

## Georgia Department of Audits and Accounts Performance Audit Division

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#### Why we did this review

The purpose of this audit was to review the Department of Agriculture's efforts to ensure a safe food supply by ensuring food processing facilities are adhering to standards. The objectives of the audit were to assess the effectiveness and efficiency with which the food processing inspection unit, within the Food Safety Division, inspects licensed facilities and whether the unit takes appropriate action when problems are identified.

#### Who we are

The Performance Audit Division was established in 1971 to conduct indepth reviews of state programs. The purpose of our reviews is to determine if programs are meeting their goals and objectives; provide measurements of program results and effectiveness; identify other means of meeting goals; evaluate the efficiency of resource allocation; assess compliance with laws and regulations; and provide credible management information to decision-makers.

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#### **Food Processing Inspections**

# The Program should continue planned improvements to monitoring and oversight

#### What we found

The Georgia Department of Agriculture's (DOA) food processing inspection unit is charged with ensuring that the state's 740 licensed food processing facilities comply with the food safety statutes and regulations. Our review found areas for improving the effectiveness and efficiency of inspection activities by improving monitoring, oversight, and prioritizing activities. During the course of the audit, DOA began making changes to the inspection processes that should improve its effectiveness and efficiency.

To improve its overall effectiveness and efficiency, the department should develop a risk-based inspection process. Currently, the unit's goal is to conduct a routine inspection of each processing facility every six months. However, this goal is not based on a risk assessment, and the goal is not currently being met. According to the U.S. Food and Drug Administration (FDA), and other states we contacted, using a risk-based system to identify facilities for inspection provides assurance that those processors that pose the greatest risk to health are inspected more frequently.

Other areas for improvement that were identified are discussed on the following page. It should be noted that DOA has recently implemented new strategies that will address several of the areas identified during the audit. These strategies were developed as part of an internal assessment DOA conducted in the Spring of 2011.

- A new inspection form has been developed and implemented, which is based on the FDA's Good Manufacturing Practices. This form was implemented in February 2012. Prior to this, the unit's inspectors used a form that was generally intended for retail food establishments and did not specifically address standards or problems that apply in the processing environment.
- During the review, sufficient controls were not in place to ensure inspectors properly interpreted and applied regulations. The development and implementation of the new inspection form earlier this year will provide one control in this area. Additionally, the department indicated it plans to develop an audit function which will serve to monitor how regulations have been applied. Consideration should be given to including routine onsite evaluations conducted by a member of the management team; management participation in selected follow-up inspections to ensure information detailed in the inspection report accurately reflects conditions; periodic reviews of inspection report data to ensure adequate coverage of all relevant areas; and, routine reassignment of inspectors, for a defined number of inspections, between regions to compare results and completion times.
- Currently, management has not established a goal for the number of inspections to be completed in a given timeframe, nor is management monitoring the amount of time inspectors spend actually conducting inspections. Absent a goal for the number of inspections to be conducted and the amount of time this should take, management cannot assess whether employees are operating at an acceptable level, are under-productive, or are thorough enough in their inspections. In January 2012, the division began implementing a Field Force Management (FFM) program that will allow for real-time monitoring of inspector activity. The system is not fully operational as yet, but once it is, will supply information to set productivity benchmarks.
- Through our review of inspection data, as well as field site visits, we found opportunities for increasing the amount of time available for conducting inspections. Inspectors plan and coordinate their own inspection activities; however, better planning of inspections could maximize productive time. The audit identified specific strategies related to inspector travel, report preparation, enhanced enforcement actions, and sample collection and delivery that, if implemented, would allow inspectors to work more efficiently in the field. The department recently revised the courier routes for sample pickup and the Field Force Management program should help with more efficient scheduling of inspections.
- Inspectors have the authority to stop the sale of products if violations pose a danger to the public. However, for those situations where violations occur and corrective action is not immediately taken, procedures are needed to ensure the appropriate enforcement process is followed. Problems were identified in the processes for determining if a follow-up inspection should be conducted, the escalation of enforcement efforts, and the timeliness of enforcement actions. The department reports that it recently appointed a Compliance Officer. Inspectors will now complete a newly created form when these violations are identified and forward it to the Compliance Officer for determination of the appropriate action.
- We also recommended that DOA collect information on the products and tests facilities are conducting to meet statutory requirements. This information would provide a baseline for the amount of testing being done. According to statute, food processors are required to regularly test their own products for contaminants and report any positive tests to DOA. Processors are classified into three tiers low, medium, and high and the testing frequency is determined by this classification. Our review revealed questions about whether processors had fully implemented the testing as required.

These areas are discussed in more detail in the Findings and Recommendations section of the report.

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#### **Audit Purpose**

The purpose of this audit was to review the Department of Agriculture's (DOA) efforts to ensure a safe food supply at the processing level. Specifically, the audit determined:

- Whether DOA has an effective process for identifying food processing facilities under its authority and whether all facilities had been identified;
- Whether DOA's established inspection frequency provides reasonable assurance that food manufacturing facilities are adhering to state food safety regulations;
- Whether DOA's inspections provide an accurate record of the relevant conditions found during the inspections, and are the results utilized in a meaningful way;
- Whether Georgia's food safety testing regimen is effective at ensuring a safe and unadulterated food supply; and,
- Whether DOA is effectively enforcing compliance with state food safety guidelines.

Details regarding the objectives, scope, and methodology are located in Appendix A. Findings in the report have been communicated to appropriate department of Agriculture (DOA) personnel. In addition, a draft copy of this report was provided to DOA for its review and comment. Pertinent responses have been included in the report as appropriate.

#### **Background**

Over the last decade, foodborne illness outbreaks have been tied to a variety of food products, including spinach, peppers, alfalfa sprouts, shellfish, and cantaloupes. Outbreaks occur when food products contaminated with pathogens including Salmonella, Listeria monocytogenes (L. mono), Escherichia coli (E. coli), and norovirus, among others, reach consumers through the food supply. Such pathogens cause foodborne illnesses with symptoms ranging from nausea, vomiting and diarrhea to death. The Centers for Disease Control and Prevention (CDC) estimates more than 3,000 deaths and 128,000 hospitalizations each year are due to the consumption of contaminated food or beverage products. A report from the University of Florida's Emerging Pathogens Institute estimates over \$14 billion in annual economic losses due to foodborne illness occur from lost wages, healthcare expenses, and premature deaths.

Contamination can occur at any point in the food supply chain, including growing and harvesting, manufacturing, transporting, warehousing and storing, retail, or at the point of consumption. To protect consumers from foodborne illnesses, government agencies have established food safety standards and retained regulatory jurisdiction over food related establishments such as farms, butcheries, food processors, retail establishments, and restaurants. Many food safety regulations, as well as the regulatory authority granted to government agencies, have been in place since the early 1900's.

As part of their regulatory efforts, government agencies utilize inspections and product testing to ensure that food handlers comply with the various food safety standards. Such inspections are conducted at all types of food handling facilities on a routine basis, and are intended to identify risk factors that could promote the spread of harmful pathogens.

#### **DOA Food Processing Inspection Unit**

In Georgia, DOA's food processing inspection unit, located within the Food Safety Division, regulates and inspects food processing facilities. Georgia's food processors must pass an initial food safety inspection prior to obtaining a state license to manufacture food. The state law requires processors pay a licensing fee, which ranges from \$100 to \$300. The amount paid by each facility is determined by DOA and is based on the facility's risk level, and the procedural effort and time required for the department to complete an inspection. Licenses must be renewed annually and may be revoked, or a fee imposed, if a company is found to be in violation of the department's regulations. In most counties and municipalities, food processors must have a DOA license in order to obtain a local occupational permit or business license to operate.

As of May 2011, there were 740 licensed food processing facilities. These facilities manufacture or process products of all types including beverages, baked products, seafood, sandwiches, ice, condiments, etc.

#### **Laws and Rules**

#### Federal Legislation, Guidance, and Standards

The federal Food, Drug and Cosmetic Act (FDCA) of 1938 and Food Safety Modernization Act (FSMA) outline the federal government's food safety objectives. The FDCA required standards related to food quality and labeling, and specifically addressed conditions in food manufacturing facilities. The legislation provided a platform for food safety inspection programs to focus on facility conditions as a way to improve food safety. The FSMA, signed into law on January 4, 2011, shifted the federal government's focus on food safety from response and reaction to risk-based prevention. The FSMA focuses on the following five components: prevention, inspection and compliance, response, imports, and enhanced partnerships.

The U.S. Food and Drug Administration (FDA) is responsible for *protecting the public health by assuring that foods are safe*, *wholesome*, *sanitary and properly labeled*. Currently, the FDA contracts with state regulatory agencies to perform food safety inspections on its behalf. In 2007, the FDA released the Manufactured Food Regulatory Program Standards (MFRPS) to align states' regulatory approaches. Through the standards, the FDA define[s] best practices for the critical elements of state regulatory programs designed to protect the public from foodborne illness and injury. The standards target areas including: regulatory foundations, staff training, and incident investigations, violation enforcement, resource management, and laboratory resources.

#### Georgia Law and Regulations

The Georgia Food Act governs food sales establishments in Georgia, including food processing facilities. The Act prohibits the manufacture, sale, or storage of any adulterated food (defined as containing any substance that may *render it injurious to health*). Foods containing a contaminated, filthy or decomposed component or foods prepared or stored in unsanitary conditions are also deemed adulterated. The Act authorizes DOA to license and inspect facilities, impound and quarantine adulterated products, impose fines and penalties, and establish pathogen testing criteria for finished products.

DOA also establishes the rules and regulations that govern the safety of manufactured foods. Currently, there are two sets of rules applicable to food processing: the General Rules (40-7-1) and a set of additional regulations specific to processing facilities (40-7-18). The General Rules mirror the 2001 edition of the FDA Food Code<sup>1</sup> by establishing practical, science-based guidance and enforceable provisions for mitigating risk factors known to cause foodborne illness. These regulations generally address risk factors FDA has identified related to employee behaviors and processing practices. They contain standard practices governing all facets of food production, including: hygiene, transportation, water source, cooking, utensil cleaning, labeling, equipment cleaning, and pest control. The processing facility regulations were adopted in 2010 in response to a Salmonella outbreak at a Georgia peanut processing facility. The outbreak cased nine deaths and sickened more than 700 people nationwide. According to these regulations DOA may inspect facilities, review testing records and secure food or environmental samples. As part of the regulations, DOA also adopted much of the Code of Federal Regulations applicable to food processing, including the Good Manufacturing Practices (GMPs). The GMPs were developed by the FDA. The GMPs discuss five major categories describing the methods, equipment, facilities, and controls for producing processed food. The categories include general provisions, buildings and facilities, equipment, production and process controls, and defect action levels.

Risk means the likelihood that an adverse health effect will occur as a result of a hazard in a food. The testing risk category is established by a committee appointed by the Commissioner. **Testing Regulations** 

Effective May 2010, DOA regulations also require that food processors regularly test their own products for contaminants. Any positive tests must be reported to DOA. DOA has established a three-tier testing risk classification on which the testing frequency is based. Low risk facilities test quarterly, medium risk facilities test monthly and high risk facilities test bi-monthly. If a firm meets one of the following criteria, it is exempt from the testing requirements: type of products produced (raw agricultural products are exempted), status as a low volume business, or submission and approval of a food safety plan as an alternative to frequent testing. Currently, 174 (24%) of the 740 food manufacturers in Georgia are exempt from testing regulations because they meet one of these criteria.

<sup>&</sup>lt;sup>1</sup>In the early 1990s, the FDA published the Food Code, a food safety guide. Many states adopted the Food Code into their food sales establishment regulations to address food safety issues. The regulations address employee hygiene, food handling and storage, cooking practices, and equipment cleaning.

<sup>&</sup>lt;sup>2</sup>Food safety plans must be accepted by DOA and may subject the firm to a less frequent testing regimen, however, DOA indicates that all food safety plans must include an element of internal testing.

Also in 2010, the General Assembly passed legislation imposing penalties of up to \$5,000 for a violation of the testing requirements and made it a felony for a company to knowingly allow a contaminated food product to enter the food supply. Violation of this law is punishable by imprisonment for one to 20 years and/or a fine of up to \$20,000. Between May 2009, when testing requirements were implemented, and November 2011, seven facilities have reported a positive test.

#### **Facilities and Inspections**

#### **Facilities**

Food processing facilities are located throughout the state; however, a greater concentration of facilities exists in urban areas. Food processing facilities are classified for two purposes – licensing and testing. The licensing classification determines the annual fee a facility must pay. It is based on the level of risk, procedural effort, and inspection time needed for each food sales establishment according to O.C.G.A 26-2-25. DOA has classified all 740 facilities into one of the five licensing classifications. As shown in Exhibit 1, 313 of 740 (42%) facilities are categorized as a level 4 facility.

Exhibit 1 Licensing Classifications					
	L	icensing Str	ucture	Licensing Fee	
Description	Tier	Number	Percentage	9	
Lowest Risk	1	17	2%	\$100	
1	2	79	11%	\$150	
	3	277	37%	\$200	
$oldsymbol{\vee}$	4	313	42%	\$250	
Highest Risk	5	54	7%	\$300	
Total Number of Facilities		740	99%¹	·	
<sup>1</sup> Due to rounding					
Source: Auditor analysis of DOA facility inventory and classification structures					

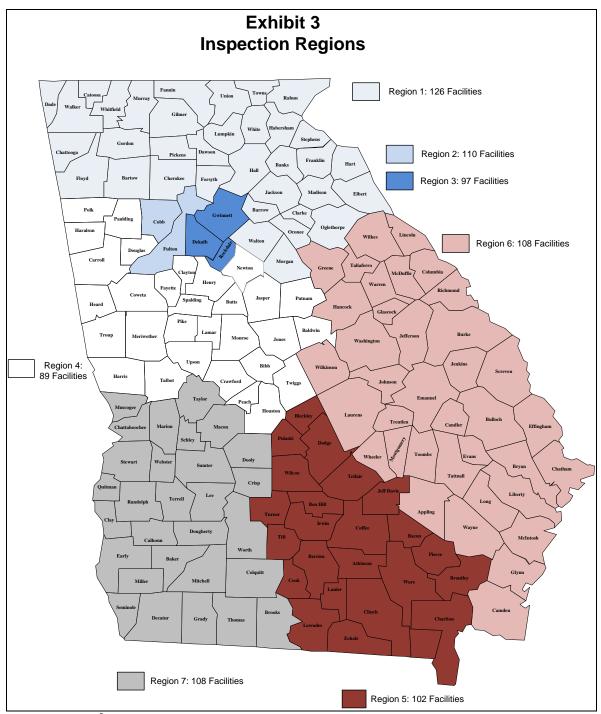
The testing risk classification is based on the *highest risk product the facility produces*, according to the department's rules. The testing classification guides the frequency with which a facility must conduct its own internal testing. (See Exhibit 2.) As discussed earlier, the facilities must test quarterly to bi-monthly, depending on the risk associated with the products produced. DOA has classified 448 (61%) of the 740 facilities for testing purposes; of the 448 classified, 181 (40%) are low risk.

Exhibit 2 Testing Classifications				
		Testing Structure		
<u>Tier</u>	<u>Number</u>	% of All Facilities	Minimum Frequency	
Low	181	24%	Quarterly	
Medium	153	21%	Monthly	
High	<u>114</u>	15%	Bi-Monthly	
Subtotal	448	61%	,	
Exempt	174	24%	N/A	
Unclassified <sup>1</sup>	<u>118</u>	<u>16%</u>	N/A	
Total	740	100%		

<sup>1</sup>According to management, these include facilities excluded from classification due to inactivity or re-designation
Source: Auditor analysis of DOA facility inventory and classification structures.

#### Inspectors

The unit employs seven inspectors, each responsible for the regular inspections of food processing facilities located within an assigned geographical region (See Exhibit 3).



Source: Review of inspection region assignments

As shown in Exhibit 4, there are seven types of onsite activities conducted by the unit's inspectors. During the year reviewed, 612 of the 1,068 (57%) activities completed were routine inspections.

Exhibit 4				
Food Processing Activities				
(June 2010 – May 2011)				
Activity Type	Number <sup>1</sup>			
<b>Regular/Routine</b> – review of all facility and production areas; occurs at fixed intervals throughout the year.	612 (57%)			
Investigation – review conducted following an adverse event such as a positive test result, consumer or customer complaint; also used to execute a restoration plan <sup>2</sup> .	158³ (15%)			
Follow-up – review to assess actions taken by the facility to correct previous violations.	154 (14%)			
<b>Sample Collection</b> – a visit to a facility specifically to secure a food product for testing purposes.	46 (4%)			
Other – review for miscellaneous purposes	39 (4%)			
Facility Closed – review type noted when, upon an unannounced arrival at a facility, the inspector finds the facility is not in operation.	36 (3%)			
Pre-licensing – review performed before the DOA license is issued.	23 (2%)			
Total	1,068			

<sup>&</sup>lt;sup>1</sup>Due to rounding adjustments, percentages may not add to 100%.

Source: Review of DHD program records

According to DOA management, inspectors should conduct a routine inspection of each licensed facility every six months. The inspectors are responsible for scheduling their own inspections. As deemed necessary, inspectors may suspend a planned routine inspection to investigate a complaint, conduct a follow-up inspection, or investigate a facility that has had a product test positive for a pathogen. If a positive test result is received, inspectors may spend days or weeks in the facility to determine how the contamination occurred and to ensure that management is addressing the problem. If necessary, inspectors may ask their peers in other regions to assist with return visits to the problem facility.

Routine inspections are unannounced and generally last between two and three hours. After meeting with the facility manager or person in charge, the inspector conducts a physical inspection of the premises. Typically, inspections begin at the initial stages of the production process and follow the product through the facility. Inspectors apply the department's General Rules as the criteria for the inspections and any violations are linked back to these rules. In addition, management noted that inspectors apply the FDA's Good Manufacturing Practices (GMPs). Effective February 2012, the department has implemented a new inspection form that focuses the inspection on the GMPs.

<sup>&</sup>lt;sup>2</sup>If a pathogenic contamination is identified, facility management must develop a restoration plan that details the process for reconditioning the premises.

<sup>&</sup>lt;sup>3</sup>Our review found that some reports labeled as "Investigation" did not fit the definition shown above, and most likely should have been labeled as "Other." Such activities included arriving for an inspection and finding that the facility is closed, and returning sample results to a facility that were non-actionable.

Once the physical inspection of the facility is completed, the inspector reviews the firm's testing, pest control records, and, if applicable, food safety plan. Inspectors are also responsible for reviewing any additional plans the facility is required to maintain because of particular biological, chemical and physical risks associated with a particular production process.

If inspectors find conditions that violate the department's rules and regulations, they tell the facility management. If the violation can be easily corrected, management is expected to make the changes immediately. Certain critical violations, identified in the rules, require correction before the inspector leaves the facility. For instance, if a food preparation surface is unsanitary, the inspector is supposed to ensure that it is cleaned before leaving. If an inspector determines that violations create an immediate food safety concern, he can stop the sale of finished products by detaining them onsite.

Inspectors file an electronic inspection report noting the violations observed. If the violation was not corrected onsite, the inspector and facility management negotiate a date by which the correction should be made. If appropriate, the inspector schedules a follow-up inspection date to review the corrective actions taken.

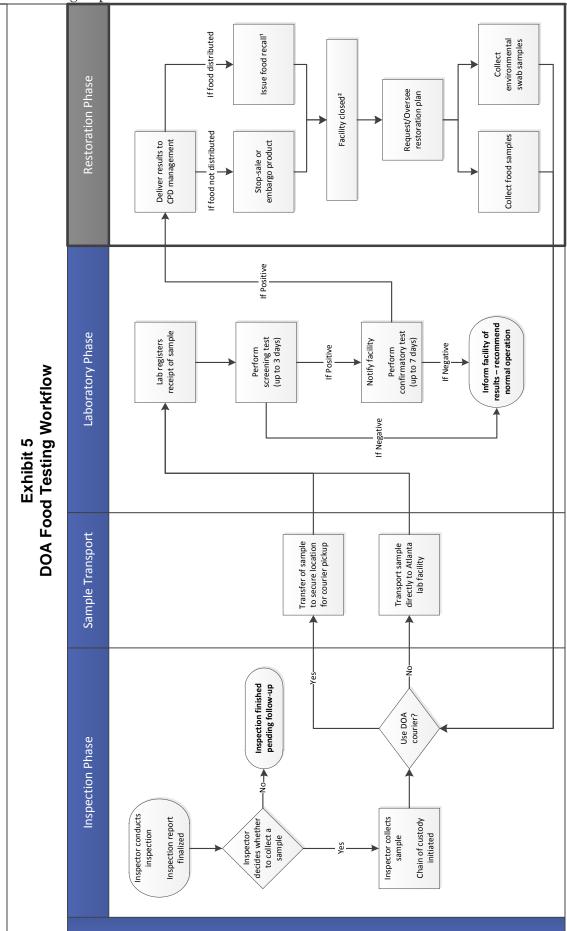
DOA maintains all processing facility information and inspection activity in the Digital Health Department (DHD) database, a web-based system which provides inspectors with real-time access to facility and inspection documentation. Additionally, inspectors can log other daily activities (such as administrative duties) into the database. Management can use DHD to review and approve inspection reports, review administrative or other time charged, and run summary reports. In addition to the daily entries in DHD, inspectors also email a summary of work hours and mileage to management each week.

#### Sample and Testing Procedures

DOA operates a courier network used to transport food samples, and other products, throughout the state.

According to DOA management, inspectors should collect a food sample during each routine inspection for testing by DOA's lab. Once the sample is taken, facility management will often choose to hold shipment of the product pending the test result. However, they are not required to do so. After inspectors collect product samples, they either personally deliver the sample to the lab, or arrange for DOA's courier to deliver the sample.

Inspectors using the courier take the product to a predetermined pickup location and sign the chain of custody documents. These documents provide assurance of sample security and support the legal foundation of the sample in the event of a positive result. The program operates routes throughout the state and transports samples for the Consumer Protection Division as well as other divisions. The inspectors in the northern and central parts of the state (regions 1-4) typically drive samples directly to the Atlanta lab.



<sup>1</sup> Under certain circumstances, the Department will coordinate with the FDA to issue the food recall.
<sup>2</sup>After completion of all restoration activities including a satisfactory number of negative test results (swabs or food samples), a closed facility will be allowed to reopen.
Source: Observation of testing activities, interviews with lab and other departmental personnel.

Samples arrive at the lab in sealed boxes or coolers, as necessitated by the type of product. Lab personnel log the samples into their information management system. Generally, the lab tests for Salmonella, E. coli, and L. mono. If the processing facility uses a private water source, inspectors collect an annual water sample to test for coliform bacteria and E. coli. Additionally, inspectors can request other product-specific tests including, for example, brix, or insect fragments and Aflatoxins in corn meal.

As shown in Exhibit 5, product testing takes from three to ten days. The initial screening test takes three days and determines if contaminates or pathogens are present. If the screening test is negative, testing is complete. If the screening test is positive, the lab conducts a confirmatory testing battery to identify the pathogen strain. If the confirmatory test comes back positive, and the facility held the product, the department can have the product embargoed or destroyed. If the product has been distributed, the facility or FDA will issue a food recall.

During our review, 649 samples yielded 29 positive tests, including 11 positive finished product tests. Of these positives, two were pathogenic (both were positive for L. mono)<sup>3</sup>. As a result, the products for both of these firms were voluntarily held/destroyed. Since the lab maintains a separate database for processing manufactured food samples, lab results must be manually scanned into the inspection database (DHD) for management review.

Typically, if the samples test positive for a pathogen, the department oversees a restoration process which involves cleaning and sanitizing the facility, multiple follow-up product tests, and environmental swabbing. DOA uses environmental swabbing, which is the collection of microbiological samples, to specifically identify the source of the contamination. Once the restoration process is completed, and several consecutive test results show no contamination, the facility can resume normal operations.

#### **Administrative Enforcement Actions**

As noted earlier, if an inspector identifies violations that pose a risk to human health, he can immediately stop the sale or distribution of products at the facility. However, the department also has a process for addressing repeat violations by a facility to encourage compliance with the food standards. The first time a facility is cited for a repeat violation, DOA can send a compliance letter, which requires the facility submit a plan of action outlining a long-term resolution to the issue. If cited for a second repeat violation, DOA can require an informal compliance meeting at the Central Office in Atlanta to determine the reason for the persistent problem and identify further administrative penalties should the problem occur again. Upon a third repeat violation, a formal settlement conference is held and DOA details any imposed penalties, probation or other administrative action. During our review, the department sent 34 plan of action letters, conducted 3 compliance meetings, and held one settlement conference.

<sup>&</sup>lt;sup>3</sup> DOA escalated the case by requiring corrective action and conducting a series of follow-ups to oversee a restoration process and conduct further sampling.

#### **Financial Data**

As shown in Exhibit 6, the processing inspection unit's expenditures were approximately \$444,000 during fiscal year 2011. An additional \$90,000 was spent on lab testing.

Exhibit 6 Food Processing Inspection Unit Revenues and Expenditures, FY 2011				
Revenue				
State Funds	\$428,142			
Federal Funds	\$7,556			
Fees Collected	\$8,035			
Total Revenue <u>\$443,733</u>				
Expenditures				
Personal Services	\$394,034			
Regular Operating	34,841			
Computer Charges	1,865			
Real Estate Rentals	10,129			
Telecommunications	2,864			
Total Expenditures <u>\$443,733</u>				
Source: PeopleSoft Accounting System				

#### **Findings and Recommendations**

DOA should implement a risk-based approach for scheduling routine inspections.

Currently, DOA has developed risk-based classification structures for licensing and testing food that are based on the type of food and ingredients, processing requirement, and processing risks. However, a similar risk-based approach is not currently used to prioritize inspections.

The FDA supports a risk-based inspection approach. In its Manufactured Food Regulatory Program Standards, the FDA recommends a science-based and risk-based method for classifying food plants into at least three risk categories with a baseline inspection frequency for each category. While not prescriptive, FDA offers the following as possible criteria for designing a system: type of food and ingredients; processing requirements; volume of product manufactured or distributed; intended consumer; and compliance history of the food facilities. We also contacted seven states' food safety divisions and six have implemented a risk-based inspection schedule. Generally, the risk classification systems were based on the food product, types of processes, and the facility's compliance history. The frequency of inspections, based on risk, varied among the states. For example, states ranged from inspecting high risk facilities once every 4 months to once a year.

Rather than selecting facilities for inspection based on risk, DOA's goal is to conduct a routine inspection of each facility every six months. This goal, however, is not currently being met. As of May 2011, 379 (51%) facilities received an inspection within the last six months and another 218 (29%) had received an inspection within the previous year. The remaining 143 (19%) facilities had not been inspected in twelve months or more. It should be noted that the department added three inspectors to the food processing unit near the end of the period reviewed, and management indicated that inspectors completed a total of 880 regular inspections between May 2011 and April 2012.

Based on its current process, DOA does not have assurance that facilities with the highest level of risk are inspected more frequently than lower risk facilities. We analyzed the inspections conducted to determine if the licensing or testing risk categories influenced the inspection frequency. However, we did not find a correlation between the risk category and the inspections for either category. Of the 367 facilities classified as a 4 or 5 licensing tier (the two highest tiers), 194 (53%) had been inspected in the past six months; the remaining 47% were not. Of these 173, 69 (40%) have not been inspected in over 12 months. Of the 114 facilities classified as high risk for testing purposes, 52 (46%) were inspected within the last six months. Of the 114 facilities, 22 (19%) have not been inspected in the past 12 months.

DOA acknowledged the importance of using risk to guide its inspection frequency in a self-assessment conducted under FDA's Manufactured Food Regulatory Program Standards, and staff noted that it intends to implement this as a practice beginning July 2012. DOA should adopt a risk-based approach, which includes baseline frequencies for inspections. By incorporating a risk analysis into the inspection process, DOA can focus its inspection activities on the facilities that pose the greatest risk to health.

Agency Response: The department indicated that it concurs with this finding and has developed a risk based assessment template based on recommendations from the Commissioner's strategic planning process and the Manufactured Food Regulatory Program Standards. During routine inspections, inspectors will gather information to incorporate into the assessment template. Any changes in the type of products produced, processing methods, scope of distribution, or compliance with the regulations will result in a re-evaluation of risk for the facility which directly affects its inspection frequency.

## DOA should continue efforts to improve its inspection form and related processes.

The inspection form used by the unit provides the foundation for how inspections are conducted and how the information on the condition of facilities is captured. As a result, it is also the tool that ensures consistency among inspectors and provides information to management, both in the form of the reports produced and the data loaded into the department's data system. During the period under review, DOA's inspections were based on the Georgia Food Act and DOA's Rules and Regulations, which were designed for the more general food safety requirements of grocery and convenience stores and its criteria did not reflect the specific risks associated with the manufacturing operations found in food processing facilities. For example, there was no place on the form to note issues related to the food processing areas being separated from other operations which may cause contamination of the food being processed. In February 2012, DOA began implementing a new inspection form and revised some inspection processes. Under the new system, the Good Manufacturing Practices (GMP)<sup>4</sup> serve as the basis for conducting inspections.

While the new inspection form includes criteria specific to the food processing environment, which will allow DOA to more specifically direct the activities of the inspectors, DOA should consider additional steps to ensure the form's utility. According to the Director of the University of Georgia's Center for Food Safety, inspection programs should develop tailored inspection forms for different processing and facility types. For example, the Michigan Department of Agriculture developed a processing-specific inspection report, as well as specialized forms for acidified foods and low-acid canned foods. The Director also noted that, while certain criteria may remain constant across the forms, conditions and criteria specific to each process can be clearly identified and evaluated by inspectors. For instance, some processes require a cleaning in-place procedure, which is the process by which a closed system of food processing (one where food is mixed, heated, treated, and produced without exposure to the exterior environment) is sanitized. The inclusion of an inspection addendum containing inspection processes for specialized inspection environments will ensure that the inspector reviews these processes as part of the regular inspection.

In addition to ensuring processes specific to the individual facility type are addressed, the tailored addendums to the form could be used to assess additional time that must be spent inspecting these types of facilities. This information could inform expectations about the length of time necessary to conduct inspections and

<sup>&</sup>lt;sup>4</sup> The Good Manufacturing Practices relate to the food processing environment more specifically than the Georgia Food Act or the rules and regulations, which primarily address the food safety conditions of retail establishments.

be used to set baseline targets. In addition, DOA should ensure that noted violations tie directly to the food processing regulations adopted by DOA. Also, an evaluation of each facility's compliance with food safety testing laws found in the Sanitary Activity for Food-processing Enterprises Act should be included on the form.

The department should continue implementation of the new inspection form and processes to more specifically address processing environments. In addition, management should evaluate opportunities to develop addendums to the base form for application in different types of processing environments. Additional information on ensuring consistency across inspectors is included in the following finding.

Agency Response: The department indicated that it concurs with this finding. While the previous inspection form was based on the FDA model form intended for retail food establishments, the department implemented a new form in February 2012 that focuses on processes and record retention which are more relevant to processing plants. The department further indicated that it will continue to explore the addition of new inspection forms for specialized processes, and it plans to issue a regulation update to further differentiate the processing regulations from the retail regulations, clarifying the delineation between the retail and food processing units.

## Management does not have a systematic process for ensuring that inspectors are consistent in their interpretation and application of the food safety regulations.

Because the inspection process requires inspectors to interpret and apply the food safety regulations in a variety of circumstances, management must rely on an inspector's judgment in identifying violations of the regulations. As a result, it is critical that management have sufficient controls in place to ensure that the inspectors' judgment is sound and the application of the regulations is both appropriate and consistent. An incorrect interpretation or application of a regulation would cause inaccurate inspection findings and management would have an erroneous impression of conditions in the facility. Additionally, inconsistent application of inspection regulations could result in inequitable treatment of the facilities with those in one region being held to a more stringent interpretation of the regulation than those in another region. During the review, controls were not in place to ensure regulations were properly interpreted and applied. However, in February 2012, as noted in an earlier finding, the department began using a new inspection form which will serve as one control in this area. Additionally, the department has plans to develop an audit function which will serve to monitor how regulations have been applied.

There is variability between the inspectors in the number of violations written and the average length of time it takes to complete inspections. Absent a process for monitoring the inspectors' activities and an assessment of the completeness and accuracy of the inspections conducted, it is not clear whether the average length of 4:07 hours is indicative of an inspector being too exacting, or if 1:45 hours is indicative of an inspector not being thorough enough. As shown in Exhibit 7, two of the inspectors wrote an average of 2.1 violations per inspection while another wrote 0.6 per inspection. In addition, during this period, one inspector identified more than three violations during each of 21 inspections, while another inspector has not documented more than three violations per inspection during the last three years. As shown below, we also identified disparity in the average length of inspections, even when controlling for the type of facilities inspected.

Exhibit 7
Comparison by Inspector
Routine Inspections Conducted from June 1, 2010 to May 30, 2011

Inspector	Number of Inspections	Number of Violations Cited	Avg. Violations per Inspection	Avg. Length of Inspection (h:mm)		
1	87	179	2.1	04:07		
2	79	163	2.1	03:50		
3	27	53	2	02:50		
4	19	27	1.4	02:48		
5	17	24	1.4	02:42		
6	167	185	1.1	02:16		
7	60	61	1	03:18		
8	36	33	0.9	02:30		
9	120	72	0.6	01:45		
Source: Auditor analysis of DOA inspection data						

To ensure proper application of the food safety regulations, the department relies on each inspector's science-related education and training to ensure proper judgment in the field. Inspectors also undergo an annual evaluation by FDA auditors to ensure that their inspections are appropriate. Our interviews of staff indicate that FDA bases its conclusion on 1-2 inspections; as such, these inspections may not represent the full realm of the inspectors' duties throughout the year. In addition, the scoring mechanism indicates that the inspections were *Acceptable* or *Needs Improvement*. The FDA audit process does not provide a comprehensive evaluation of the inspectors' actions or of the inspection process. As a result, additional periodic on-site review by Division management is necessary to ensure inspectors are properly applying the standards in a correct and consistent manner.

As noted earlier, the department reports that it is developing an audit function within the inspection unit, and expects to implement the program upon receipt of grant funding from the FDA. Due to the inherent subjective nature of the food safety inspections, it is necessary that management develop a comprehensive process for evaluating the quality of inspections completed by its employees. Examples of management controls that could provide such assurances include: periodic on-site evaluations conducted by a member of the management team; management participation in selected follow-up inspections to ensure information detailed in the original inspection report accurately reflects conditions; periodic reviews of inspection report data to ensure adequate coverage of all relevant areas; and, routine reassignment of inspectors, for a defined number of inspections, between regions to compare results and completion times. All of these processes would need to be conducted with sufficient regularity to ensure that deficiencies are corrected quickly. Results of these activities would allow management to identify trends in the types of violations that each inspector identifies and direct training, as necessary, to ensure proper and consistent coverage of all standards.

Agency Response: The department indicated that the new inspection form coupled with additional specialized training on the Good Manufacturing Practices and an internal audit

component will continue to address this finding. The department reported that processing inspectors have attended 3,077 hours of specialized training through FDA, USDA, and the International Food Protection Training Institute at little to no cost to the department. In addition, the department reported that it has worked with FDA to develop an audit component for contract inspections which includes inspectional procedures, sampling protocol and supporting documentation. In addition, the department reported that it has applied for federal grant funding to work towards conformance with the national standards including the development of a comprehensive audit program.

## DOA should establish productivity standards for inspectors and monitor inspectors to ensure inspections are conducted as expected.

Currently, management has not established a target number of inspections to be completed in a given timeframe, nor is management monitoring the amount of time inspectors spend actually conducting inspections. Inspectors are assigned a region and are responsible for managing their work schedules, which includes completion of their inspection duties. Without a target number of inspections, and an expected amount of time inspectors should spend conducting their inspections, it is not possible for management to determine if employees are operating at an acceptable level, are under-productive, or are thorough enough in their inspections.

As shown in Exhibit 8, the three inspectors for whom data was available spent an average of 42% of their time on inspection activities, ranging from 21% to 54%. Travel accounted for approximately 14% of their time, ranging from 7% to 31%. The direction on how to document time has not been standardized and DOA management indicated that inspectors could be recording travel time to other categories or not recording it at all. Two inspectors did not account for all working hours during the month.

Exhibit 8	
<b>Inspector Timesheet Analysis for One Selected Month</b>	1

	Inspe	ctor l	Inspe	ctor 2	Inspe	ctor 3	То	tal
Activity	Hours	%	Hours	%	Hours	%	Hours	%
Inspection	79	48%	96	54%	31	21%	206	42%
Administration	32	20%	39	22%	39	26%	110	22%
Travel	11	7%	13	7%	47	31%	71	14%
FDA/Administration	9	5%	12	7%	8	5%	28	6%
Unaccounted	30	18%	0	0%	10	7%	39	8%
Other <sup>2</sup>	3	2%	18	10%	17	11%	37	8%
Total <sup>3</sup>	163	100%	178	100%	152	100%	492	100%

 $<sup>^{</sup>m I}$ We selected one month for each inspector in which processing inspections were their primary activity.

Source: Auditor analysis of inspector timesheet data

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<sup>&</sup>lt;sup>2</sup>Other includes sample collection, consulting, meetings, and inspector assistance

<sup>&</sup>lt;sup>3</sup>Hours may not total evenly due to the rounding adjustments of the raw data.

<sup>&</sup>lt;sup>5</sup> We limited the sample to those inspectors whose primary responsibilities were conducting processing inspections (as opposed to retail inspections) and whose time was sufficiently documented to allow for analysis.

As shown in Exhibit 9, our review found that inspectors completed an average of 1.85 inspections per day (ranging from 1.43 to 3.58). On average, inspectors spent three hours and fifty-one minutes per-day conducting inspections.<sup>6</sup> Because approximately half of the inspectors were also conducting retail facility inspections during this timeframe, we included retail and all other types of inspections (regular, follow-up, investigation, complaint, etc.) in this analysis. We also reviewed the average duration of an inspection for each inspector and found these times varied from approximately 1½ hours to 3 hours and 20 minutes (see Exhibit 9).

# Exhibit 9 Daily Inspector Productivity<sup>1</sup> (June 2010 – May 2011) (h:mm)

Inspector	Number of Inspections per Day (average)	Length of time per Inspection (average)	Total Inspection Time per Day
1	1.43	3:20	4:47
2	1.49	3:08	4:40
3	3.58	1:30	5:24
4	2.63	1:50	4:49
5	2.00	1:46	3:32
6	1.78	1:55	3:25
7	1.67	2:42	4:30
8	1.72	1:49	3:07
9	1.49	1:25	2:07
Total Average	1.85	2:05	3:51

<sup>1</sup> Time averages and totals do not include travel time. Source: Auditor analysis of DOA inspection data

Because it is not expected that inspectors would spend 100% of their time onsite completing inspections, we also analyzed inspectors' time by category. For example, travel could account for a portion of the inspectors' day, as could FDA inspection duties. We reviewed inspector timesheets and daily activity logs submitted by the inspectors to determine how the inspectors' time was actually spent. The timesheets and daily activity logs were only available for three of the inspectors. Currently, this information is submitted manually by the inspectors and management does not aggregate it for review. As a result, to conduct this analysis, the audit team manually coded inspection data for the month. DOA management is not currently reviewing the timesheets and/or daily inspection logs to evaluate how inspectors are spending their time.

In addition to a lack of complete information, inspectors did not always document the activities conducted under the individual categories, so it is not possible to determine if the categories were used consistently. For example, records indicate that administrative time generally included checking emails, making phone calls, and syncing computers, but this information was not always complete. Inspectors spent

<sup>&</sup>lt;sup>6</sup> Our review included only those days on which an inspection was conducted. For example, if an inspector conducted only administrative tasks on a day, or was on leave, those days were not factored into the analysis.

<sup>&</sup>lt;sup>7</sup> Timesheets for the remaining inspectors contained either incomplete records, or indicated activity primarily related to inspections of retail facilities.

an average of 22% of their time on administrative activities. As a result of the incomplete and inconsistent nature of the information, much of this timesheet data is not useful for monitoring employee time or informing management decisions.

It should be noted that, in January 2012, the department began implementing a Field Force Management program that will allow for real-time monitoring of inspector activity. The system is not fully operational as yet, but once it is, will supply information to set benchmarks for productivity. The department will still have to determine the reasonable amount of time required to inspect a "basic" facility. A comprehensive program would include: productivity goals based on an analysis of historical data; and, monitoring of results by management to evaluate inspectors' performance against established goals. The goals should be routinely re-evaluated and updated as necessary.

Agency Response: The department reports that it is currently collecting additional information (square footage, product variations, etc.) for its risk based model, but indicated that the variation in facility size requires a firm-by-firm classification to properly measure employee productivity. The department indicated that there are differences in the time requirements within firms of the same type. For example, within Multi Product Food Processing (FTC-400) firms, the square footage varies from 200 to 130,000 sq. ft.; Acidified/Acid Foods (FTC-342) firms range from 200 to 24,000 sq. ft.; Fresh Fruit and Vegetable Processing (FTC-332) firms range from 1,000 and 63,650 sq. ft.; and Sandwich Manufacturing (FTC-905) firms range from 1,200 to 21,250 sq. ft. The department further indicated that the firm-by-firm time category classification, coupled with the new Field Force Manager system and new policies and procedures, will provide additional tools for daily supervision.

## Opportunities exist for DOA to increase the amount of time available for conducting inspections.

Through our review of inspection data, as well as our field site visits, we identified areas in which changes could be made to improve efficiency. As noted in a previous finding, inspectors plan and coordinate their own inspection activities; however, better planning of inspections could maximize productive time. While the average hourly cost per inspector (\$26) is relevant to decisions in each of the areas discussed below, it is also important to consider the opportunity cost of having an inspector engaged in these activities instead of inspecting additional facilities. There are six areas in which processes could be affected:

• Travel: Inspectors could reduce their travel time, and expense, by grouping inspections of facilities in the same general area. Currently, inspectors spend a significant portion of their time traveling to and from inspection locations. On average, they drive 93 miles per day on the days they are conducting inspections of processing facilities. However, we found examples of inspectors traveling across their region to conduct a single inspection, only to travel back to the same area soon thereafter. For example, one inspector drove 97 miles round-trip to conduct a two-hour inspection at Facility A. The remainder of his time was charged to administrative activities (no additional detail is available). Approximately one month later, he traveled to Facility B, located within three miles of Facility A, and conducted a three-hour inspection. Therefore, the inspector could have gained approximately

 $1\frac{1}{2}$  hours of productive time by driving to the location once and conducting the two inspections.

Management could also consider adopting a flexible work schedule that allows inspectors to work four 10-hour days in a week, allowing more time in the field during those four days.

- Reports: Consideration could be given to completing the walk-through inspection and obtaining facility management's signature on-site, but then completing the inspection report remotely, then emailing it to facility management. This procedure would allow inspectors to complete multiple routine inspections in one day and consolidate completion and distribution of inspection reports. It should be noted that DOA management would need to develop criteria for when inspectors should complete the inspection report onsite. For example, it may be more beneficial to complete the report on-site if multiple or critical violations are identified that require immediate attention by facility management.
- Enforcement: As noted in a subsequent finding, inspectors could conduct more routine inspections if repeat follow-up inspections were replaced with other enforcement activities. For example, inspectors routinely conduct multiple follow-up inspections to ensure problems identified during an inspection have been resolved. However, while policies and procedures state that repeat violations should result in administrative compliance letters, meetings, and hearings, these issues are not consistently escalated to ensure resolution. Rather, inspectors continue conducting follow-up inspections until all issues are resolved. A review of available data found that inspectors completed multiple follow-up inspections at 45 facilities during the period of our review. The number of follow-ups to a single location ranged from 2 to 11. On average, it took 1:40 to conduct a follow-up inspection. By making use of escalation procedures, inspectors could be available to conduct routine inspections of other facilities rather than continuing to inspect the same facilities time after time.
- Samples: While data is not collected on the number of times inspectors personally deliver samples to the lab, inspectors reported making such deliveries routinely. Inspectors in more rural areas of the state often utilize the statewide courier service to deliver samples to the lab. In addition, data on the distances traveled was not available; however, our review found that significant distances were traveled to deliver samples to the courier pick-up points.

While hand delivering samples may be necessary at times, management should explore opportunities to reduce inspector delivery by utilizing commercial services. As indicated by management, some products must be transported while maintaining temperature control, however, the benefits associated with savings in inspector travel time and an increase in inspector availability may outweigh the costs associated with the commercial service. Due to the fact that the courier service only visits each pickup location an average of one time per week, utilizing a commercial carrier would also be more efficient because samples could be shipped any week day.

Non-Inspection Activity: DOA must go onsite to conduct inspections and collect samples; however, inspectors also went onsite numerous times throughout the year to carryout functions that could have been handled differently, and at a lower cost. A review of the inspection database found that inspectors go onsite to deliver correspondence, discuss processes with facility management, pick up a sample that was previously collected and stored at the facility, or consult with management about various topics. Additionally, as noted earlier, many of these activities are categorized as investigations even though not all are investigative in nature. Data was not available to determine the frequency with which this occurs.

While it might be beneficial to appear in-person to address facility issues or concerns, there is a cost to this service. Inspectors should only travel to facilities to perform official functions of DOA when no alternative options are available. Management should create criteria for when inspectors should go onsite and review documentation of these visits to ensure that they are appropriate.

• Advanced Contact: Inspectors generally arrive unannounced to ensure facilities are observed in their actual operating state without prior intervention by facility personnel. While this practice likely increases the authenticity of the inspection, there is a risk that an inspector will travel an extensive distance only to find that the facility is closed. The risk is increased when the facility is small or employs few personnel. Records indicate that inspectors arrived to find the facility closed at least 36 times (3% of the 1,068 onsite visits). However, inspectors indicated that they do not always document a closed facility when this happens. As a result, it is likely that the 36 closed facilities is under-estimated. The Director of the University of Georgia's Center for Food Safety noted that, for small or seasonal facilities, a call confirming the operational status of the facility would not impact the quality of an onsite inspection.

We accompanied inspectors on 15 inspections. We traveled with inspectors to three additional sites only to find them closed. Two of the unsuccessful attempts occurred on the same day with the same inspector. Each of the three facilities was a small facility located in a rural area of the state. At one facility, the inspector produced a report noting the closure at the time of the inspection, at the other two facilities, no report was completed. Total work time associated with the three closed facilities amounted to approximately 4 hours and 40 minutes spent traveling to the facility, investigating the closure, updating an inspection form, and traveling to the next location. Management should develop guidance for when inspectors should call prior to an inspection. This could include inspections: of small facilities with few personnel; that require extensive travel; and, of facilities with a fluctuating processing schedule.

As noted, opportunities exist for inspectors to increase the efficiency of their duties. The department should review these cost-saving strategies, and develop others to increase inspector productivity.

Agency Response: The department reports that it will review these recommendations and develop strategies for streamlining travel, sampling, and non-inspectional activities to increase the amount of time available for conducting inspections. The department noted that it remains committed to an "educate as we regulate" approach that requires additional time for face-to-face contact with firms. This "educational inspection" approach is designed to stress the need for compliance and to encourage the firm to become a stakeholder in food safety. The department further noted that the courier service has been revamped to increase coverage across the state, which provides more options to inspectors for sample delivery, thereby, increasing the time available for completing inspections.

## Additional action should be taken to ensure the state's testing regulations are being implemented.

The Sanitary Activity for Food-processing Enterprises (SAFE) Act was passed in 2009 and amended in 2010.

The Act requires food processing facilities to test their products and ingredients for substances or contaminants that could "render such foods or ingredients injurious to health." Violations of the law are punishable by criminal and civil penalties.

While food processing facilities in Georgia have been statutorily required to test finished products since May 2009, DOA does not currently have processes in place to monitor and ensure facilities are compliant. We accompanied inspectors on-site at 11 facilities that are required to test their finished products under this law. However, management at 6 of the 11 facilities reported they were not conducting the required tests. They stated they were unaware of the law, misunderstood the regulations, or were waiting for DOA to review food safety plan. In each case, inspectors informed management about the testing requirements; however, no additional enforcement action was taken onsite.

According to the Act, DOA is responsible for defining product testing frequencies, classifying or exempting facilities, and notifying each facility of their testing requirement. Facilities determine which tests to conduct based on the inherent risks of their products or processes; however, they must report any positive test results to DOA within 24

hours. DOA completed the initial classification process and notified facilities in 2010. Currently, 448 (61%) of the 740 facilities are classified as high, medium, or low risk; 118 (16%) are unclassified; and 174 (24%) are exempt. High risk facilities must test at least bi-monthly, medium risk facilities must test monthly and low risk facilities must test quarterly. Given these requirements on testing frequency, in the 17 months (from July 2010 to December 2011) following implementation of the Act, a total of 7,503 tests should have been conducted by facilities. DOA does not collect information on the number of tests conducted; however, according to its records, seven positive tests have been reported during this period. During the same period, 458 finished product samples were taken during inspections and resulted in 11 positive tests. It appears that the incidence of positive tests is either significantly lower in the facilities' internal testing (25 times less than that of DOA testing) or not all facilities are testing as required.

Over three years have elapsed since the General Assembly passed the testing legislation and over two years have elapsed since DOA established the regulations requiring facilities to begin testing. To ensure food processors are compliant with

<sup>&</sup>lt;sup>8</sup> As noted on page 3, Food Safety Plans must be accepted by DOA, and may reduce the frequency of internal testing.

state testing laws, DOA management should establish oversight and enforcement procedures. DOA should consider collecting information on the products selected for testing by each facility, and the types of tests each facility conducts. This information would provide DOA a baseline for what facilities are and should be testing. Additionally, DOA should periodically review the incidence rates of reported positive tests from both facility testing and DOA testing to approximate the effectiveness of the law.

Agency Response: The department indicated that, with large, multi-state companies, the on-site personnel may not always be aware of the testing programs. They note that the new inspection form incorporates a category for testing, reporting, and records to identify facilities that are not complying with the regulations. Each time an inspector identifies a firm not conducting required testing, or cannot provide lab analysis, the firm is contact by the Food Safety Division to verify compliance with the testing requirements. Enforcement action is taken according to the findings noted at the firm. According to department staff, they have since contacted the six firms noted above and believe that four of the firms are conducting testing.

## The department could improve its guidance to inspectors regarding escalation of violations for corrective action.

We found an overall lack of internal controls to ensure the enforcement process is followed. Problems were identified in the processes for determining if a follow-up inspection should be conducted, the escalation of enforcement efforts, and the timeliness of enforcement actions. It should be noted, because of the way data is captured, it is not possible to determine whether a follow-up inspection was necessary, as required by the rules and regulations. Each inspection has to be reviewed individually to identify when the inspection occurred, what violations were identified, and whether additional inspections resulted. As noted earlier, inspectors do have the authority to stop the sale of products if violations that pose a danger to the public are identified. This review focused on the process DOA has to addresses violations that, while in need of correction, do not warrant immediate closure of the facility (see Exhibit 10).

• Our review found that a follow-up was not always conducted when a critical violation was identified. For example, the following violations were noted and no follow-up inspection was conducted: cabbage spinner not cleanable, leaking drain in production area, chemicals not stored properly, no handwash sink in processing area, and condensate leaking and pooling. The audit team does not contend that any of these are a food safety risk; however, the inspectors recorded each and they are all violations of a critical item. As such, a follow-up inspection would have been justified. Staff noted that the decision to conduct a follow-up inspection is made by the inspector and based on the degree of violation observed while onsite and whether or not the violation could impact food safety.

<sup>&</sup>lt;sup>9</sup> According to the rules and regulations, there are *critical items*, defined as a provision of [the code], that, if in noncompliance, is more likely than other violations to contribute to food contamination, illness, or environmental health hazard.

Exhibit 10 Administrative Enforcement Escalation Process				
Process Step	Department Activity	Action Taken		
Step 1	Original Inspection	If a violation can be corrected during the inspection, the facility is expected to do so. The violation is still recorded in the report, but no further action is required. If the violation cannot be corrected immediately, the inspector schedules a follow-up inspection.		
Step 2	Compliance Letter	Items that were not corrected during the original inspection should be corrected by the negotiated date. If, at the time of the follow-up inspection, the issue is not corrected, the department issues a letter requiring the facility submit a plan of action detailing its intended long-term solution.		
Step 3	Compliance Meeting	If the violation continues to occur, the department instructs facility representatives to appear at the department headquarters for an informal compliance hearing to discuss the issue.		
Step 4	Settlement Conference	If the item still has not been corrected, the department will initiate a formal settlement conference and present other enforcement procedures, which may include assessing a fine or suspending the firm's license.		
Source: Department of Agriculture Memo 03-3				

- Our review found occasions where multiple follow-up inspections were completed to address repeat violations; however, no additional action was taken to escalate enforcement. For example, DOA conducted 26 onsite inspections at one facility between December 2010 and January 2012. A total of 52 repeat violations regarding, among other problems, infestation of rodents and roaches were identified. During this time, the firm voluntarily ceased operations on four occasions for a total of 36 days. However, in two cases, the facility was allowed to re-open during a subsequent inspection when no evidence of rodent or roach activity was observed. In October 2011, the audit team questioned management about this facility and in January 2012, the department held a settlement conference and placed the facility on a two-year probation and collected a \$1,000 fine. Over the 14 month period, the inspectors spent a total of 88 hours on-site, an average of approximately six hours each month. In another example, DOA conducted 11 inspections at a second facility over the course of four months. During three of these inspections, inspectors found repeat violations involving rodent activity. Enforcement activities were not escalated until the issue was identified by the audit team. In addition to having non-compliant processors continue operations, failure to escalate enforcement procedures also causes a drain on department resources.
- Our review found that, when DOA did determine escalation was necessary, there was often a delay in taking action. On average, administrative enforcement actions began approximately 20 work days after a repeat violation citation. Over half of the cases were initiated between 4 and 13 weeks after the repeat violation. Initiating such actions in a timely manner is necessary to convey the proper urgency to ensure violations are corrected.

It should be noted that the department reports that it recently appointed a Compliance Officer. When firms violate the food safety regulations, the Compliance Officer will be responsible for determining the steps that should be taken to achieve

compliance. Inspectors will complete a newly created form when these violations are identified and forward it to the Compliance Officer for action. The department should develop specific criteria that would trigger a follow-up inspection; management should then conduct a regular desk review of a cross-section of inspection reports to ensure consistency among the inspectors in their decisions to conduct follow-ups. The department should review its process for escalating enforcement action to ensure that it is adequate, update its processes as necessary, and institute internal controls to ensure processes are followed. Such controls could include the implementation of an automatic notification in the inspection software noting when repeat violations occur, or allow inspectors to initiate the second phase of enforcement escalation (compliance letter to the facility) instead of management. Finally, enforcement actions should be prioritized to ensure that violative conditions are addressed as quickly as possible. Management should develop procedures that will address the delays in initiating such actions. The implementation of enhanced enforcement strategies will ensure that violative conditions are corrected so that food safety is not compromised.

Agency Response: The department indicated that, in January 2012, it developed a Reportable Conditions Form to identify firms that should be tracked by the Compliance Section. The field inspectors must complete the form for inspections with significant critical violations or if an enforcement tactic has been used. From there, the form is used to prompt compliance activity, such as follow-up inspections, contacts, with owners/managers to discuss inspection findings, issues compliance letters, etc. The department reports that this new form has been utilized to call attention to firms where escalation was necessary, and has greatly improved the tracking and expediting of enforcement actions.

## Consideration should be given to making inspection reports available to the public.

Currently, the inspection reports are viewed by the facility's management and DOA. However, unless a member of the public submits an Open Records Request for a specific inspection report, the public remains largely unaware of the violations and inspection results of processing facilities manufacturing food in the state.

DOA management expressed concern with disclosing inspection reports *en masse* due to the potential release of proprietary information that may be included in the reports. While protecting proprietary information is important, some states do provide public access to inspection documents and have found ways to balance confidentiality with the public's right to review the information. For example, Iowa's department of Agriculture provides a web-based searchable database with public access to documentation on inspection activity for all food sales establishments in the state including processors. Iowa addresses the preservation of proprietary business information by training inspectors to avoid specific descriptions of equipment and processes when composing their remarks in the report. Other states offer facilities the opportunity to request the redaction of any part of the report if they provide a compelling business reason for the exclusion. This method places the responsibility of the proprietary designation on the facility instead of the department, while honoring the notion of the competitive business environment.

#### The department's process for identifying unknown firms appears adequate.

Food processing facilities operating in Georgia must obtain a license from DOA prior to beginning operations. DOA uses the applications and approvals of these licenses to populate its database and identify facilities requiring inspection. According to management, county governments require the facilities produce a state license prior to granting them a local occupational tax permit or local business license. Therefore, unlicensed businesses would not be able to operate in the state. In addition, management checks the DOA database against an FDA list of businesses to identify missing facilities. Finally, DOA noted that it relies on industry competitors to alert them to processors operating without a state license.

We researched 17 counties to determine if all require proof of a state license prior to issuing an occupational tax permit or business license. We found that 10 of these 17 do not issue business licenses or occupational tax permits. In addition, a survey of a portion of those that do issue local business licenses revealed that they did not require the disclosure of a state-level license as a formal criterion during the application process. As a result, food processors operating in the unincorporated portions of these counties may not be required to secure a license from either the local county government or DOA.

However, in response to this information, we did an Internet search to determine if unlicensed facilities were operating in the state. Our methodology also included a review of data provided by the Georgia Department of Labor. Our research identified six firms that were operating as unlicensed food processors, which demonstrated negligible adverse effects associated with this potential gap in controls. DOA could consider identifying counties where a license or permit is not required and monitoring the businesses in that area that may require licensure.

## **Appendix A**Objectives, Scope, and Methodology

#### Objectives:

This performance audit of the food processing inspection unit within the Georgia Department of Agriculture (DOA) was selected based on an internal risk assessment. Factors considered included the public safety aspect of the organization's mission, the size of the population impacted by the program, and the timeliness of food inspections as an audit topic.

The audit team set out to complete the following five objectives relevant to the food processing inspection unit:

- <u>Objective 1</u>: Has DOA identified all food processing facilities that it has statutory authority to inspect, and does it have a reasonable process for identifying and inspecting new facilities prior to them beginning operations? If not, what is prohibiting them and what are the consequences?
- <u>Objective 2</u>: Does the inspection <u>frequency</u> standard established by DOA provide reasonable assurance that food manufacturing facilities are adhering to state food safety regulations? If not, what is preventing the establishment of such standards, and what steps can DOA take to improve inspection scheduling?
- <u>Objective 3</u>: Does the <u>quality</u> of the food manufacturing inspections conducted by DOA provide reasonable assurance that facilities are complying with the state's food safety regulations? Do the inspection reports provide an accurate record of the relevant conditions found during the inspections, and are the results utilized in a meaningful way? If not, what is the potential impact?
- <u>Objective 4</u>: Is the food safety testing regimen currently utilized in Georgia effective at ensuring a safe and unadulterated food supply? If not, what improvements can be made?
- <u>Objective 5</u>: Is the state effective at enforcing compliance with state food safety guidelines? If not, what are the roadblocks to effective enforcement, and how can DOA better utilize the enforcement powers granted to it under the law?

#### Scope:

This audit generally covered activity related to food processing inspection within the Food Safety Division during the period June 2010 through May 2011, with consideration of earlier or later periods when relevant. The Food Safety Division also conducts inspections of the retail food outlets and dairy plants, and also grades poultry eggs. These areas were not included in this review. Information used in this report was obtained by reviewing relevant laws, rules, and regulations; interviewing agency officials and staff from DOA, other state food processing personnel, and expert at the University of Georgia; analyzing data from the department's Digital Health Department (a web-based inspection database); and accompanying inspectors for a period of two days. The Digital Health Department database is a commercially available product currently in widespread use nationally. We reviewed

the data relevant to our review period and determined it sufficiently reliable for our purposes.

Government auditing standards require that we also report the scope of our work on internal control that is significant within the context of the audit objectives. All of our objectives address aspects of the food processing inspection unit's internal control structure. Specific information related to the scope of our internal control work is described by objective in the methodology section below.

#### Methodology:

- To determine if DOA's facility inventory was complete, we obtained a list of food processing facilities from the Department of Labor and compared the list to DOA's inventory. We then conducted phone interviews of selected facilities to determine if they were currently manufacturing a food product. We also collected data from the Association of County Commissioners of Georgia to determine if counties had business or occupational taxes. We also interviewed officials from a sample of local governments to determine the steps they take to identify food processors.
- To determine if the inspection frequency standard was sufficient to ensure compliance with state regulations, the audit team analyzed food processing inspection data from a recent 12-month period (June 2010 through May 2011). We reviewed reports generated through DOA's web-based inspection database, and also obtained access to the database, which allowed us to conduct file reviews of inspection activities.
- To determine if the quality of the inspections was sufficient to ensure compliance with state regulations, the audit team observed each inspector for a period of two days while they conducted inspections. We documented our observations and shared them with DOA management, who were then invited to provide a response, or to explain the irregularities.
- To determine if the food safety testing regimen was sufficient, we conducted a walk-through of the sample collection, processing, and testing process. We then obtained testing data and analyzed the results. Once all positive tests were identified (approximately 30 for the year), we reviewed DOA's response to each case to determine if the response was appropriate.
- To determine if the state is effective at enforcing compliance with state food safety guidelines, the audit team identified cases where multiple follow-up inspections were completed without escalation. We also conducted an analysis of the administrative enforcement timelines to identify gaps or delays in escalation.
- We discussed the performance audit with an expert from the University of Georgia's Center for Food Safety to verify certain conclusions and gather an external perspective concerning the risks associated with certain DOA policies and procedures.

We conducted this performance audit in accordance with generally accepted 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.

### **Appendix B**

Count of Facilities by	County
Classified by Licens	ing Tier

	Lowest Risk Highest Risk						
County	Tier l	Tier 2	Tier 3	Tier 4	Tier 5	Total	
A 1	Tier i				1101 3	=	
Appling		1	3	1		5	
Atkinson		3	2				
Bacon		3	2	1		6	
Baker Baldwin		1		1		2	
		1	1	1			
Banks			1	2		3	
Barrow			2	3		3	
Bartow		1	2	2	2	5	
Ben Hill		1	-		2		
Berrien		1	5	1		7	
Bibb			1	4		5	
Bleckley			1	1		1	
Brantley			2	1		1	
Brooks			2	2		4	
Bryan		-	2	1	-	3	
Bulloch		1	2	_	1	4	
Burke			1	1	-	2	
Butts			_	_	1	1	
Calhoun			1	2		3	
Camden			2	1		3	
Candler			1	_		1	
Carroll			1	9	1	11	
Catoosa			1			1	
Charlton			1			1	
Chatham		4	10	7	2	23	
Chattahoochee						0	
Chattooga			1			1	
Cherokee		1	1	3		5	
Clarke		4	3	1		8	
Clay			1			1	
Clayton			3	4	4	11	
Clinch	16	5	1			22	
Cobb		3	10	24	2	39	
Coffee		1	1	2		4	
Colquitt		1	2	4		7	
Columbia			1	2	1	4	
Cook			1			1	
Coweta		1	5	1		7	
Crawford			1			1	
Crisp			3			3	
Dade						0	
Dawson		1	3	1		5	
Decatur				2	1	3	

Count of Facilities by C	ounty
Classified by Licensin	g Tier

	Lowest Risk Highest Risk					
County	Tier l	Tier 2	Tier 3	Tier 4	Tier 5	Total
D 11 11	11011					7.0
DeKalb		3	11	34	4	52
Dodge			1	2		1
Dooly			_	3	_	3
Dougherty			5	3	2	10
Douglas				1		1
Early		1	1	3	1	6
Echols				1		1
Effingham			3			3
Elbert			1			1
Emanuel		1		4		5
Evans		1		3		4
Fannin			7	1		8
Fayette			2	1		3
Floyd			4	4		8
Forsyth		1	3	3		7
Franklin						0
Fulton		6	18	40	7	71
Gilmer						0
Glascock						0
Glynn			1	3	1	5
Gordon			3	4		7
Grady			1	1		2
Greene						0
Gwinnett		4	12	21	4	41
Habersham		1			1	2
Hall		2	6		1	9
Hancock		_	2			2
Haralson		1		2	1	4
Harris		1	1	2	1	3
Hart		2	1	1		3
Heard				1		0
Henry			3	2	1	6
Houston			3	2	-	6
Irwin			3	2	1	5
Jackson		2	1	2	1	6
			1	1	1	1
Jasper Leff Davis			1	1		2
Jeff Davis		1	1	3		
Jefferson		1				4
Jenkins			1	1		1
Johnson			1			1
Jones			1	2		1
Lamar			1	2		3
Lanier		2				2
Laurens						0
Lee			1	2		3

Co	ount of	Facilit	ies by	Count	·v	
	laccifi <i>c</i>	n donin	icensi	na Tie	r r	
	Classified by Licensing Tier  Lowest Risk Highest Risk					
County	Tier 1	Tier 2	Tier 3	Tier 4	Tier 5	Total
7.0	Heri	Her 2	Her 3	Her 4	Her 3	
Liberty			1			0
Lincoln			1			1
Long	1	1	0	12		0
Lowndes	1	1	3	12		22
Lumpkin				1		3
Macon		1	4	1		5
Madison		1	2			
Marion McDuffie						0
McIntosh			2	-		0
			3	6		9
Meriwether			3	2		3
Miller			~	2		2
Mitchell			5	3		8
Monroe			1	-		1
Montgomery		_	1	1		2
Morgan		1	-	1		2
Murray			2	_		2
Muscogee		4	6	8		18
Newton			2	1	1	4
Oconee				1		1
Oglethorpe						0
Paulding						0
Peach		1	2			3
Pickens			1	1		2
Pierce		1			1	2
Pike			1	1		2
Polk			1			1
Pulaski				2		2
Putnam			1			1
Quitman						0
Rabun		2	3	4	1	10
Randolph				1		1
Richmond		2	2	2	2	8
Rockdale			3		1	4
Schley			1	1		2
Screven			2		1	3
Seminole				2		2
Spalding				3		3
Stephens			1			1
Stewart				1		1
Sumter		1	4	1		6
Talbot						0
Taliaferro						0
Tattnall			1	3	1	5
Taylor						0

## Count of Facilities by County Classified by Licensing Tier Lowest Risk — Highest

		t Risk — Highest Risk				
County	Tier l	Tier 2	Tier 3	Tier 4	Tier 5	Total
Telfair				1		1
Terrell			1	3		4
Thomas			4	3	1	8
Tift		1	6		1	8
Toombs			2	1	2	5
Towns			3			3
Treutlen						0
Troup			1	1		2
Turner		1	1		1	3
Twiggs						0
Union		1	3			4
Upson		2	1			3
Walker			1	1		2
Walton			2			2
Ware		1	2			3
Warren						0
Washington				1		1
Wayne			2	1		3
Webster				1		1
Wheeler						0
White		2	8	1		11
Whitfield			1	1		2
Wilcox				1		1
Wilkes						0
Wilkinson			1			1
Worth			1	3	1	5
Total	17	79	277	313	54	740

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