Secretary of State Audit Report

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Oregon Department of Agriculture: Improved Management Practices, Use of Resources Could Help Food Safety Program Achieve its Mission

Executive Summary

The Oregon Department of Agriculture's (ODA) Food Safety Program is struggling with a backlog of establishments needing inspection. This backlog was caused by an increase in the number of licensed businesses and complexity of business practices, and an inspection staff busy with other duties. By implementing stronger management practices, making better use of data, and more strategically deploying its resources, the program can reduce its backlog of inspections, better achieve its mission of preventing the spread of foodborne illness, and prepare for more regulatory challenges in the near future.

The Food Safety Program has an inspection backlog

According to ODA, a backlogged firm is one that is three or more months late for an inspection. We found that, as of October 2016, 2,841 firms were late for an inspection.

Inspectors have not kept up with this workload in part because the number of licensed businesses has been steadily increasing for the last 10 years. There are now more than 12,000 licensees needing regular inspection by the Food Safety Program.

Inspectors are also spending significant amounts of time on duties that are not related to inspections, such as attending training courses in specialized license types or answering customer questions on the phone. Management has established goals for how much time inspectors should be spending on inspection-related tasks, but it is not clear these goals are being met.

Federal grants, contracts take time away from inspections

Many firms in Oregon are subject to inspection not only by ODA, but also by the federal Food and Drug Administration, or FDA. The Food Safety Program has a contract with FDA to conduct some of these inspections in exchange for reimbursement. Currently, ODA conducts 500 contract

inspections each year, one of the highest contract workloads in the country. These inspections take significantly longer than a routine ODA inspection.

ODA's Food Safety Program was one of the first in the country to enroll in the federal Manufactured Food Regulatory Program Standards, or MFRPS. Through MFRPS, the program has developed policies and procedures related to enforcement actions, responding to food-related illness, and training. This work has taken time away from conducting food safety inspections and was one of the factors contributing to the backlog.

Staff turnover is a challenge

Since 2006, 28 inspectors have either left the agency or retired. Retiring inspectors often take decades of expertise and experience with them. Hiring and training new staff to replace them is time-intensive. And there is no formal succession plan to prepare for their departure.

Turnover has been especially challenging for the program's two field operations managers, who are responsible for supervising inspectors. ODA has struggled to keep people in these two positions.

The program uses a tool from FDA that allows food safety regulatory programs to calculate the number of inspectors required to manage the workload. But we found the Food Safety Program was incorrectly using this tool and may not have an accurate estimate of its own staffing needs.

The program needs more management oversight

More oversight of food safety inspectors is needed to ensure the quality and consistency of inspections. Field operations managers only review the inspection reports of new inspectors while they are trained. Although field operations managers are expected to supervise inspectors in the field, this is not happening because managers are busy with office work.

Management could offer more guidance to help inspectors be more consistent in their interactions with licensees. Currently, inspectors are inconsistent in how they issue enforcement actions and how much time they spend explaining the rules and regulations to food establishments.

The program is also at risk of overlooking some businesses that are operating without a license. Currently, ODA relies on new businesses to contact them to obtain a license. But for businesses that may not, there is no formal policy or procedure to proactively identify them.

The program could benefit from better use of data

We found the Food Safety Program is missing several opportunities to use data to help make decisions.

Although management can access the program's Be Food Safe database to see how many firms are overdue for an inspection, they have not been consistently tracking and storing these data. Keeping track of these

numbers could be helpful in identifying patterns and strategies to reduce the backlog.

Some data are not being kept in the most efficient form for analysis. Inspectors fill out daily paper reports of how they spend their hours, but management does not analyze these. By keeping these data in a digital format that can be easily accessed, and regularly analyzing them, management could identify how staff spend their time and look for opportunities for improvement.

We also found that the program could benefit from a designated data analysis position. Managers say they do not have time to collect and analyze data because of their other responsibilities. By having someone whose role is primarily data analysis, the program could benefit from this data without compromising these other duties.

Recommendations

To work toward the goal of reducing the backlog of inspections, we recommend ODA reconsider some of its workload, provide more guidance to inspectors, and better track and analyze data to inform these decisions. To help the program better achieve its mission, we recommend ODA develop policies and procedures to improve oversight of inspectors and develop partnerships with other agencies. And to address some of the staffing challenges, we recommend the program use data to analyze its staffing needs and develop a succession plan for retiring inspectors. Our specific recommendations can be found on Page 22 of the report.

Agency Response

The agency generally agrees with our findings and recommendations. The full agency response can be found at the end of the report.

Background

A farmer stands in his field in the early days of Oregon agriculture.

Photo by Oregon Department of Agriculture

Agriculture has existed in Oregon for as long as it has been a state. Early boards and commissions reflected the range of activities falling under the umbrella of Oregon agriculture; from pest and disease prevention to commodity inspection to animal and livestock regulation.

In 1931, the legislature moved to gather 13 separate boards, bureaus, and commissions and unite them as a single State Department of Agriculture. This agency is now known as the Oregon Department of Agriculture (ODA).

Since then, agriculture in Oregon has grown, as have the agency's responsibilities. Those responsibilities include regulating the use of pesticides; protecting Oregon from plant pests and diseases; inspecting commodity crops; helping producers sell and ship products domestically and overseas; and inspecting almost all facets of the food distribution system for health and safety.

These wide-ranging duties are encompassed by three policy areas of the agency's mission:

- to ensure food safety and provide consumer protection;
- protect the natural resource base for present and future generations of farmers and ranchers; and
- promote economic development and expand market opportunities for Oregon agricultural products.

Of all these, the agency's highest priority is the Food Safety Program.

Roles and responsibilities of the Food Safety Program

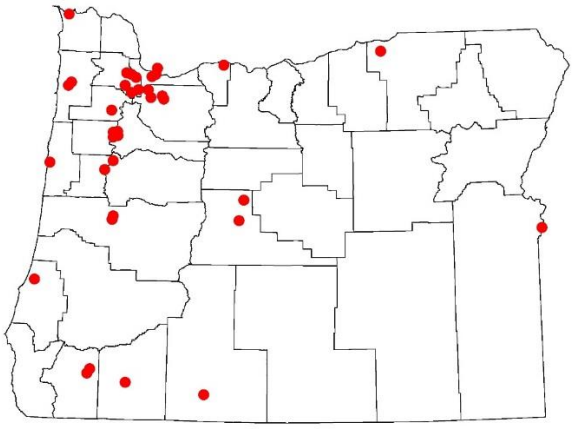
Even before there was a State Department of Agriculture, there were food safety inspectors. In the early 1900s, the Dairy and Food Commission sent inspectors out in a Model T, spending weeks driving across the state to visit farms that needed to be checked.

Today's Food Safety Program employs 38 ins7pectors, spread throughout the state (see figure 1). These inspectors are supervised by two field operations managers, who are in turn led by two program managers and the program director.

The program is responsible for licensing and regulating more than 12,000 food production, processing and distribution establishments throughout the state, including grocery stores, bakeries, processors and manufacturers, as well as regulating Oregon's dairy and shellfish industries.

The program's inspection staff conduct routine food safety inspections. Seven of these inspectors are specialists, who provide expertise for inspections of certain specialized license types, such as dairy, shellfish or manufactured foods.

Figure 1: Food safety inspectors are located throughout Oregon



ODA works in tandem with the Oregon Health Authority, whose county health departments are responsible for inspecting restaurants and other food service establishments.

During a retail food safety inspection, inspectors refer to the Food Code to ensure that food is being handled and sold safely. The United States Food and Drug Administration (FDA) issues an updated model Food Code every several years, which states can either adopt entirely or use to create their own version. Oregon has adopted almost all of the 2009 Food Code, with some minor changes to reflect the state's unique agriculture landscape.

Inspectors describe the Food Code as prescriptive. For instance, it requires that potentially hazardous food be maintained at a minimum of 130°F for hot foods, and a maximum of 41°F for cold foods. It also specifies how to keep food preparation areas clean; how to properly store and label potentially hazardous food; and how to maintain entrances to prevent pest access, among other things.

The Food Code applies only to retail licensees such as grocery and convenience stores. Other licensees, such as manufacturers and processors, are regulated by other federal codes that are more complicated, but ensure that food is being processed and created to avoid contamination and maintain public health.

All food safety licensees are inspected in regular intervals, although how frequently varies by the license type, the level of risk at each facility, and record of compliance. A low-risk retail firm, such as a convenience store, may only be inspected once every three years. But a high-risk retail establishment, such as a large grocery store that prepares food on-site, is inspected annually.

In 2014, the Food Safety Program launched its own application for inspectors to electronically fill out reports in the field, known as Be Food Safe. The application stores some data, such as the dates when an establishment is inspected and the number of licenses assigned to each

inspector. Inspectors told us this new system is preferable to the former method of filling out paper reports and helps complete inspections faster.

Program revenue includes federal contracts and grants

For the 2015-17 biennium, ODA was operating with a $105.8 million budget, $10.9 million of which was earmarked for the Food Safety Program. The bulk of the program's budget lies in Other Funds, which includes license fees and reimbursement for inspections conducted under a contract with FDA.

A food safety inspector checks the temperature of product.

Photo by Oregon Department of Agriculture

Food establishments that sell or receive products across state lines are required to be inspected not only by ODA, but by FDA. To streamline this process, FDA contracts with states to conduct some of these inspections. Forty-three states, including Oregon, are currently under contract.

States meet individually with FDA to negotiate the number of contract inspections they do each year. Oregon currently conducts 500 FDA contract inspections annually — one of the highest workloads in the country.

As part of that negotiation, ODA calculates the cost to the agency for conducting an individual FDA contract inspection. FDA then reimburses the agency for those costs at the contract year's end.

Participation in these FDA contract inspections means states are eligible to enroll in the Manufactured Food Regulatory Program Standards, otherwise known as MFRPS. MFRPS includes guidelines for developing 10 standards, the goal of which is to help states implement quality regulatory programs that are consistent nationwide.

For 2015-16, ODA received a grant of $300,000 to help with the implementation of MFRPS and offset the cost to the program of developing the standards.

In addition to the FDA contract reimbursement and the MFRPS grant, the Food Safety Program earns revenue from license fees. The amounts that ODA charges for its licenses varies by both the type of license and, in most cases, the gross annual sales reported by the firm. These annual fees range from as little as $108 to as much as $1,624.

ODA has statutory authority to raise license fees by no more than 3 percent annually. The program has not increased its license fees since 2009.

Audit Results

The Food Safety Program faces challenges to achieving its mission

Freshly-caught shrimp await processing.

Photo by Oregon Department of Agriculture

The mission of ODA's Food Safety Program is to help prevent the spread of foodborne illness. Program staff accomplish this mission through monitoring Oregon's food industry, enforcing sanitation laws, inspecting food establishments, and working to ensure food is not contaminated, mislabeled, misrepresented, or changed in any way that impairs its safety.

We identified a number of issues that challenge the program's ability to fully achieve its mission.

- Inspectors are struggling to inspect food establishments as frequently as they should.
- Federal grants and contracts, while beneficial, are taking up valuable time and resources.
- The program has faced significant staff turnover.
- Stronger oversight is needed by program management.
- The program is not fully taking advantage of data to strategically deploy its staff.

The stakes are high. The safety of the food system impacts every Oregonian. ODA plays a crucial role in ensuring not only the health and safety of the public, but the strength of Oregon's billion-dollar agriculture economy.

Not addressing these challenges could increase the risk to both public safety and the agriculture economy

Foodborne illness is common. The Centers for Disease Control and Prevention estimate that 48 million people — one in six — gets sick from a foodborne illness each year. The bacteria most often responsible, including Listeria monocytogenes, Salmonella, and Escherichia coli, are present at all stages of the food system.

Infection by these bacteria can have serious or even deadly consequences. Each year, an estimated 128,000 people are hospitalized for a foodborne illness; another 3,000 people die. And pinpointing the cause of an outbreak is notoriously difficult: not all illnesses are reported; symptoms may take days to appear; and people may struggle to remember everything they ate.

Adhering to food safety regulations is crucial to minimize the risk of contamination. It's up to food safety inspectors to make sure those regulations are followed.

Failure to comply with regulations increases the risk of foodborne illness

In the course of doing a food safety inspection, inspectors are looking for violations to the retail Food Code or other applicable regulations. Some of these violations may not be obvious to the average consumer, while others are more readily apparent.

In June 2015, two food safety inspectors made a visit to a grocery store in Portland to conduct a routine inspection.

They found hundreds of rodent droppings scattered throughout the store, from the beverage station in the front to the dry food storage area in the back. Seven dead mice were still locked in snap traps. The creatures had apparently found their way in through gaps around plumbing fixtures, between walls and floors and under doors.

Inspectors issued a notice of closure and condemnation to the firm for the affected areas. But rather than improve, the problem spread to other parts of the store.

During a later visit, the inspectors found thousands of insects on glue traps and dead insects visible inside wrapped packages of lettuce. This time, the rodents spotted were alive; one stuck to a glue trap behind the bread display, another running near the front of the store. Inspectors issued a notice of closure and condemnation to the entire store until the problem could be resolved.

Not all violations are so obvious. An employee may be failing to properly sanitize a food preparation area. Food may be held at an improper temperature, allowing bacteria to grow. A product may contain an allergen, like peanuts or soy, without declaring it on the label.

When food safety inspectors regularly visit these establishments, they can catch and help correct these violations, or even run tests to identify the presence of harmful bacteria, before someone becomes ill.

During an inspection of a Portland-based meat processor in March 2014, one food safety inspector took routine samples of the product. Those samples confirmed the presence of Listeria monocytogenes, prompting the firm to voluntarily recall the contaminated product. No illnesses were reported in connection with the incident.

A risk of unsafe food can also affect the reputation of a business

Several inspectors told us they see their job as protecting not only consumers, but businesses as well. A firm that garners a reputation as unsafe, unclean, or not in compliance with food safety regulations risks losing customers.

In October 2015, 13 people in Oregon and 27 in Washington were sickened in an outbreak of E. coli that was later determined to have originated with the restaurant chain Chipotle Mexican Grill.

The business suffered. In the three months after the outbreak, profits were down 44% compared to the year before. Its stock dropped by 37%.

Although restaurants like Chipotle are not inspected by ODA, businesses that ODA does inspect could be similarly affected by an outbreak of foodborne illness.

When inspectors are able to conduct inspections on a regular basis, these risks are mitigated. But challenges facing the program have resulted in inspectors scrambling to complete their workload and some firms going without an inspection for years.

Inspectors are behind on inspections

ODA's Food Safety Program uses a risk matrix to determine how frequently licensed firms should be inspected. High-risk firms, such as large grocery stores or producers of acidified foods, are to be inspected at least once a year. Medium-risk firms should be inspected at least once every two years, and low-risk firms once every three.

But inspectors have not been meeting these frequencies.

According to ODA, a backlogged firm is one that is three months late for an inspection. We found that, as of October 2016, 2,841 firms were overdue for an inspection.

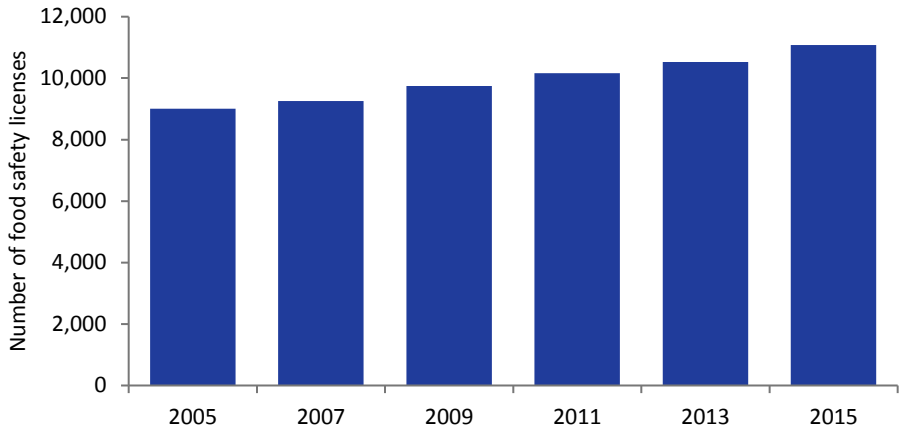
ODA does not know how long this backlog of inspections has existed. Agency staff are able to access their Be Food Safe database and determine how many firms are past due at that moment. But the program has not been keeping track of these data and is unable to say how many firms were past due a year ago or five years ago.

The number of licensees and demand for inspections has increased

According to inspectors, keeping up with the workload is increasingly difficult as the number of food establishments in the state grows.

In 2005, the Food Safety Program licensed 9,000 firms in the state of Oregon. By 2015, that number had increased to 11,000 firms. Now, the number of licensed firms in the state is more than 12,000.

Figure 2: The number of licenses has increased in the last 10 years



Note: License counts are from December of each year.

Meanwhile, staffing levels have changed very little. There are currently 38 food safety inspectors responsible for inspecting all 12,000 licenses. Staffing levels have fluctuated in recent years, but by a relatively small amount, give or take two or three positions.

Inspectors also told us that not only has the number of licensees increased, but business practices are more complex, increasing the amount of time needed for individual inspections. For example, more grocery stores are now participating in high-risk food preparation activities, such as sushi.

Management has not made it a practice to regularly track how long inspections take, so we were unable to independently verify if inspection times are, in fact, increasing.

Inspectors are spending time on non-inspection duties

The job of a food safety inspector goes beyond conducting inspections. Tasks and duties vary from inspector to inspector, depending on their own expertise, background, and job classification.

An ODA inspector gathers shellfish samples.

Photo by Oregon Department of Agriculture

In addition to inspecting food establishments, inspectors investigate consumer complaints, perform facility plan reviews, examine packaging and labels, gather samples for routine testing, offer consultation for new businesses, and are available to answer questions from business owners.

Inspectors involved with the dairy and shellfish programs have additional duties, which range from sampling water at the Oregon coast to evaluating highly technical pasteurization and processing equipment. Other tasks may include coordinating recalls, attending training, auditing FDA contract inspection reports, and testing the program's Be Food Safe app.

Management's goal is that most inspectors spend about 63% of their total working hours conducting inspections. Specialists are expected to spend 50% of their total hours on inspections.

However, it is not clear these goals are being met. Inspectors fill out daily reports accounting for their work hours, but management is not using this information to analyze how inspectors spend their time. Some inspectors told us they spend very little time conducting inspections because they are too busy with other duties and projects, including Be Food Safe and MFRPS.

Inspectors cannot keep up with the license inspection demand

In interviews, many inspectors said they were simply unable to complete all their work and assignments in the time they were given.

Many inspectors said they needed to prioritize their work. For some inspection types, such as dairy or FDA contract inspections, there are consequences if an inspection is missed or completed late. Dairy inspections must be completed in order for Oregon's dairy farmers to ship out of state; FDA contract inspections must be completed on time for the program to receive reimbursement.

As a result, other inspection types — primarily retail — are given a lower priority or simply not done. Several inspectors told us that the inability to keep up with the work was stressful, distressing, and difficult.

Management has set goals to reduce the number of licenses that are overdue for an inspection. By the end of 2016, they hope to eliminate the backlog of high-risk firms that haven't been visited in two years. But they told us "It took years to get to this point, and it will take years to dig ourselves back out."

The program started to fall behind around 2009 or 2010 — right around the time the Food Safety Program implemented MFRPS.

Federal grants and contracts are beneficial, but come at a cost

Ten standards of MFRPS

Standard 1: Regulatory Foundation
Standard 2: Training Program
Standard 3: Inspection Program
Standard 4: Inspection Audit Program
Standard 5: Food-related Illness and Outbreaks and Response
Standard 6: Compliance and Enforcement Program
Standard 7: Industry and Community Relations
Standard 8: Program Resources
Standard 9: Program Assessment
Standard 10: Laboratory Services

MFRPS has been beneficial in developing policies, procedures

Oregon was one of the first states to enroll in FDA's Manufactured Food Regulatory Program Standards, or MFRPS, in 2007.

Since then, the Food Safety Program has invested considerable time and energy in developing the 10 standards. Several food safety inspectors have taken time away from their usual duties to accomplish this. To help offset the cost of staff time, FDA offers a grant of up to $300,000 each year with enrollment in MFRPS.

Management told us that while MFRPS has taken away from time spent on inspections, the investment has been worth it. MFRPS helped the program organize, develop, and document policies and procedures related to enforcement actions, responding to food-related illness, and training. For example, the risk matrix that determines how frequently licenses should be inspected was developed through MFRPS.

With the standards now developed, it is unclear what impact MFRPS will have on the program's workload in the future. But by scaling back the amount of time spent on MFRPS, staff could spend more time on inspections and working to reduce the backlog.

But MFRPS isn't the only thing taking time away from inspections. There is a requirement that states must meet before they can be awarded the MFRPS grant — they must maintain an FDA inspection contract.

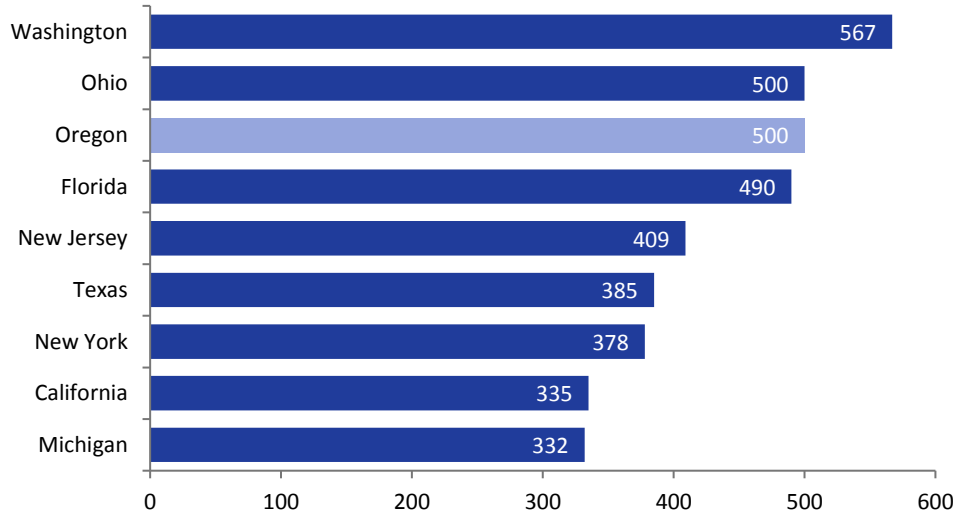
FDA contract inspections are time-consuming

Forty-three states have a contract with FDA to conduct inspections in some food manufacturing and processing firms, but Oregon has agreed to take on a much higher number than almost every state.

During contract years 2015 and 2016, ODA agreed to conduct 500 inspections on behalf of FDA. This is tied with Ohio for the 2nd highest number of contract inspections nationwide, surpassed only by Washington. As recently as 2010, the program had agreed to conduct 750 contract inspections.

Contract inspections can vary by state. For example, Alaska conducts fewer contract inspections than Oregon, but many of them are complex and may take longer.

Figure 3: Oregon is tied for the 2nd highest number of FDA contract inspections



Note: All numbers are from the 2015-16 contract year

Representatives from ODA and FDA meet annually to negotiate the number of firms to inspect, which firms to inspect, and the unit price per inspection. The unit price is the cost ODA estimates for a single contract inspection accounting for the hourly wage of the inspector, how long the average contract inspection takes, the average travel time, and other factors.

FDA also requires ODA to conduct desk audits of the inspection reports and send inspectors out in the field to audit each other. This additional cost for time spent auditing is included in the negotiation.

Once all of the contract inspections are completed, FDA reimburses the Food Safety Program for these costs. For fiscal year 2015-16, ODA estimated the total cost to the program to be $676,941.65.

These FDA contract inspections take significantly longer than routine inspections. In addition to the routine inspection work, contract inspection reports must include a detailed questionnaire and documentation about the firm's operations. Reports are reviewed by other staff, who then submit them directly to FDA.

Some inspectors estimated FDA contract inspections take four to six hours longer than a routine inspection, much of that due to writing the report. Particularly complex facilities can take as long as 12 hours to complete a contract inspection.

Participating in the FDA contract, regardless of the number of inspections completed, offers a number of benefits for state food safety programs. It allows them to enroll in MFRPS. It offers access to training on how to inspect specialty license types, such as acidified foods or low-acid canned foods. It also provides the opportunity for states to get funding to seek accreditation for their laboratory.

But the high number of these time-intensive inspections may be prohibiting ODA from completing some of its own routine inspections. If the Food Safety Program were to reduce the number of contract inspections by 100, we estimate they would gain back 700 inspection hours that could be used to reduce the backlog.

The program could do a better job of addressing its staffing challenges

In February 2014, representatives from the Northwest Grocery Association approached the Legislature to ask their approval for three limited duration inspector positions to be hired by the Food Safety Program.

The Legislature granted the request. ODA began recruiting for three limited duration positions in December 2014, to add to the existing team of 35 food safety inspectors. In the upcoming legislative session, ODA plans to request that two of those positions be made permanent.

Management told us they believe this strategy to reduce the backlog appears to be working. However, since the Food Safety Program does not track the extent of the backlog over time, it is unclear how much of an effect these extra positions are having.

In interviews with inspectors, almost everyone told us the one thing that could help with the backlog would be to add more staff. They think the Food Safety Program is understaffed, given the number of licenses and other duties they are responsible for and due to staffing challenges the Food Safety Program has recently faced.

The program has experienced significant turnover

Since 2006, 28 inspectors have either left the agency or retired.

Retiring inspectors are a challenge for the program. Inspectors who retire after decades of service take the accompanying knowledge and expertise with them. And there is no formal succession plan for the agency as a whole, let alone the Food Safety Program, to prepare for their departure.

In recent months, some staff have agreed to stay on part-time to help train and prepare their successors. But these efforts have been initiated by staff themselves; this does not occur on a regular basis.

An inspector conducts an inspection of a processing plant.

Photo by Oregon Department of Agriculture

Hiring and training new inspectors is a time-intensive process. New inspectors undergo rigorous training that lasts weeks before they begin conducting inspections. This process involves much of the food safety staff, who take time away from their own duties to help with training.

Turnover has been especially challenging for the program's two field operations manager positions, which are responsible for supervising food safety inspectors. In the course of conducting our audit, one manager retired and the other has been in the position less than two years. One candidate who moved up to fill the vacant position decided against it. As of the writing of this audit, the slot remained vacant.

Several inspectors told us this turnover was due to compensation and workload. In fact, specialists have the potential to earn higher salaries than field operations managers. Staff described the field operations manager roles as more time-intensive and more stressful. Several staff told us that specialist positions are preferable to supervisory roles.

Staffing needs are being incorrectly calculated

FDA offers a tool for state regulatory programs to estimate their staffing needs based on factors like the number of licenses, how frequently licenses are being re-inspected, and how long inspections take.

Using this tool, the Food Safety Program determined they needed 49.4 full time equivalent (FTE) inspectors.

But we found the program was incorrectly using the tool and over-estimating the number of inspectors needed to be fully staffed.

The Food Safety Program was incorrectly using the following factors in their calculations:

- The re-inspection frequency — the percentage of total firms requiring a follow-up inspection — was based on the figure FDA uses in the example of how to use the tool instead of the program's actual rate.
- The average inspection times were incorrect. Again, the program was using figures provided by FDA as an example. Program data showed these inspections, on average, took fewer hours than the examples provided.
- When the Food Safety Program did their calculations, they accounted for hours inspectors were spending on duties like MFRPS and sampling. While they also accounted for FDA contract inspections, they incorrectly calculated the number of hours spent on these inspections. When we re-calculated the staffing needs of the program, we used the agency's own data instead of the example figures provided by FDA. Our calculations resulted in an FTE total that was significantly less than the 49.4 FTE the Food Safety Program calculated using the tool.

It is important to note the staffing tool cannot account for every task required of inspectors among different states' regulatory programs. The tool is intended to give programs a starting point to estimate their own staffing needs. To get the most accurate estimates, management should be using their own data, instead of relying on FDA's example figures.

There are opportunities for improvement in program management practices

Wine as it is being processed and bottled.

Photo by Oregon Department of Agriculture

In addition to the field operations managers, the Food Safety Program is managed by two program managers and one director.

Agency leadership and staff all praised the work managers have done to maintain a positive atmosphere in the Food Safety Program. Inspectors said managers were receptive to their concerns and contributed to their satisfaction with working for ODA.

Management has already taken steps to address some of the challenges we have outlined in this report. For instance, management had begun to take a closer look at the available data for the backlog before this audit began. They also assigned some inspectors to conduct retail-only inspections in parts of the state where retail firms were most overdue.

But we also identified several areas in which management could improve.

Stronger management oversight is needed

The program's 38 inspectors are spread throughout the state, where they work out of their homes to see that businesses from Portland to Ontario are inspected in a timely fashion. In some instances, inspectors work together — when training or being audited for FDA contract inspections, for instance. But most of the time, inspectors work unsupervised.

Each inspection results in a report, which is saved in the program's Be Food Safe database and also emailed to the business owner. We reviewed a sample of reports to determine how much information they contain about the quality of inspections.

We found that the reports did not contain enough information to determine the quality of the inspection. We also accompanied some inspectors out in the field to observe them as they conducted routine food safety inspections. Based on our observations and review of reports, it appears that direct supervision and observation is the more effective way to evaluate the quality of a food safety inspection.

The job of the field operations managers is to supervise these inspectors and ensure inspections are being completed thoroughly and consistently.

Previously field operations managers would review a random sample of inspections reports. According to management, they did away with this practice due to time constraints after one of the field operations managers retired.

Now field operations managers only review the reports of newly-hired inspectors who are still being trained. After a period of time, field operations managers stop reviewing these reports.

Field operations managers also said they are not spending time observing staff in the field. They may occasionally accompany an inspector at his or her request. Inspectors will sometimes reach out to one another for assistance with inspections. But direct supervision of inspections is not happening on a regular or consistent basis.

Some inspectors said they wished they could spend more time working directly with their field operations managers. Other inspectors mentioned this makes performance evaluations more difficult.

Field operations managers, meanwhile, said they are unable to spend time in the field because duties in the office keep them at their desks, whether they are answering questions or working on special projects.

Some inspections are audited. FDA requires that some contract inspections undergo an auditing process, which includes reviewing the report as well as observing the inspection. FDA also recently informed ODA it should be conducting audits for all of its manufacturing inspections, not just the ones being performed under contract.

But no similar procedure exists to audit the other license types the Food Safety Program is responsible for inspecting, such as retail.

Management should reassess staff training needs

Before inspecting a specialty license type, an inspector must: attend training courses, often held by FDA; conduct practice trainings in the company of another inspector; and be approved for that particular license.

New inspectors start with retail inspections before moving on to manufactured foods, processors and increasingly specialized license types, such as low-acid canned foods, shellfish, dairy and more.

All food safety inspectors are required to be Registered Environmental Health Specialists with the Oregon Health Licensing Office. To maintain that license, inspectors must earn a minimum of 20 continuing education credit hours every two years; this is often accomplished by attending the all-staff conferences held by the Food Safety Program.

All that training adds up. And while training is a crucial component for maintaining skilled and qualified staff, inspectors appear to be spending a significant portion of time on training, which takes away from time spent on inspections.

In interviews with inspectors, agency management, and food safety programs in other states, we identified two possible approaches to training.

One is described as a jack-of-all-trades approach; inspectors may receive training in all license types. In a state as geographically diverse as Oregon, this strategy can be useful in that all inspectors are equally qualified to inspect all of the license types in their area, reducing the need for travel. However, inspectors may spend weeks training for a license type they will infrequently encounter.

The other is one where inspectors are more specialized. This is a useful strategy for complex and evolving industries, such as manufactured and processed foods. It may also reduce the total amount of time inspectors spend on training and free them up for inspections. But it adds a challenge in that specialized inspectors may be required to travel extensively to visit the one or two firms across the state that they are qualified to inspect.

Management currently has a blend of these two approaches, but has not identified a clear strategy of how to best train inspectors to meet the needs of their assigned areas. As a result, it is unclear if the current amount of training inspectors receive is necessary. To more efficiently use inspectors' time, management could be more strategic in determining which inspectors should be trained in which license types.

More guidance could help address inconsistency among inspectors

Many inspectors we interviewed said that consistency varies when it comes to things such as issuing enforcement actions or spending time to explain regulations.

For example, some inspectors may issue an enforcement action, such as a sanitation warning, even if the business owner resolves the issue on the spot. Other inspectors may choose not to issue the warning if they see the violation is corrected.

One benefit of consistently and uniformly issuing enforcement actions is to have reliable data the program can use to identify repeat offenders of food

safety laws and regulations. This allows the program to escalate its enforcement action to more serious consequences, all the way up to suspending a firm's license. If inspectors are inconsistently issuing enforcement actions, the program loses these valuable data points.

Inspectors also spend a significant portion of time educating business owners to help them understand and comply with food safety regulations. In addition to educating during inspections, staff spend time consulting with firms before issuing licenses, or reviewing plans for a business to make sure they account for safety regulations.

The Food Safety Program takes these duties seriously. The agency has documented in enforcement policies and procedures that being helpful, rather than punitive, is the best strategy to achieve compliance.

But the amount of time inspectors spend assisting varies widely from person to person. In some instances, this can mean the difference between a food safety inspection that lasts a couple of hours and one that lasts all day.

It is not clear that a strict policy on these issues would be beneficial to the program's goal of compliance. But management could offer guidance — on both enforcement actions and the time spent on helping — to achieve greater consistency among all inspectors.

The program risks overlooking some new food businesses

It is the responsibility of ODA to regulate the production, processing, and distribution of food products. Licensing businesses that participate in these industries is a key step in the regulatory process.

But when it comes to obtaining a license, it is left up to the business to contact ODA and initiate the licensing process.

Sometimes, these people are unaware they need to be licensed through ODA. And they may be licensed by more than one entity — cities or other agencies, such as the Oregon Liquor Control Commission. Or, the firm may simply avoid obtaining a license.

The Food Safety Program does not have a policy or procedure to proactively identify businesses needing a license. Without it, the program risks failing to properly license and regulate these food establishments.

Not only do these firms risk noncompliance with food safety regulations, but the program risks missing out on potential license fee revenue.

Determining the best way to find these businesses is difficult. In interviews with food safety programs in other states, none had identified a best practice to accomplish this. Instead, their inspectors often find unlicensed businesses the same way as Oregon inspectors — they stumble upon them.

We observed one inspector in the course of his daily routine when he saw what appeared to be a gas station food mart preparing to open. The

business had not yet obtained a license from ODA. The inspector stopped briefly to inform them of the requirements and left his contact information.

Some inspectors have established relationships with other licensing entities, such as cities and counties, to share information about new businesses. The Food Safety Program could benefit from adopting a policy to formalize this process program-wide, rather than relying on inspectors to develop these individual relationships.

The program could use data to better address its challenges

For some time now, the Food Safety Program has been aware of the backlog in the food safety inspections. They have taken some steps to address it, including hiring some limited duration inspector positions, reducing the number of FDA contract inspections between 2010 and 2015, partnering with other ODA programs, and prioritizing some inspections based on risk.

While these actions are commendable, we identified several ways the Food Safety Program can do more to resolve existing issues and prevent future ones. Many of these strategies are based in using data to help make informed decisions.

An inspector uses the iPad and Be Food Safe in the course of an inspection.

Photo by Oregon Department of Agriculture

There are data the Food Safety Program could be collecting

In October 2016, at the request of the audit team, the Food Safety Program tallied the number of firms that were overdue for an inspection. They counted 2,841 firms that were at least three months late for an inspection.

For any moment in time, management can access Be Food Safe and conduct a similar count. But these figures are not stored anywhere and not tracked over time, so there is no way to determine the extent of the backlog in 2015, 2014 or any time before.

Management should routinely collect these data. Examining these numbers over time might point to a pattern in the inspection backlog, or make clear where the backlog is at its worst. It can help management identify strategies to reduce the backlog and where to best deploy their resources.

Some data are not kept in most efficient form for analysis

Each day, inspectors fill out a paper report documenting the hours they spent on inspecting, training, or responding to consumer complaints. These daily reports, referred to by staff as "dailies," are kept by the Food Safety Program for the duration of the public records retention period. However, they are not analyzed.

There is an opportunity for program management to make a regular practice of entering daily reports into a database for the purpose of analyzing them. Management could better identify areas where inspectors could improve the number of hours they spend on inspections, which could

contribute to reducing the backlog and ensure the program is most efficiently using its staff and their time.

Management also told us they are planning to participate in a pilot project, along with the Oregon Department of Transportation, called TAMS: Time and Attendance Management System. This system would help the program track inspectors' work hours in a digital format, eliminating the step of transferring hours from dailies into a database and avoiding the risk of data entry errors.

According to agency leadership, TAMS is still at least a year away from full implementation. ODA could benefit from adopting a time-keeping system sooner, rather than later, that allows them to analyze inspector hours.

The program could benefit from a designated position for data analysis

The Food Safety Program does not have any staff person whose primary task is to analyze the data available to the program, including the Be Food Safe database. Management, including field operations managers, do not regularly analyze this data because of their other duties.

Be Food Safe was developed by ODA's Food Safety Program in conjunction with the agency's in-house information technology department. One inspector played a large role in developing the program; to this day, she continues to be heavily involved in troubleshooting and adding improvements to the app.

Other inspectors told us it was helpful to have a fellow inspector involved in developing Be Food Safe because she was someone who understood in a practical sense what the application needed to accomplish.

The trade-off for the Food Safety Program of having an inspector be involved in the app's development was one less inspector conducting inspections. That inspector told us that she very rarely conducts inspections anymore because so much of her time for the last two years has been invested in Be Food Safe.

Identifying someone whose role is primarily data analysis could help staff focus on their duties, while also taking advantage of the benefits data analysis can provide.

Additional regulations on the horizon will only add to existing challenges

In January 2011, President Obama signed into law the Food Safety Modernization Act, or FSMA. The goal of the act is to ensure the safety of the country's food supply by shifting the focus from responding to contamination to a focus on preventing it. It was the most sweeping reform of our federal food safety laws in more than 70 years.

Cannabis-infused candy is on display in a store.

Photo by Oregon Department of Agriculture

Since its enactment, FDA has been developing seven foundational rules to implement FSMA. The last versions of these rules were issued this year. FSMA will have a direct impact on states, as they are expected to adopt and enforce these rules.

This was also the year that saw the beginning of the legal sale and use of recreational cannabis, including edibles such as brownies and candy. Those businesses that produce and distribute edibles will be subject to ODA regulation much in the same way other food production and distribution firms are.

Both the implementation of FSMA and the sale of cannabis edibles will have a significant impact on ODA and the Food Safety Program's workload. With FSMA, inspectors will have new and different regulations to use when conducting food safety inspections. Some of FSMA now covers parts of the industry not previously regulated by ODA.

As a result, ODA anticipates an increase in the number of firms it will license and inspect. Which agency programs this will affect is yet to be determined.

In September, FDA announced it would be awarding $21.8 million in grant money to help 42 states implement FSMA's produce safety rule. Oregon's share was $3.5 million, to be spread out over a five-year period.

With the Food Safety Program already facing a backlog in inspections, these looming responsibilities pose even more challenges. The best way ODA can prepare for the additional work is to implement better management practices and other strategies we've outlined before these changes arrive.

Recommendations

To work toward the goal of reducing the backlog of food establishments overdue for an inspection, we recommend ODA:

- Develop a process to track the backlog of food safety inspections that are overdue for an inspection.
- Develop a process to track and analyze data on how inspectors are spending their work hours and identify ways inspectors can better meet established goals on how much time to spend on inspection duties.
- Consider providing guidelines on how much time inspectors should spend assisting and educating businesses on food safety regulations.
- Consider doing fewer FDA contract inspections to more easily balance this workload with the program's other duties.
- Consider designating a position for data analysis, rather than relying on inspection staff or management.

To achieve the program's mission of helping prevent the spread of foodborne illness by monitoring the food industry, we recommend ODA:

- Develop, where feasible, partnerships with cities, counties and other agencies, such as the Oregon Liquor Control Commission, to share information about businesses needing inspection and licensing.
- Develop or adjust existing policies and procedures so that field operations managers review a sample of inspection reports from all staff, not just new hires.
- Identify methods that will allow field operations managers to spend more time in the field supervising inspectors.
- Consider developing policies and procedures to audit non-FDA inspections.

To address many of the challenges in staffing facing the Food Safety Program, we recommend ODA:

- Use the agency's own data and the FDA staffing tool to better estimate the program's staffing needs.
- Develop a formal succession plan to prepare for retirements among inspectors.
- Consider reassessing the program structure, classifications and compensations to more fairly reflect the expectations of specialists and field operations managers.

Objectives, Scope and Methodology

Our audit objective was to determine strategies that the Oregon Department of Agriculture could use to improve its Food Safety Program.

To address our audit objective, we interviewed staff with the Food Safety Program, including food safety inspectors, field operations managers, program managers and the program director. We also interviewed the agency's leadership team, including the director, deputy director and assistant director. Interviews addressed current practices.

We spoke to individuals with knowledge of ODA's budget, members of the Oregon Board of Agriculture, and ODA stakeholders, including representatives of Oregon State University, the Oregon Farm Bureau, Friends of Family Farmers and Oregon Aglink. We spoke to representatives from the Legislative Fiscal Office, Food and Drug Administration and state Departments of Agriculture in California, Florida, New York, Washington and Wisconsin.

We reviewed laws and rules related to ODA's Food Safety Program. We reviewed training documents, program policies and procedures, relevant grant and contract documentation, and audits of other food safety programs. We accompanied several food safety inspectors on inspections of businesses to observe how food safety inspections are conducted.

We obtained and analyzed data on the number of licenses ODA issues. Specifically, we wanted to determine how ODA's inspection workload has changed over time. License data is entered directly into their system by inspectors, thereby eliminating paper documentation to compare against. Therefore, we were unable to test the reliability of this data.

We attempted to obtain and analyze data to demonstrate the inspection backlog over time. However, the agency is not tracking these data. We also attempted to analyze how inspectors were spending their daily hours. These data are kept in paper form and are not easily analyzed. We asked management to input this data into digital form so the audit team could analyze it, but found the resulting data to be unreliable and therefore did not use it to draw any conclusions.

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 objective. We believe that the evidence obtained and reported provides a reasonable basis to achieve our audit objective.

Auditors from our office, who were not involved with the audit, reviewed our report for accuracy, checking facts and conclusions against our supporting evidence.

Oregon
Kate Brown, Governor

Department of Agriculture
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Salem, OR 97301-2532

Mary Wenger, Director
Oregon Audits Division
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RE: Improved management practices, use of resources could help Food Safety Program achieve its mission

Dear Ms. Wenger,

Thank you for the opportunity to respond to the Secretary of State's Performance Audit for the Oregon Department of Agriculture (ODA) Food Safety Program.

We are pleased that the audit team chose to focus its review on the ODA Food Safety Program. The program has a relatively new management team, and the managers appreciated the opportunity for an outside assessment of program. We believe the recommendations in the report will help the managers better track how the program is spending its time, address the backlog of inspections, and ultimately manage the program more efficiently.

ODA generally agrees with the recommendations included in the report. The report notes some opportunities to free up inspector time to conduct more routine inspections, and recommends better use of data that the program is already collecting. ODA is fortunate to have a new database with broad reporting and analysis capabilities, and looks forward to fully using these tools to guide the program's performance.

In addition to implementing the recommendations in the report, we have also identified activities such as Machinery and Equipment tax exemption certifications that we plan to transfer to other ODA programs, because these activities are not central to our program's mission of public health protection.

ODA is addressing the specific recommendations in the report in the ways described below.

To work toward the goal of reducing the backlog of food establishments overdue for an inspection, the report recommends that ODA:

- **Develop a process to track the backlog of food safety inspections that are overdue for an inspection.**

The program has already begun to address this recommendation by setting goals to address the backlog and by generating monthly reports from the database to track how we are doing in progressing toward those goals. On a monthly basis, the program will start to evaluate the reports and respond to the backlog in retail, food processing, and high-risk inspections. We plan to continue generating these reports on a monthly basis using a consistent methodology, as well as generating monthly reports of the total inspection backlog across all license types. We will work to develop a

way to track the backlog in a central tracking system and review our data regularly for trends, so that we can shift resources accordingly. As discussed during the audit, firms are evaluated based on risk and those with the highest-risk activities will be prioritized as we work through the backlog.

- **Develop a process to track and analyze data on how inspectors are spending their work hours and identify ways inspectors can better meet established goals on how much time to spend on inspection duties.**

As the report noted, ODA is pursuing a system together with ODOT and DEQ that will allow for web-based reporting and accounting of daily activities. Currently, these reports are completed on paper. To track inspector time between now and the time the web-based system becomes operational, we plan to have inspectors enter their time in simple electronic spreadsheets or a database so they may be submitted, reviewed and electronically tabulated.

- **Consider providing guidelines on how much time inspectors should spend assisting and educating businesses on food safety regulations.**

The program will develop operational guidelines describing what is considered "compliance assistance and education" versus "inspection" time, since these activities are often conducted together on the same visit, and provide guidelines on how much time inspectors should spend on assistance and education. In addition, ODA believes that better tracking of how inspectors spend their time will assist us in better characterizing the range of staff time spent on education and other consultation activities.

We believe that assistance and education are key tools to help licensed firms achieve and maintain compliance, and that given the variability in licensed firms, varying amounts of time may need to be invested. However, we also recognize that it is ultimately the firm's responsibility to comply and that it will be helpful to our staff to provide some parameters describing the assistance that we can and cannot provide to licensees.

- **Consider doing fewer FDA contract inspections to more easily balance this workload with the program's other duties.**

While we believe that conducting FDA contract inspections offers benefits to our Oregon regulated firms and to the program, including access to FDA-funded, specialized FDA training courses and improved quality of all types of inspections we perform, we agree that contract inspections are more time-consuming and result in less retail inspections being completed. Our current contract year expires at the end of July 2017, and we will work with FDA to explore opportunities to further reduce the number of contract inspections going forward.

- **Consider designating a position for data analysis, rather than relying on inspection staff or management.**

Because data analysis responsibilities may reduce time available to conduct inspections, we will explore alternative staffing options to handle data analysis. We plan to seek assistance from other programs in ODA to identify the data elements that we should be tracking, set a tracking frequency, begin generating regular reports with this information, and adjust and allocate resources based on the additional data.

To achieve the program's mission of helping prevent the spread of foodborne illness by monitoring the food industry, we recommend ODA:

- **Develop, where feasible, partnerships with cities, counties and other agencies, such as the Oregon Liquor Control Commission, to share information about businesses needing inspection and licensing.**

The report makes this recommendation because county, city, and other agency staff sometimes interact with businesses that need an ODA Food Safety license, but have not yet obtained one. For example, a local government may issue a plumbing permit to a new convenience store, or OLCC may license a new distillery. The audit correctly notes that while we have relationships with many counties and individual inspectors at OLCC to share information about businesses such as these, we do not have a formal plan or structure.

We believe that our current work with OLCC to license and inspect cannabis edible firms will help us also develop a closer working relationship with OLCC related to firms that produce and sell alcoholic beverages, and identify a plan/structure to share this information. We will also work with our partners at Oregon Health Authority, county health departments, and other related agencies such as plumbing inspection agencies to establish a process to better identify businesses needing inspection and licensing.

- **Develop or adjust existing policies and procedures so that field operations managers review a sample of inspection reports from all staff, not just new hires.**

The current field operations manager vacancy limits our ability to implement this recommendation immediately; however, we will work to incorporate this recommendation into our policies and procedures, and into position descriptions of field operations managers and lead workers. We are currently recruiting for the vacant field operations manager position and hope to hire the new manager soon.

- **Identify methods that will allow field operations managers to spend more time in the field supervising inspectors.**

One of our key strategies to accomplish this recommendation will be to discontinue our participation in the Manufactured Food Regulatory Program Standards (MFRPS) project after our current cooperative agreement with the FDA expires July 31, 2017. The report notes that MFRPS has been valuable to the program in establishing policies, procedures, and training, but it has also consumed a significant amount of staff and manager time.

We will assess the benefits of leaving the MFRPS program and calculate the potential time saved for our field operations managers to spend more time with staff. It is likely that additional strategies, such as bringing on a third field operations manager, may be needed in the long term, but this is dependent on the ability of ODA to receive approval for new positions.

- **Consider developing policies and procedures to audit non-FDA inspections.**

We plan to develop policies and procedures to field audit non-FDA inspections and involve our lead workers in field auditing these inspections.

To address many of the challenges in staffing facing the Food Safety Program, we recommend ODA:

- **Use the agency's own data and the FDA staffing tool to better estimate the program's staffing needs.**

As part of enhanced data analysis efforts, we plan to determine how to best gather these data and regularly update them to better estimate our staffing needs based on program priorities, new demands for services such as FSMA inspections, and technological changes in food businesses. The agency will use this information to develop strategies to best address program needs and develop future agency budget requests.

- **Develop a formal succession plan to prepare for retirements among inspectors.**

We plan to build upon an existing list of specializations that our inspectors possess and develop training plans and lead trainers for each specialization. Conducting this work will help the program to absorb knowledge loss from both retirements and departures for other reasons (moving on to FDA, for example). We have been doing some of this work informally already, but agree that it would be beneficial to formally develop more structured succession plans.

- **Consider reassessing the program structure, classifications and compensations to more fairly reflect the expectations of specialists and field operations managers.**

We have already started to pursue a compensation structure for our field operations managers that will more fairly reflect the responsibilities and importance of these positions. We will continue to pursue this issue with the Oregon Department of Administrative Services.

Conclusion

Once again, thank you for the learning opportunity the audit provided to our management team, and for the chance to respond to the recommendations raised in the report. We believe the audit has been helpful to the program and the agency and appreciate the thoroughness and professionalism of the audit team.

Sincerely,

Lisa Hanson
Acting Director

cc: Katy Coba, Director, Oregon Department of Administrative Services

About the Secretary of State Audits Division

The Oregon Constitution provides that the Secretary of State shall be, by virtue of her office, Auditor of Public Accounts. The Audits Division exists to carry out this duty. The division reports to the elected Secretary of State and is independent of other agencies within the Executive, Legislative, and Judicial branches of Oregon government. The division is authorized to audit all state officers, agencies, boards, and commissions and oversees audits and financial reporting for local governments.

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The courtesies and cooperation extended by officials and employees of the Oregon Department of Agriculture during the course of this audit were commendable and sincerely appreciated.