



United States Department of Agriculture
Office of Inspector General





What Were OIG's Objectives

The overall objective of the audit was to review the Department's oversight of its goals and plans addressing major issues related to antibiotic resistance. We also examined the Department's efforts to improve the surveillance, stewardship, and development of new treatment methods. Last, we evaluated key short- and long-term actions planned to address these concerns.

What OIG Reviewed

We reviewed USDA's antibiotic resistance goals and activities delegated to USDA agencies, focusing on fiscal years 2012 through 2015.

What OIG Recommends

ARS, FSIS, and APHIS should work together to establish antibiotic resistance priorities related to budget requirements that also communicate agency interdependency; develop a strategy for the development and retention of specialized positions; enhance communication channels; and consider antibiotic resistance when they develop specific strategic goals.

OIG reviewed USDA's efforts to address antibiotic resistance and align with the President's initiative set forth in the National Strategy for Combating Antibiotic-Resistant Bacteria.

What OIG Found

The Office of Inspector General (OIG) found that agencies within the Department of Agriculture (USDA) need to more effectively and efficiently manage their limited resources for addressing antibiotic resistance issues relating to funding and certain staffing needs. Although change is occurring, we found that various agency budgets did not effectively address the inter-agency collaboration needed for this initiative. We found two agencies are experiencing problems filling key positions that require specialized scientific and data knowledge. If the agencies do not address these budgetary impediments and staffing challenges, the Department may not be able to fully address its antibiotic resistance goals.

In addition, we found that USDA does not have a well-developed central communication platform for distributing a unified, scientifically based, antibiotic resistance message. USDA should consider a communication plan that utilizes social media and a robust website to disseminate its antibiotic resistance information, which would educate the public and other interested parties on relevant concerns.

Lastly, we found that the agencies' performance goals and objectives related to antibiotic resistance are not well-defined. Antibiotic resistance was not a high priority when the agencies developed their strategic plans; therefore, the strategic plans did not have specific performance measures and outcomes. Without defined goals in the strategic plans, there is no specific measurable outcome to assess the effectiveness of this initiative.

The agencies agreed with our recommendations, and we reached management decision on all recommendations.



United States Department of Agriculture
Office of Inspector General
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AUDIT
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SUBJECT: USDA's Response to Antibiotic Resistance

This report presents the results of the subject audit. Your written responses to the official draft report (dated March 3, 2016, March 22, 2016, March 7, 2016, and March 10, 2016, respectively) are included, in their entirety, at the end of this report. Your responses and the Office of Inspector General's position are incorporated into the relevant sections of the report. Based on your written responses, we are accepting your management decisions for all audit recommendations in the report, and no further response to this office is necessary.

In accordance with Departmental Regulation 1720-1, final action needs to be taken within 1 year of each management decision to prevent being listed in the Department's annual Agency Financial Report. Please follow your internal agency procedures in forwarding final action correspondence to Office of the Chief Financial Officer.

We appreciate the courtesies and cooperation extended to us by members of your staffs during our audit fieldwork and subsequent discussions. This report contains publically available information and will be posted in its entirety to our website (<http://www.usda.gov/oig>) in the near future.

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Background & Objectives

Background

The 1928 discovery of penicillin, one of the first and most commonly known antibiotics, marked the birth of the antibiotic era. With this discovery also came a warning. In his 1945 Nobel Prize lecture, Dr. Alexander Fleming warned that improper exposure of microorganisms to the penicillin drug could develop resistance.

Dr. Keiji Fukuda, the current World Health Organization's (WHO) Assistant Director-General for Health Security, stated that "[e]ffective antibiotics have been one of the pillars allowing us to live longer, live healthier, and benefit from modern medicine." However, in regards to the emerging issue of antibiotic resistance,¹ he also issued this warning: "Without urgent, coordinated action by many stakeholders, the world is headed for a post-antibiotic era, in which common infections and minor injuries which have been treatable for decades can once again kill . . . Unless we take significant actions to improve efforts to prevent infections and also change how we produce, prescribe and use antibiotics, the world will lose more and more of these global public health goods and the implications will be devastating."²

According to the White House, antibiotic resistance has become a serious threat because the number of pathogens developing resistance to antibiotics is outpacing the pharmaceutical industry's ability to develop new ones. The loss of effective antibiotics will undermine the medical community's ability to fight infectious diseases and manage infectious complications common in vulnerable patients undergoing chemotherapy, dialysis, and surgery. Compounding this problem is the lack of new therapeutic options in the development pipeline to replace the drugs that lose their efficacy as bacteria become resistant to them.³ Antibiotic resistance also has a global human health and economic impact. In the United States alone, the Centers for Disease Control and Prevention (CDC) estimate that more than 2 million people are sickened every year with antibiotic-resistant infections, resulting in at least 23,000 deaths. A United Kingdom consulting firm recently published studies that suggested that an unchecked antibiotic resistance

¹ Antibiotic resistance results from mutations or acquisition of new genes in bacteria that reduce or eliminate the effectiveness of antibiotics. Antimicrobial resistance is a broader term that encompasses resistance to drugs to treat infections caused by many different types of pathogens, including bacteria, viruses, and parasites. While all of these pathogens are dangerous for human health, this report focuses on resistance in bacteria that presents a serious or urgent threat to public health. In this report, we will use the term antibiotic resistance instead of "antimicrobial resistance" unless it is used in a title or footnote or taken from quoted material.

² World Health Organization news release, *WHO's first global report on antibiotic resistance reveals serious, worldwide threat to public health*, p.1 (WHO Media Centre, April 30, 2014).

³ The White House, *National Action Plan for Combating Antibiotic-Resistant Bacteria*, dated March 2015.

problem could have a cumulative cost of as much as \$100 trillion on the world's economy by 2050 due to the losses in the gross domestic product (GDP).⁴

Factors contributing to the rise of antibiotic resistance microorganisms are relevant to both the human health industry and aspects of agriculture, especially animal husbandry, which gives the Department of Agriculture (USDA) a meaningful role in addressing this issue. Some of these factors include the frequency of antibiotic use to treat and prevent diseases, and using antibiotics as additives in food and water for promoting growth in food animals. Using antibiotics as growth promoters has been in practice for many years, but has come under recent scrutiny due to the growing antibiotic resistance problem.

In light of USDA's responsibility for ensuring the United States (U.S.) agricultural resources contribute to enhancing global food security;⁵ the Department's leadership began early discussions with stakeholders and other governmental departments in order to develop a plan for addressing the issue. To meet the leadership's vision, USDA sponsored a 3-day workshop in May 2012. The workshop was designed to review and assess antibiotic use and resistance monitoring, management practices to reduce antibiotic resistance, and alternatives to the use of antibiotics to treat and prevent diseases or enhance production in food animals. USDA brought 35 different stakeholders to the table, representing agriculture, consumer, and health groups, and listened to the concerns of all sides before it began considering plans that could affect all stakeholders. USDA also held discussions with other Federal agencies that would directly benefit or be impacted by its actions to identify how to effectively collaborate and share data and information. In 2014, based on the findings from the 3-day workshop, USDA developed a draft action plan that proposed a voluntary, comprehensive, integrated approach for future surveillance; research and development initiatives; and education, extension, and outreach activities that spanned the meeting's three objectives.

Since antibiotic resistance continued to rise as a national health concern, in November 2013, the President's Council of Advisors on Science and Technology (PCAST)⁶ was tasked with making practical and actionable recommendations on how the Federal Government should address this issue. In September 2014, PCAST published the "Report to the President on Combating Antibiotic Resistance," which recommended practical and actionable steps that the Federal Government should take over the next few years to help bring the crisis under control. The report focused on three areas: improving surveillance of the rise of antibiotic-resistant bacteria;

⁴ We obtained the financial impact information the two companies reported from the *Review of Antibiotic Resistance*, "Antimicrobial Resistance: Tackling a Crisis for the Health and Wealth of Nations," pp. 6 and 8-9 (Chaired by Jim O'Neill, Advisor to Prime Minister Cameron, December 2014).

⁵ USDA's *Strategic Plan FY 2014-2018*, Strategic Goal 3, Objective 3.1.

⁶ PCAST is an advisory group of the nation's leading scientists and engineers, appointed by the President to augment the science and technology advice available to him from inside the White House and from cabinet departments and other Federal agencies.

increasing the longevity of current antibiotics (stewardship),⁷ and increasing the rate at which new antibiotics, as well as other interventions, are discovered and developed.

Based on the PCAST report, President Obama signed an executive order⁸ directing key Federal departments and agencies to take action to control the rise of antibiotic-resistant bacteria, and the administration released its National Strategy.⁹ The executive order authorized a task force with USDA and the Departments of Defense and Health and Human Services as the co-chairs, whose primary responsibility was to develop a 5-year action plan for implementing the strategy. USDA was able to build on the work it had already done on these issues and incorporated information from the action plan it had already drafted as it worked together with other Federal Departments and agencies to draft the national action plan.

In March 2015, the *National Action Plan for Combating Antibiotic-Resistant Bacteria* (National Action Plan) was published, which outlined steps for implementing the National Strategy and addressing the policy recommendations of the PCAST report. The National Action Plan stated that “its primary purpose is to guide activities by the U.S. Government,” and it also “is designed to guide action by public health, healthcare, and veterinary partners in a common effort to address urgent and serious drug resistant threats that affect people in the U.S and around the world.”¹⁰ The National Action Plan is organized around five goals for collaborative action by the U.S. Government and others.¹¹ These goals are: (1) slow the emergence of resistant bacteria and prevent the spread of resistant infections; (2) strengthen national one-health surveillance efforts to combat resistance; (3) advance development and use of rapid and innovative diagnostic tests for identification and characterization of resistant bacteria; (4) accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines; and (5) improve international collaboration and capacities for antibiotic-resistance prevention, surveillance, control, and antibiotic research and development.

Apart from the National Action Plan, the Food and Drug Administration (FDA) issued two Guidances for Industry (GFI) on the use of medically important antibiotics in food-producing animals, one in 2012 and the other in 2013.¹² Starting in December 2016, antibiotics medically important for human health will only be allowed for therapeutic use in animals; essentially,

⁷ Stewardship goals include improving the appropriate use of existing antibiotics, preventing the spread of antibiotic-resistant bacteria, and scaling up proven interventions to decrease the rate at which microbes develop resistance to current antibiotics.

⁸ Executive Order 13676, Combating Antibiotic-Resistant Bacteria, dated September 18, 2014.

⁹ *National Strategy for Combating Antibiotic-Resistant Bacteria*, dated September 2014.

¹⁰ *National Action Plan for Combating Antibiotic-Resistant Bacteria*, dated March 2015, www.whitehouse.gov/sites/default/files/docs/national_action_plan_for_combating_antibiotic-resistant_bacteria.pdf

¹¹ “Others” include foreign governments, individuals, and organizations who are aiming to strengthen healthcare, public health, veterinary medicine, agriculture, food safety, and research and manufacturing.

¹² In April 2012, FDA issued GFI 209, *The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals*, and in December 2013 FDA issued GFI 213, *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals*.

antibiotics will no longer be allowed for animal growth promotion usage. The FDA Veterinary Feed Directive (VFD) final rule¹³ outlines the process for authorizing use of VFD drugs (animal drugs intended for use in or on animal feed that require the supervision of a licensed veterinarian) and provides veterinarians in all States with a framework for authorizing the use of medically important antibiotics in feed when needed for specific animal health purposes. USDA's responsibilities under the National Action Plan related to the VFD are to collect quantitative data about antibiotic use, antibiotic resistance patterns, and management practices on farms, their relationships, and trends over time.

Currently USDA conducts several surveillance activities used to gather antibiotic use or antibiotic resistance data. One surveillance activity is the Agricultural Resource Management Survey (ARMS), which is an annual survey focused on farm finances within the 48 contiguous states. In selected years, the survey will be directed towards producers of specific livestock commodities and will include questions on production practices, including antibiotic use. The Economic Research Service obtained data through ARMS on antibiotic use in feed or water during 2004 and 2009 for hogs, and during 2006 and 2011 for broilers. This data provided estimates of antibiotic drugs used, the purpose of their use, stage of production, and type of farm.

Another form of surveillance for on-farm data collection is the National Animal Health Monitoring System (NAHMS). The National Agricultural Statistics Service conducts the NAHMS survey with consultation of Animal and Plant Health Inspection Service (APHIS) and the cooperation of the Agricultural Research Service (ARS). NAHMS is an annual national-level study of a particular commodity, with a 5-8 year interval between commodity studies. NAHMS commodity studies involve the use of questionnaires administered to U.S. livestock, poultry, and aquaculture farmers about general farm policy to establish nationally representative estimates of management practices and operation/animal health characteristics. A component of the NAHMS questionnaire includes gathering information about general farm policy and management practices related to both antibiotic use and antibiotic resistance. In addition, NAHMS studies typically incorporate collection of on-farm biological samples to isolate important pathogens and commensal bacteria and to determine the presence of antibiotic class, and the method of administration (such as injection, feed, or water). NAHMS studies can provide important information on antibiotic resistance patterns; however, they are periodic point-in-time estimates, rather than ongoing real-time surveillance of antibiotic resistance, which is currently needed to better understand the quantities of antibiotic use in animal agriculture.

For surveillance at the point of slaughter, FSIS also works in coordination with FDA in collecting random cecal¹⁴ samples at slaughter plants for the National Antimicrobial Resistance Monitoring System (NARMS). The cecal samples are taken from the gut of livestock and poultry to provide NARMS with data on the amount, if any, of antibiotic-resistant bacteria that are present. FSIS plans to bolster this sampling by taking an antibiotic residue sample from the

¹³ Veterinary Feed Directive, 80 FR 31708, p. 31708-31735 issued June 3, 2015.

¹⁴ Cecal samples are taken from the large intestines of swine, cattle, and poultry. The cecum is a pouch at the beginning of the large intestine.

kidney of the same animal and determine if any traces of antibiotics, whether volatile or not, are present when antibiotic-resistant bacteria are found. FSIS also administers the National Residue Program, which tests organs and muscle tissue for levels of residues, including antibiotics, in meat, poultry, and egg products.

We initiated this audit to determine whether USDA was actively working towards addressing the issue of antibiotics and using its mission areas best suited for stewardship, surveillance, and the development of new treatments as presented in the PCAST report. At the onset of our fieldwork, we also received a request from the Senate to address specific questions related to USDA's plans to address (1) monitoring of antibiotic use and resistance, (2) research used to support Federal agencies' regulation of veterinary drugs and food, and (3) veterinarians' adherence to oversight requirements for antibiotics. Exhibit A of this report provides our answers to these questions.

Objectives

The overall objective of the audit was to review the Department's oversight of its goals and plans to address major issues and impediments related to antibiotic resistance. We also examined the Department's efforts to improve the surveillance, stewardship, and development of new treatment methods that are designed to address concerns regarding the prevention and control of antibiotic-resistant infections and diseases. In addition, we evaluated key short- and long-term actions planned to address these concerns.

We have also responded to three specific questions from the Senate in Exhibit A of this report.

Section 1: The Department’s Oversight Efforts are Critical to Improving Surveillance, Stewardship, and Development of New Treatments

Finding 1: USDA Needs to Address Issues and Impediments Related to Budget and Staffing to More Effectively and Efficiently Confront Antibiotic Resistance

In September 2014, the President issued an executive order to address the issue of antibiotic resistance. In response, the National Action Plan was developed that outlines steps and guides activities that require sustained, coordinated, and complementary efforts by the Federal Government, various groups, and individuals.¹⁵ Additionally, it lays out the Department’s programmatic and budgetary priorities using a comprehensive, integrated approach that necessitates long-term commitments for funding. If USDA is to meet its goals related to surveillance, stewardship, and the development of new treatments prescribed by the National Action Plan, it will need to more effectively and efficiently manage its limited resources for addressing cross-cutting antibiotic resistance issues, especially budgetary funding and staffing needs. Managing these resources is difficult because each USDA agency has individual budget constraints, often with competing priorities, to manage in the short- and long-term, as well as the need to retain staff with specialized skills and unique competencies over multiple years. If the agencies do not properly address these budgetary impediments and staffing challenges, the Department will not adequately achieve the goals necessary to successfully address antibiotic resistance.

National Action Plan Goals for USDA

USDA is responsible for certain goals in three areas outlined in the National Action Plan: surveillance, stewardship, and the development of new treatments. Successfully achieving these goals is necessary for the Department to adequately address antibiotic resistance.

Surveillance

The National Action Plan discusses surveillance under Goal 2, which is to strengthen national one-health surveillance efforts to combat resistance. Objective 2.4 is to enhance monitoring of antibiotic resistance patterns, as well as antibiotic sales, usage, and management practices, at multiple points in the production chain for food animals and retail meat by: (1) enhancing surveillance of antibiotic resistance in animal and zoonotic¹⁶ pathogens and commensal

¹⁵ The national action plan describes groups and individuals including veterinarians, policy makers, and human health patients.

¹⁶ A zoonotic disease is one that can be transmitted from animals to humans. MedicineNet.com, *Definition of Zoonotic* (Oct. 5, 2015), <http://www.medicinenet.com/script.main>.

organisms by strengthening the NARMS¹⁷ and leveraging other field and laboratory based surveillance systems; (2) implementing voluntary monitoring of antibiotic use and resistance in pre-harvest settings to provide nationally representative data while maintaining producer confidentiality; and (3) collecting quantitative data on antibiotic resistance and management practices along various points at pre-harvest, harvest, and processing stages in collaboration with producers and other stakeholders, and disseminating information as appropriate.

APHIS has been given the task of implementing certain proposed surveillance activities in the National Action Plan. To address these goals, APHIS intends to develop ongoing longitudinal studies that are directed towards collecting quantitative data on antibiotic drug use and management practices, along with biological samples from a limited number of farms over time. The data collection focuses on specific drugs, instead of antibiotic class. Additionally, it plans to conduct annual antibiotic use surveys, analysis of previous data from past NAHMS studies, targeted studies such as epidemiological studies and focused NAHMS studies outside of its planned study rotation, and to work with stakeholders to acquire second party data from large companies raising feedlot cattle, poultry, or swine.

Stewardship

The National Action Plan discusses stewardship under Goal 1, which is to slow the emergence of resistant bacteria and prevent the spread of resistant infections. Objective 1.3 is to identify and implement measures to foster stewardship of antibiotics in animals. The objective states that implementation steps include working with veterinary organizations, animal producer organizations, and other partners to: (1) develop, implement, and measure the effectiveness of evidence-based educational outreach to veterinarians and animal producers to advance antibiotic stewardship and judicious use of antibiotics in agricultural settings; (2) foster collaboration and public-private partnerships with public health, pharmaceutical, and agricultural stakeholders to facilitate identification and implementation of interventions (e.g., good husbandry practices) to reduce the spread of antibiotic resistance; (3) identify, develop, and revise key agricultural practices that allow timely, effective implementation of interventions that improve animal health and efficient production; and (4) develop appropriate metrics to gauge the success of stewardship efforts and guide their continued evolution and optimization. Currently, APHIS offers an antibiotic stewardship training module as part of its Accredited Veterinarians Program. Also, antibiotic stewardship information is available to producers through their local Cooperative Extension System. Additionally, on June 2, 2015, the White House held a forum regarding the stewardship of antibiotics as it relates to various aspects of antibiotic resistance. The forum identified three major challenges: (1) communication that all parties understand, (2) finding science-based solutions, and (3) implementing a One Health approach¹⁸ to engage the human and animal health sectors together in finding solutions.

¹⁷ NARMS is not to be confused with the NAHMS system here. In cooperation with FDA, FSIS collects tissue samples to test for zoonotic pathogens and commensal organisms, which are added to NARMS. In general, NAHMS is an on-farm survey related to a particular commodity.

¹⁸ A “One Health approach” is an approach to antibiotic resistance solution(s) that would consider what is best for all sectors, including human health as well as animal health.

New Treatment Development

The National Action Plan also discusses new treatment development under Goal 4: accelerate basic and applied research and development for new antibiotics, other therapeutics, and vaccines. Objective 4.1 is to conduct research to enhance understanding of environmental factors that facilitate the development of antibiotic resistance and the spread of resistance genes that are common to animals and humans; Objective 4.2 is to increase research focused on understanding the nature of microbial communities, how antibiotics affect them, and how they can be harnessed to prevent disease; and Objective 4.4 is to develop non-traditional therapeutics, vaccines, and innovative strategies to minimize outbreaks caused by resistant bacteria in human and animal populations.

In September 2012, prior to the development of the National Action Plan, ARS held an international symposium in cooperation with the World Organization for Animal Health to highlight promising research results and new technologies that could potentially lead to the development of alternatives to conventional antibiotics. Regarding future plans for developing new treatments, ARS' food safety action plan¹⁹ covers 5-year periods and identifies future research areas, such as: multidisciplinary approaches to more fully understand antibiotic resistance in foodborne microorganisms; methods to assist other Federal agencies in measuring and assessing antibiotic resistance in food animal populations; alternatives to antibiotics, including management practices, pre-and probiotics, bacteriophage gene products, lytic enzymes, vaccines, and other novel products to reduce their levels in food animals; and other research areas. According to an ARS official, there are numerous research projects in the area of antibiotic resistance that have already been proposed that are currently undergoing the approval process. The official stated that these research projects are covered in the budget request for fiscal year (FY) 2016.

Since the surveillance, stewardship, and new treatment activities can be resource-intensive, APHIS officials explained that these activities would require new appropriations for proper implementation. When asked to identify the challenges the research agencies faced in completing the research projects related to the National Action Plan goals, the official stated that bringing on and retaining staff with the specialized skills and expertise to perform this research will be key in achieving these objectives.

Budgetary Impediments and Staffing Challenges

¹⁹ The ARS food safety action plan is part of the agency's strategic plan, which is titled "National Program 108: Food Safety (animal and plant products)." The program's vision is "to enhance and protect public health and agriculture through the development of technologies, strategies, and data that safeguard food from pathogens, toxins, and chemical contaminants during production, processing, and preparation, thus increasing the safety of the food supply." ARS, "Food Safety," http://www.ars.usda.gov/research/programs/programs.htm?NP_CODE=108 (last visited September 17, 2015).

During our fieldwork, we talked to officials at the National Offices of APHIS, ARS, and FSIS, APHIS Veterinary Services personnel, and officials from the National Veterinary Services Laboratories (NVSL). Also, we reviewed documents related to the NAHMS study, FY 2016 budget requests, and ARS research projects relating to antibiotic resistance. Based on our audit work, we identified issues related to budgetary impediments and staffing challenges that may preclude USDA from effectively and efficiently achieving its goals to combat antibiotic resistance.

Budgetary Impediments

Before the Department and its agencies can fully address the goals for surveillance, stewardship, and development of alternatives to antibiotics, they must first ensure budgetary resources are available and coordinated across agencies. We found that the FY 2016 budgets were not developed to effectively address the needed inter-agency collaboration to provide the Department the coordinated approach it seeks. However, we noted that agencies took steps to coordinate their effort for the FY 2017 budget. Therefore, the agencies need to make future budget coordination a priority, or the Department will be limited in its ability to address the goals set forth in the National Action Plan.

APHIS faces budgetary challenges, such as shifting priorities and shrinking budgets, causing it to select and deselect activities it can fund. For example, APHIS did not receive sufficient funding to conduct newly proposed data collection activities that support the goals of the National Action Plan. APHIS requested \$10 million in appropriated funding for antibiotic surveillance work in its FY 2016 budget, but it was not approved. Additionally APHIS can be faced with unexpected challenges that cause unforeseen pressure on its financial management. For example, in FY 2015, APHIS had to prioritize limited resources to address the highly pathogenic avian influenza outbreak, which impacted its ability to devote resources to antibiotic surveillance work. Therefore, without this appropriation, APHIS' ability to accomplish as much of the surveillance piece of the National Action Plan will be limited. Without the needed surveillance data, efforts in attaining the National Action Plan goals will be impacted. The data APHIS intended to collect would have been used in studies and support information for other USDA agencies like ARS, non-USDA government agencies such as FDA (for activities pursuant to GFI 213),²⁰ and university partners to identify critical areas for further research, as well as education and outreach activities.

APHIS' potential funding shortfall illustrates the importance of agencies collectively prioritizing their individual antibiotic resistance activities before budget submission and after budget approval. This would help to ensure activities from one agency that are inter-linked to other agencies receive the proper prioritization. Since antibiotic resistance is an important Presidential priority, the Office of Management and Budget (OMB) issued specific guidance for the FY 2017 budget, which mandated that agencies and departments work together on antibiotic resistance. Realizing the need for coordinating budgetary aspects within USDA, the Office of the Chief

²⁰ FDA may not have sufficient data to evaluate its policies on antibiotic use, such as the GFI 213.

Scientist (OCS) requested the Office of Budget and Program Analysis (OBPA) be involved in a multi-agency meeting to discuss budget coordination for FY 2017. Department officials told us the meeting was beneficial because agencies learned about their counterparts' activities and enabled OBPA to provide shared language for use in each of the agencies' FY 2017 budget requests.

Since a lack of budget coordination and prioritization could hinder USDA in meeting the goals prescribed in the National Action Plan, we concluded that the Department needs to continue to establish a routine process for the various agencies to meet and coordinate antibiotic resistance priorities before individual budgets are submitted and after funding approval. Additionally, we concluded that the Department needs to ensure the budget requirements for antibiotic resistance relayed to OBPA effectively communicate the importance of agency interdependency in their submissions for antibiotic-resistant activities. We spoke to agency officials and received supportive comments for these recommendations.

Staffing Challenges

At least two USDA agencies are having difficulties filling key positions that require specialized knowledge, such as bioinformaticists²¹ who specialize in analyzing data from whole-genome sequencing.²² Agency officials have attributed this difficulty to competition with private sector job openings. Without adequate staffing for specialized areas, USDA may not be able to meet the goals included in the National Action Plan.

In order for USDA to meet several of the goals and objectives within the National Action Plan, it will need specialized staff in key positions. A milestone within Objective 2.3,²³ in the National Action Plan, states that USDA will support five or more National Animal Health Laboratory Network and/or Veterinary Laboratory Investigation and Response Network member laboratories for next-generation sequencing equipment and training on the use of whole-genome sequencing techniques and bioinformatics. Also, USDA is tasked with conducting reviews to ensure that U.S. Government research focuses on high priority antibiotic resistance issues and facilitates the use of advanced technologies in research on antibiotic resistance (e.g., whole

²¹ A bioinformaticist is skilled in molecular biology and computer science as it pertains to bioinformatics. Bioinformatics are used in analyzing genomes, proteomes (protein sequences), and three-dimensional modeling of biomolecules and biologic systems, etc. MedicineNet, *Definition of Bioinformatics* (Oct. 1, 2015), <https://www.medicinenet.com/script/main>.

²² Whole genome sequencing reveals the complete DNA make-up of an organism, enabling a better understanding of the variations both within and between species. FDA is using this technology to perform basic foodborne pathogen identification during foodborne illness outbreaks. U.S. Food and Drug Administration, *Whole Genome Sequencing (WGS) Program* (Oct. 1, 2015), <http://www.fda.gov/Food/FoodScienceResearch/WholeGenomeSequencingProgram/WGS>.

²³ Objective 2.3 of the national action plan is to “[d]evelop, expand, and maintain capacity in veterinary and food safety laboratories to conduct standardized antibiotic susceptibility testing and characterize select zoonotic and animal pathogens.”

genome sequencing, proteomics,²⁴ metagenomics,²⁵ structural biology,²⁶ and bioinformatics). Last, USDA will initiate regional collaborations to monitor the emergence and spread of resistant genes in food, animals, and human foodborne pathogens using genome sequencing techniques. USDA officials from ARS and APHIS stated that, not only is whole-genome sequencing a specialized area, but the large amounts of data that result from the sequencing require the specialized expertise of a bioinformaticist.

In addition, ARS researchers and APHIS' NVSL need bioinformaticists for genome sequencing and computerized sequence analysis as part of their surveillance and development of new treatment activities. Much of ARS' research work also involves the need for a bioinformaticist, and an ARS official said that posting job announcements that would effectively recruit these individuals is difficult. Also, APHIS needs more of these technical positions filled. There are currently three bioinformaticists working at NVSL. However, based on its current growth and future projected needs, NVSL would like to have an additional four positions, bringing its bioinformatics core to seven. In its budget justification, APHIS requested the four additional positions. None of the three bioinformaticists currently working at NVSL work exclusively on antibiotic resistance, but one of the additional positions NVSL requested would work exclusively on antibiotic resistant matters.

We concluded that USDA needs to determine which USDA agencies have strong equities in antibiotic resistance or other related specialized areas. Then, USDA needs to develop a strategy to strengthen the recruitment and retention of key, specialized positions to assist agencies with maintaining a cadre of experts in these specialized areas. Agency officials agreed that USDA needs to be able to attract and retain potential candidates to these positions.

Another area where USDA could potentially face staffing issues is in OCS' senior advisor positions. These individuals, often considered to be among the top experts in their respective fields, serve on a rotational basis with a statutory maximum length of four years. However, most senior advisors only serve a 1-year term. The responsibility of coordinating USDA's response to antibiotic resistance has been given to the OCS Senior Advisor for Animal Health. The individual currently in this position is scheduled to leave the position in July 2016, after receiving a 1-year extension, making it a 2-year term. Several agency officials from APHIS, ARS, and FSIS informed us that the current senior advisor for animal health is crucial to the success of USDA implementing the National Action Plan's goals.

²⁴ Proteomics is the large-scale analysis of proteins. Microbiology and Molecular Biology Reviews, *Molecular Biologist's Guide to Proteomics* (Oct. 1, 2015), <http://www.ncbi.nlm.nih.gov/pmc/articles/PMC120780>.

²⁵ Metagenomics is the study of a collection of genetic material (genomes) from a mixed community of organisms. Metagenomics usually refers to the study of microbial communities. U.S. National Library of Medicine, *Genetics Home Reference* (Oct. 1, 2015), <http://ghr.nlm.nih.gov/glossary=metagenomics>.

²⁶ Structural biology is a field of science focused on understanding the structures of biological molecules in order to learn more about how they function and interact. These molecules include DNA, RNA, proteins, carbohydrates, and sugars. National Institute of General Medical Sciences, *Structural Biology Fact Sheet* (Oct. 1, 2015), http://www.nigms.nih.gov/education/pages/factsheet_structuralbiology.aspx.

We believe that statutory limitation of short-term details for these positions, when long-term problems exist, could have adverse effects on USDA's ability to fulfill its mission. However, getting agencies to commit to the statutory maximum 4-year period is difficult because agencies cannot fill the vacated position of the person on detail to OCS. The short-term position also causes difficulties in OCS. For example, the OCS director told us that in the 8 months she has held her position, four senior advisors have rotated in and out. Although the director tries to prepare the new individuals as much as possible for the transition, she said by the time the individual becomes settled into the position, he/she ends up leaving a short time later. The director explained it takes about 6 months to get a new senior advisor trained to begin carrying out their duties. We agree that 6 month delays in coordinating USDA's antibiotic resistance efforts hinder its ability to effectively and efficiently meet the goals and objectives for combating antibiotic resistance.

We concluded that USDA needs to explore opportunities that allow OCS' senior advisors to maximize their legislated terms to the extent practicable and enable USDA to better meet the goals and objectives of the National Action Plan. OCS officials agreed that extending senior advisor rotational assignments would be beneficial to the Department's efforts.

Recommendation 1

ARS should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

Agency Response

In its March 3, 2016, response, ARS stated:

ARS's role in establishing a process for routinely meeting with other agencies on issues related to the National Action Plan is currently in place as part of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group. This sub-group will coordinate antibiotic resistance priorities for achieving the National Action Plan goals before individual budgets are submitted.

ARS, through its participation in the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group has implemented this process by meeting with other agencies on issues related to the National Action Plan in a January 2016 strategic planning meeting prior to submitting its budget request.

Action was completed on January 22, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 2

ARS should ensure that it effectively communicates the importance of interagency dependencies to OBPA when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

Agency Response

In its March 3, 2016, response, ARS stated:

A process was put in place for the fiscal year (FY) 2017 budget submission to better communicate interagency dependencies, and we will continue this process moving forward. This process consists of the three co-chairs of the USDA One Health Joint Working Group meeting with the OBPA to ensure the importance of interagency dependencies needed to achieve the National Action Plan goals for antibiotic resistance are communicated for future budget submissions.

ARS has implemented and used this process for its FY 2017 budget submissions to communicate the importance of interagency dependencies and will continue this process for future budget submissions.

Action will be completed on July 1, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 3

ARS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

Agency Response

In its March 3, 2016, response, ARS stated:

ARS has considered the positions in the agency that have strong equities in antibiotic resistance and is already trying to fill key positions.

ARS has filled a key Research Leader position and will fill key National Program Leader positions by February 28, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 4

FSIS should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

Agency Response

In its March 7, 2016, response, FSIS stated:

While FSIS has a very limited role in antimicrobial resistance (AMR) and has not led USDA's establishment of routine meetings with other agencies, FSIS does routinely meet with other agencies on issues related to the National Action Plan as part of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group. This sub-group will coordinate antibiotic resistance priorities for achieving the National Action Plan goals before individual budgets are submitted.

FSIS action has been completed. FSIS, through its participation in the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group has implemented this process by meeting with other agencies on issues related to the National Action Plan in a January 2016 strategic planning meeting prior to submitting its budget request and which will occur annually thereafter.

Action was completed on January 22, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 5

FSIS should ensure that it effectively communicates the importance of interagency dependencies to OBPA when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

Agency Response

In its March 7, 2016, response, FSIS stated:

FSIS has completed applicable actions regarding this recommendation, in collaboration with OPBA. FSIS has implemented and used the process described above in developing its FY 2017 budget submission. FSIS will continue to work with the Department to communicate interagency dependencies. As OBPA is the responsible component in USDA for coordinating the Department's budget estimates and for reviewing program and legislative proposals for program and budget related implications, it is the office that has the entity-wide knowledge and perspective to ensure interagency dependencies are appropriately considered in the process. Additionally, a new process was implemented coinciding with the FY 2017 budget submission to better communicate interagency dependencies, and USDA will continue this process moving forward. The new process consists of OBPA meeting with the three Co-Chairs of the USDA One Health Joint Working Group to ensure the importance of interagency dependencies needed to achieve the National Action Plan goals for antibiotic resistance are communicated for future budget submissions. It should be noted that the language in this recommendation also appears to imply a requirement that agencies submit budget requirements to achieve the National Action Plan goals for antibiotic resistance, which is not the case.

Action was completed on June 5, 2015.

OIG Position

We accept management decision for this recommendation.

Recommendation 6

FSIS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

Agency Response

In its March 7, 2016, response, FSIS stated:

Within FSIS, the Office of Public Health Science (OPHS) contains the majority of the expertise including laboratory analysis, interpretation of data, and communication of results regarding AMR and related fields. FSIS currently has a process to identify key deliverables from the Agency's strategic plan and align budget and personnel resources to ensure that those objectives are met. FSIS has determined that addressing AMR through the agency's traditional role in contributing to surveillance of AMR conducted in the National Antimicrobial Resistance Monitoring System (NARMS) is a strategic aspect of

our public health and regulatory role and an intrinsic part of the job description of microbiologists, veterinarians, epidemiologists, and bioinformatics staff. There are two senior level positions designated in the OPHS Assistant Administrator's office dedicated to address the AMR activities that are internal or external to USDA, and over two dozen staff who are involved in day-to-day AMR work. The agency already has the required cadre of experts to handle and lead AMR and related issues in the context of its mission and to meet the departmental needs.

Action was completed on February 24, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 7

APHIS should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation, but cautions that there has been no new funding approved for antibiotic resistance activities. APHIS implemented this Recommendation through its participation in the January 22, 2016 USDA strategic planning meeting concerning the antimicrobial resistance Action Plan. APHIS will continue to participate in these USDA-wide meetings.

APHIS also interacts regularly with other USDA agencies through the One Health Joint Working Group, co-chaired by APHIS, FSIS, and ARS. Budget requests for antibiotic resistance activities are directly related to the mission areas of each agency and align with the President's National Action Plan; thus, there are no duplicative requests for agencies within the USDA.

Additionally, APHIS works very closely with the Food and Drug Administration's Center for Veterinary Medicine and other public health partners. The One Health Joint Working Group has met to strategize what might be accomplished without funding, as there has been no funding approved. If funding is approved, the One Health Joint Working Group will coordinate USDA activities related to antibiotic resistance.

Action was completed on January 22, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 8

APHIS should ensure that it effectively communicates the importance of interagency dependency to OBPA when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation, and has implemented this Recommendation with its participation in the June 5, 2015 multi-agency budget meeting with OBPA to review planned budget submissions for the FY 2017 President's budget. APHIS will continue to participate in and/or host such meetings with OBPA and other USDA agencies related to joint, interagency dependent antimicrobial resistance budget requests and provide documentation in the budget requests that also explain the interagency dependencies.

Action was completed June 5, 2015.

OIG Position

We accept management decision for this recommendation.

Recommendation 9

APHIS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation. APHIS has identified four areas of major investment for antibiotic resistance activities: the National Animal Health Laboratory Network/National Veterinary Services Laboratories; the National Animal Health Monitoring System; the National Veterinary Accreditation Program; and the Center for Veterinary Biologics. Each of these areas, as well as data management, requires the

development of specialized positions. VS will develop a staffing plan by December 30, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 10

OCS should work with the office of Human Resources and appropriate USDA agencies to explore opportunities to extend the OCS' senior advisors legislated terms to the 4-year maximum or greatest extent practical; and, if needed, OCS should develop a plan to explore the initiation of legislative change that would maximize the benefit of the senior advisor positions to the office.

Agency Response

In its March 10, 2016, response, OCS stated:

Since completion of the fieldwork for this audit, OCS worked with OSEC-DM-OHRM [Office of the Secretary – Department Management – Office of Human Resources Management] to explore opportunities that could extend the OCS' Senior Advisors legislated terms to the 4-year maximum or greatest extent practical. This exploration was collated by OHRM in an Issues Paper on staffing positions in OCS. OHRM conceded there are no good solutions to extending OCS Senior Advisors rotational assignments as legislated; because the Senior Advisors are encumbering positions with in their home agencies and institutions, the agencies and institutions cannot fill behind them and their own missions become adversely impacted. Consequently, agencies find they are unable to allow their employees to serve longer (i.e., 4-year) terms.

As such, OCS concurs with OIG's recommendation to initiate legislative change related to senior advisor positions in the Office. A General Provision has been included the 2017 President's Budget proposal that will make funds available to OCS to use to pay for the salaries and related administrative expenses of Senior Advisors (i.e., Division Chiefs) without any limitation on the term of service.

(Source:<http://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/agr.pdf>)

OHRM completed the Issues Paper on staffing positions in OCS January 5, 2016. The President's 2017 proposed Budget was released on February 9, 2016.

OIG Position

We accept management decision for this recommendation.

Finding 2: USDA Needs to Enhance Antibiotic Resistance Communication with its Stakeholders and the General Public

USDA does not have a well-developed means of communicating important aspects of antibiotic resistance to its stakeholders and the general public. Although USDA uses several means to communicate related information to each agency's stakeholders, it does not use a central platform to clearly present a unified, scientifically-based antibiotic resistance message to the public. This occurred because the Department has not put a focus on quality communication of its antibiotic resistance website or other social media outlets. As a result, the public or stakeholders may not be adequately informed on the antibiotic resistance issue and how it relates to animal husbandry.

The National Action Plan objectives require the Department to measure the effectiveness of educational outreach to veterinarians and animal producers promoting antibiotic stewardship. It also requires the implementation of voluntary monitoring and collection of quantitative data, while maintaining stakeholders' confidentiality and disseminating information, as appropriate. The ability to disseminate scientifically balanced information is important so that individuals within the general public can make informed decisions about antibiotics and antibiotic resistance related to the foods they consume.

Difference Between Antibiotic Resistance and Antibiotic Residue

For example, the public needs to know there is a difference between Antibiotic-Resistant Bacteria and actual antibiotics in meat they consume. Antibiotic resistance refers to bacteria that are resistant to antibiotics, whereas antibiotic residues refer to antibiotics that might still be present in the meat a person consumes. With a scientifically based platform, USDA could disseminate scientifically based facts that antibiotics themselves do not remain indefinitely in an animal's system, and any animal given antibiotics must follow FDA's prescribed withdrawal period²⁷ before it can be presented for slaughter. Additionally, if Antibiotic-Resistant Bacteria were present in the raw meat that a consumer purchases, CDC points out that the threat of transference of the bacteria would be reduced if the consumer practiced safe food handling techniques, such as cooking meat to proper temperatures.²⁸ By having quality science-based information available on its antibiotic resistance website and other social media outlets, USDA will be able to better educate the public and stakeholders on relevant antibiotic resistance issues, such as the difference between antibiotic resistance and antibiotic residues.

²⁷ FDA approves a "withdrawal period" or the minimum amount of time from the discontinuance of use until slaughter for the various types of antibiotics or other drugs. For example, FDA's fact sheet for New Animal Drug Application (NADA) Number 113-232, states that for cattle and swine the drug must be discontinued "...at least 28 days prior to slaughter."

²⁸ Examples of safe cooking temperatures can be found on FSIS' fact sheet. For example, ground beef and poultry should be cooked to internal temperatures of 160°F and 165°F, respectively.

The Need for Data

USDA, in its May 2012 conference to address antibiotic resistance, began trying to determine what “gaps” in data needed to be filled.²⁹ Additionally, the CDC’s 2013 publication *Antibiotic Resistance Threats in the United States* pointed out that one of the “gaps in knowledge” regarding antibiotic resistance is that “data on antibiotic use in human health care and agriculture are not systematically collected.” To resolve this issue, CDC suggested establishing routine systems of reporting and benchmarking antibiotic use wherever it occurs nationwide. Although this may seem like a simple recommendation to address, scientists and government officials are not always sure what information to collect, where it could be collected, or how to collect, present, and disseminate this information. If USDA used a more robust website or other social media, it could practice transparency by informing the public, especially stakeholders, of the challenges it faces in gathering surveillance data to address “gaps” in the knowledge.

Scientists know of at least four methods of transference of antibiotic-resistant bacteria in the realm of agriculture: direct foodborne transmission from animal to human through consumption of contaminated meat, animal to animal, animal to human, or animal to the environment to humans. However, scientists do not always understand how this occurs. Understanding that “gaps” in transference knowledge exist could help the consumer to make wiser choices. USDA officials explained that studies have shown an animal, such as a cow, that is free of antibiotic-resistant bacteria on the farm may acquire antibiotic-resistant bacteria after being exposed to large populations of other cows. Therefore, consumers should understand that, just because the meat they are purchasing is marketed as “antibiotic free,” does not necessarily mean that the meat is free from antibiotic-resistant bacteria.

The question becomes where and how could USDA gather important antibiotic use data to begin addressing these knowledge gaps. The production side of raising, transporting, and processing livestock and poultry will be the areas from which most of these data need to be obtained. However, USDA officials have explained that in certain circumstances, stakeholders are concerned how the data will be used if USDA is allowed access to this information. Although some stakeholders have asked that USDA be allowed to gather certain surveillance data because they know that the information will be handled confidentially,³⁰ APHIS officials stated that some producers have concerns about the confidentiality and use of data provided to the government. Therefore, USDA needs to have a robust method of communicating how it will preserve the confidentiality of the data it gains from stakeholders.

²⁹ The workshop’s summary document identified three areas of “data gaps” where “correction of these data deficits would allow standardized comparisons to be made across production systems, a refinement in prudent use guidelines, an ability to monitor the impacts of antibiotic policy changes, antibiotic resistance control efforts with a better focus, and better predictions of the consequences of policy changes.” The three areas included antibiotic use and resistance measures, ecologic assessment, and economic impact.

³⁰ APHIS’ information is protected under the Confidential Information Protection and Statistical Efficiency Act (CIPSEA), which is a Federal law enacted in 2002 as Title V of the E-Government Act of 2002 (Pub. L. 107-347, 116 Stat. 2899, 44 U.S.C. § 101). The law provides a mechanism to collect statistical data and protects a respondent’s information by providing that the data should not be used in such a way that identifies the respondent. As a result, the respondent’s data are for statistical purposes only.

Potential Communications Improvement

USDA does not have a well-developed central communication platform for distributing a unified antibiotic resistance message. USDA has created a web resource for information about this issue. However, after consulting authoritative publications on website design, we determined that USDA should consider some best practices to increase the site's effectiveness. Although each agency often uses its own website, publications, or other forms of media to address antibiotic resistance, these platforms are usually designed to reach a targeted audience for individual agencies. Since the current USDA antibiotic resistance website lacks engaging, readable content, it could adversely affect the user experience,³¹ and poor user interface design³² could diminish the Department's outreach on an important topic.

One of the best practices we noted includes the use of multimedia. On USDA's antibiotic resistance website, there is a lack of multimedia content on the page. While there are links to the social media accounts for USDA in the upper right hand bar, there are no photos, videos, or any other interactive components that may hold the reader's attention. Currently, the website relies heavily on the use of Portable Document Format (PDF)³³ documents. PDF documents, when used appropriately, are a useful means of distribution. However, they are not a substitute for web content. People generally visit a website to perform actions, as opposed to read documents, and when they do read documents, they rarely read all of the text. USDA's antibiotic resistance website provides often long and technical PDF reports, and, on the rare occasions when readers open a PDF, they are highly unlikely to read all the way through it. In our opinion, the Department should rely less on using PDF documents and more on the development of interactive content that will engage and inform the public.

Aside from the lack of interactivity, another aspect the antibiotic resistance website needs to improve is how it communicates with the audience through readable content that addresses relevant concerns. One way this can be accomplished is through mining information from social media sites and other various sources. Doing so can provide a clearer picture of the public's attitude towards antibiotic resistance and allow the Department to respond accordingly. The Department also needs to consider using social media outlets so its antibiotic resistance message can be widely disseminated and ultimately lead readers back to the information on the website. Certain best practice features that could enhance the user interface design is a Frequently Asked Question (FAQ) page that could support a scientifically-based position or well-researched resource links. Similarly, a consistent communications plan draws from and utilizes multiple

³¹ The "user experience" focuses on having a deep understanding of users, what they need, what they value, their abilities and limitations. The "user experience" should promote improving the quality of the user's interaction with and perceptions of the site's product or services.

³² "User interface design" focuses on anticipating what users might need to do and ensuring that the interface has elements that are easy to access, understand, and use to facilitate those actions.

³³ PDF (Portable Document Format) is a file format that has captured all the elements of a printed document as an electronic image that you can view, navigate, print, or forward to someone else.

social media and web channels. This website should be the central source for the Department's information and research regarding antibiotic resistance. The Department should review the contents of the website and ensure that the content is adequate and appropriate for the general public. Based on discussions with agency officials, they agreed that communication is an issue, and they believe that a unified and scientifically based message, as well as a central website for all antibiotic resistance information, would benefit USDA.

Recommendation 11

ARS should work with OCS, FSIS and APHIS through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

Agency Response

In its March 3, 2016, response, ARS stated:

As a member of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group, ARS has agreed to engage in a new Communication working group. Once established, this new Communication working group will develop, for the USDA Office of Communications, a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and to the general public.

ARS will engage in the establishment of the new Communication working group by June 2016 with completion of a plan by February 28, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 12

ARS should work with OCS, FSIS and APHIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

Agency Response

In its March 3, 2016, response, ARS stated:

The Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group agreed in January 2016 to form a new Communication working group. This

Communication working group will provide the USDA Office of Communications with a plan that would ensure USDA conveys a unified and scientifically based message to the public and to all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

The new Communication workgroup will be established and will provide a plan to the USDA Office of Communications that ensures USDA conveys a unified and scientifically based message by February 28, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 13

FSIS should work with ARS, OCS, and APHIS through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

Agency Response

In its March 7, 2016, response, FSIS stated:

As a member of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group, FSIS has agreed to engage in a new Communication working group. Once established, this new Communication working group will develop, for the USDA Office of Communications, a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and to the general public. The plan will promote the development of a more robust antibiotic resistance website that will explore the use of other social media outlets and address the needed resources.

FSIS will engage in the establishment of the new Communication working group, which will develop a comprehensive strategic communication plan by March 31, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 14

FSIS should work with ARS, OCS, and APHIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

Agency Response

In its March 7, 2016, response, FSIS stated:

The Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group agreed in January 2016 to form a new Communication working group. This Communication working group will provide the USDA Office of Communications with a plan that would ensure USDA conveys a unified and scientifically based message to the public and to all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

The new Communication workgroup will be established and will provide a plan to the USDA Office of Communications that ensures USDA conveys a unified and scientifically based message by March 31, 2017.

OIG Position

We accept management decision for this recommendation.

Recommendation 15

APHIS should work with ARS, OCS, and FSIS through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation and is outlining additional communications as part of current budget planning. This plan will include an antibiotic resistance website and the use of other social media outlets for reporting and will be completed by December 30, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 16

APHIS should work with ARS, OCS, and FSIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation. Communications related to antibiotic resistance are coordinated through OCS. If funding is provided, information flow should increase as a result of research, surveillance and monitoring, and the need for education/outreach. Data gathering and analysis for research and surveillance are dependent upon adequate funding for the activities described in the President's National Action Plan. The Joint Working Group will develop a communications plan by January 2, 2017.

OIG Position

We accept management decision for this recommendation.

Finding 3: USDA Needs to Strengthen its Oversight of Agencies' Performance Measures to Adequately Address the Department's Top Priorities

We found the agencies' performance goals and objectives related to antibiotic resistance are not well-defined in their strategic plans. This occurred because antibiotic resistance was not a priority when the agencies developed their plans. As a result, the performance measures and outcomes used to address the strategic plans' goals and objectives were not specific enough to gauge each agency's progress in this area.

The Government Performance and Results Modernization Act of 2010 requires strategic plans to have general goals and objectives, including outcome-oriented goals for the major functions and operations of the agency and a description of how any goals and objectives contribute to the Federal Government's priority goals.³⁴

Combating antibiotic-resistant bacteria is one of the President's and Secretary's top priorities; therefore, agencies should consider including antibiotic resistance as a performance goal in their strategic plan. We found that the agencies' current strategic plans have very broad goals, performance measures, and outcomes that are not specific to antibiotic resistance. For example, FSIS' *Strategic Plan* FY 2011-2016 goal is to effectively use science to understand foodborne illness and emerging trends. To accomplish this goal, FSIS' strategies are to improve the understanding behind drug-resistant pathogens and understand existing and emerging trends in food safety. The performance measures refer to science agendas and increasing the application of cutting-edge science to improve public health. The outcomes refer to using science in policy development to better defend against public health risks.

We searched ARS' *Strategic Plan* for FY 2012-2017, and only found one mention of antibiotic resistance. Under its Strategic Goal Area 2, Natural Resources and Sustainable Agricultural Systems, the objective of Goal 2.4 is to "effectively and safely manage and use manure and other agricultural and industrial byproducts in ways that maximize their potential benefits while protecting the environment and human and animal health." As a component of this goal, we found that the only mention of antibiotic resistance was to reduce its presence in manure and wastes.

Performance measures track progress and specify baseline information and long-term performance targets. As agency officials explained, antibiotic resistance was not as high a priority when the latest strategic plans were developed; therefore, it did not receive consideration in developing measurable goals. Since antibiotic resistance was not one of the goals defined in the strategic plans, it does not have a specific measurable outcome. Going forward, we believe agencies should develop and report antibiotic resistance performance goals and measures in their future strategic plans to assess the effectiveness of this initiative. Based on discussion with

³⁴ GPRA Modernization Act of 2010, H.R. 2142, Sec 306.a.3

agency officials, they agreed that antibiotic resistance needs to have a higher level of importance in future strategic plans.

Recommendation 17

In order to measure the progress of antibiotic resistance efforts, ARS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If ARS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide the Office of the Chief Financial Officer (OCFO) with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

Agency Response

In its March 3, 2016, response, ARS stated:

ARS will consider the development of specific strategic goal(s) for antibiotic resistance by December 31, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 18

In order to measure the progress of antibiotic resistance efforts, FSIS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If FSIS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide OCFO with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

Agency Response

In its March 7, 2016, response, FSIS stated:

FSIS's limited role in addressing antibiotic resistance through its Anti-Microbial Resistance (AMR) activities begins at the point of when animals and birds are delivered for slaughter. In the context of FSIS' responsibilities on testing and sampling for foodborne pathogens, FSIS's intra- and inter-agency collaborative role will continue to include providing testing and sampling data that includes resistance data to inform establishments and federal partners. In this context, FSIS includes reference to AMR in its draft strategic plan, as well as some focus on building Whole Genome Sequencing capacity, and consequently, FSIS' ability to detect AMR genes of concern. As FSIS

currently has three strategic goals in this draft plan that are of greater scope and breadth than the subject of antibiotic resistance, it would not be appropriate practice to designate one of these overarching goals as being specific to antibiotic resistance.

This action has been completed. FSIS has considered development of specific strategies for AMR for inclusion in its FY 2017-2021 strategic plan and already includes appropriate information on this area in one of the plan's objectives.

Action was completed on February 18, 2016.

OIG Position

We accept management decision for this recommendation.

Recommendation 19

In order to measure the progress of antibiotic resistance efforts, APHIS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If APHIS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide OCFO with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

Agency Response

In its March 22, 2016, response, APHIS stated:

APHIS agrees with this Recommendation. APHIS recognizes that goals and performance measures are necessary to make progress against antibiotic resistance. APHIS has taken initial steps at identifying strategic goals and will include these in the next update of APHIS' strategic goals. While APHIS will develop strategic goals for its antibiotic resistance activities by March 31, 2017, APHIS will not issue a new strategic plan until 2019-2020 when the current APHIS strategic plan expires. We will inform the OCFO with written communication if lack of funding prevents us from incorporating these goals.

Action will be completed by March 31, 2017.

OIG Position

We accept management decision for this recommendation.

Scope and Methodology

We conducted our audit of USDA's response to antibiotic resistance at the offices of APHIS, FSIS, OCS, and OBPA in Washington, D.C.; ARS' National Office in Beltsville, Maryland; APHIS' Veterinary Services office in Ft. Collins, Colorado; and APHIS' NVSL in Ames, Iowa. We also interviewed officials with National Institute of Food and Agriculture (NIFA), the Government Accountability Office, and the Department of Health and Human Services Office of Inspector General. We performed fieldwork for this audit from October 2014 through August 2015. Our audit covered the Department's antibiotic resistance efforts in FYs 2012 through 2015.

To accomplish our objectives, we performed the following audit procedures:

- Reviewed laws, regulations, written policies, procedures, directives, notices, handbooks, and other published guidance to gain sufficient knowledge for completing the audit.
- Interviewed USDA and non-USDA agency officials to gain an understanding of the roles and responsibilities related to antibiotic resistance.
- Attended the "Antibiotic Use and Resistance: Moving Forward Through Shared Stewardship" Symposium in Atlanta, Georgia, to gain an understanding of the issues associated with antibiotic use and resistance through science-based information and potential solutions from academia, government, and other stakeholders within animal agriculture and human health related to antibiotic use and resistance.
- Evaluated USDA's organizational structure and how it provides/obtains information related to antibiotic resistance.
- Evaluated coordination, resources, and communication within and among the agencies' organizational levels to meet the Executive Order 13676, *Combating Antibiotic-Resistant Bacteria*; Interagency Task Force on Antimicrobial Resistance: A Public Health Action Plan to Combat Antimicrobial Resistance; President's Council of Advisors on Science and Technology Report to the President on Combating Antibiotic Resistance; National Strategy for Combating Antibiotic-Resistant Bacteria; USDA's Antimicrobial Resistance Action Plan; and the *National Action Plan for Combating Antibiotic-Resistant Bacteria* goals and objectives.

During the course of our audit, we did not verify information in any USDA electronic information system and we make no representation regarding the adequacy of any agency

computer systems or the information generated from them. However, we did evaluate various public facing websites, as described in our report.

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 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.

Abbreviations

APHIS	Animal and Plant Health Inspection Service
ARS	Agricultural Research Service
CDC	Centers for Disease Control and Prevention
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
FY	fiscal year
GDP	Gross Domestic Product
GFI	Guidance for Industry
NAHLN	National Animal Health Laboratory Network
NAHMS	National Animal Health Monitoring System
NARMS	National Antimicrobial Resistance Monitoring System
NIFA	National Institute of Food and Agriculture
NVSL	National Veterinary Services Laboratories
OBPA	Office of Budget and Program Analysis
OCS	Office of the Chief Scientist
OIG	Office of Inspector General
OMB	Office of Management and Budget
PCAST	President’s Council of Advisors on Science and Technology
USDA	Department of Agriculture
Vet-LIRN	Veterinary Laboratory Investigation and Response Network
VFD	Veterinary Feed Directive
WHO	World Health Organization

Exhibit A: OIG Response to Questions in the Senatorial Request

1. *What steps could the Department take to collect and report data on how antibiotics are actually used in food-producing animals that would help federal agencies monitor antibiotic use and resistance?*

USDA has steps built into the *National Action Plan for Combating Antibiotic-Resistant Bacteria* that will involve activities to collect and report data relating to antibiotic resistance. However, as discussed in Finding 1 of the report, achieving these goals is contingent upon USDA receiving the required resources. Currently, the national action plan lists the following data collection activities for USDA:

Surveillance Data Collection

- Within 1 year, USDA will develop a plan to enhance efforts to monitor the occurrence of drug-resistant zoonotic pathogens in food animals on farms and at slaughter.
- Within 3 years, USDA and FDA will initiate collection of drug use and resistance data on farms. This information will be used to determine baselines and trends in drug use and resistance.
- Within 3 years, USDA will implement routine susceptibility testing of veterinary diagnostic isolates and report its findings, and will coordinate investigations of emerging zoonotic antibiotic resistant pathogens on the farm and at slaughter.
- Within 3 years, USDA will expand its meat sample and cecal sample surveillance for antibiotic resistance in collaboration with FDA and NARMS, and will implement collection of data on antibiotic-resistance and management practices during pre-harvest, harvest, and processing of food products. This information will be used to monitor trends in drug-resistant bacteria and identify potential mitigation strategies for further investigation.

Surveillance Laboratories

- Within 1 year, USDA and FDA will develop standardized protocols for assessing proficiency in susceptibility testing.
- Within 5 years, 10 to 20 National Animal Health Laboratory Network (NAHLN) and/or Veterinary Laboratory Investigation and Response Network (Vet-LIRN) will conduct antibiotic susceptibility testing standardized methodologies.
- Within 3 years, USDA and FDA will identify requirements for a system to facilitate national collection, analysis, and reporting of antibiotic susceptibility testing data by the NAHLN and/or Vet-LIRN laboratories, develop guidelines for data collection and

for sharing metadata,³⁵ and generate mechanisms and criteria for linking veterinary data to public health data (e.g., by entering veterinary data into the National Antimicrobial Resistance Monitoring System (NARMS)). USDA and FDA will launch pilot projects in three to five NAHLN and/or Vet-LIRN laboratories to conduct standardized antibiotic susceptibility testing.

- Within 5 years, USDA and FDA will establish an information technology (IT) system that links NAHLN and Vet-LRN laboratories that conduct antibiotic susceptibility testing and facilitate sharing, analysis, and reporting of veterinary antibiotic resistance data through centralized repository.

As discussed in Finding 2 of this report, there are certain “gaps” in antibiotic information. For example, USDA needs to understand “gaps” in antibiotic-resistant bacteria transference knowledge. To understand these “gaps,” USDA will need to begin collecting data from numerous points along the animals’ lifecycle, such as raising, transporting, and slaughtering of livestock and poultry. Currently, USDA is collecting farm data through NAHMS, but as described in Finding 1 of this report, the NAHMS data are limited. At the request of FDA, USDA also collects cecal samples at the time of slaughter for NARMS. To be more robust, USDA would need to have a surveillance plan that could link data obtained from a slaughtered animal, flock, or herd to drug or care information about the same animal(s) when they were on the farm or in-between points. However, implementing any larger scale surveillance plan will require USDA to obtain the needed funds and cooperation from producers who may be reluctant to participate in USDA-sponsored studies and surveys related to antibiotic use in animal production.

2. *Does the Department target its research on antibiotic resistance to address key public health concerns to inform how federal agencies regulate veterinary drugs and foods?*

USDA’s ARS can target research to support upcoming decisions on public health or agricultural-related regulations for agencies such as, FDA and FSIS. For example, FDA requested that ARS perform preliminary research when it began collecting information to help with the drafting Guidance for Industry (GFI) 213.³⁶ However, ARS officials explained they are no longer doing any research for the guidance since it has already been issued. For guidance or regulations that have already been developed and implemented, USDA could collect supporting data through FSIS or APHIS. Examples of the two agencies’ data

³⁵ Metadata is structured information that describes, explains, locates, or otherwise makes it easier to retrieve, use, or manage an information source. National Information Standards Organization, *Understanding Metadata*, 2004.

³⁶ GFI 213, *New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed for Drinking Water of Food Producing Animals*, states, “...production use indications such as ‘increased rate of weight gain’ or ‘improved feed efficiency’ are no longer appropriate for the approved conditions of use for medically important antimicrobial drugs. In contrast, FDA considers uses that are associated with the treatment, control, and prevention of specific diseases to be therapeutic uses that are necessary for assuring the health of food-producing animals.”

collections would be data FSIS collects from samples at slaughter plants for NARMS, and data APHIS collects through NAHMS studies. An APHIS official said the agency is not currently collecting any information for FDA, but it is doing some data mining of information the agency already has to identify trends prior to the establishment of GFI 213.

Additionally, ARS has a number of ongoing research projects related to the development of alternatives to antibiotics. Although the current research project might not be directly related to antibiotic resistance, it often is a component of the project. However, as discussed in Finding 1, ARS has numerous research proposals undergoing its approval process that will target antibiotic resistance. Recently, Agriculture Secretary Tom Vilsack announced USDA's Agriculture and Food Research Initiative³⁷ would receive \$15.1 million for the funding of 35 food safety research grants, and a component of the research will receive \$3.4 million in grants to focus on "effective mitigation strategies for antimicrobial resistance."

USDA will also be working on research items listed in the National Action Plan. Below is a list of action plan items:

- Health and Human Services, National Institutes of Health (NIH), FDA, USDA, CDC, Department of Defense, and Environmental Protection Agency will conduct a review to ensure that U. S. Government research resources are focused on high-priority antibiotic resistance issues (including basic research on the emergence and spread of resistance genes) and facilitate use of advanced technologies in research on antibiotic resistance (e.g., whole genome sequencing, proteomics, metagenomics, structural biology, bioinformatics).
- FDA, USDA, CDC, and NIH will bring together experts in food production, agriculture, and public health to encourage collaborative research, from basic research to clinical testing, on antibiotic resistance.
- USDA, NIH, and CDC will support research on the spread of resistance genes between zoonotic pathogens and the commensal microbiota that live in the gastrointestinal tracts of animals and humans (i.e., in animal and human microbiomes).
- USDA, in consultation with NIH and CDC, will support research to map the gut microbiome of at least one animal species raised for food, using metagenomic techniques and "big data" analysis tools. This research will help us understand how antibiotic treatments disrupt the normal gut microbiome and how animal growth may be promoted without antibiotics. It may also suggest ways to treat bacterial animal diseases without using antibiotics.
- USDA, in collaboration with NIH, FDA, and the agriculture industry, will develop a research and development strategy to promote understanding of antibiotic resistance and the creation of alternatives to (or improved uses of) antibiotics in food animals.

³⁷ NIFA awards Agriculture and Food Research Initiative grants in six Farm Bill priority areas: plant health and production and plant products; animal health and production and animal products; food safety, nutrition, and health; bioenergy, natural resources, and environment; agriculture systems and technology; and agriculture economics and rural communities.

- USDA will solicit proposals that comprehensively develop research and outreach programs targeting development of novel alternatives to antibiotics for use in animals.
3. *What steps could the Department take to ensure veterinarians adhere to the oversight requirements for antibiotics, including the guidelines for disease prevention uses laid out in GFI 213?*

Veterinarians can receive accreditation through APHIS; however, the veterinarians' licensure is at the State level. The States' Practice Act regulates veterinary practices and they have to meet State licensing requirements such as continuing education, ethical standards, and Drug Enforcement Administration requirements for controlled substances. Through USDA, APHIS uses the National Veterinary Accreditation Program's Training Module 23: "Use of Antibiotics in Animals" as one step to educate and update both USDA veterinarians and accredited veterinarians about the guidelines and requirements of antibiotics in animal disease prevention that are laid out in GFI 213. Additionally, a State licensed veterinarian could use APHIS Training Module 23 as a means to help fulfill his/her continuing education requirements.

USDA uses additional steps to help facilitate the information in GFI 213 by partnering with animal agriculture industry groups, as these groups often disseminate information about judiciously using antibiotics to their constituents. USDA also uses the cooperative extension system³⁸ as a means to educate the public and livestock producers about antibiotic stewardship.

³⁸ The cooperative extension system is a partner of NIFA, and also receives support from States and counties in which it operates. Among its roles is outreach and education that provides agricultural information to producers.

**USDA's RESPONSE TO ANTIBIOTIC
RESISTANCE
RESPONSES TO AUDIT REPORT**



United States Department of Agriculture

Research, Education, and Economics
Agricultural Research Service

March 3, 2016

SUBJECT: ARS Management's Response to Recommendations in Audit Report 50601-0004-31 USDA's Response to Antibiotic Resistance

TO: Gil H. Harden
Assistant Inspector General for Audit
Office of the Inspector General

Jon M. Holladay
Chief Financial Officer
Office of the Chief Financial Officer

FROM: Lisa A. Baldus /s/
Associate Deputy Administrator

The Agricultural Research Service (ARS) provides the following response to Recommendations 1, 2, 3, 11, 12, and 17 in Audit Report 50601-0004-31 Department of Agriculture (USDA)'s Response to Antibiotic Resistance.

Finding 1: USDA Needs to Address Issues and Impediments Related to Budget and Staffing to More Effectively and Efficiently Confront Antibiotic Resistance

Recommendation 1

The ARS should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

ARS Response:

ARS's role in establishing a process for routinely meeting with other agencies on issues related to the National Action Plan is currently in place as part of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group. This sub-group will coordinate antibiotic resistance priorities for achieving the National Action Plan goals before individual budgets are submitted.

Estimated Completion Date:

ARS, through its participation in the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group has implemented this process by meeting with other agencies on issues related to the National Action Plan in a January 2016 strategic planning meeting prior to submitting its budget request.

Recommendation 2

ARS should ensure that it effectively communicates the importance of interagency dependencies to the Office of Budget and Program Analysis (OBPA) when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

ARS Response:

A process was put in place for the fiscal year (FY) 2017 budget submission to better communicate interagency dependencies, and we will continue this process moving forward. This process consists of the three co-chairs of the USDA One Health Joint Working Group meeting with the OBPA to ensure the importance of interagency dependencies needed to achieve the National Action Plan goals for antibiotic resistance are communicated for future budget submissions.

Estimated Completion Date:

ARS has implemented and used this process for its FY 2017 budget submissions to communicate the importance of interagency dependencies and will continue this process for future budget submissions.

Recommendation 3

ARS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

ARS Response:

ARS has considered the positions in the agency that have strong equities in antibiotic resistance and is already trying to fill key positions.

Estimated Completion Date:

ARS has filled a key Research Leader position and will fill key National Program Leader positions by February 28, 2017.

Finding 2: USDA Needs to Enhance Antibiotic Resistance Communication with its Stakeholders and the General Public**Recommendation 11**

ARS should work with Office of the Chief Scientist (OCS), Food Safety and Inspection Service (FSIS), and Animal and Plant Health Inspection Service (APHIS) through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

ARS Response:

As a member of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group, ARS has agreed to engage in a new Communication working group. Once established,

this new Communication working group will develop, for the USDA Office of Communications, a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and to the general public.

Estimated Completion Date:

ARS will engage in the establishment of the new Communication working group by June 2016 with completion of a plan by February 28, 2017.

Recommendation 12

ARS should work with OCS, FSIS and APHIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

ARS Response:

The Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group agreed in January 2016 to form a new Communication working group. This Communication working group will provide the USDA Office of Communications with a plan that would ensure USDA conveys a unified and scientifically based message to the public and to all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

Estimated Completion Date:

The new Communication workgroup will be established and will provide a plan to the USDA Office of Communications that ensures USDA conveys a unified and scientifically based message by February 28, 2017.

Finding 3: USDA Needs to Strengthen its Oversight of Agencies' Performance Measures to Adequately Address the Department's Top Priorities

Recommendation 17

In order to measure the progress of antibiotic resistance efforts, ARS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If ARS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide the Office of the Chief Financial Officer with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

ARS Response:

ARS will consider the development of specific strategic goal(s) for antibiotic resistance.

Estimated Completion Date:

ARS will consider the development of specific strategic goal(s) for antibiotic resistance by December 31, 2016.



United States Department of Agriculture

Food Safety and
Inspection Service

1400 Independence
Avenue, SW,
Washington, D.C.
20250

TO: Gil H. Harden March 7, 2016
Assistant Inspector General
Office of Inspector General

FROM: Alfred V. Almanza /s/
Deputy Under Secretary, Office of Food Safety
Acting Administrator, Food Safety and Inspection Service

SUBJECT: Office of Inspector General (OIG) Official Draft Report - USDA's
Response to Antibiotic Resistance, Report Number
50601-0004-31

We appreciate the opportunity to review and comment on this Official Draft report. FSIS did not comment on the recommendations in the Discussion Draft Report because none of them were directed at the Food Safety and Inspection Service (FSIS). FSIS agrees with the OIG's prior position that the Under Secretary for Research, Education and Economics (REE) should be responsible for coordinating the responses among all of the involved agencies. In reviewing the Official Draft report containing several recommendations to FSIS, we respond below that we have completed several actions regarding recommendations that are within our Agency's purview and also provide responses regarding other recommendations that are not fully within FSIS' scope or mission responsibility to complete or lead.

Responses to Recommendations

Recommendation 4:

The Food Safety and Inspection Service (FSIS) should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

FSIS Response:

While FSIS has a very limited role in antimicrobial resistance (AMR) and has not led USDA's establishment of routine meetings with other agencies, FSIS does routinely meet with other agencies on issues related to the National Action Plan as part of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group. This sub-group will coordinate antibiotic resistance priorities for achieving the National Action Plan goals before individual budgets are submitted.

Estimated Completion Date:

FSIS action has been completed. FSIS, through its participation in the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group has implemented this process by meeting with other agencies on issues related to the National Action Plan in a January 2016 strategic planning meeting prior to submitting its budget request and which will occur annually thereafter.

Recommendation 5:

FSIS should ensure that it effectively communicates the importance of interagency dependencies to OBPA when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

FSIS Response:

FSIS has completed applicable actions regarding this recommendation, in collaboration with OPBA. FSIS has implemented and used the process described above in developing its FY 2017 budget submission. FSIS will continue to work with the Department to communicate interagency dependencies. As OBPA is the responsible component in USDA for coordinating the Department's budget estimates and for reviewing program and legislative proposals for program and budget related implications, it is the office that has the entity-wide knowledge and perspective to ensure interagency dependencies are appropriately considered in the process. Additionally, a new process was implemented coinciding with the FY 2017 budget submission to better communicate interagency dependencies, and USDA will continue this process moving forward. The new process consists of OBPA meeting with the three Co-Chairs of the USDA One Health Joint Working Group to ensure the importance of interagency dependencies needed to achieve the National Action Plan goals for antibiotic resistance are communicated for future budget submissions. It should be noted that the language in this recommendation also appears to imply a requirement that agencies submit budget requirements to achieve the National Action Plan goals for antibiotic resistance, which is not the case.

Estimated Completion Date:

FSIS action has been completed.

Recommendation 6:

FSIS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

FSIS Response:

Within FSIS, the Office of Public Health Science (OPHS) contains the majority of the expertise including laboratory analysis, interpretation of data, and communication of results regarding AMR and related fields. FSIS currently has a process to identify key deliverables from the Agency's strategic plan and align budget and personnel resources to ensure that those objectives are met. FSIS has determined that addressing AMR through the agency's traditional role in contributing to surveillance of AMR conducted in the National Antimicrobial Resistance Monitoring System (NARMS) is a strategic aspect of our public health and regulatory role and an intrinsic part of the job description of microbiologists, veterinarians, epidemiologists, and bioinformatics staff. There are two senior level positions designated in the OPHS Assistant Administrator's office dedicated to address the AMR activities that are internal or external to USDA, and over two dozen

staff who are involved in day-to-day AMR work. The agency already has the required cadre of experts to handle and lead AMR and related issues in the context of its mission and to meet the departmental needs.

Estimated Completion Date:

This action has been completed.

Recommendation 13:

FSIS should work with ARS, OCS, and APHIS through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

FSIS Response:

As a member of the Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group, FSIS has agreed to engage in a new Communication working group. Once established, this new Communication working group will develop, for the USDA Office of Communications, a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and to the general public. The plan will promote the development of a more robust antibiotic resistance website that will explore the use of other social media outlets and address the needed resources.

Estimated Completion Date:

FSIS will engage in the establishment of the new Communication working group, which will develop a comprehensive strategic communication plan by March 31, 2017.

Recommendation 14:

FSIS should work with ARS, OCS, and APHIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

FSIS Response:

The Antimicrobial Resistance sub-group of the USDA One Health Joint Working Group agreed in January 2016 to form a new Communication working group. This Communication working group will provide the USDA Office of Communications with a plan that would ensure USDA conveys a unified and scientifically based message to the public and to all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

Estimated Completion Date:

The new Communication workgroup will be established and will provide a plan to the USDA Office of Communications that ensures USDA conveys a unified and scientifically based message by March 31, 2017.

Recommendation 18:

In order to measure the progress of antibiotic resistance efforts, FSIS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If FSIS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide OCFO with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

FSIS Response:

FSIS's limited role in addressing antibiotic resistance through its Anti-Microbial Resistance (AMR) activities begins at the point of when animals and birds are delivered for slaughter. In the context of FSIS' responsibilities on testing and sampling for foodborne pathogens, FSIS's intra- and inter-agency collaborative role will continue to include providing testing and sampling data that includes resistance data to inform establishments and federal partners. In this context, FSIS includes reference to AMR in its draft strategic plan, as well as some focus on building Whole Genome Sequencing capacity, and consequently, FSIS' ability to detect AMR genes of concern. As FSIS currently has three strategic goals in this draft plan that are of greater scope and breadth than the subject of antibiotic resistance, it would not be appropriate practice to designate one of these overarching goals as being specific to antibiotic resistance.

Estimated Completion Date:

This action has been completed. FSIS has considered development of specific strategies for AMR for inclusion in its FY 2017-2021 strategic plan and already includes appropriate information on this area in one of the plan's objectives.



Marketing and
Regulatory
Programs

TO: Gil H. Harden
Assistant Inspector General
for Audit

Animal and Plant
Health
Inspection
Service

FROM: Kevin Shea
Administrator /s/ 3/22/2016

Office of the
Administrator

SUBJECT: APHIS Response and Request for Management Decision
on the Office of Inspector General (OIG) Report "USDA's
Response to Antibiotic Resistance" (50601-04-31)

1400
Independence
Ave, SW
Room 312-E
Washington, DC
20250

Thank you for the opportunity for the Animal and Plant Health Inspection Service (APHIS) to comment on this draft report. We have restated each Recommendation made to APHIS and have provided further information on each one. Regarding Recommendations where other USDA agencies are asked to work with APHIS, we commit to collaborating with these agencies as needed.

Recommendation 7: APHIS should establish a routine process for meeting with the other agencies involved in achieving the National Action Plan goals so antibiotic resistance priorities are coordinated before individual budgets are submitted and after funding approval.

APHIS Response: APHIS agrees with this Recommendation, but cautions that there has been no new funding approved for antibiotic resistance activities. APHIS implemented this Recommendation through its participation in the January 22, 2016 USDA strategic planning meeting concerning the antimicrobial resistance Action Plan. APHIS will continue to participate in these USDA-wide meetings.

APHIS also interacts regularly with other USDA agencies through the One Health Joint Working Group, co-chaired by APHIS, the Food Safety and Inspection Service (FSIS), and the Agricultural Research Service (ARS). Budget requests for antibiotic resistance activities are directly related to the mission areas of each agency and align with the President's National Action Plan; thus, there are no duplicative requests for agencies within the USDA.

Additionally, APHIS works very closely with the Food and Drug Administration's Center for Veterinary Medicine and other public health partners. The One Health Joint Working Group has met to strategize what might be accomplished without funding, as there has been no funding approved. If funding is approved, the One Health Joint Working Group will coordinate USDA activities related to antibiotic resistance.

Recommendation 8: APHIS should ensure that it effectively communicates the importance of interagency dependency to OBPA [Office of Budget and Program Analysis] when it submits its budget requirements needed to achieve the National Action Plan goals for antibiotic resistance.

APHIS Response: APHIS agrees with this Recommendation, and has implemented this Recommendation with its participation in the June 5, 2015 multi-agency budget meeting with OBPA to review planned budget submissions for the FY 2017 President's budget. APHIS will continue to participate in and/or host such meetings with OBPA and other USDA agencies related to joint, interagency dependent antimicrobial resistance budget requests and provide documentation in the budget requests that also explain the interagency dependencies.

Recommendation 9: APHIS needs to determine which positions within the agency have strong equities in antibiotic resistance or other related specialized areas. The agency should then develop a strategy to strengthen the development and retention of key, specialized positions so that it maintains a cadre of experts in the identified areas.

APHIS Response: APHIS agrees with this Recommendation. APHIS has identified four areas of major investment for antibiotic resistance activities: the National Animal Health Laboratory Network/National Veterinary Services Laboratories; the National Animal Health Monitoring System; the National Veterinary Accreditation Program; and the Center for Veterinary Biologics. Each of these areas, as well as data management, requires the development of specialized positions. VS will develop a staffing plan by December 30, 2016.

Recommendation 15: APHIS should work with ARS, Office of the Chief Scientist (OCS), and FSIS through the One Health Joint Working Group to provide the Office of Communications a comprehensive strategic communication plan for providing antibiotic resistance information to stakeholders and the general public. The plan should promote the development of a more central, robust antibiotic resistance website, explore the use of other social media outlets, and address the resources needed.

APHIS Response: APHIS agrees with this Recommendation and is outlining additional communications as part of current budget planning. This plan will include an antibiotic resistance website and the use of other social media outlets for reporting and will be completed by December 30, 2016.

Recommendation 16: APHIS should work with ARS, OCS, and FSIS through the One Health Joint Working Group to provide the Office of Communications a plan that would ensure USDA conveys a unified and scientifically based message to the public and all interested parties, including matters regarding antibiotic resistance and the gathering of stakeholders' data.

APHIS Response: APHIS agrees with this Recommendation. Communications related to antibiotic resistance are coordinated through OCS. If funding is provided, information flow should increase as a result of research, surveillance and monitoring, and the need for education/outreach. Data gathering and analysis for research and surveillance are dependent upon adequate funding for the activities described in the President's National Action Plan. The Joint Working Group will develop a communications plan by January 2, 2017.

Recommendation 19: In order to measure the progress of antibiotic resistance efforts, APHIS should consider the development of specific strategic goal(s) for antibiotic resistance and it should identify any performance measures and desired outcomes necessary to support the strategic goal(s). If APHIS does not consider antibiotic resistance necessary to include in its strategic goals, it should provide OCFO with written communication outlining the reasoning for not including antibiotic resistance in the strategic goals.

APHIS Response: APHIS agrees with this Recommendation. APHIS recognizes that goals and performance measures are necessary to make progress against antibiotic resistance. APHIS has taken initial steps at identifying strategic goals and will include these in the next update of APHIS' strategic goals. While APHIS will develop strategic goals for its antibiotic resistance activities by March 31, 2017, APHIS will not issue a new strategic plan until 2019-2020 when the current APHIS strategic plan expires. We will inform the OCFO with written communication if lack of funding prevents us from incorporating these goals.

In closing, thank you for your review of USDA's response to antibiotic resistance. If you have any questions or if there is any further information we can provide, please let us know.



United States
Department of
Agriculture

Research
Education
Economics

Office
of the Chief
Scientist

Room 338A
Jamie L. Whitten Building
Washington, DC 20250-0110

DATE: March 10, 2016

**AUDIT
NUMBER:** 50601-0004-31

TO: Gil H. Harden
Assistant Inspector General for Audit

THROUGH: Catherine E. Woteki, Ph.D.
Under Secretary
Chief Scientist, USDA

CEWoteki

MAR 10 2016

FROM: Kim Green
Director, Office of the Chief Scientist

MAR 10 2016

SUBJECT: Office of the Inspector General (OIG) Official Draft Audit Report –
“USDA’s Response to Antibiotic Resistance”

USDA’s Chief Scientist and the Office of the Chief Scientist (OCS) appreciate the opportunity to review and comment on this official draft report. We have reviewed the report and have responded to Recommendation No. 10, which is directed to OCS.

General Comments

One of the challenges for the OCS, as noted in the OIG report, are legislatively-mandated staffing restrictions that the office faces with regards to senior advisor positions. In accordance with the legislation establishing the office, Senior Advisor positions are to be filled only through term (temporary) appointments. These individuals, often considered to be among the top experts in their respective fields, serve on a rotational basis with a statutory maximum length of four years. However, in practice most Senior Advisors only serve a one-year term, and finding a continuous source of replacements is very difficult, and often negatively impacts other agencies within USDA. We concur with OIG in the belief that short-term assignments for these positions could have adverse effects on the Chief Scientist and the OCS’s ability to fulfill their responsibilities. However, getting agencies to commit to the maximum four-year period is extremely difficult because agencies cannot fill the vacated position of the person on detail to the OCS. We concur with OIG assessment and recommendation that amending the legislation to make these permanent positions would greatly improve the coordination of the Chief Scientist’s science and research priorities across the Department.

Recommendation 10

The Office of the Chief Scientist (OCS) should work with the office of Human Resources and appropriate USDA agencies to explore opportunities to extend the OCS' Senior Advisors legislated terms to the 4-year maximum or greatest extent practical; and, if needed, OCS should develop a plan to explore the initiation of legislative change that would maximize the benefit of the senior advisor positions to the office.

Agency Response

Since completion of the fieldwork for this audit, OCS worked with OSEC-DM-OHRM to explore opportunities that could extend the OCS' Senior Advisors legislated terms to the 4-year maximum or greatest extent practical. This exploration was collated by OHRM in an Issues Paper on staffing positions in OCS. OHRM conceded there are no good solutions to extending OCS Senior Advisors rotational assignments as legislated; because the Senior Advisors are encumbering positions within their home agencies and institutions, the agencies and institutions cannot fill behind them and their own missions become adversely impacted. Consequently, agencies find they are unable to allow their employees to serve longer (i.e., 4-year) terms.

As such, OCS concurs with OIG's recommendation to initiate legislative change related to senior advisor positions in the Office. A General Provision has been included the 2017 President's Budget proposal that will make funds available to OCS to use to pay for the salaries and related administrative expenses of Senior Advisors (i.e., Division Chiefs) without any limitation on the term of service.

(Source: <https://www.whitehouse.gov/sites/default/files/omb/budget/fy2017/assets/agr.pdf>)

Completion Date: OHRM completed the Issues Paper on staffing positions in OCS January 5, 2016. The President's 2017 proposed Budget was released on February 9, 2016.

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