and controls to mitigate these risks.

- In addition, even if rigorous controls are in place, companies are learning the hard way that compliance is an operational issue. Quality assurance and operations teams must collaborate to “operationalize” food safety and quality processes and systems.

- Quality Assurance professionals, for whom I am have the utmost respect, are often scientists, academics and in some case regulators. They don’t always have the background or ability to think and act strategically and often have difficulty getting traction with their programs.

- Frequently, companies operate in blind faith, relying on regulations and regulators, any number of different industry standards, and an army of third-party auditors who audit against those standards.

- Regulators, for a myriad of reasons one of which is budgetary constraints, do not have a good track record and don’t own the problem to the extent that the large producers, manufacturers and purchasers do.

- Although there has been a lot of momentum around the harmonization of standards, mainly under the Global Food Safety Initiative (GFSI), there are still significant differences from one standard to the next, often resulting in gaps of compliance.
Auditor competency is a real issue. Auditor credentials and training, technical accuracy, rigor, level of engagement, calibration and even the use of technology to enable accurate and detailed capture of information are all a significant challenge. Few third-party auditing companies invest enough time and effort into these issues. The predominant model in third-party auditing is one in which certifying bodies subcontract all of their work to auditors who are not adequately trained, calibrated and supervised.

Price competition being what it is, many small audit companies, and even some large ones; compete by offering shorter, cheaper audits. Shorter is not only cheaper; it is usually easier and not nearly rigorous enough.

Not all audits are created equal. While picking a good standard to audit against is important, it pales in significance to the quality and rigor of the audit itself. It is less about the standard and more about the quality of the audit.

Often auditors with expertise in one field will be sent to perform an audit in an area in which they are not subject matter experts.

While an audit is only a snapshot in many cases, auditors must make every effort to “dig deeper.” In order to make an accurate assessment of conformity, a competent auditor must obtain sufficient evidence to support a certification. That means interacting with employees of the audited facility, asking questions, and not being bullied by staff who just want finish the audit and get on with their daily duties.

Finally, left to their own devices, some companies will “shop” around for a good audit. It is not unusual for a plant that fails an audit to contact another third party auditor in the hopes of getting a passing grade.

Good standards exist – the SQF standard is excellent and requires careful scrutiny of processes, systems and documentation; as well as a thorough evaluation of how well those systems are working in the plant.

Great technology is also available and is an absolute necessity for managing compliance at an enterprise level. At Steritech, we say “Data without action is overhead.” What we mean by this is that too often, companies do not even know what they know – having good, accurate information at your disposal, and being able to act on it in an efficient and effective manner is the key to success.
A few points to start:
∞ An audit is more likely to uncover bad practices than deceitful practices. If someone does an illegal act, they are more likely to hide it, making detection in an audit much less likely.

∞ The third party audit is overstated in their ability to determine microbiological risk. These audits give an indication of the quality system within a facility, but in most all cases, microbiological testing is not a part of the audit process. Rarely is the process control system challenged, including a thorough analysis of the HACCP (Hazard Analysis and Critical Control Point) plan. The third-party audit is a tool that has been used by companies that are purchasing product from the audited company. As they are performed today, this test should be done in conjunction with other tools such as incoming ingredient testing by the purchasing company as well as on-site visits. Given an audit’s short duration (these are one and two-day audits) and the number of audit items to cover (pest control, chemical control, etc), it is difficult delve into more complicated issues with any depth, specifically process control.

∞ Seasonality – an audit performed in January is more likely to show roof leak problems than an audit done in the summer.

The Georgia Audits
∞ The Cook & Thurber audit appeared to be a more thorough audit. It was a two-day audit. While the AIB audit gave a pass to the HACCP plan documentation and sanitation procedures, shortcomings of this paperwork were identified by Cook &Thurber - the lack of written sanitation procedure (SSOP), inadequate hazard analysis upon which the HACCP plan was developed. It also identified an inadequate Master Sanitation List – a detailed cleaning list that should encompass the cleaning of all parts of the plant. The Cook & Thurber audit also identified negative pressure in the packaging area where product is exposed. This is another critical item that could lead to cross contamination.

∞ Both audits identified the lack of a Quality Manager. In this plant, all facets of quality reported to the Operations Manager. This means there was less likely a checks-and-balance situation regarding quality.

∞ Both audits identified potential sources of cross contamination, although the items listed were different in each of the audits.

∞ Both audits identified shoddy maintenance (use of duct tape, rusty equipment, etc.)

∞ Both audits had shortcomings:
   o Both audits scored the plant at 91% for the food-safety related elements. The final score for the Cook & Thurber audit becomes skewed upward when you add in items that are less critical to food safety – 96%
   o There was not a listing of the documentation reviewed (no audit trail). The auditor should list the documents reviewed, the dates of the documents, etc. As a purchaser, I would want to see how deep this audit went. As written, we have to trust that the auditor actually reviewed these
records or made appropriate observations. One area that was of concern
was product and environmental testing. Both audits gave an acceptable
mark on this, but I would want to see what records were accessed.

- Neither audit questions the lack of a CCP (Critical Control Point)
designated in the HACCP plan.

- Neither plant audit was performed during the clean-up of the operation (a
pre-operational inspection would reveal cleaning practices and how the
plant looked prior to start-up).

- One audit was clearly an announced audit and the other was probably
announced. This allows the plant to be in better-than-normal conditions
during the audit.

The questions I have are the same ones manufactures who use these audits for
their purchasing specifications should be asking. They need to be more critical of
these audits.

- What are the credentials of the auditor? Are they familiar with the type of
processing operation they are auditing?

- How intensive is this audit? What records were reviewed, how much time
did the auditor spend on the floor evaluating cleaning, traffic, actual
practices, etc.? And what observations were made?

- Did they take evaluate all of the potential risks associated with that type
of operation and the type of product they make in performing the audit?

- What are the actual conditions when no comments are made for a line item
on the checklist? Even acceptable grades should indicate how this grade
was achieved, and the records or observations that were made to justify
the comment.

- Manufacturers requiring this audit need to evaluate the independence of
these audit. When a manufacturer can choose the auditor and pay for their
services, who does that auditor really work for?

- Manufacturers requiring this particular score on the audit need to
understand that the score of an audit can be skewed, perhaps
overshadowing food-safety related items. For instance, cross-
contamination is especially critical for ready-to-eat foods where no further
processing is required. Traffic patterns, air flows, dirty floors and
equipment in the food processing areas should send up a red flag.

- When a manufacturer is buying ready-to-eat items, they need to evaluate
such products and determine if product testing is needed before use.
Guidance for Industry

**VOLUNTARY THIRD-PARTY CERTIFICATION PROGRAMS FOR FOODS AND FEEDS**

Additional copies of this guidance are available on the Internet at http://www.fda.gov/oc/guidance/thirdpartycert.html or http://www.regulations.gov or from the Office of Policy, (HF-11), 5600 Fishers Lane, rm. 14-101, Rockville, MD 20857-1448, or by calling 301-827-3360.

For questions on the content of this guidance, contact the Office of Policy and Planning at 301-827-3360.

United States Department of Health and Human Services
Food and Drug Administration
Office of Policy
December 2008
Contains Nonbinding Recommendations

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Guidance for Industry

VOLUNTARY THIRD-PARTY CERTIFICATION PROGRAMS FOR FOODS AND FEEDS

This guidance represents the Food and Drug Administration's (FDA's) current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. You can use an alternative approach if the approach satisfies the requirements of the applicable statutes and regulations. If you want to discuss an alternative approach, contact the appropriate FDA staff. If you cannot identify the appropriate FDA staff, call the appropriate number listed on the title page of this guidance.

I. INTRODUCTION

This document is intended to provide guidance about voluntary third-party certification programs for foods and animal feeds (hereinafter foods). An increasing number of establishments that sell foods to the public, such as retailers and food service providers, are independently requesting, as a condition of doing business, that their suppliers, both foreign and domestic, become certified as meeting safety (as well as other) standards. In addition, domestic and foreign suppliers (such as producers, co-manufacturers, or re-packers) are increasingly looking to third-party certification programs to assist them in meeting U.S. regulatory requirements. The Federal government supports voluntary certification programs as one way to help ensure products meet U.S. safety and security standards and to allow Federal agencies to target their resources more effectively.

This guidance is intended as one of the steps in FDA’s future recognition of one or more voluntary third-party certification programs for particular product types. It describes the general attributes FDA believes a certification program should have to provide quality verification of product safety. If FDA has confidence in a certification program, we may choose to recognize the program. Recognition does not make the certification body an agent of FDA or grant the certification body any regulatory or enforcement authority. Rather, recognition in this context means only that FDA has determined that certification may be a reliable reflection that the foods from an establishment certified by that certification body meet applicable FDA requirements, as well as other certification criteria. We recognize that there are many established third-party certification programs designed for various reasons that are currently being used by industry. We anticipate that some of those programs that focus on food safety will be eligible for recognition as FDA moves forward in this area, either in their present form or with program modifications. Recognition of existing programs may lessen the need for establishments to be subject to audits from multiple certification bodies in the future.
FDA may provide greater detail about recognition in future guidance documents pertaining to particular product areas. Such guidance documents would contain recommendations for product-specific criteria against which a certification body would audit. In addition, such a future guidance may provide incentives for food establishments to obtain certification by recognized certification programs for particular categories of products. Participation in certification programs would be voluntary, and the fact as to whether an establishment participates would not affect the establishment’s rights or obligations. Participation may, however, be beneficial. For example, FDA may take into consideration an establishment’s product-specific certification by a recognized certification body when determining our establishment inspection priorities, as well as our entry admissibility decisions and field exam and sampling priorities. We may also take certification into consideration when determining “may proceed” rates for imported products, which may result in expediting entry for certain product types from particular establishments. Moreover, we may publicly acknowledge certified establishments by developing a publicly accessible database. Certification may also be useful during a foodborne illness outbreak. Establishments that are certified and have effective product tracing systems in place may be more easily and quickly investigated to be excluded by FDA. In addition to these types of benefits, voluntary third certification could be used in other ways. For example, in appropriate circumstances we may take such certification into account when considering requests by establishments to have their products removed from an FDA Import Alert that is for Detention Without Physical Examination (DWPE).

While FDA may provide incentives for participation, neither establishments nor certifying bodies are under an obligation to participate. FDA does not intend to target uncertified establishments or products for inspection or sampling, for example, based solely on their lack of certification.

FDA’s guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe FDA’s current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word should in FDA’s guidances means that something is suggested or recommended, but not required.

II. BACKGROUND

Ensuring the safety and security of food products is a shared responsibility between the public and private sectors. FDA has the authority to establish regulatory standards, inspect facilities, and take action if there are violations, but industry has the primary responsibility to ensure that

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1 The “may proceed” rate means the rate of import entries entered into domestic commerce after electronic review, but without FDA staff review of the entry, including physical examination or sampling. FDA sets this rate based on various considerations, such as product risk and the demonstrated degree of compliance of the commodity/establishment/country.

2 Nothing in this guidance, or any potential future recognition of a particular certification program, would restrict FDA from conducting its own inspections or taking regulatory action, nor would it affect the legal responsibilities of establishments. Moreover, FDA typically would not provide these types of incentives if it had information that a problem existed in a certified establishment.
food products intended for human and animal consumption in the United States are safe and meet applicable FDA requirements. Certification programs can help industry fulfill its responsibility by providing an independent evaluation of an establishment’s food safety system and, if a problem is discovered, by providing information that can help a firm to fix the problem. This document is intended to support the process for FDA’s recognition of one or more third-party certification programs and builds upon the following actions.

**A. Interagency Working Group on Import Safety and Food Protection Plan**

On July 18, 2007, the President issued Executive Order 13439 to establish the Interagency Working Group on Import Safety (hereinafter referred to as the “Working Group”). On November 6, 2007, the Working Group released an “Action Plan for Import Safety: A Roadmap for Continual Improvement” (Action Plan) (http://www.importsafety.gov/report/actionplan.pdf). The Action Plan contains 14 broad recommendations and 50 specific short- and long-term action steps to better protect consumers and enhance the safety of the increasing volume of imports entering the United States. The Action Plan stresses the importance of the private sector’s responsibility for the safety of its products and the importance of ongoing private-sector mechanisms and experience as a basis for ongoing, substantive public-private collaboration. The public and private sectors have a shared interest in import safety, and substantive improvement will require the careful collaboration of the entire importing community.

Recommendation 2 of the Action Plan is to “verify compliance of foreign producers with U.S. safety and security standards through certification.” Third-party certification programs can augment ability of the Federal government and the importing community to help ensure that products imported into the United States meet Federal safety and security standards. The Action Plan states “[f]or foreign producers, the ability to participate in voluntary certification programs could allow products from establishments that comply with U.S. safety and security standards to enter the United States more quickly. This would facilitate trade, while allowing Federal departments and agencies to focus their resources on products from non-certified establishments or for which information suggests there may be safety or security concerns. This would allow Federal departments and agencies to more effectively target their resources.” Action Steps 2.2 and 2.4 of the Action Plan call for the development of voluntary third-party certification programs, based on risk, for foreign producers of certain products who export to the United States, and the creation of incentives for foreign establishments to participate in voluntary certification programs, and for importers to purchase only from certified establishments.

In conjunction with the Action Plan, on November 6, 2007, FDA released our Food Protection Plan (hereinafter referred to as the “FPP”), a comprehensive strategy designed to bolster efforts to better protect the Nation's food supply (http://www.fda.gov/oc/initiatives/advance/food/plan.html). The FPP emphasizes certification as a way to help verify the safety of products from a growing food establishment inventory, both domestic and foreign.

**B. Federal Register Notice Requesting Comment on Third-Party Certification Programs for Foods and Feeds**
On April 2, 2008, FDA issued a Federal Register notice requesting comments on the use of third-party certification programs for foods and animal feeds. [Federal Register Vol. 73 No. 64 pg. 17989 (April 2, 2008)] In addition to general information about existing programs, we asked four specific questions:

1. What domestic and foreign third-party certification programs for suppliers are currently in use by U.S. companies?

2. Do the current third-party certification programs ensure compliance with FDA requirements?

3. What are the obstacles to private sector participation in these third-party certification programs?

4. What incentives would increase participation in these third-party certification programs?

FDA received approximately 70 comments in response to that notice. Many of the comments note that U.S. suppliers currently use various third-party certification programs in part because of customer demand. The certification programs audit to the required criteria, which vary by product and client. The audits include both a document review and an on-site visit. Several comments provide details on criteria that the establishment must meet to receive certification. There is extensive support for certification programs that audit to determine compliance with internationally recognized criteria. Compliance with these criteria may include conduct or actions that exceed requirements under applicable U.S. law. Procedures to prevent conflicts of interest are also discussed. A few comments also address how governments interface with or recognize these certification bodies.

Many comments state that FDA’s recognition of third-party programs will encourage expanded, voluntary participation. The comments vary on whether we should make modifications to the existing programs. Certain obstacles to participation are mentioned, most notably the added costs of the certification process, especially for small businesses, and the redundancy created by suppliers requiring different criteria. Most comments agree that expedited treatment at ports of entry, making the names of certified establishments publicly available, and FDA’s consideration of certification as one factor in determining inspection priorities will encourage participation. Additionally, several comments express a desire for a set of criteria to reduce redundancy.

III. DEFINITIONS

For the purposes of this document, the following definitions apply:

A. Accreditation means an attestation related to a certification body (but not by the certification body itself) conveying formal demonstration of its competence to carry out specific certification tasks.

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3 The definitions in this guidance are generally consistent with accepted international definitions, such as those used in documents by the International Organization for Standardization (ISO) and the Codex Alimentarius Commission (Codex).
B. *Accreditation body* means an authoritative body that performs accreditation.

C. *Attributes* mean the characteristics of a certification body that FDA intends to consider when evaluating whether its certifications are a reliable reflection that food from establishments a certification body certifies meets the certification criteria.

D. *Audit* means the systematic and functionally independent examination of a product, process, and establishment, including records and laboratory testing, as appropriate, to determine an establishment's conformance with certification criteria. Audit activities may include a range of activities, such as on-site examinations of establishments, review of records, review of quality assurance systems, and examination or laboratory testing of product samples.

E. *Auditor* means a person acting for the certification body who conducts audits and makes a determination of the degree to which certification criteria have been met by an establishment for a particular product type.

F. *Certification* means the procedure by which a certification body provides assurance that the establishment conforms to certification criteria. Certification should be granted for particular product types produced, manufactured, processed, packed, or held by the establishment. Certification should be, as appropriate, based on a range of audit activities, as discussed in section III.D.

G. *Certification body* means a third-party organization that operates a certification program. A certification body could be a Federal, State, local, or foreign government agency, as well as a non-government entity that is independent of the businesses it certifies and free from conflicts of interest.

H. *Certification criteria* mean those criteria used by the certification body during an audit to determine whether an establishment should receive certification. Certification criteria for the purpose of this document should, at a minimum, include applicable FDA requirements.

I. *Certification program* means a third-party system that verifies, through audits, an establishment's conformance with certification criteria.

J. *Certification program assessment* means a systematic examination by FDA to assess a certification body's conformance with the attributes in this document.

K. *Establishment* means a site-specific domestic or foreign facility that produces, manufactures, processes, packs, or holds food for use, consumption, or further processing in the United States.

L. *Inspection* means the examination of a product, process, or establishment, including records and laboratory testing, by FDA (or another governmental entity acting under our authority, such as a State regulatory authority, with which FDA has a contract, partnership
arrangement, or Memorandum of Understanding (MOU) for the purpose of conducting inspections that pertain to the establishment's compliance status with FDA requirements).

M. **Self-assessment** means a certification body’s systematic assessment to determine whether its activities and related results meet planned objectives (e.g., the attributes in this document).

N. **Third party** means an organization other than the establishment or FDA (or another governmental entity acting under our authority, such as a State regulatory authority, with which FDA has a contract, partnership arrangement, or MOU for the purpose of conducting inspections that pertain to the establishment's compliance status with FDA requirements). A third party could include a Federal, State, local, or foreign government authority that is not conducting inspections under our authority, as well as a private entity.

### IV. CERTIFICATION PROCESS

The certification body should communicate the conditions for granting and maintaining certification, as well as the conditions under which the certification body may withdraw certification.

#### A. Application Process

The certification body should require completion of an official application form, signed by a duly authorized representative of the establishment, which includes the following:

- Name, address, and contact information of the applicant;
- Affirmation that the establishment is registered as required under 21 C.F.R. §1.225 or that the establishment is exempt under 21 C.F.R. §1.226;
- List of product market forms, packaging, and processes used by the establishment for the product types to be certified;
- Name, address, and unique facility (establishment) identification code, if applicable, of the site-specific establishment(s) to be certified for a particular food product it produces, manufactures, processes, packs, or holds;
- Statement regarding its regulatory standing that includes whether:
  - An FDA warning letter has been issued to the establishment and, if one has been issued, whether FDA has concluded that the conditions that resulted in the warning letter have been satisfactorily addressed;
  - An FDA legal action has been filed in court against the establishment or its products, such as an injunction, seizure, or prosecution, under any of the laws or regulations administered by FDA, and if one has been filed, whether FDA has concluded that the conditions that resulted in the legal action have been satisfactorily addressed;
  - The establishment or any of its officers or employees is not being prosecuted and has not been convicted of a crime relating to FDA regulatory requirements;
Contains Nonbinding Recommendations

- The establishment had been inspected by FDA or by another U.S. or international governmental entity, such as a State regulatory authority and, if it had been so inspected, the date of the inspection and whether the inspection resulted in an adverse classification, such as Official Action Indicated (OAI), and if there was such a finding, whether corrective actions successfully resolved the observed violations or deviations.
- The establishment or its products are subject to an FDA Import Alert;
  - Statement that the applicant agrees to comply with the terms established by the certification body, including the certification criteria, and to supply any information needed for the evaluation of the establishment and processes to be certified.

B. Certification

The certification body should review the application to confirm that the establishment has provided all requested information and should determine if any regulatory issues have not been resolved. This includes supplying the certification body with documents requested in conformance with this guidance document, such as copies of FDA inspection reports and previous certification audit reports. Upon satisfactory completion of the application and review by the certification body, an auditor acting for the certification body should then perform an audit of the establishment and records, consistent with the elements set forth in section V.C. below. Certification should not be granted if the establishment unduly delays, limits, or denies the certification body or any auditors acting on its behalf, access to the establishment, processes, product types, or records needed to verify conformance with certification criteria. A decision on certification should be specific to an establishment and processes for particular product types. It should be possible for an establishment to be certified for processes for a particular product type and not for other product types.

The establishment should promptly notify the certification body of any intended significant changes to the safety systems the establishment has in place or any other changes or occurrences that may affect product safety or certification. In addition the establishment should notify the certification body of any new conditions that would cause certification to be withdrawn, as described below in section IV.D.

C. Recertification

The purpose of recertification is to confirm the establishment’s continued conformity with the certification criteria. The frequency of recertification may vary depending on the risks posed by the establishment and the processes used. The frequency of recertification should ensure that establishments associated with greater risk are recertified more frequently. Risk factors include those associated directly with the establishment itself, including its compliance history and its internal auditing procedures, as well as the inherent risks associated with the processes and product types for which certification is sought and the processes used to produce, manufacture, process, pack, or hold those products. In general, recertification should occur at least once every two years for most products. Higher risk product types, processes, or establishments should be audited at least annually. FDA may provide further guidance on the frequency of recertification when recognizing certification programs in particular product areas.
D. Withdrawing Certification

The certification body should have an established, clearly articulated procedure for withdrawing certification. Withdrawing certification should be considered under the following circumstances:

- The auditor determines that there are significant deviations from one or more certification criteria, and the establishment fails to address the deficiencies in a timely and acceptable manner (see section V.E., below).
- The establishment unduly delays, limits, or denies the certification body, or any auditors acting on its behalf, access to the establishment, products, or records needed to verify compliance with certification criteria.
- The certification body discovers that the establishment, or any of its officers or employees, engages in any fraudulent acts related to FDA regulatory requirements, as well as providing false information to the certification body or any auditors acting on its behalf.
- The certification body discovers that the statement regarding the establishment’s regulatory standing made in section IV.A. above has changed (e.g., a warning letter has been issued, an OAI classification has been made, an Import Alert has been issued, etc.)

The certification body should immediately notify FDA if certification has been withdrawn, as well as the basis for withdrawal (see section V.J. below).

V. ATTRIBUTES FOR THIRD-PARTY CERTIFICATION PROGRAMS

FDA would need sufficient confidence in the credibility of the certification program in order to recognize such a program. More specifically, we would need to have confidence in the quality of the audits performed and the validity of the decisions made by the certification bodies and their auditors. Therefore, we have identified the following general attributes that are intended to provide a model that might be tailored for particular categories of products and incorporated by FDA as we develop programs to recognize third-party certification programs for those product types. These attributes incorporate a comprehensive self-assessment by the certification body of its performance in relation to these attributes to encourage continuous improvement and innovation. FDA may perform a certification program assessment to determine a certification body’s level of conformance to these attributes prior to recognition and periodically thereafter.

It is expected that the certification body would fully cooperate with FDA during such a certification program assessment, which could include access to the certification body’s documents and records relevant to its conformance with these attributes. The certification program assessment may also include observing on-site audits, in which case it is expected that the certification body would cooperate in arranging such on-site audits for FDA to observe.

To facilitate an FDA assessment, the certification body could seek accreditation from an accreditation body that is operating in accordance with the International Organization for Standardization (ISO) standard ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. Such accreditation can provide an additional assurance that the certification body is reliable.
A. **Authority of the Certification Body**

A certification body should enter into a contract or other arrangement with an establishment that grants the certifying body authority to ensure that the establishments and processes they are hired to certify meet the certification criteria. All certification contracts entered into between a certification body and an establishment should include the following authorities.

1. **Authority to Perform Audit Activities**

The certification body and its auditors should have access to the establishment for the purpose of auditing the production, manufacturing, processing, packing, and holding of product for which certification is sought. The certification body should communicate its audit plan in advance with the establishment and the dates of the initial audit and recertification audits should be agreed upon. Nevertheless, the certification body should have the right to perform unannounced audits, as appropriate. The scope of access may be determined by the types of products and processes for which certification is sought. For example, if the establishment is seeking certification for all product types being produced, manufactured, processed, packed, or held there, then the certification body and the auditor should have access to aspects relating to the safety of all those product types, including incoming materials, all aspects of production, manufacturing, processing, packing, or holding, and records relating to compliance with certification criteria. If, however, the establishment is only seeking certification for a subset of product types, access may be more limited.

2. **Authority to Examine and Gather Records and Other Information**

The certification body and its auditors should be able to examine records and other information relevant to the safety of the product types for which certification is sought. This should include access to relevant records relating to the production, manufacturing, processing, packing, and holding of product types for which certification is sought, including, but not limited to, receiving records, preventive control plans and records, laboratory results, records regarding the upkeep and use of equipment, consumer complaint files, and supply chain records.

3. **Authority to Collect and Analyze Samples**

The certification body and auditors should have authority to collect and analyze samples as appropriate. These samples should be collected and analyzed in a manner that is consistent with the other aspects of this document, including the use of laboratories, as discussed in section V.I. below. In the future, additional guidance regarding sampling and laboratory testing may be provided as FDA recognizes third-party certification programs in particular product areas.

4. **Authority to Assess and Report on Compliance with Certification Criteria**

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4 This is consistent with section 9.1.8 in ISO/IEC 17021:2006, *Conformity assessment – Requirements for bodies providing audit and certification of management systems.*
Certification bodies should have the authority to determine whether to certify, recertify, or withdraw certification based upon information gathered. This includes the authority to determine if the establishment has appropriately addressed problems or deficiencies identified by the certifying body or its auditors. Moreover, they should also have authority to provide information to FDA in accordance with this guidance. Such information should also be available to FDA when requested to perform a certification program assessment.

B. Qualifications and Training for Auditors

All auditors should understand the food safety issues related to the processes and products that they audit. This should include knowledge and understanding of current certification criteria (including FDA regulations) and a process to help ensure that this knowledge and understanding are kept up to date.

In order to assist certifying bodies in preparing for future recognition of third-party certification programs, FDA makes the following general recommendations for certification bodies and their auditors. However, FDA recognizes the need for flexibility in auditor qualifications, as well as the importance of prior auditing experience.

FDA recommends that all auditors acting for a certification body meet or exceed the minimum educational requirements applicable to FDA Consumer Safety Officers (CSOs) who perform inspections on behalf of the agency. Therefore, we recommend that the auditors have at least:

- A full course of study at an accredited college or university leading to a bachelor's or higher degree, including 30 semester hours in one or a combination of biological sciences, chemistry, pharmacy, physical sciences, food technology, nutrition, medical science, engineering, epidemiology, veterinary medical science, or related scientific fields that provide knowledge directly related to consumer safety officer work.

or

- 30 semester hours of course work as described above, plus appropriate experience or additional education. The required 30 semester hours can include up to eight semester hours in statistics or course work that includes the principles, theory, or practical application of computers or computer programming.

See [http://www.fda.gov/jobs/cso.htm](http://www.fda.gov/jobs/cso.htm).

In addition, the certification body should have a training plan that ensures that all auditors receive the necessary training to adequately perform their work assignments. The training plan should provide for basic and advanced audit training, as well as continued training for
professional development. As FDA recognizes third-party certification programs, we may recommend qualifications and training that are tailored to particular product areas.

1. Coursework

Training and qualifications may vary depending on the processes and product areas being audited. Each auditor should demonstrate competency in the areas pertaining to the processes and product areas that they are auditing. These may include all or some of the following areas:

- Certification criteria
- Public health principles
- Risk assessment
- Manufacturing techniques and technologies
- Proper audit procedures
- Proper sample collection procedures
- Product Tracing
- Product security awareness
- Communications skills
- Basics of Hazard Analysis and Critical Control Point (HACCP) or other preventive control systems
- Basics of consumer product labeling
- Sanitation and Good Manufacturing Practices
- Microbiology
- Epidemiology
- Control of allergens and food intolerances
- Ethics and conflicts of interest

It may also be beneficial for auditors to complete more advanced audit training through coursework or other means that are related to specific processes and product areas that an auditor will audit, e.g., seafood HACCP and seafood safety, low acid canned food safety, etc. While coursework is recommended, FDA recognizes that, in certain instances, experience may provide adequate competency.

2. Field Training

The certification body should ensure that each auditor receives field training and is evaluated by a qualified and experienced trainer in the field that can ensure competency in the above areas, as applicable. To accomplish this, FDA recommends that each auditor perform a minimum of five joint audits with a qualified and experienced trainer. Joint audits should be conducted in

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5 This training standard is based on our experience training FDA inspectors and is consistent with the standard we use for our state inspection program. See http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gdl0002-voll.pdf

6 The term "product tracing" generally refers to the ability to track a product and its ingredients or components through the supply chain.
establishments that are representative of the establishments in the certification program’s establishment inventory. At least two of those joint audits should be evaluations during which a qualified, experienced trainer observes the candidate conducting an audit without assistance. The auditor’s performance should be rated acceptable in those evaluations. Each auditor should complete, or be able to demonstrate by prior experience, the minimum field training requirements before conducting independent audits.

Each auditor should also complete more advanced field training in his or her specialized areas, if applicable, such as seafood HACCP. Such advanced training should include three joint audits with a qualified trainer. At least two of those joint audits should be evaluations of the auditors. The auditor’s performance should be rated acceptable in those evaluations. The joint audits should be conducted in establishments that are representative of the specialty area.

3. Continuing Education

Each auditor should also participate in continuing education that includes coursework and joint audits to keep the auditor’s knowledge current. At least every 36-month interval, each auditor should participate in a minimum of 36 hours of classroom training and participate in at least two joint audits with a qualified trainer. These joint audits are intended to help the auditor apply what was learned in the classroom to what should be covered during an audit.

C. Elements of an Effective Audit Program

The certification body should ensure that its auditors are consistently meeting established standards for a high quality audit, as well as consistently auditing for conformance with certification criteria when auditing an establishment. The audit program should contain the following elements:

1. Risk-Based

Audits should be performed using a risk-based approach. With respect to the certification process, this means that the auditor should focus the most attention on the elements of the production, manufacturing, processing, packing, and holding that pose the greatest risk to human and/or animal health. An auditor may consider an establishment’s internal auditing practices when determining the level of scrutiny to apply. FDA may provide further guidance on risk prioritization when recognizing certification programs in particular product areas.

2. Written Policies and Procedures

The certification body should have written policies and procedures describing the protocol to be used by all auditors during an audit. These procedures should include, but are not limited to:

- Reviewing the certification body’s own previous certification audit reports (at least the previous report and all other reports done in the last year) relating to food safety
Contains Nonbinding Recommendations

• Inquiring as to whether FDA or another U.S. or international governmental entity, such as a State regulatory authority, has inspected the establishment and examining the resulting inspection report relating to food safety

• Inquiring as to whether another third-party recognized by FDA has audited the establishment and examining the resulting report relating to food safety

• Inquiring as to whether the statements made in section IV.A. above are up to date

• Reviewing internal establishment audits and consumer complaints relating to food safety

• Having appropriate equipment and forms needed to conduct audits

• Verifying that the establishment's employees have the appropriate educational background and training relating to food safety

• Assessing conditions and practices critical to the safe and sanitary production, manufacturing, processing, packing, and holding of the products

• Properly evaluating the likelihood that incoming materials, conditions, practices, ingredients or components, and/or labeling could cause the product to be unsafe or not meet applicable FDA requirements

• Recognizing significant, violative conditions or practices relating to food safety, if present, and recording findings

• Distinguishing between significant and insignificant observations relating to food safety, and isolated incidents versus trends

• Reviewing and evaluating appropriate records and procedures relating to food safety for the establishment's operations and effectively applying the information obtained from this review during the audit

• Collecting adequate information and documentation to support audit observations and certification relating to food safety

• Collecting representative samples, as appropriate, using sampling techniques that prevent contamination of the product and ensure that a representative sample is collected

• Verifying the correction of deficiencies identified during the previous audit;

• Behaving professionally during the audit

• Demonstrating proper sanitary practices during the audit

• Making appropriate introductions, presenting proper identification upon arrival at the establishment, and explaining the purpose and scope of the audit

• Using suitable interviewing techniques

• Explaining findings clearly and adequately throughout the audit

• Alerting the establishment's person in charge when an immediate corrective action relating to food safety is necessary

• Answering questions and providing information in an appropriate manner

• Documenting findings relating to food safety accurately, clearly, and concisely, and providing a copy to the establishment's person in charge

• Requesting assistance for complex technical issues beyond the ability of the auditor

• Dealing effectively with obstacles to the audit or adversarial situations.

3. Verification That the Establishment Meets Certification Criteria

The audit should provide the certification body with reasonable assurance that the establishment produces, manufactures, processes, packs, or holds foods that are safe and in compliance with
certification criteria. The auditor should have access to the relevant parts of the establishment, processes, and product types, and records relating to food safety in order to make this determination. As FDA recognizes third-party certification programs in particular product areas, FDA plans to provide additional guidance on specific certification criteria for those product areas.

4. Establishment Complaints about Audits

The certification body should have a system to resolve complaints from establishments about audits. This system should include providing contact information, as well as written procedures for receiving, evaluating, answering, and maintaining records of establishment complaints about audits.

5. Documentation and Recordkeeping

The certification body should retain the documentation for all audit findings. Documentation should include, but is not limited to, an audit report, auditor notes, laboratory testing records and results, correspondence with the establishment, as well as follow-up documentation regarding corrective actions taken to address deficiencies that affect certification (i.e., demonstrating whether the corrective action was effectively executed to remedy the problem). The certification body should keep these records for at least three years.  

D. Quality Assurance Program for Audits and Auditors

The certification body should implement a quality assurance program (QAP) that monitors its auditors (including subcontractors), audits, and sample collection processes for consistency and competency, to identify areas that need improvement, and to quickly execute appropriate corrective actions when problems are found. The QAP should include the following components:

1. Field Evaluation

The certification body should conduct a field evaluation of audits done on its behalf to verify that audits are consistently performed according to its established policies and procedures. Two field evaluations of audits performed by each auditor should be conducted every 36 months.  

2. Audit Report Evaluation

The certification body should perform periodic reviews of audit reports to verify that audit findings are obtained and reported according to its established procedures and policies.

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7 This records maintenance requirement is based on the standard we use for our state inspection program. See http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gd0002-v01.pdf.

8 We have based this frequency rate on the standard we use for our state inspection program. See http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gd0002-v01.pdf.
3. Sample Report Evaluation

The certification body should perform periodic reviews of sample reports to verify that samples were properly collected, identified, and submitted according to established procedures and policies and that appropriate information was recorded.

4. Individual Auditor Performance

If, during a self-assessment (see section V.H. below), the certification body determines that an auditor is not performing adequately, the certification body should not authorize the auditor to conduct additional audits until such time as the auditor has received sufficient training and an acceptable re-evaluation. It may be appropriate for the certification body to re-evaluate audits that the auditor has performed.

E. Compliance and Corrective Action

The certification body should have strategies, procedures, and actions to ensure that the establishments and processes for particular product types it certifies comply with FDA requirements and otherwise meet certification criteria. The certification body should take appropriate steps when there is non-compliance. More specifically, the certification body should:

- Use a risk-based system to determine when an investigation, follow-up, or re-audit is needed;
- Evaluate whether the establishment has executed corrective actions that resolve the deviations that would affect certification in a timely and acceptable manner; and
- Withdraw certification if the establishment fails to take corrective actions to address deficiencies that would affect certification in a timely and acceptable manner (see section IV.D. above.).

In addition to notifying FDA consistent with section V.J. below, the certification body should immediately notify the establishment if an auditor finds or discovers a situation in which there is a reasonable probability that the use of, or exposure to, food or feed produced, manufactured, processed, packed, or held in that establishment will cause serious adverse health consequences or death to humans or animals. FDA notes that an establishment that receives this information may be subject to the requirement imposed by section 1005 of the Food and Drug Administration Amendments Act of 2007 to report certain information to FDA via an electronic portal.

F. Industry Relations

At a minimum, the certification body should provide establishments seeking certification with information about current FDA requirements and guidances. The certification body may also conduct activities that foster communication and information exchange among regulators, industry, academia, and consumer representatives on product safety and security. In addition, the certification body may sponsor or participate in meetings where product safety and security
topics may be discussed or provide the establishments they certify with other educational materials related to product safety and security, such as scientific literature.

G. Resources

The third party certification body should have sufficient resources, such as equipment and infrastructure, etc., to accomplish the elements of the program described in this guidance.

H. Self-Assessment of the Overall Certification Program

The certification body should conduct an initial self-assessment to assess its performance in relation to the attributes in this document, including identification of the strengths and weaknesses of the program. Subsequent self-assessments should be done at least every 36 months thereafter and after any significant changes to the certification program, including any changes to the certification criteria used by the certification body.9 After each self-assessment, the certification body should develop an improvement plan based on analysis of the self-assessment and a timeline for implementing improvements. Subsequent self-assessments should be used to track progress toward meeting and maintaining conformance with these attributes. The certification body should maintain records sufficient to document the results of all self-assessments, improvement plans, and verification audits. Such records should be maintained for at least three years.10 Consistent with section V.J. below, FDA should be notified of significant changes to the certification program.

I. Laboratories

The certification body should have access to the laboratory services needed to support the audit program functions and document these laboratory services, including those obtained through agreements with external laboratories. These laboratories should be capable of analyzing a variety of appropriate samples, using widely recognized methods, for assessing the compliance of establishments with applicable certification criteria, including product and environmental samples. The certification body should maintain a record of tests conducted, as well as a record of the results of the testing.

The certification body should have a contract or written agreement with its servicing laboratories. The laboratories, whether internal or external, should be accredited, and the accreditation should be issued by an accreditation body operating in accordance with the ISO standard ISO/IEC 17011:2004, Conformity assessment – General requirements for accreditation bodies accrediting conformity assessment bodies. The accreditation body should be a signatory to the International Laboratory Accreditation (ILAC) Mutual Recognition Arrangement. This will help ensure that all laboratories that are accredited by the accreditation body comply with

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9 This frequency rate is consistent with the standard we use for our state inspection program. See http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gdl0002-vol1.pdf
10 This records maintenance standard is the standard we use for our state inspection program. See http://www.fda.gov/ohrms/dockets/dockets/06d0246/06d-0246-gdl0002-vol1.pdf
appropriate laboratory standards and also should result in consistent standards and requirements among accrediting bodies and laboratories regardless of their location.

Laboratories should conform to ISO/IEC 17025:2005, *General requirements for the competence of testing and calibration laboratories*, and should be qualified to use the specific method(s) for testing foods. The methods should demonstrate suitable performance and fit for the intended use. Additionally, we recommend that, where appropriate, laboratories incorporate into their implementation of ISO-IEC 17025 the criteria established in the AOAC International *Guidelines for Laboratories Performing Microbiological and Chemical Analyses of Food and Pharmaceuticals — An Aid to interpretation of ISO/IEC 17025: 2005*. The AOAC document provides a section-by-section interpretation of the ISO/IEC 17025 requirements and following its criteria offers additional assurance that the laboratory’s accreditation includes a sufficient level of detail for the testing being performed and to the laboratory’s implementation of ISO/IEC 17025.

**J. Notification to FDA**

This section outlines the circumstances that warrant notification to FDA, some of which have been mentioned elsewhere in this guidance. While we may elaborate more on notification in future documents that address third-party certification programs in particular product areas, as a general matter the certification body should notify FDA of the following:

1. **Safety Issues**

The certification body should immediately notify FDA if an auditor finds or discovers a situation in which there is a reasonable probability that the use of, or exposure to, food or feed produced, manufactured, processed, packed, or held in that establishment will cause serious adverse health consequences or death to humans or animals. This information may pertain to intentional or unintentional contamination. The certification body should provide detailed information that describes the extent and nature of the problem, as well as the product and its source.

2. **Withdrawing Certification**

The certification body should immediately notify FDA if certification has been withdrawn, as well as of the basis for withdrawal.

3. **Changes to Certification Program**

Once recognized by FDA, the certification body should notify us 60 days prior to any significant change the certification body intends to make in its certification program, including any changes to the certification criteria used by the certification body. The certification body should provide an explanation for the purpose of the change. Some changes may trigger a reassessment of the certification program by FDA and may affect our recognition of the program.
K. Conflict of Interest

The certification body and its auditors should be free from conflicts of interest. The certification body should have a committee or management structure for safeguarding impartiality. Conflict of interest policies for a certification body and auditors acting for the certification body should be written.

1. Criteria

FDA recommends that the following criteria be included in a conflict of interest policy:

- The certification body should not be owned, operated, or controlled by a producer, manufacturer, processor, packer, holder, supplier, or vendor of any article of the type it certifies.
- The certification body should not have any ownership or financial interest in any product, producer, manufacturer, processor, packer, holder, supplier or vendor of the type it certifies.
- No auditor acting for the certification body (or spouse or minor children) should have any significant ownership or other financial interest\(^\text{11}\) regarding any product of the type it certifies. The certification body should maintain records pertaining to the financial interests of the personnel involved in audits.
- Neither the certification body nor any of its auditors acting for the certification body should participate in the production, manufacture, processing, packing, holding, promotion, or sale of any product of the type it certifies.
- Neither the certification body nor any of its auditors should provide consultative services to any producer, manufacturer, processor, packer, or holder, supplier, or vendor of products of the type it certifies.
- No auditors acting for the certification body should participate in an audit of an establishment they were employed by within the last 12 months.
- Fees charged or accepted should not be contingent or based upon the report made by the certification body or any personnel involved in the audit process.
- Neither the certification body nor any of its auditors should accept anything of value from anyone in connection with the establishment being audited other than the audit fee. The term “anything of value” includes, but is not limited to, gifts, gratuities, reimbursement of expenses, entertainment, loans, or any other form of compensation in cash or in kind.
- The certification body should not be owned, operated, or controlled by a trade association whose member companies operate establishments that it certifies.
- The certification body and its auditors should be free from any other conflicts of interest that threaten impartiality.

\(^{11}\) By “significant,” we refer to 5 C.F.R. 5501.104, which allows an FDA employee (or a spouse or minor children) to own certain de minimis holdings in a regulated entity, as well as a financial interest, such as a pension, arising from employment with a regulated entity. While this provision does not apply to certification bodies or their auditors, it provides a basis for defining this term.
2. Signed Statement

The certification body and its auditors should sign a statement attesting to compliance with these conflict of interest criteria. Certification bodies should also ensure that any subcontractors that might be used (laboratories, sampling services, etc.) provide similar assurances.
COMMENTS FROM AIB INTERNATIONAL  
DOCKET # FDA 2008-D-0381  
GUIDANCE FOR INDUSTRY  
VOLUNTARY THIRD PARTY CERTIFICATION PROGRAMS FOR FOODS AND FEEDS

I. Introduction
In July 2008, FDA issued a draft guidance document regarding possible recognition by FDA of one or more voluntary third-party certification programs that should provide quality verification of product safety of food products from domestic and international sources.

AIB International appreciates the opportunity to comment on this thoughtful and thought-provoking document. The establishment of a robust, enforceable and manageable food safety and quality regimen that is global in scope and which minimizes the risk of unintentional and intentional harm to the Nation’s food supply is an ideal to which the food industry, government and the public can all ascribe.

II. AIB International
AIB International has extensive experience and solid credentials in the field of food safety. We began by providing safety education services to the bakery products industry in the late 1940s. The scope of our activities has greatly expanded, driven initially by the development of the AIB GMP inspection and subsequently by the addition of numerous audit schemes. Our focus has grown from the bakery products industry to covering the entire food industry and its suppliers, worldwide. A continuing commitment to food safety education has achieved a leadership position for AIB in this arena.

AIB headquarters are located in Manhattan, Kansas. We maintain offices in London, Mexico and Shanghai. In 2007, we conducted inspections and audits of over 10,000 food establishments; many operated by the world’s leading companies, and located in nearly 80 countries. Presently, our US and Canada business constitutes 75% of our activity. However, the international component is gaining in share and increasingly driving our growth. AIB is committed to continuous improvement. We have recently completed an 18-month process to completely update and revise our consolidated standards for inspection of GMP prerequisite and food safety programs. Inspections against these updated standards will commence, worldwide, in January 2009.

III. Comments on the FDA Draft Guidance for Voluntary Third-Party Certification Programs
The FDA draft guidance document is impressive in its scope and attention to detail. It demands responses that lead to practical solutions and do not simply provide a litany of questions and objections. AIB will provide a possible, or at least partial, solution at the conclusion of this document in Section IV below. Our comments have been guided by considerable dialogue on this matter with our clients before preparing this response and address FDA’s proposal of a “Certification Program” that will act as a “third-party system that verifies, through inspection, an establishment’s conformance with certification criteria”.

We do have concerns regarding the draft guidance. These concerns may be characterized by their centering around two key and connected issues of operability and proportionality. In other words, is it feasible on a voluntary basis for third party inspectors to be certified in the manner described and to be able to perform what has been proposed in the environment of privately owned establishments, especially those operating outside of the jurisdiction of FDA and the United States? Further, is the process whereby establishments can attain certification proportional to the extent of the possible benefit of unsatisfactory food safety program management practices that may be discovered, probably in a small minority of such establishments?
### A. Operability

We have several concerns:

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<thead>
<tr>
<th>Title</th>
<th>Reference</th>
<th>Comment</th>
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<tbody>
<tr>
<td>Certification</td>
<td>IV.B.</td>
<td>Who will be responsible for this activity?</td>
</tr>
<tr>
<td>Recertification</td>
<td>IV.C.</td>
<td>There is a document on recertification frequency being based on risk posed by the audited establishment. Will FDA provide a list of risk factors?</td>
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<tr>
<td>Decertification</td>
<td>IV.D.</td>
<td>There is a statement that if the officers or employees in a company engage in fraudulent acts related to foods, they will be decertified. How will the auditor determine fraudulent acts? There is a comment on conviction of crimes relating to foods by officers, employees, etc. The permissibility of conducting criminal searches is not the same around the world. How would a food safety auditor have the background and knowledge to carry out this type of activity?</td>
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### Authority of the Certification Body

**Authority to Perform Inspection Activities**

- **V.A.1.** There is a statement that the establishment can seek certification for a subset of products. This approach would provide for significant challenge on the part of the auditor in knowing the true flow of the product or process. For example, products could be at a single stage in an area being audited, whereas the principal area of production may not be inspected.

**Authority to Examine and Gather Records and Other Information**

- **V.A.2.** Records that are not currently available to FDA would be included in this audit.

**Authority to Collect and Analyze Samples**

- **V.A.3.** Auditors are not trained in effective sampling techniques, and even if they were trained, there are serious issues to consider in the handling of samples (chain of custody) once they have been gathered. Who would analyze the samples, how would they be transported, etc.

### Qualification and Training for Inspectors

**Coursework**

- **V.B.1.** There is a requirement for eight semester hours of study on statistics or coursework that includes the principles, theory or practical application of computers or computer programming. In the area of Food Safety, this requirement would eliminate a significant number of inspectors for what are non-core skill requirements.
Elements of an Effective Inspection Program

*Written Policies and Procedures*  
V.C.2. There is a comment regarding the review of previous certification inspection reports, internal establishment audits, and consumer complaints and inquiring as to whether a foreign regulatory authority or third-party has inspected the establishment and examining the resulting inspection reports. This would allow competing third party groups to review each other’s audits. Further, it would provide information to FDA that has traditionally been confidential to the establishment.

*Verification that the Establishment Meets Certification Criteria*  
V.C.3. B.iii There is a statement on employee screening. Some countries have strict regulations in this area, prohibiting this type of screening.

*Documentation and Recordkeeping*  
V.C.5. There is a statement that inspector notes, laboratory testing records and results, correspondence with the establishment and follow-up documentation regarding corrective action plans will have to be saved by the certification body with records kept for 3 years. This would become a most onerous requirement.

Notification to FDA

*Safety Issues*  
V.K.1. There is a statement on Notification to FDA – Safety Issues that the certification body should immediately notify FDA if an inspector finds or discovers a situation in which there is a reasonable probability that US consumers may consume or be exposed to a food that could cause serious adverse health consequences or death (SAHCD). The liability that would be assumed by an independent organization such as AIB, in the event of a false call on its part, could be financially crippling.

*Criminal Acts*  
V.K.3. There is a statement on Notification to FDA – Criminal Acts that the certification body should promptly notify FDA if it has information that any of the officers or employees of an establishment has been convicted of crime relating to food or any crime involving false statements, fraud or dishonesty. This would be very difficult to determine and in some country jurisdictions would be most likely be against the law.

Other Comments

Food Defense

We were surprised to note the lack of reference to food defense. FDA in 2007 described the architecture of a Food Protection Plan in which the two key elements were food safety or the prevention of unintentional adulteration of food products and food defense which is the prevention of intentional acts that have the intent of causing harm to the food supply. Both fall within the continuum of prevention, intervention and response separately described by FDA. AIB has taken a leadership role in developing an array of food defense tools for food establishments some of which are educational in nature and others such as vulnerability assessments that play an important role within a food safety management regimen. We believe that any certification program, in particular for food products manufactured outside of the United States, should contain a distinct but integrated food defense component.
Fee Structure

Discussion of possible fee structure for certification bodies, as well as for plants certified and FDA’s position in regards to these matters was clearly out of scope of the draft guidance document. However, this will become a significant issue. The guidance as set forth is expansive and the cost of conducting inspections of the scope described could be burdensome to the establishment concerned. The food industry already considers itself to be over-inspected with numerous audits related to various schemes demanded by its customers and is looking for rationalization, greater standardization and more consistency to reduce duplication and activity considered to be non value-adding.

B. Proportionality

If Wikipedia is to be believed, proportionality may be described as a political maxim which states that any layer of government should not take any action that exceeds that which is necessary to achieve the objective of government.

AIB International is one of several well-respected organizations providing food safety services. Some of these organizations, such as AIB, are managed as 401(C) (3) corporations. Many others are large multinational businesses. Most, if not all, offer their own distinctive food safety services. An excellent example would be AIB and its industry-leading GMP inspection. Most, if not all, provide audits accredited to schemes administered by an independent body, presumably along the lines of what FDA might be envisioning. Examples would be various ISO schemes, GMA-SAFE and the Global Food Safety Initiative (GFSI). GFSI in particular has been attracting much attention in the United States as various large food retailers and some manufacturers have chosen to endorse and adopt it.

In aggregate, the United States food industry and its suppliers, domestically and worldwide, invest an undisclosed annual sum in food safety programs, which is estimated to run into the hundreds of millions of dollars. The decision by the great majority of operators of food establishments to invest in food safety programs, although underpinned by regulatory, customer and legal liability considerations is nonetheless driven electively by the desire to provide high quality, safe food that meets the needs of their various stakeholders, protects their reputations and with the knowledge of so doing, enables their managers to “sleep better at night”.

It is the suggestion of AIB and many of our clients that FDA takes into account this large investment, which constitutes massive and continually updated management programs and data, and in some manner agreeable to all involved parties, utilizes it to meet the goal stated in the Introduction to the draft guidance of “(supporting) voluntary certification programs as a way to help ensure products meet U.S. safety and security standards and allow Federal agencies to more effectively target their resources.” (Italics added.)

IV. First Steps and Possible Solution

Following from III B. Proportionality above, we suggest FDA explores a pragmatic and non-regulatory approach to third party certification that is far more likely to succeed when operating on the proposed voluntary basis. This approach, once the design and comment phases have been completed and industry buy-in achieved within a specified time frame, would require significantly fewer resources from FDA to administer and from industry to comply and should provide an effective measuring and monitoring mechanism of food safety practices in establishments supplying the United States food industry.
The suggested approach is as follows:

- FDA accepts certain food safety inspection programs and audit schemes and their reports
- FDA accepts certain third party food safety inspection and audit organizations
- FDA would oversee third party organization; audit organization; and administer either theirs or accepted standards and schemes
- Domestic and international food establishments would voluntarily share with FDA either entire third party reports (unlikely) or excerpted reports that meet FDA requirements and which would contain an evaluation/score/placement as well as information on corrective actions required
- FDA would determine which establishments require follow-up or further action, reduced surveillance or increased surveillance. Increased surveillance would require an additional overlay to the process briefly described here

It is the belief of AIB International that by effectively leveraging a food safety management infrastructure that is already in place and by FDA offering concomitant benefits to participating companies, such a voluntary program would receive immediate acceptance from the food industry. Food companies may well consider that a voluntary program with FDA would, in many instances, beneficially augment supplier approval programs that are already in place. The industry fully understands that strengthening the quality of supply chain management and reducing risk through working closely with Government is to everyone’s advantage. After all, when food safety problems occur in the marketplace, and notwithstanding the suffering of the victims, it is the manufacturers who bear the legal, financial and possible regulatory consequences.

Respectfully submitted,

AIB International
September 8, 2008
Sheryl A. Marcouiller
Chief Counsel, Food Law

September 8, 2008
Division of Dockets Management
Food and Drug Administration
3650 Fishers Lane, Rm. 1061
Rockville, MD 20852

Re: Docket No. FDA-2008-D-0381
Draft Guidance for Industry
Voluntary Third party Certification Programs for Foods and Feeds

Dear Sir or Madam:

With annual revenues of more than $37 billion, Kraft Foods is one of the largest food and beverage companies in the world. Consumers have trusted our delicious, wholesome foods for over 100 years. The company markets a broad portfolio of iconic brands in 155 countries, including Kraft and Philadelphia brand cheeses, Kraft dinners and dressings, Maxwell House coffees, Jell-O desserts, DiGiorno pizza, Nabisco cookies and crackers, and Oscar Mayer meat and poultry products. The safety of these products is the essential foundation upon which the success of our business is built, so food safety is of paramount importance to Kraft.

Although food safety is primarily the food industry’s responsibility, a strong and adequately funded Food and Drug Administration (FDA) is necessary to ensure consistent compliance with regulatory requirements and to bolster consumer confidence in the safety of foods sold in the United States, whether produced domestically or internationally. That is why Kraft supports increasing resources for FDA through the appropriations process.

The draft “Guidance for Industry on Voluntary Third Party Certification Programs for Foods and Feeds” (draft program or guidance) attempts to stretch FDA resources by turning privately funded auditors into pseudo government inspectors. In doing so, the draft program would create an unnecessary new certification bureaucracy that not only seems unlikely to improve the agency’s enforcement capability but could actually degrade the existing food safety infrastructure. In short, FDA resources are too scarce to be diverted to the task of constructing a certification bureaucracy that would duplicate the work of existing competent professional organizations like the International Standards Organization (ISO) and the American National Standards Institute (ANSI).

Government inspectors and privately funded auditors play fundamentally different roles. Only the government has the power to bring enforcement actions after judging whether industry has satisfied minimally acceptable requirements. In contrast, industry uses privately funded auditors on a confidential basis to evaluate systems critically and comprehensively so the audited
company can find and fix potential food safety gaps and continually improve production systems. If those roles are intertwined or confused, as the draft guidance directs, two things seem predictable to us. The overall food safety system will be less efficient and reliable, and FDA will expend a great deal of resources creating an elaborate certification program that industry will elect not to use, at least for purposes of driving improvements in food safety.

Instead of the approach in the draft guidance, Kraft recommends that FDA work directly with state and foreign government agencies, focus on updating the Good Manufacturing Practices rules, and increase the agency’s capacity to evaluate information industry provides voluntarily, including information about audits conducted using internationally accepted standards and guidelines. If FDA continues on the path of adopting a formal certification program intended to provide a benefit to the company audited, rulemaking will be necessary. Our reasons for reaching these conclusions are explained below, along with a few comments on specific elements of the draft guidance.

**FDA’s Conceptual Approach to Third party Certification Programs**

**The Respective Roles of Industry and Government Should Remain Distinct**

In the Background section of the draft guidance, the agency explains as follow:

> Ensuring the safety and security of food products is a shared responsibility between the public and private sectors. FDA has authority to establish regulatory standards, inspect facilities, and take action if there are violations, but it is primarily the responsibility of industry to ensure that food products intended for human and animal consumption in the United States are safe and meet applicable FDA requirements. Certification programs can help ensure that these products are safe by verifying compliance with safety and security standards.

Kraft agrees that a strong partnership between industry and FDA is essential to an effective food safety system. The draft guidance explains the respective roles of industry and government very well. It is industry’s job to produce safe food that complies with applicable regulations. Government’s job is to promulgate regulations, evaluate products and facilities, and initiate regulatory action when necessary.

The draft guidance suggests, however, that FDA intends to use third party certification programs to ensure that companies comply with FDA requirements. It states that “certification may be a reliable reflection that the foods from the establishment a certification body certifies are safe and meet applicable FDA requirements.” Likewise, the draft guidance states that third party certifiers should ensure that establishments and products certified “comply with FDA laws and regulations,” and “take action when there is non-compliance,” and “evaluate the effectiveness of corrective action programs.”
In our view, third party certifiers should not replace FDA inspectors; the agency should not, in effect, delegate its enforcement responsibilities to private entities. Certifying compliance with regulatory requirements is fundamentally a government function, based on inspections by properly trained government officials who are completely independent of the company, product, and facility being inspected. The government is directly accountable to the public; third party auditors are not. Only the government has the power to bring enforcement actions, yet the government always has the authority to consider the entire universe of available information, including whatever information may be provided voluntarily.

Whether operating domestically or internationally, food companies are responsible for producing safe and wholesome food in strict compliance with government regulations. Kraft takes this responsibility very seriously. In addition to employing state of the art science and food safety technology in developing and producing our products, Kraft routinely conducts internal audits of our programs and facilities. We also require our suppliers and their facilities to meet or exceed applicable regulatory requirements as well as Kraft’s standards. Our auditors are selected based on training and experience because they are an integral part of our quality and food safety infrastructure. Whether employed directly by Kraft or by another company, long experience has shown that the identity of the party commissioning the audit does not affect the quality of the work produced, but confidentiality is critical if a company is to find and fix potential food safety gaps and continually improve production systems.

The importance of confidentiality is not recognized in the draft guidance, which contemplates that third party certifiers will provide inspection reports, corrective action reports, and records to FDA. Significantly, the draft guidance also provides that third party certifiers will notify FDA and other relevant agencies inside and outside the U.S. when certain alleged violations of the regulations are noted.

Making a third party certifier a de facto part of FDA’s inspection apparatus will undermine the ability of the auditor and company to work cooperatively to enhance food safety. Once a third party auditor is converted into a government-like inspector with responsibility to report potential problems directly to FDA, the relationship between the auditor and company being audited is fundamentally and irrevocably changed. The incentive to use the auditor to help find problems will be compromised by the loss of confidentiality on which the relationship is based. The result, we have every reason to expect, will be manufacturers limiting their use of privately funded auditors to certifying goods for purposes of expediting trade rather than for identifying improvements that truly strengthen food safety.

Of course, some companies will still want auditors to examine their systems critically. For those companies, the draft program will simply create another system of auditors, essentially one to generate a “clean” report showing that a facility meets minimum requirements for the government alongside the existing confidential system to do the real food safety system improvement work. Besides increasing costs, the inefficiency of multiple audits is a distraction for the production facility that will make it more difficult for personnel to focus on key food safety improvement activities.
FDA Should Not Use Its Limited Resources to Accredit Third Parties

In the draft guidance, FDA states that in the future it may recognize one or more third party certification programs and describes the general attributes a third party certification program should have in order to help ensure its certification is a reliable reflection that the foods from certified establishments are safe and meet applicable FDA requirements. The amount of FDA resources necessary to set up and maintain such a certification system should not be underestimated. It would be highly inefficient for FDA to redirect its limited resources to create a new bureaucracy to accredit third parties.

The private sector has already developed a system for accrediting third party certifiers consistent with well recognized international standards. This accreditation process ensures that the certification body meets certain criteria, including conflicts of interest and auditor competence standards. In the United States, the accreditation body is the American National Standards Institute (ANSI). FDA should not attempt to undermine or supplant the current private sector accreditation system, nor should FDA accredit or certify third party certification programs.

Currently, one facility may be subject to multiple audits covering the same requirements, wasting valuable time and energy and creating a significant burden on companies. Governments and industry both would benefit from more harmonized, publicly available, independent standards or criteria that could be applied by third party certifiers, so long as it also is possible to tailor audits to particular industry segments that present special challenges, such as the processing of dairy products. The most efficient way for FDA to promote appropriate harmonization is to modernize the current Good Manufacturing Practices rules and consider information produced by existing accreditation bodies and third party certifiers that use publicly available criteria or standards to evaluate an establishment’s food safety system.

Elements of FDA’s Proposed Third Party Certification Program

Proposed Certification Program Would Interfere with or Undermine Existing Relationships

As earlier noted, privately funded auditors are an integral part of most existing quality and food safety systems. Several elements of the program FDA is contemplating would interfere with or undermine the value of these existing relationships.

For example, the draft guidance recommends that “the certification body should not be owned, operated, or controlled by a manufacturer, supplier, or vendor of any article of the type it certifies.” Although we recognize that this provision is designed to prevent conflicts of interest, it suggests an FDA bias against internal company auditing teams, raising questions about their independence and, hence, credibility. In our experience, internal audits can be an effective way for a food manufacturer to ensure that all divisions of the company are properly implementing company standards and procedures -- standards and procedures that are often more rigorous than applicable regulatory requirements. From a food safety policy perspective, internal auditing should be encouraged, not denigrated.
The draft guidance states that certification of a facility would not be possible if the establishment had received a warning letter, unless FDA concluded that the conditions that resulted in the warning letter had been satisfactorily addressed. Yet FDA does not usually send a letter concluding that the conditions that led to a warning letter have been satisfactorily addressed. More importantly, if the warning letter pertains to food safety conditions in the establishment, inspection by a third party would be particularly useful and constructive. In short, as currently drafted, the FDA program would curtail the consultative process that enables third party certifiers to help establishments ensure the safety of food.

Perhaps most troubling, as earlier described, is the recommendation in the draft guidance that third party certifiers provide inspection reports, records, and corrective action plans to FDA and notify FDA when certain alleged violations are identified. These provisions would eliminate confidential communications between third party certifiers and establishment personnel. The effect may well be fewer food safety inspections.

Additionally, the draft guidance contemplates an ongoing relationship, different from the typical audit of today, which would require the auditor to retain large volumes of documentation for years and would require the audited company to notify the auditor of changes to safety or security systems. The draft program also contemplates the collection and analysis of samples by auditors, another change to typical relationships existing today. These requirements start to duplicate a company’s own quality and food safety function and go far beyond typical measures taken to assure that audits are robust examinations of operations and systems.

**FDA’s Proposed Third party Certification Program Would Give Too Much Authority to Third Party Certifiers**

In a number of instances, FDA’s draft guidance would give too much authority to third party certifiers. For example, the draft guidance states that the frequency and process used by third party certifiers during inspections should be risk-based. This suggests that third party inspectors would have independent authority to decide the inherent risk posed by a particular product or process in an establishment. It is essential that all establishments be certified to the same standard. Providing third party certifiers with the authority to decide the inherent risk posed by an establishment would create an uneven playing field in the certification process.

In addition, the draft guidance states that contracts between third party certifiers and establishments should give the certification body the authority to access and retain for three years records regarding production and processing, preventive controls, laboratory results, and consumer complaints. Moreover, third party certifiers should provide these records to FDA. Such a contractual provision would grant third party certifiers records access beyond the scope of FDA’s current authority. FDA should not dictate contract terms between third party certifiers and establishments, nor should the agency indirectly broaden its own authority by demanding records through private third parties that it could not ask for of its own accord.
Similarly, Kraft is concerned about the recommendations in the draft guidance that discuss those management systems third party certifiers should ensure establishments have in place. Among other things, the draft guidance notes that establishments should have management systems that address employee training, supplier management, preventive controls, verification, traceability, consumer complaints, recalls, and crisis management. Kraft agrees with FDA that these are important systems for ensuring the safety of foods. At the same time, FDA does not have the authority to require food manufacturers to implement these systems. Therefore, the agency should not require these systems as a condition of third party certification. Additionally, as a practical matter, many companies manage these systems from headquarters locations rather than manufacturing facilities.

FDA Should Consider Initiating Notice and Comment Rulemaking

Although the agency’s proposed third party certification program purports to be merely “voluntary,” the draft guidance contemplates “the creation of incentives . . . to participate in voluntary certification programs and for importers to purchase only from certified establishments.” To the extent those “incentives” will impose obligations on producers who opt not to participate in the voluntary regime—or, conversely, relax existing burdens for competitors that do choose to participate—FDA must engage in notice and comment rulemaking. Under the Administrative Procedure Act, FDA must engage in notice and comment rulemaking before adopting any regime that “grant[s] rights, impose[s] obligations, or produce[s] other significant effects on private interests.” American Hosp. Ass’n v. Bowen, 834 F.2d 1037, 1045 (D.C. Cir. 1987).

The D.C. Circuit squarely resolved this question nearly a decade ago when considering an analogous “voluntary” program. See Chamber of Commerce v. United States Dep’t of Labor, 174 F.3d 206 (D.C. Cir. 1999). The Occupational Safety and Health Administration issued a “Directive” that encouraged certain industries to adopt—on a purely voluntary basis—a set of stringent safety rules. Much like the “incentives” FDA is contemplating, OSHA established its own set of motivations: businesses that joined this voluntary regime were rewarded with fewer safety inspections, while those that did not join ran the risk of more inspections. The D.C. Circuit held that this regime could not be implemented through a mere “Directive,” but required instead formal notice and comment rulemaking. The court emphasized that “the Directive will affect employers’ interests in the same way that a plainly substantive rule mandating a comprehensive safety program would affect their rights.” Id. at 366. Noting that the inquiry for “whether a rule is substantive or procedural . . . is functional, not formal,” the court concluded that “[i]n practical terms, the Directive places the burden of inspection upon those employers that fail to adopt [the voluntary standard], and will have a substantial impact upon all employers within its purview—including those that acquiesce in the agency’s use of ‘leverage’ against them.” Id. As with FDA’s draft guidance, it did not matter that OSHA’s regime was “voluntary” because “the voluntary form of the rule is but a veil for the threat it obscures.” Id. at 374.
Although the draft guidance does not identify the incentives that FDA is contemplating, almost any incentive structure will be “the practical equivalent of a rule that obliges [a company] to comply or to suffer the consequences.” *Id.* Because a program backed by “the creation of incentives . . . to participate in voluntary certification programs” (draft guidance at 3) would significantly affect industry’s interests, if not impose additional obligations as a practical matter, FDA must resort to notice and comment rulemaking if the agency intends to implement a third party certification program.

**Conclusion**

Rather than delegate its regulatory function and commit already scarce resources to the certification of privately funded auditors, FDA can improve the current system by working directly with state and foreign government agencies and updating the Good Manufacturing Practices rules. FDA also has the discretion to consider information produced by existing accreditation bodies and third party certifiers that use publicly available criteria or standards to evaluate an establishment’s food safety system. The fact that the audit occurred and findings were addressed could be provided to FDA voluntarily if the information would help FDA perform an accurate overall assessment of a particular company or set priorities for inspection resources.

Kraft appreciates the agency’s consideration of these comments. We look forward to working with FDA as the agency strives to improve the safety of the food supply.

Respectfully submitted,

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