



March 2017

ANTIBIOTIC RESISTANCE

More Information Needed to Oversee Use of Medically Important Drugs in Food Animals

Accessible Version

GAO Highlights

Highlights of [GAO-17-192](#), a report to congressional requesters

Why GAO Did This Study

According to the World Health Organization, antibiotic resistance is one of the biggest threats to global health. CDC estimates antibiotic-resistant bacteria cause at least 2 million human illnesses in the United States each year, and there is strong evidence that some resistance in bacteria is caused by antibiotic use in food animals (cattle, poultry, and swine). HHS and USDA are primarily responsible for ensuring food safety, including safe use of antibiotics in food animals. In 2011, GAO reported on antibiotic use and recommended addressing gaps in data collection. GAO was asked to update this information. This report (1) examines actions HHS and USDA have taken to manage use of antibiotics in food animals and assess the impact of their actions, (2) identifies actions selected countries and the EU have taken to manage use of antibiotics in food animals, and (3) examines the extent to which HHS and USDA conducted on-farm investigations of foodborne illness outbreaks from antibiotic-resistant bacteria in animal products.

GAO reviewed documents and interviewed officials and stakeholders. GAO selected three countries and the EU for review because they have taken actions to mitigate antibiotic resistance.

What GAO Recommends

GAO is making six recommendations, including that HHS address oversight gaps, HHS and USDA develop metrics for assessing progress in achieving goals, and USDA develop a framework with HHS to decide when to conduct on-farm investigations. USDA agreed and HHS neither agreed nor disagreed with GAO's recommendations.

View [GAO-17-192](#). For more information, contact John Neumann at (202) 512-3841 or neumannj@gao.gov

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ANTIBIOTIC RESISTANCE

More Information Needed to Oversee Use of Medically Important Drugs in Food Animals

What GAO Found

Since 2011, when GAO last reported on this issue, the Department of Health and Human Services (HHS) has increased veterinary oversight of antibiotics and, with the Department of Agriculture (USDA), has made several improvements in collecting data on antibiotic use in food animals and resistance in bacteria. For example, HHS's Food and Drug Administration (FDA) issued a regulation and guidance for industry recommending changes to drug labels. However, oversight gaps still exist. For example, changes to drug labels do not address long-term and open-ended use of antibiotics for disease prevention because some antibiotics do not define duration of use on their labels. FDA officials told GAO they are seeking public comments on establishing durations of use on labels, but FDA has not clearly defined objectives for closing this gap, which is inconsistent with federal internal control standards. Without doing so, FDA will not know whether it is ensuring judicious use of antibiotics. Moreover, gaps in farm-specific data on antibiotic use and resistance that GAO found in 2011 remain. GAO continues to believe HHS and USDA need to implement a joint on-farm data collection plan as previously recommended. In addition, FDA and USDA's Animal and Plant Health Inspection Service (APHIS) do not have metrics to assess the impact of actions they have taken, which is inconsistent with leading practices for performance measurement. Without metrics, FDA and APHIS cannot assess the effects of actions taken to manage the use of antibiotics.

Three selected countries and the European Union (EU), which GAO reviewed, have taken various actions to manage use of antibiotics in food animals, including strengthening oversight of veterinarians' and producers' use of antibiotics, collecting farm-specific data, and setting targets to reduce antibiotic use. The Netherlands has primarily relied on a public-private partnership, whereas Canada, Denmark, and the EU have relied on government policies and regulations to strengthen oversight and collect farm-specific data. Since taking these actions, the use or sales of antibiotics in food animals decreased and data collection improved, according to foreign officials and data reports GAO reviewed. Still, some U.S. federal officials and stakeholders believe that similar U.S. actions are not feasible because of production differences and other factors.

HHS and USDA officials said they have not conducted on-farm investigations during foodborne illness outbreaks including those from antibiotic-resistant bacteria in animal products. In 2014, USDA agencies established a memorandum of understanding to assess the root cause of foodborne illness outbreaks. However, in 2015 in the agencies' first use of the memorandum, there was no consensus among stakeholders on whether to conduct foodborne illness investigations on farms and the memorandum does not include a framework to make this determination, similar to a decision matrix used in other investigations. According to a directive issued by USDA's Food Safety and Inspection Service, foodborne illness investigations shall include identifying contributing factors and recommending actions or new policies to prevent future occurrences. Developing a framework, in coordination with HHS's Centers for Disease Control and Prevention (CDC) and other stakeholders, would help USDA identify factors that contribute to or cause foodborne illness outbreaks, including those from antibiotic-resistant bacteria in animal products.

Contents

Letter		1
	Background	6
	HHS and USDA Increased Oversight and Data Collection for Antibiotic Use in Animals, but Gaps Exist, and the Impact of These Actions Is Unknown	12
	Selected Countries and the EU Have Taken Various Actions to Manage Use of Antibiotics	29
	HHS and USDA Have Not Conducted On-Farm Investigations and No Consensus Exists on When Such Investigations Are Warranted	41
	Conclusions	46
	Recommendations for Executive Action	47
	Agency Comments	48
<hr/>		
	Appendix I: Objectives, Scope, and Methodology	50
	Appendix II: Medically Important Antibiotics That Changed Dispensing Status	54
	Appendix III: Companies That Sell Products with No Antibiotic Use Claims	56
	Appendix IV: Comments from the Department of Agriculture	59
	Appendix V: Comments from the Department of Health and Human Services	61
	Appendix VI: GAO Contact and Staff Acknowledgments	62
	GAO Contact	62
	Staff Acknowledgments	62
<hr/>		
	Appendix VII: Accessible Data	63
	Data Tables	63
	Agency Comment Letters	65
<hr/>		
Tables		
	Table 1: Selected Agencies' Efforts Related to Antibiotic Resistance	10

Table 2: Limitations in Federal Efforts to Collect Antibiotic Use and Resistance Data	23
Table 3: Medically Important Antibiotics Used in the Feed and Water of Food Animals Changed from Over-the-Counter to Veterinary Feed Directive and Prescription Status, as of January 2017	54
Data Table for Figure 2: National Antimicrobial Resistance Monitoring System Data Collection	63

Figures

Figure 1: How Antibiotic-Resistant Bacteria Can Develop and Spread	7
Figure 2: National Antimicrobial Resistance Monitoring System Data Collection	17
Figure 3: Pigs in Birthing and Feeding Crate	39
Figure 4: Example of Multistate Foodborne Illness Outbreak Investigation Process	43

Abbreviations

APHIS	Animal and Plant Health Inspection Service
CDC	Centers for Disease Control and Prevention
EU	European Union
FDA	Food and Drug Administration
FSIS	Food Safety and Inspection Service
GPRA	Government Performance and Results Act of 1993
GPRAMA	GPRA Modernization Act of 2010
HHS	Department of Health and Human Services
MRSA	methicillin-resistant <i>Staphylococcus aureus</i>
USDA	U.S. Department of Agriculture
WHO	World Health Organization

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March 2, 2017

The Honorable Kirsten Gillibrand Ranking Member Subcommittee on Livestock, Marketing, and Agriculture Security Committee on Agriculture, Nutrition, and Forestry United States Senate

The Honorable Rosa L. DeLauro Ranking Member Subcommittee on Labor, Health and Human Services, Education, and Related Agencies Committee on Appropriations House of Representatives

The Honorable Dianne Feinstein United States Senate

The Honorable Elizabeth Warren United States Senate

The Honorable Louise M. Slaughter House of Representatives

Antibiotics are essential to treat infections caused by bacteria, and the rise of antibiotic resistance is one of the biggest threats to global health, according to the World Health Organization (WHO). In 2013, the U.S. Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC) estimated that antibiotic-resistant bacteria cause at least 2 million illnesses and 23,000 deaths in humans each year in the United States alone.¹ WHO has stated that the emergence and spread of antibiotic-resistant bacteria have been linked to the overuse and misuse of antibiotics in veterinary and human medicine. According to CDC's website, there is strong evidence that some antibiotic resistance in bacteria is caused by antibiotic use in food animals—dairy and beef cattle, poultry (chicken and turkey), and swine raised for human consumption. Antibiotics are used in food animals to prevent, control, and treat disease as well as to promote efficient growth. Although any use of antibiotics can lead to resistance, certain uses in food animals expose bacteria to low doses of these drugs over a long period. This long-term, low-level exposure to antibiotics may lead to the survival and growth of resistant bacteria, according to CDC. Also, once the resistant bacteria grow in food animals, they may pass to humans through the consumption or handling of meat, poultry, or other food animal products; contact with animals by farm workers or food processors; or runoff of animal waste

¹Centers for Disease Control and Prevention, *Antibiotic Resistance Threats in the United States 2013*, (Atlanta, GA: April 2013).

into water or soil used for growing food crops. This can lead to foodborne illness, including outbreaks from resistant bacteria in animal products.² Federal agencies responding to outbreaks of foodborne illness from pathogens, including those involving antibiotic-resistant bacteria, may conduct investigations at the farm, slaughter processing plant, and other points where bacteria from food animals can be transferred to the human population.³

Two federal departments are primarily responsible for ensuring the safety of the food supply, including the safe use of antibiotics in food animals—HHS and the U.S. Department of Agriculture (USDA). Within HHS, the Food and Drug Administration (FDA) approves for sale, and regulates the manufacture and distribution of, antibiotics used in animals. Agencies within USDA including the Food Safety and Inspection Service (FSIS) and the Animal and Plant Health Inspection Service (APHIS), collect information about antibiotic use and resistance in food animals and educates producers and other users about appropriate antibiotic use, respectively, among other things.

Antibiotic resistance is a global issue, and WHO and countries including the United States have been examining the emergence of antibiotic resistance. In January 2014, WHO recommended that the World Health Assembly adopt a resolution on antibiotic resistance that urges countries to take action at the national level to combat antibiotic-resistant bacteria. In the United States, in September 2014, the President signed Executive Order 13676, which, among other things, established the interagency Task Force for Combating Antibiotic-Resistant Bacteria and directed agencies to use enhanced surveillance activities, as appropriate, to prevent and respond to antibiotic-resistant outbreaks.⁴ Also, in September 2014, the President's Council of Advisors on Science and Technology released a report on antibiotic resistance that recommended strong federal coordination and oversight of efforts to combat antibiotic

²Foodborne illness occurs when bacteria or other harmful substances are ingested in food. According to CDC, an outbreak of foodborne illness consists of two or more cases of a similar illness from consumption of a common food.

³Pathogens are disease-causing organisms, including bacteria such as *Salmonella*; some pathogens can cause foodborne illness.

⁴Exec. Order No. 13,676, 79 Fed. Reg. 56,931 (Sept. 18, 2014).

resistance.⁵ In March 2015, the White House released the *National Action Plan for Combating Antibiotic-Resistant Bacteria* to provide a roadmap for federal agencies' actions and response to the rise of antibiotic-resistant bacteria.⁶ According to the *National Action Plan*, implementation of the plan supports the World Health Assembly resolution.

For more than 15 years, we have reported on federal efforts to address the use of antibiotics in food animals and recommended actions to improve these efforts.⁷ For example, in 2004, we found that federal agencies needed to better focus efforts to address risk to humans from antibiotic use in food animals. We also found that federal agencies did not have critical data on antibiotic use in food animals that would help them assess the relative contribution of such use to resistance in humans. To address these gaps, we recommended that HHS and USDA develop and implement a joint plan to collect data on antibiotic use in animals that would adequately (1) support research on the relationship between use and resistance, (2) help assess the human health risk related to antibiotic use in animals, and (3) help agencies develop strategies to mitigate antibiotic resistance. HHS and USDA generally agreed with our findings, but they did not jointly develop a plan for data collection. In 2011, we again found that HHS and USDA had made limited progress in addressing antibiotic use in food animals and continued to have gaps in data collection.⁸ We recommended that the agencies take three actions: (1) identify and evaluate approaches to collect detailed data on antibiotic use, and utilize these data to evaluate FDA's voluntary strategy; (2) collect more representative data on resistance; and (3) assess previous efforts on antibiotic alternatives to identify where research is needed.

⁵Executive Office of the President, President's Council of Advisors on Science and Technology, *Report to the President on Combating Antibiotic Resistance*. (September 2014). The President's Council of Advisors on Science and Technology 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.

⁶The White House, *National Action Plan for Combating Antibiotic-Resistant Bacteria*. (Washington, D.C.: March 2015).

⁷GAO, *Food Safety: The Agricultural Use of Antibiotics and Its Implications for Human Health*, [GAO/RCED-99-74](#) (Washington, D.C.: Apr. 28, 1999); *Antibiotic Resistance: Federal Agencies Need to Better Focus Efforts to Address Risk to Humans from Antibiotic Use in Animals*, [GAO-04-490](#) (Washington, D.C.: Apr. 22, 2004); and *Antibiotic Resistance: Agencies Have Made Limited Progress Addressing Antibiotic Use in Animals*, [GAO-11-801](#) (Washington, D.C.: Sept. 7, 2011).

⁸[GAO-11-801](#).

HHS and USDA agreed with our recommendations and took several steps to address them. However, their actions did not fully address our recommendations to identify and evaluate approaches to collect detailed data on antibiotic use and to assess previous efforts to identify where research on antibiotic alternatives were needed.⁹

You asked us to provide an update on U.S. federal agencies and other countries' efforts to address the use of antibiotics in food animals, among other things. This report (1) examines actions HHS and USDA have taken since 2011 to manage the use of antibiotics in food animals and to assess the impact of their actions, (2) identifies actions that selected countries and the European Union (EU) have taken to manage the use of antibiotics in food animals, and (3) examines the extent to which HHS and USDA have conducted on-farm investigations of outbreaks of foodborne illness from antibiotic-resistant pathogens in animal products.

To examine actions HHS and USDA have taken since 2011 to manage the use of antibiotics in food animals and to assess the impact of their actions, we reviewed relevant statutes and regulations, agencies' plans and guidance, and stakeholders' reports related to managing the use of antibiotics in food animals. Also, we reviewed federal data reports on the collection of data on antibiotic sales, use, and resistance. We compared information from federal agencies on actions taken with federal standards for internal controls.¹⁰ We identified any relevant goals, performance measures, and targets developed by federal agencies to gauge the impact of their efforts and compared them with agencies' goals, *National Action Plan* goals and milestones, and leading practices for improving agency performance, specifically practices identified in the GPRA Modernization Act of 2010 (GPRAMA) and our prior work on performance

⁹In this report, we did not evaluate HHS and USDA efforts to identify where research on antibiotic alternatives are needed. USDA officials told us the agency collaborated with HHS to organize the second International Symposium on Alternatives to Antibiotics in December 2016 with the support of the World Organization for Animal Health.

¹⁰GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014).

management.¹¹ We also interviewed federal officials and representatives of stakeholder organizations—national food animal industry, pharmaceutical (drug), veterinary, consumer advocacy, and other groups—about federal actions taken to manage the use of antibiotics since 2011. We also interviewed representatives of several companies (producers and restaurants) that provide food products from animals raised without antibiotics to obtain a better understanding of production practices, the types of antibiotic use data available at the farm level, and perspectives on federal efforts to educate producers about antibiotics. In addition, we compared federal agencies' actions with relevant goals outlined in national and agencies' plans and interviewed representatives of stakeholder organizations to obtain views on agencies' efforts taken to date.

To identify actions that selected countries and the EU have taken to manage the use of antibiotics in food animals, we reviewed documents and interviewed officials from Canada, Denmark, the Netherlands, and the EU. We selected these countries and region because they have taken actions to mitigate antibiotic resistance.¹²

To examine the extent to which HHS and USDA conducted on-farm investigations of outbreaks of foodborne illness from antibiotic-resistant pathogens in animal products, we reviewed relevant documentation, including directives on investigations of foodborne illness outbreaks from CDC, APHIS, and FSIS. We also reviewed a 2014 APHIS-FSIS memorandum of understanding to access farms for investigations during these outbreaks, as well as documentation on a 2015 *Salmonella* outbreak—identified as the only outbreak in which APHIS and FSIS used their memorandum of understanding. We interviewed federal and state

¹¹The statutory framework for performance management in the federal government was originally set out in the Government Performance and Results Act of 1993 (GPRA), Pub. L. No. 103-62, 107 Stat. 285. It was later updated by GPRAMA, Pub. L. No. 111-352, 124 Stat. 3866 (2011). GPRAMA requires executive agencies to complete strategic plans in which they define their missions, establish results-oriented goals, and identify the strategies that will be needed to achieve those goals. It also requires agencies to complete annual performance plans that establish performance goals—which contribute to the strategic goals—and measure performance toward achieving performance goals. Performance measures, called performance indicators, are important management tools that help agencies monitor and report progress toward their goals. Numerical targets are a key attribute of performance measures because they allow managers to compare planned performance with actual results.

¹²Denmark and the Netherlands are EU members that have made changes beyond EU directives to manage the use of antibiotics in food animals.

officials who investigated the 2015 *Salmonella* outbreak. We also interviewed federal officials about the agencies' authority to conduct on-farm investigations during foodborne illness outbreaks, including those involving antibiotic-resistant pathogens. Appendix I contains more detailed information on the scope and methodology of our review.

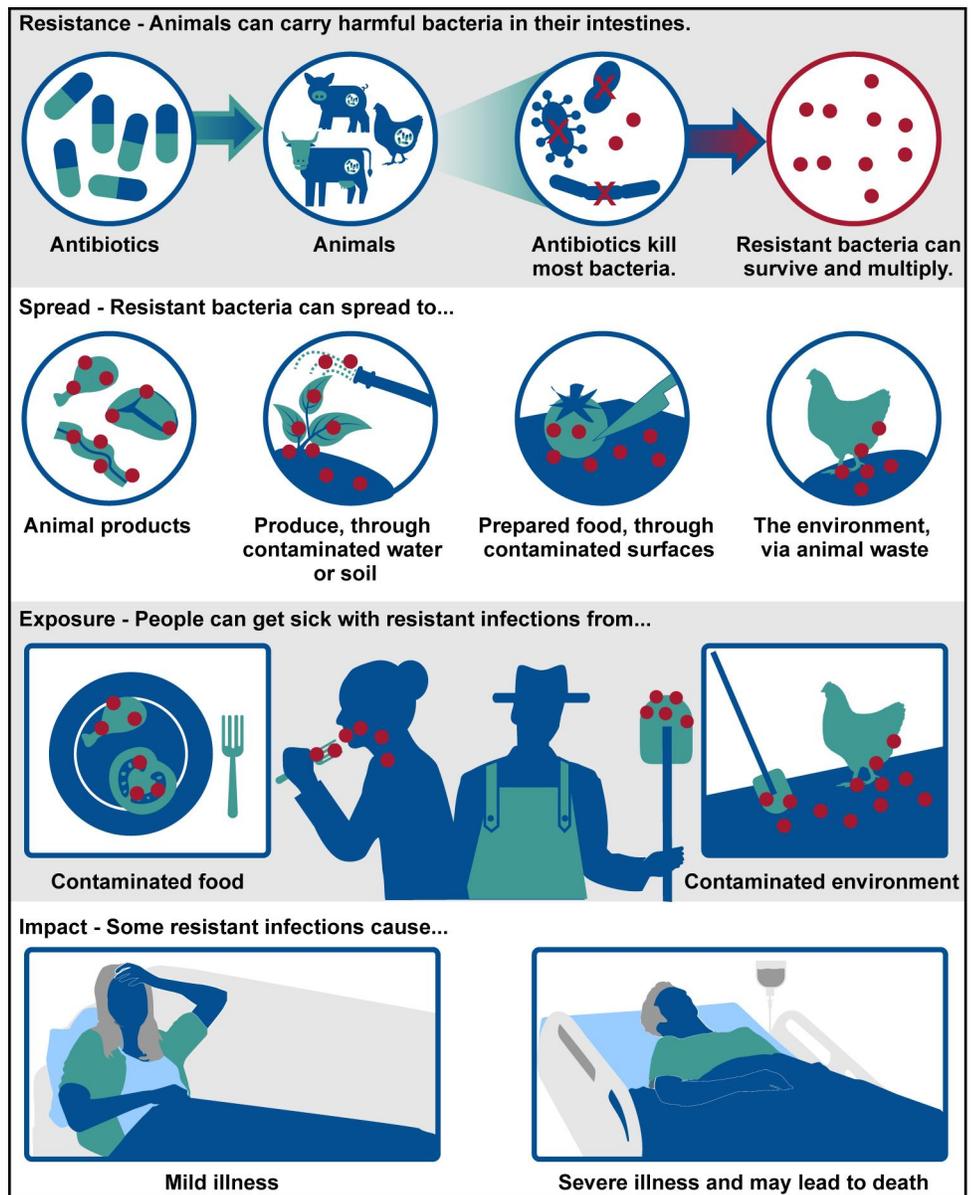
We conducted this performance audit from August 2015 to March 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Background

Antimicrobial drugs are a broad class of drugs that combat many pathogens, including bacteria, viruses, fungi, or parasites. Antibiotics are a subset of these drugs that work against bacteria.¹³ Antibiotics work by killing the bacteria directly or halting their growth. According to WHO, the evolution of strains of bacteria that are resistant to antibiotics is a natural phenomenon that occurs when microorganisms exchange resistant traits; however, WHO also states that the use and misuse of antimicrobial drugs, including antibiotics, accelerates the emergence of resistant strains. Antibiotic resistance began to be recognized soon after penicillin, one of the first antibiotics, came into use over 70 years ago. Antibiotic-resistant bacteria can spread from animals and cause disease in humans through a number of pathways (see fig. 1).

¹³FDA uses the term "antimicrobials," which includes antibiotics, in its publications. Most drugs of concern in this report are antibiotics.

Figure 1: How Antibiotic-Resistant Bacteria Can Develop and Spread



Source: Centers for Disease Control and Prevention. | GAO-17-192

Note: This figure is not intended to represent the full complexity of resistance transmission. For example, antibiotic-resistant bacteria can also be transferred from humans to animals; disseminated from hospitals and other human sources; and transferred from other food products, such as fish, which may contribute to the spread of resistance.

The use of antibiotics in animals is an integral part of food animal production. To improve efficiencies, modern industrial farms raise animals

in high concentrations, but this practice has the potential to spread disease because animals live in close confinement. Long-term, low-dose treatments with antibiotics may help prevent diseases, particularly where animals are housed in large groups in close confinement facilities, such as concentrated animal feed operations. The concentrated nature of such agricultural operations means that a disease, if it occurs, can spread rapidly and become quickly devastating—increasing the need to rely on antibiotics as a preventive measure.

The purposes for which FDA approves the use of antibiotics can be divided into four categories:

- to treat animals that exhibit clinical signs of disease;
- to control a disease in a group of animals when a proportion of them exhibit clinical signs of disease;
- to prevent disease in a group of animals when none are exhibiting clinical signs of disease, but disease is likely to occur in the absence of an antibiotic; or
- to promote faster weight gain (growth promotion) or weight gain with less feed (feed efficiency).

Antibiotics for food animals are administered either by mixing them into feed or water, or by injection and other routes. For example, according to representatives from the poultry industry, the majority of antibiotics used in poultry production are administered through feed and water. In lactating dairy cattle, mastitis—an inflammation of the udder—is the most common reason for antibiotic use and antibiotics are given by injection either to treat or prevent disease, according to representatives from the National Milk Producers Federation.

Antibiotics for food animals may be sold or dispensed in several ways, with varying levels of restriction.

- Some antibiotics may be purchased over-the-counter and used by producers without veterinarian consultation or oversight.

- Certain antibiotics added to feed must be accompanied by a veterinary feed directive, a type of order for this use.¹⁴ The directive authorizes the producer to obtain and use animal feed containing a certain drug or drug combination to treat the producer's animals in accordance with the conditions for use approved by FDA.
- Some antibiotics may require a prescription from a licensed veterinarian.

Although veterinarians may prescribe most approved drugs “extra label” (for a species or indication other than those on the drug label), restrictions on the extra-label use of antibiotics in food animals exist. For example, no extra-label use of approved drugs, including antibiotics, is legally permissible in or on animal feed, according to FDA officials. Certain types of drugs, including some types of antibiotics, are prohibited from extra-label use in food animals under any circumstances because the use of these drugs may lead to antibiotic resistance in humans (e.g., fluoroquinolones—broad-spectrum antibiotics that play an important role in treatment of serious bacterial infections, such as hospital-acquired infections).

Antibiotics used for food animals can be the same, or belong to the same drug classes, as those used in human medicine. FDA and WHO have sought to identify antibiotics that are used in both animals and humans and that are important to treat human infections—such antibiotics are known as medically important antibiotics. In 2003, FDA issued guidance to industry on the use of antibiotics in food animals, which included a list of antibiotics that it considers important to human medicine.¹⁵ In this

¹⁴In 1996, Congress passed the Animal Drug Availability Act, Pub. L. No. 104–250, 110 Stat.3151 (1996), to improve the process of approving and using animal drugs. In passing the act, Congress created a new regulatory category for certain animal drugs, including antibiotics, used in or on animal food (animal feed) called “veterinary feed directive drugs.” Such drugs are new animal drugs intended for use in or on animal feed that are limited to use under the professional supervision of a licensed veterinarian. Any animal feed containing such a drug can only be fed to animals based upon an order, called a veterinary feed directive, issued by a licensed veterinarian in the course of the veterinarian’s professional practice. In 2000, FDA finalized regulations relating to the distribution and use of veterinary feed directive drugs. FDA amended these regulations in 2015.

¹⁵Food and Drug Administration, *Guidance for Industry #152. Evaluating the Safety of Antimicrobial New Animal Drugs with Regards to Their Microbiological Effects on Bacteria of Human Health Concern* (Rockville, MD: Oct. 23, 2003), accessed January 20, 2016, <http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM052519.pdf>.

guidance, FDA ranked each antibiotic according to its importance in human medicine, as “critically important” (the highest ranking), “highly important,” or “important” based on criteria that focused on antimicrobials, including antibiotics, used to treat foodborne illness in humans. Similarly, WHO developed criteria for ranking antimicrobials, including antibiotics, according to their importance in human medicine and first ranked them in 2005.¹⁶

Two federal departments are primarily responsible for ensuring the safety of the U.S. food supply, including the safe use of antibiotics in food animals—HHS and USDA. Each department contains multiple agencies that contribute to the national effort to control, monitor, and educate others on antibiotic use and resistance. For example, HHS’s CDC and FDA as well as USDA’s APHIS and FSIS have responsibilities related to the White House’s 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria*. The plan identifies several goals, including a goal to slow the development of resistant bacteria and prevent the spread of resistant infections as well as a goal to strengthen national “one-health” surveillance efforts to combat resistance, which include collecting data on antibiotic use and resistance.¹⁷ The “one-health” concept recognizes that the health of humans, animals, and the environment are interconnected. Table 1 provides information on selected agencies’ efforts related to antibiotic resistance.

Table 1: Selected Agencies’ Efforts Related to Antibiotic Resistance

Agency	Type of activity	Agency efforts
U.S. Department of Health and Human Services	Centers for Disease Control and Prevention	Conduct surveillance of antibiotic resistance in foodborne bacteria in ill humans. Promote appropriate use of antibiotics in food animals through educational activities.

¹⁶World Health Organization, *Critically Important Antimicrobials for Human Medicine*, 3rd Revision (Geneva, Switzerland: 2011), accessed July 27, 2016, http://apps.who.int/iris/bitstream/10665/77376/1/9789241504485_eng.pdf.

¹⁷Antibiotic use data indicate the amount of antibiotics used in food animals and antibiotic resistance data indicate the presence and level of resistance in bacteria found in food animals and retail meat.

Agency	Type of activity	Agency efforts
Food and Drug Administration	Oversight, data collection, education	<p>Approve for sale and regulate the manufacture and distribution of antibiotics for food animals.</p> <p>Collect and report annual veterinary antibiotic sales data by drug class—a drug may be classified by the chemical type of the active ingredient or by the way it is used to treat a particular condition.</p> <p>Conduct surveillance of antibiotic resistance in isolates—a bacterial strain that has been isolated—of foodborne bacteria from retail meat and poultry.</p> <p>Promote appropriate use of antibiotics in food animals through educational activities.</p>
U.S. Department of Agriculture (USDA)	Animal and Plant Health Inspection Service	<p>Data collection, education</p> <p>Manage periodic, national surveys of producers that focus on animal health, welfare, and production.</p> <p>Manage the program that certifies private veterinarians to carry out certain federal animal health programs.</p> <p>Promote appropriate use of antibiotics in food animals through educational activities.</p>
	Agricultural Research Service	<p>Data collection</p> <p>Conducted surveillance of antibiotic resistance in food animal isolates of foodborne bacteria (ended by 2013).</p> <p>Conduct research on antibiotic resistance, which may include data collection.</p>
	Economic Research Service	<p>Data collection</p> <p>Manage and conduct producer surveys; principally focused on farm finances and also used to track and analyze practices, including antibiotic use.</p>
	Food Safety and Inspection Service	<p>Data collection</p> <p>Conduct inspections at slaughter plants in the United States.</p> <p>Conduct surveillance of antibiotic resistance in food animal isolates of foodborne bacteria (started in 2013).</p>
	National Agricultural Statistics Service	<p>Data collection</p> <p>With USDA's Economic Research Service, manage and conduct producer surveys principally focused on farm finances and also used to track and analyze practices, including antibiotic use.</p>

Sources: Centers for Disease Control and Prevention, GAO, Food and Drug Administration, and USDA. | GAO-17-192

To help ensure public health and the safety of the food supply, HHS's CDC leads investigations of multi-state foodborne illness outbreaks, including those involving antibiotic-resistant pathogens, and collaborates with USDA, FDA, and state public health partners in this effort. To identify an outbreak, CDC monitors data voluntarily reported from state health departments on cases of laboratory-confirmed illness and analyzes these data to identify elevated rates of disease that may indicate an outbreak, according to CDC officials. According to CDC's website, determining the food source of human illness is an important part of improving food safety. In general, foods often associated with foodborne illnesses include raw foods of animal origin—meat, poultry, eggs, and shellfish, and also unpasteurized (raw) milk—that can cause infections if undercooked or through cross-contamination.

HHS and USDA Increased Oversight and Data Collection for Antibiotic Use in Animals, but Gaps Exist, and the Impact of These Actions Is Unknown

Since 2011, HHS has increased veterinary oversight of antibiotics in food animals and, along with USDA, collected additional data on antibiotic use and resistance, but gaps exist in oversight and data collection, and the impact of the agencies' efforts is unknown. For medically important antibiotics administered in animal feed and water, HHS's FDA increased veterinary oversight and prohibited certain uses through a combination of guidance and regulation. In addition, agencies in HHS and USDA made several improvements in collecting and reporting data on antibiotic sales, resistance, and use. However, the agencies' actions do not address oversight gaps such as long-term and open-ended use of medically important antibiotics for disease prevention or collection of farm-specific data, and FDA and APHIS do not have measures to assess the impact of their actions.

HHS Increased Veterinary Oversight of Medically Important Antibiotics Used in Food Animals

To promote the judicious use of antibiotics in food animals, FDA increased veterinary oversight of medically important antibiotics in feed and water through voluntary guidance to industry and revising the veterinary feed directive regulation.¹⁸ As a result, as of January 2017, medically important antimicrobials, including antibiotics, in the feed and water of food animals may only be used under the supervision of licensed veterinarians, according to FDA officials (see app. II for a list of these drugs).

¹⁸Food and Drug Administration, *Guidance for Industry #209: The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals* (Rockville, MD: April 2012); Food and Drug Administration, *Guidance for Industry #213: New Animal Drugs and New Animal Drug Combination Products Administered in or on Medicated Feed or Drinking Water of Food-Producing Animals: Recommendations for Drug Sponsors for Voluntarily Aligning Product Use Conditions with GFI #209* (Rockville, MD: December 2013); and Veterinary Feed Directive, 80 Fed. Reg. 31,708 (June 3, 2015) (amending sections of 21 C.F.R. Parts 514 and 558).

Voluntary Guidance to Industry. In 2012, FDA finalized guidance that lays out a strategy for phasing out the use of medically important antibiotics for growth promotion or feed efficiency, and for bringing other uses under veterinary oversight.¹⁹ Specifically, in *Guidance for Industry #209*, FDA outlined and recommended adoption of two principles for judicious use of antibiotics in food animals: (1) limit medically important antibiotics to uses that are considered necessary for assuring animal health, such as to prevent, control, and treat diseases, and (2) limit antibiotic uses to those that include veterinary oversight. In 2013, to help ensure implementation of its strategy, FDA issued *Guidance for Industry #213*, which asked animal drug companies to voluntarily stop labeling antibiotics for growth promotion or feed efficiency within 3 years. The guidance also recommended more veterinary oversight.²⁰ Specifically, FDA (1) asked drug companies to voluntarily revise labels of medically important antibiotics to remove the use for growth promotion and feed efficiency; (2) outlined procedures for adding, where appropriate, scientifically supported uses for disease treatment, control, or prevention; and (3) recommended that companies change the means of sale or dispensation from over-the-counter to require veterinary oversight—either through a veterinary feed directive for antimicrobials administered through feed or through a prescription for antimicrobials administered through water—by December 31, 2016. According to FDA, as of January 3, 2017, all applications for medically important antimicrobials, including antibiotics, for use in the feed or water for food animals have been aligned with the judicious use principles as recommended in *Guidance for Industry #213*, or their approvals have been voluntarily withdrawn.²¹ As a result of these actions, these products cannot be used for production purposes (e.g., growth promotion) and may only be used under the authorization of a licensed veterinarian, according to FDA.

¹⁹*Guidance for Industry #209.*

²⁰*Guidance for Industry #213.*

²¹According to FDA, of the 292 new animal drug applications initially affected by *Guidance for Industry #213*, 84 were completely withdrawn and the remaining 208 applications were converted from over-the-counter to prescription status or to veterinary feed directive status.

Agencies Respond to Colistin Resistance

In May 2016, the U.S. Department of Defense identified the first person in the United States to be carrying *E. coli* bacteria with a gene that makes bacteria resistant to colistin. The U.S. Department of Agriculture (USDA) also found colistin-resistant *E. coli* in samples collected from the intestines of two pigs. According to the U.S. Department of Health and Human Services (HHS), these discoveries are of concern because colistin is used as a last-resort drug to treat patients with multidrug-resistant infections. Finding colistin-resistant bacteria in the United States is important because in 2015 scientists in China first reported that colistin resistance can be transferred across bacteria via a specific gene. HHS and USDA are continuing to search for evidence of colistin-resistant bacteria in the United States through the National Antimicrobial Resistance Monitoring System, according to the HHS website. According to officials from HHS's Centers for Disease Control and Prevention, the agency is also expanding the capability of public health laboratories to conduct surveillance.

Source: GAO. | GAO-17-192

Guidance for Industry #213 further defined medically important antimicrobials, including antibiotics, as those listed in FDA's ranking of drug classes and class-specific products based on importance to human medicine.²² According to FDA officials, the agency plans to update this list in the near future, and the update will address whether to add or remove drug classes and class-specific products, as well as the need to update the relative rankings of these drug classes and class-specific products. Colistin—an antibiotic used as the last line of medical treatment for certain infections—is not listed in the ranking of drugs and drug classes. However, according to FDA officials, the ranking of a closely related drug (polymixin B) covers colistin's relative importance to human medicine and colistin has never been marketed for use in animals in the United States.

Veterinary Feed Directive Final Rule. In light of the 2013 guidance asking animal drug companies to change the labels of medically important antibiotics to bring them under veterinary oversight (*Guidance for Industry #213*), in June 2015, FDA issued a final rule revising its existing veterinary feed directive regulation to define minimum requirements for a valid veterinarian-client-patient relationship, among other things.²³ The final rule requires a licensed veterinarian to issue the directive in the context of a valid veterinarian-client-patient relationship as defined by the state where the veterinarian practices medicine or by the federal standard in the absence of an appropriate state standard that applies to veterinary feed directive drugs. There are three key elements of the veterinarian-client-patient relationship: (1) the veterinarian engages with the client (e.g., animal producer) to assume responsibility for making clinical judgments about animal health, (2) the veterinarian has sufficient knowledge of the animal by virtue of an examination and visits to the facility (e.g., farm) where the animal is managed, and (3) the veterinarian provides for any necessary follow-up evaluation or care. The veterinarian is also responsible for ensuring the directive is complete and accurate. For example, the directive must include the approximate number of animals to be fed the medicated feed. The final rule also (1) established a 6-month expiration date for directives unless an expiration date shorter than 6 months is specified in the drug's approved labeling; (2) limited refills to those listed on the product's label; and (3) established a 2-year recordkeeping requirement for producers, veterinarians, and feed distributors.

²²This listing is contained in appendix A of *Guidance for Industry #152*.

²³80 Fed. Reg. 31,708 (June 3, 2015) (codified at 21 C.F.R. pts. 514 and 558).

HHS and USDA Have Gathered Additional Data about Antibiotic Sales, Resistance, and Use in Animals

Since 2011, agencies within HHS and USDA have made several improvements in collecting and reporting data on antibiotic sales, resistance, and use.

Sales Data

In 2014, FDA enhanced its annual summary report on antimicrobials sold or distributed for use in food animals. The enhanced annual report includes additional data tables on the importance of each drug class in human medicine; the approved routes of administration for antibiotics; whether antibiotics are available over-the-counter or require veterinary oversight; and whether the drug products are approved for therapeutic (disease prevention, control, or treatment) purposes, production purposes (e.g., growth promotion), or both therapeutic and production purposes. In 2016, FDA finalized a rule requiring drug companies to report sales and distribution of antimicrobials, including medically important antibiotics approved for use in specific food animals (cattle, swine, and poultry—chickens and turkeys) based on an estimated percentage of total annual sales.²⁴ According to FDA documents, the additional data will improve FDA's understanding of how antibiotics are sold or distributed for use in food animals and help the agency further target its efforts to ensure judicious use of medically important antibiotics. Before the rule was finalized, however, some organizations cautioned that the proposed requirement for drug companies to submit species-specific estimates of antibiotic product sales and distribution for use in food animal species would not result in useful data, in part, because sales are not a proxy for

²⁴81 Fed. Reg. 29,129 (May 11, 2016) (amending and codifying sections at 21 C.F.R. Part 514). The final rule codified reporting requirements enacted in 2008 and expanded reporting of sales to include estimates by species. Under section 105 of the Animal Drug User Fee Amendments of 2008, Pub. L. No. 110-316, 122 Stat. 3509, the sponsor of an animal antibiotic that is sold or distributed for use in food animals must submit an annual report to FDA, that specifies the amount of each antibiotic sold or distributed for such use, including, (1) active ingredient by container size, strength, and dosage form; (2) quantities distributed domestically and exported; and (3) a listing of the target animals. FDA began in 2009 to publicly report summaries of the sales and distribution data it received from antimicrobial new animal drug companies. FDA antibiotic sales reports for 2009 through 2011 include volumes sold and distributed by class of antimicrobial drugs, including antibiotics, and a breakdown by class of the active ingredients.

antibiotic use. FDA's action partially addressed our 2011 recommendation to provide sales data by food animal group and indication for use.²⁵

Antibiotic Resistance Data

Federal agencies have made several improvements to the National Antimicrobial Resistance Monitoring System—the national public health surveillance system that tracks changes in the antibiotic susceptibility of bacteria found in ill people, retail meats, and food animals.²⁶ Specifically, beginning in 2013, FSIS collected random samples from animal intestines at slaughter plants, including chickens, turkeys, swine, and cattle, in addition to non-random sampling under its regulatory program.²⁷ In 2013, FDA also expanded its retail meat sampling to collect data from laboratories in three new states: Louisiana, Missouri, and Washington.²⁸ This increased the number of states from 11 to 14. In addition, FDA increased retail meat samples from 6,700 in 2015 to 13,400 in 2016 by requiring the 14 participating laboratories to double the amount of food samples purchased and tested. In 2017, FDA plans to add another five states (Iowa, Kansas, South Carolina, South Dakota, and Texas) to retail

²⁵[GAO-11-801](#).

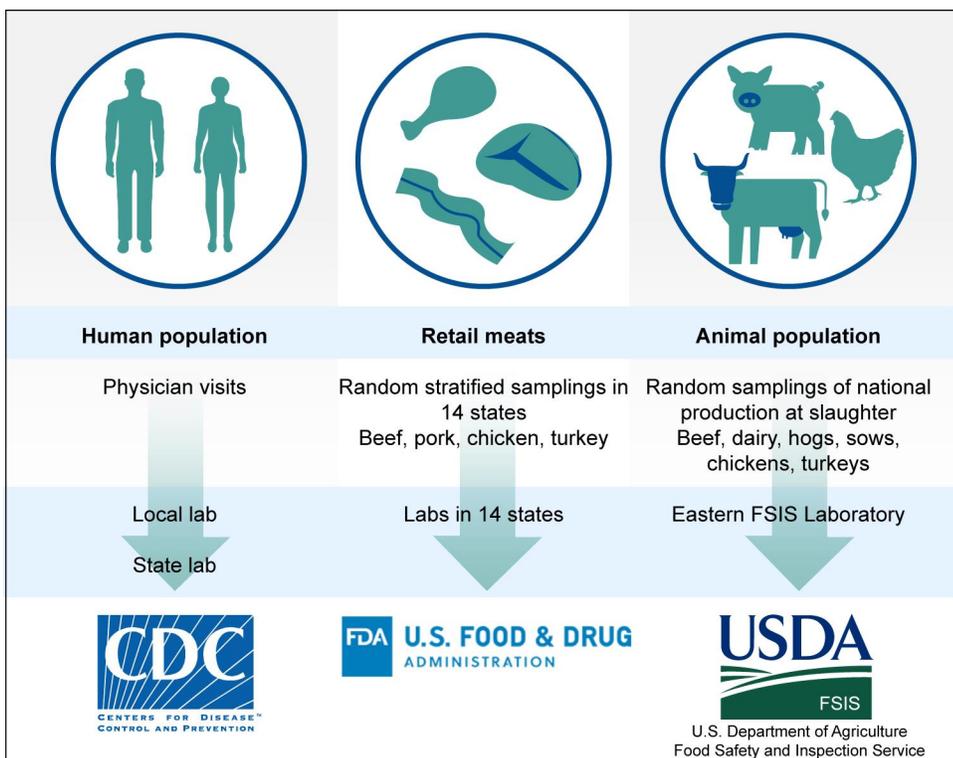
²⁶The National Antimicrobial Resistance Monitoring System, established in 1996, is a collaboration of FDA, CDC, USDA, and state and local health departments to monitor antimicrobial (antibiotic) susceptibility in enteric bacteria from humans, retail meats, and food animals. The National Antimicrobial Resistance Monitoring System includes sample results from *Salmonella*, *Campylobacter*, *Enterococcus*, and *E. coli*.

²⁷FSIS uses two programs—random and regulatory—for food animal surveillance. According to FSIS officials, for cecal sampling, the agency uses a random algorithm to collect samples based on a percentage of total slaughter production volume. FSIS's regulatory sampling program at slaughter plants is known as the Hazard Analysis Critical Control Point program. Under this program, industry identifies food safety hazards (e.g., pathogen contamination) and establishes controls at critical points to control for those hazards, and FSIS takes samples at these critical control points to determine the effectiveness of controls. In 2011, we found that samples from this program are not representative of food animals across the country and cannot be used for trend analysis because bacteria are collected at greater rates from plants not in compliance with food standards. In fiscal year 2016, FSIS expanded its regulatory sampling program including sampling of additional poultry products such as chicken parts, but isolates from these products have not been reported in the National Antimicrobial Resistance Monitoring System annual report, according to FSIS officials.

²⁸The goal of the retail meat component of the National Antimicrobial Resistance Monitoring System is to determine the prevalence of antibiotic resistance among *Salmonella*, *Campylobacter*, *Enterococci*, and *E. coli* isolated from samples of retail chicken, ground turkey, ground beef, and pork chops purchased from grocery stores in the United States.

meat testing, which will raise the total retail meat samples to more than 17,000 annually, according to FDA officials. FSIS and FDA actions addressed our recommendation from 2011 to modify slaughter and retail meat sampling to make the data more representative of antibiotic resistance in bacteria in food animals and retail meat throughout the United States.²⁹ Figure 2 summarizes the data collected through the National Antimicrobial Resistance Monitoring System.

Figure 2: National Antimicrobial Resistance Monitoring System Data Collection



Source: Food and Drug Administration. | GAO-17-192

Note: The National Antimicrobial Resistance Monitoring System is a collaborative effort including the Department of Health and Human Services' (HHS) Centers for Disease Control and Prevention (CDC), Food and Drug Administration (FDA), and the U.S. Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) to collect antibiotic resistance data on several pathogens including *Salmonella*, *Campylobacter*, *E. coli*, and *Enterococcus*. USDA's FSIS uses two programs—random and regulatory—for food animal surveillance, but the regulatory program uses nonrandom sampling which means these data are not representative of food animals across the country. Prior to 2013, USDA's Agricultural Research Service conducted surveillance of antibiotic resistance in food animal isolates of foodborne bacteria.

²⁹GAO-11-801.

Since 2011, FDA in collaboration with USDA's Agricultural Research Service has also initiated pilot projects to explore antibiotic-resistant bacteria on the farm and at slaughter for each major food animal group (swine, beef and dairy cattle, chickens, and turkeys). The purpose of the pilot projects was (1) to begin assessing similarities and differences between bacteria and antibiotic resistance on the farm and at the slaughter plant and (2) to determine the feasibility and value of surveillance on farms as a possible new element of the National Antimicrobial Resistance Monitoring System, including the collection of antibiotic use information from farms in a confidential manner. To collect data from farms, federal agencies collaborated with academia to obtain data from producers. According to FDA officials, USDA can use information from the pilot projects to determine options for examining antibiotic resistance in a group of food animals over time (e.g., longitudinal on-farm studies).

In 2016, for the first time, CDC, FDA, and USDA published the National Antimicrobial Resistance Monitoring System report with data from whole genome sequencing—cutting-edge technology which characterizes an organism's (individual bacterium) complete set of genes.³⁰ According to FDA officials, this represents a very significant advancement in surveillance that will provide definitive information about the genes causing resistance, including resistance compounds not currently fingerprinted, along with details on other important features of a bacterium. In addition, new reporting tools are being deployed to foster timely data sharing via web tools and they allow stakeholders to explore isolate-level antibiotic-resistance data in new ways. For example, in August 2015, FDA made available on its website 18 years of National Antimicrobial Resistance Monitoring System isolate-level data on bacteria.

Antibiotic Use Data

Since 2011, USDA agencies have collected additional antibiotic use data through national surveys of producers and engaged in efforts to leverage industry data. In particular, APHIS, through the National Animal Health Monitoring System, collected additional antibiotic use data through its national survey of producers of dairy cattle (2011 and 2014), beef cattle (2011), laying hens (2013), and swine (2012). Using these surveys,

³⁰According to CDC, whole genome sequencing is like comparing all of the words in a book, instead of just the number of chapters, to see if the books are the same or different.

generally APHIS collects information on the amount and duration of antibiotic use; reason for use; antibiotic name; and the route of administration, such as feed, water, and injection; among other things. APHIS also may collect biological samples from animals and test these samples for antibiotic resistance of foodborne pathogens; producers receive results of biological sample testing. According to APHIS officials, the agency is planning to collect data annually on antibiotic use on swine farms and beef cattle feedlots using similar surveys, with additional questions on stewardship and judicious use of antibiotics.

USDA's Economic Research Service and National Agricultural Statistics Service also conducted national surveys of producers of swine (2015) and chicken (2011) to collect data on farm finances and production practices, including antibiotic use. The surveys were components of the annual Agricultural Resource Management Survey, which is primarily focused on farm finances, commodity costs of production, and farm production practices. The surveys captured quantitative information on the extent of antibiotic use and the types of farms that use antibiotics for growth promotion and prevention. USDA has used these data to estimate the impact of antibiotic use on production outcomes.

Furthermore, APHIS provided input on a survey as part of the poultry industry effort begun in 2015 to develop a survey to collect farm-specific data. Representatives from the poultry industry told us that they plan to share aggregated survey data with APHIS and FDA when the data collection and report are finalized.

Gaps Exist in Oversight of Antibiotics and Persist in Farm-Specific Data

Despite agencies' enhanced oversight and data collection efforts, several gaps exist in the oversight of medically important antibiotics in food animals—specifically, antibiotics with no defined duration of use on their labels and antibiotics administered by routes other than feed and water (e.g., injection). Moreover, gaps that we identified in 2011 in farm-specific data on antibiotic use and resistance in bacteria persist.

Gaps in Oversight of Antibiotics in Food Animals

FDA's guidance to industry has improved oversight of some antibiotics, but it does not address long-term and open-ended use of medically important antibiotics for disease prevention because some antibiotics do

not have defined durations of use on their labels. For example, some currently approved labels do not have defined duration of use such as “feed continuously for 5 days”; instead labels may read “feed continuously,” according to FDA officials. In September 2016, FDA issued a notice in the *Federal Register* seeking public comment on how to establish appropriately targeted durations of use for medically important antimicrobial drugs including the approximately 32 percent of therapeutic antibiotic products affected by *Guidance for Industry #213* with no defined duration of use.³¹ FDA officials told us the agency will consider public comments as it develops a process for animal drug companies to establish appropriate durations of use for labels already in use.³² However, FDA has yet to develop this process, including time frames for implementation. In an October 2016 report, one stakeholder organization recommended that FDA announce a plan and timeline for making all label revision changes regarding duration limits and other aspects of appropriate use as quickly as possible to ensure labels follow the judicious use of antibiotics in food animals.³³ Under federal standards for internal control, management should define objectives clearly to enable the identification of risk and define risk tolerances; for example, in defining objectives, management may clearly define what is to be achieved, who is to achieve it, how it will be achieved, and the time frames for achievement.³⁴ Without developing a process, which may include time frames, to establish appropriate durations of use on labels of all medically important antibiotics, FDA will not know whether it is achieving its objective of ensuring judicious use of medically important antibiotics in food animals.

FDA’s *Guidance for Industry #213* also does not recommend veterinary oversight of over-the-counter medically important antibiotics administered in injections or through other routes besides feed and water (e.g., tablets).

³¹81 Fed. Reg. 63,187 (Sept. 14, 2016).

³²In November 2016, FDA extended the public comment period deadline from December 2016 to March 2017.

³³Pew Charitable Trusts aims to improve public policy, inform the public, and invigorate civic life. Pew Charitable Trusts, *Judicious Animal Antibiotic Use Requires Drug Label Refinements*, (October 2016), accessed October 5, 2016, http://www.pewtrusts.org/~media/assets/2016/10/judicious_animal_antibiotic_use_requirements_drug_label_refinements.pdf.

³⁴[GAO-14-704G](#). An internal control is a process affected by an entity’s oversight body, management, and other personnel that provides reasonable assurance that the objectives of an entity will be achieved.

According to FDA officials, the agency focused first on antibiotics administered in feed and water because officials believed these antibiotics represent the majority of antibiotics sold and distributed and therefore they posed a higher risk to human health. According to FDA's 2014 sales data report on antimicrobials, approximately 5 percent of medically important antibiotics are sold for use in other routes. Representatives of two veterinary organizations we interviewed support veterinary oversight of medically important antibiotics administered by other routes such as injections. In October 2016, FDA officials told us the agency is developing a plan that outlines its key activities over the next 5 years to further support antimicrobial stewardship in veterinary settings, including addressing veterinary oversight of other dosage forms of medically important antibiotics. According to FDA officials, the agency intended to publish the plan by the end of 2016 and to initiate steps by the end of fiscal year 2019. However, FDA was unable to provide us with this plan or specifics about the steps outlined in the plan because it was still under development. In the interim, on January 3, 2017, FDA broadly outlined on its website its key initiatives to support antimicrobial stewardship in veterinary settings, but it does not provide enough detail to know if steps will be established to increase veterinary oversight of medically important antibiotics administered in routes other than feed and water. As previously discussed, under federal standards for internal control, management should define objectives clearly to enable the identification of risk and define risks tolerances; for example, in defining objectives, management may clearly define what is to be achieved and the time frames for achievement, among other things.³⁵ Without a published plan documenting the steps to increase veterinary oversight of medically important antibiotics administered through routes other than feed and water, such as injections and tablets, FDA will not know whether it is making progress in achieving its objective of ensuring judicious use of medically important antibiotics in food animals.

Stakeholders we spoke with also identified and reported other potential gaps in FDA's actions to increase veterinary oversight, such as (1) gaps in oversight of antibiotics used for disease prevention and (2) gaps in some producers' knowledge of FDA's actions and in their access to veterinarians.

³⁵[GAO-14-704G](#).

- Representatives of consumer advocacy organizations told us the use of antibiotics for disease prevention in food animals is a problem because it promotes the routine use of antibiotics in healthy food animals. According to FDA documents, the agency believes that the use of antibiotics for disease prevention is necessary to assure the health of food animals and that such use should be appropriately targeted to animals at risk for a specific disease. Some producers and companies have already taken steps to eliminate the use of medically important antibiotics in food animals, including uses for disease prevention. For example, we interviewed representatives from companies (restaurant and producers) that sell meat and poultry products with “no antibiotic use” label claims, denoting products from animals raised without the use of any antibiotics or medically important antibiotics, even for disease prevention (see app. III for more information on companies’ efforts).
- In 2016, the Farm Foundation summarized findings from 12 workshops on FDA’s actions and one of the findings was that small- and medium-sized producers did not have sufficient knowledge about FDA’s actions to increase veterinary oversight of medically important antibiotics.³⁶ In addition, some producers may lack access to veterinarians.³⁷ In 2015, FDA announced the availability of a guidance document in the form of answers to questions about veterinary feed directive final rule implementation to help small businesses, including producers, comply with the revised regulation.³⁸ According to FDA officials, the agency continues to respond to questions from stakeholders regarding the use of medically important antimicrobials, including antibiotics, in food animals and has planned numerous outreach activities in 2017.

³⁶Farm Foundation, *Stewardship of Antimicrobial Drug Use in Food-Producing Animals: A Report of 12 Regional Educational Workshops* (Oak Brook, IL: January 2016). The Farm Foundation is a non-advocacy organization that provides objective information to foster a deeper understanding of issues shaping the future for agriculture, food systems and rural regions. In 2015, FDA, APHIS, and the Farm Foundation held 12 workshops to educate veterinarians, producers, and distributors about FDA’s actions including the 2015 veterinary feed directive final rule and *Guidance for Industry #213*.

³⁷For more information on the sufficiency of food animal veterinarians in the federal workforce, see: GAO, *Federal Veterinarians: Efforts Needed to Improve Workforce Planning*, [GAO-15-495](#) (Washington, D.C.: May 26, 2015) and GAO, *Veterinarian Workforce: Actions Are Needed to Ensure Sufficient Capacity for Protecting Public and Animal Health*, [GAO-09-178](#) (Washington, D.C.: Feb. 4, 2009).

³⁸80 Fed. Reg. 58,602 (Sept. 30 2015) announcing the availability of Food and Drug Administration, *Guidance for Industry #120 – Small Entity Compliance Guide Veterinary Feed Directive Regulation Questions and Answers* (Rockville, MD: September 2015).

Gaps in Farm-Specific Data Persist

Gaps in farm-specific data on antibiotic use and resistance in food animals persist since we last reported on this in 2011.³⁹ Agencies are making efforts to address these gaps, but they are doing so without a joint plan, as we previously recommended. A joint plan is necessary to further assess the relationship between antibiotic use and resistance in bacteria, and it could help ensure efficient use of resources in a time of budget constraints. In 2004 and 2011, we found numerous gaps in farm-specific data stemming from limitations in the data collected by the agencies. In this review, we found that the limitations we identified in 2011 remain, and that data gaps have not been fully addressed. For example, according to CDC officials, there are still critical gaps in antibiotic use data, including the amount and specific types of antibiotics used across the various food animals and the indications for their use; these data are needed to further assess the relationship between antibiotic use and resistance in bacteria. Moreover, these data are important for assessing the impact of actions being implemented by FDA to foster the judicious use of medically important antimicrobial drugs, including the use of antibiotics in food animals, according to FDA officials. Table 2 shows limitations in federal efforts to collect farm-specific data on antibiotic use and resistance in bacteria in food animals.

Table 2: Limitations in Federal Efforts to Collect Antibiotic Use and Resistance Data

Data source	Agency	Type of data	Frequency of collection	Limitations GAO identified in 2011 that remain
Animal Drug User Fee Amendments of 2008 (section 105)	Food and Drug Administration (FDA)	Antibiotic sales for food animals	Annual (data from previous year)	Sales not a proxy for antibiotic use at the farm level Lack of data on the purpose of use
Agricultural Resource Management Survey	Economic Research Service and National Agricultural Statistics Service	Antibiotic use in food animals	Varies—about every 5 years	Infrequent surveys and not solely focused on antibiotic use at the farm level
National Animal Health Monitoring System	Animal and Plant Health Inspection Service	Antibiotic use in food animals	Varies—every 5 to 7 years for most animal groups	Infrequent surveys and reliance on producers' consent

³⁹GAO-11-801.

Data source	Agency	Type of data	Frequency of collection	Limitations GAO identified in 2011 that remain
National Antimicrobial Resistance Monitoring System	Centers for Disease Control and Prevention, FDA, Agricultural Research Service, Food Safety and Inspection Service	Antibiotic resistance from bacteria in ill humans, retail meat, and slaughtered meat and poultry	Annual (data from 2 years ago)	Insufficient farm level data

Sources: GAO, FDA, and U.S. Department of Agriculture. | GAO-17-192

HHS and USDA are making individual efforts to gather additional data on antibiotic use and resistance at the farm level, but officials stated that they face funding constraints. For example, in 2014, APHIS proposed initiatives as part of USDA’s plan to improve collection of antibiotic use and resistance data on farms, including enhancements to two on-farm surveys and the initiation of longitudinal on-farm studies to collect data across time on antibiotic use, antibiotic resistance in bacteria, and management practices. According to USDA’s fiscal year 2016 budget summary and annual performance plan, the President’s budget included a \$10 million increase for APHIS’ contribution to the government-wide initiative to address antimicrobial resistance. APHIS would have used the increased funding to implement the farm-specific data collection initiatives, according to APHIS officials. However, according to USDA’s Office of Inspector General, the funding was not approved.⁴⁰ As noted above, in 2016 APHIS developed study designs for the two proposed on-farm surveys for antibiotic use on cattle feedlots and at swine operations, but the agency has not collected data because, according to USDA, additional funding has not been secured.⁴¹ In March 2016, USDA’s Office of Inspector General found inadequate collaboration in USDA’s budget process to request funds for antibiotic resistance efforts and recommended that the Agricultural Research Service, FSIS, and APHIS work together to establish antibiotic resistance priorities related to budget requirements that also communicate agency interdependency. Subsequently, APHIS collaborated with FSIS and the Agricultural Research Service in developing its fiscal year 2017 budget request to increase the likelihood of receiving funding.

⁴⁰U.S. Department of Agriculture, Office of Inspector General, *USDA’s Response to Antibiotic Resistance – Audit Report 50601-0004-31* (Washington, D.C.: Mar. 30, 2016).

⁴¹See 81 Fed. Reg. 45,450 (July 14, 2016).

Similarly, according to the fiscal year 2016 HHS's FDA justification of estimates for appropriations committees, the President requested a funding increase of \$7.1 million for FDA to achieve its antibiotic stewardship goals, including collection of data related to the use of antibiotics in food animals. According to the Presidential Advisory Council on Combating Antibiotic-Resistant Bacteria, however, FDA did not receive those funds.⁴² According to FDA, using existing fiscal year 2016 funds, in March 2016, the agency made some progress in data collection and issued a request for proposals to collect antibiotic use and resistance data on farms. In August 2016, FDA entered into two cooperative agreements with researchers for antibiotic use and resistance data collection; the awardees will develop a methodology to collect detailed information on antibiotic drug use in one or more of the major food animal groups (cattle, swine, chickens, and turkeys), according to FDA officials. The data collection efforts are expected to provide important information on data collection methodologies to help optimize long-term strategies for collecting and reporting such data, according to FDA officials. Moreover, FDA, CDC, and USDA formed a working group and proposed an analytic framework to associate foodborne bacteria resistance with antibiotic use in food animals.

However, the agencies are conducting these efforts without a joint data collection plan, thus risking inefficient use of their limited resources. In 2004, we recommended that HHS and USDA jointly develop and implement a plan for collecting data on antibiotic use in food animals. In addition, in 2011, we recommended that HHS and USDA identify potential approaches for collecting detailed data on antibiotic use in food animals, collaborate with industry to select the best approach, seek any resources necessary to implement the approach, and use the data to assess the effectiveness of policies to curb antibiotic resistance. HHS and USDA generally agreed with our recommendations but have still not developed a joint plan or selected the best approach for collecting these data. HHS and USDA officials told us they are continuing to make progress towards developing a joint data collection plan but that funding has been an impediment. In September 2015, FDA, CDC, and USDA agencies, including APHIS, held a jointly sponsored public meeting to present current data collection efforts and obtain public input on possible approaches for collecting additional farm-specific antibiotic use and

⁴²FDA received \$7.8 million in fiscal year 2016 to support retail meat sampling for the National Antimicrobial Resistance Monitoring System.

resistance data. In June 2016, FDA stated that it is collaborating with USDA and CDC to develop the data collection plan and is still reviewing September 2015 public comments on data collection; however, the continued lack of funding will significantly impact the ability to move forward with a plan, according to FDA, APHIS, and CDC officials.

The White House's 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria* calls for agencies to strengthen one-health surveillance through enhanced 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.⁴³ Moreover, in the 1-year update on the *National Action Plan*, the President's task force recommended that federal agencies coordinate with each other to ensure maximum synergy, avoidance of duplication, and coverage of key issues. It is unclear whether FDA, CDC, and APHIS will develop a joint plan to collect antibiotic use and resistance data at the farm level and whether agencies' individual current data collection efforts are coordinated to ensure the best use of resources. We continue to believe that developing a joint plan for collecting data to further assess the relationship between antibiotic use and resistance in bacteria at the farm level is essential and will help maximize resources and reduce the risk of duplicating efforts at a time when resources are constrained.

FDA and APHIS Do Not Have Measures to Assess the Impact of Actions Taken

FSIS has developed a performance measure to assess the impact of its actions to manage the use of antibiotics in food animals,⁴⁴ but FDA and APHIS have not done so.⁴⁵ The GPRA Modernization Act of 2010 requires federal agencies such as HHS and USDA to develop and report performance information—specifically, performance goals, measures,

⁴³According to the plan, detecting and controlling antibiotic resistance requires the adoption of a “one-health” approach to disease surveillance that recognizes that resistance can arise in humans, animals, and the environment.

⁴⁴Similarly, for monitoring antibiotic-resistant bacteria in humans, CDC developed a measure for the time required to detect and characterize antibiotic-resistant pathogens and set a target of decreasing this time by 50 percent in 3 years.

⁴⁵Performance measures, which typically have numerical targets, are important management tools that help an agency identify the activities that work well and those that do not.

milestones, and planned actions. We have previously found that these requirements can also serve as leading practices for planning at lower levels (e.g., FDA and APHIS) within agencies; moreover, developing goals and performance measures can help an organization balance competing priorities, particularly if resources are constrained, and help an agency assess progress toward intended results.⁴⁶ Numerical targets are a key attribute of performance measures because they allow managers to compare planned performance with actual results.

In this context, FSIS's performance measure, included in its fiscal year 2017-2021 strategic plan, relates to sampling of antibiotic-resistant bacteria.⁴⁷ Specifically, the performance measure is the percentage of FSIS slaughter meat and poultry samples that will undergo whole genome sequencing, including antibiotic-resistance testing, to assess the impact of the agency's surveillance of antibiotic-resistant bacteria in slaughtered food animals.

FDA and APHIS officials agree that performance measures are needed to assess the impact of their actions to manage the use of antibiotics in food animals. According to the White House's 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria*, metrics should be established and implemented to foster stewardship of antibiotics in food animals within 3 years. FDA has a goal to enhance the safety and effectiveness of antibiotics and an objective to reduce risks in antibiotics by supporting efforts to foster the judicious use of medically important antibiotics in food animals.⁴⁸ FDA's actions to achieve this objective include developing

⁴⁶GAO, *Homeland Security: An Overall Strategy Is Needed to Strengthen Disease Surveillance in Livestock and Poultry*, [GAO-13-424](#) (Washington, D.C.: May 21, 2013) and *Performance Measurement and Evaluation: Definitions and Relationships*, [GAO-11-646SP](#) (Washington, D.C.: May 2, 2011).

⁴⁷Food Safety and Inspection Service, *Food Safety and Inspection Service Strategic Plan 2017-2021* (Washington, D.C.: October 2016), accessed on November 4, 2016, <http://www.fsis.usda.gov/wps/portal/informational/aboutfsis/strategic-planning/fy-2017-2021-strategic-plan>. The FSIS goal linked to the performance measure is to modernize inspection systems, policies, and the use of scientific approaches.

⁴⁸Food and Drug Administration, *Foods and Veterinary Medicine Program Strategic Plan Fiscal Years 2016-2025*. FDA established a goal to protect human and animal health by enhancing the safety and effectiveness of animal health products, including antibiotics. Within this goal, FDA outlined an objective to reduce risks in manufacturing, production, distribution, and use of FDA-regulated animal health products, including antibiotics, by supporting efforts to foster the judicious use of medically important antibiotics in food animals to minimize the development of antimicrobial resistance.

voluntary guidance to industry and revising its veterinary feed directive regulation, as noted above. However, FDA does not yet have performance measures to assess the impact of these actions in achieving its goal and objective even though its revised regulation has already been implemented and actions recommended in its guidance were implemented as of January 2017. FDA officials told us the agency is taking steps to develop performance measures. In July 2016, FDA began reaching out to APHIS and producer groups to collaboratively develop metrics, according to FDA and APHIS officials. Furthermore, according to agency officials, FDA is collecting data in a pilot program for the veterinary feed directive to establish a baseline for compliance, which is needed to develop a measure.⁴⁹ FDA officials told us developing measures is a challenge without funding to support farm-specific data to assess changes in antibiotic use practices and adherence to its guidance documents. It is unclear when FDA's efforts to develop performance measures will be completed. Without developing performance measures and targets for its actions, FDA cannot assess the impact of its guidance to industry and its revised regulation in meeting the goal of enhancing the safety and effectiveness of antibiotics by fostering the judicious use of medically important antibiotics in food animals.

Similar to FDA, APHIS does not have performance measures to assess the impact of its antibiotic use and resistance data collection efforts. In March 2016, APHIS agreed to develop goals and identify measures for its antibiotic resistance efforts by March 2017 as recommended by the USDA Office of Inspector General.⁵⁰ However, little progress has been made. According to APHIS officials, if the agency does not receive new funding in fiscal year 2017 for antibiotic use and resistance activities, development of related goals and measures will be delayed. According to

⁴⁹In 2016, FDA initiated a pilot program to inspect veterinary feed directive distributors, such as feed mills—mills in which stocks of feed are prepared—and, to capture food animal industries' efforts to comply with the final rule. According to FDA officials, the agency's approach relies first on educating feed mills, retailers, veterinarians, and producers on the rule's requirements before moving into compliance assessment and corrective response. FDA is collecting data to establish a baseline for compliance which is needed to develop a measure and target, according to officials.

⁵⁰U.S. Department of Agriculture, *Animal and Plant Health Inspection Service: Safeguarding the Health and Value of American Agriculture Since 1972 – Strategic Plan Fiscal Year 2015-2019*. APHIS has not established a strategic goal for all antibiotic resistance efforts as recommended by the USDA Office of Inspector General, but the agency's current strategic plan contains a goal to protect the health of U.S. agricultural resources through surveillance for antibiotic resistance of selected bacteria. However, there are no performance measures and targets related to this goal.

USDA's 2012 report on antibiotic resistance, few useful metrics (i.e., performance measures) exist for gauging progress toward stated data collection goals.⁵¹ The report also stated that having defined metrics available would allow more appropriately focused efforts for monitoring antibiotic use and resistance and allow greater "buy in" among stakeholder groups for the monitoring efforts and their resulting actions. APHIS officials told us that performance measures and targets are needed and in July 2016, the agency began discussions with FDA and others about developing metrics, as noted above. Without developing performance measures and targets for its actions, APHIS cannot assess the impact of collecting farm-specific data on antibiotic use and resistance in meeting its goal to protect agricultural resources through surveillance for antibiotic-resistant bacteria.

Selected Countries and the EU Have Taken Various Actions to Manage Use of Antibiotics

To manage the use of antibiotics in food animals and combat the emergence and spread of antibiotic-resistant bacteria, the Netherlands, Canada, Denmark and the EU have taken actions to strengthen the oversight of veterinarians' and producers' use of antibiotics and to collect farm-specific data. In addition, the Netherlands and Denmark have set targets for reducing the use of antibiotics, and the EU has called for measurable goals and indicators for antimicrobial use and resistance.

For Oversight and Data Collection, the Netherlands Relied on a Public-Private Partnership, and the EU and Other Countries Used Government Policies and Regulations

To strengthen oversight and collect farm-specific data on antibiotic use in food animals, the Netherlands primarily relied on a public-private partnership, whereas Canada, Denmark, and the EU relied on

⁵¹U.S. Department of Agriculture, *Antibiotic Resistance Workshop Executive Summary* (Beltsville, MD: May 2012).

government policies and regulations.⁵² After taking these actions, the use or sales (depending how the data were reported) of antibiotics for food animals decreased in Denmark, the Netherlands, and the EU, and data collection on antibiotic use improved in all three countries and the EU.

Netherlands

Beginning in 2008, the Netherlands' food animal (cattle, veal, chicken, and swine) industries, national veterinary association, and government developed a public-private partnership to strengthen oversight of veterinarians' prescriptions and producers' use of antibiotics. This partnership was also used to collect farm-specific data. Government officials we interviewed from the Ministries of Health and Economic Affairs told us that in the past the Netherlands was one of the highest users of antibiotics in food animals in Europe. As a result of the partnership's actions, from 2009 through 2015, antibiotic sales fell by over 50 percent, according to government documents.⁵³ As part of the partnership, industry strengthened oversight of producers' use of antibiotics through quality assurance programs—producer education and certification programs that set standards for animal production including the use of antibiotics—and the national veterinary association established additional guidelines and policies for veterinarians. According to the Ministry of Economic Affairs, building on these actions, the government adopted new statutes and regulations that incorporated some of the oversight activities that industry and veterinary organizations had established, such as restricting the use of antibiotics that are important to human health, implementing herd health plans, and developing prudent use guidelines.⁵⁴ Similar to the

⁵²We reported in 2011 that the EU had implemented a ban on growth promotion uses of antibiotics in 2006. [GAO-11-801](#). Similar to the United States, in 2015, Canada reported that it is working towards removing growth promotion claims on antibiotic labels by December 2016.

⁵³Central Veterinary Institute of Wageningen University and Research Centre, *MARAN 2016: Monitoring of Antimicrobial Resistance in Antibiotic Usage in Animals in the Netherlands 2015* (Lelystad, Netherlands: 2016).

⁵⁴Industry groups in the Netherlands strengthened oversight and promoted judicious use of antibiotics in a variety of ways including, requiring each herd to have one veterinarian and developing action plans for farmers using high amounts of antibiotics. Similarly, the national veterinary association developed a quality assurance program for veterinarians and developed guidelines for the use of antibiotics. According to the Ministry of Economic Affairs, the Netherlands government incorporated some of these actions into an "administration by vet only" regulation for antibiotics in food animals, which required farm visits, and allowed antibiotics to be administered by veterinarians, except under certain circumstances.

Netherlands, U.S. producers and veterinarians participate in quality assurance programs and take action to promote judicious use of antibiotics, according to documents we reviewed from U.S. industry and veterinarian organizations. For example, some producers in the United States stopped the use of antibiotics for growth promotion prior to U.S. government action. The public-private partnership in the Netherlands also established a process for the continuous collection of farm-specific antibiotic use data. Specifically, in 2011, the different food animal industries and veterinary organizations leveraged their existing processes and infrastructure to create one centralized database for veterinarians and producers to report antibiotic prescriptions and use. In contrast, the United States relies primarily on an on-farm survey to collect antibiotic use data on a specific food animal every 5 to 7 years, as noted above.

In 2010, the Netherlands' government, food animal industries, and national veterinary association jointly financed an independent entity, the Netherlands Veterinary Medicines Authority, to analyze antibiotic use data and veterinary prescription patterns to produce annual antibiotic use reports, according to Dutch government documents. Representatives from the independent entity told us that the Netherlands' government funds 50 percent of the cost and the food animal industries and veterinarians fund the remaining 50 percent. The Netherlands Veterinary Medicines Authority uses the data submitted by producers and veterinarians to define annual benchmarks regarding both the quantity and the types of antibiotics used within each sector. The industries use this information to monitor producers' antibiotic use and veterinarians' prescriptions, and they work with individuals who exceeded the benchmark to reduce use. According to Dutch government documents and officials, anonymized and aggregated data—including the amounts of antibiotics given, types of antibiotics, and number of animals that each veterinarian oversees—are shared with government for a variety of purposes, such as annual reports and other studies. Additionally, in 2016 the Netherlands Veterinary Medicines Authority published a report finding that reductions in antimicrobial usage, including antibiotics, were associated with reductions in the prevalence of antimicrobial-resistant *E.coli* in fecal samples from veal, calves, pigs, and young chickens.⁵⁵ Dutch government officials told us that moving forward a variety of issues must be addressed, including overuse of antibiotics by veterinarians and

⁵⁵The Netherlands Veterinary Medicines Authority, *Associations between Antimicrobial Use and the Prevalence of Resistant Micro-organisms: Is It Possible to Benchmark Livestock Farms Based on Resistance Data?* (Utrecht, Netherlands: June 2016).

producers—for example, in the veal and cattle sectors, which are challenged in decreasing antibiotics while keeping animals healthy. Similarly, a representative from a veterinary organization told us that under the new policies, veterinarians are challenged with greater administrative and record-keeping burdens. The Netherlands' collaboration with industry is similar to some actions taken in the United States, such as the U.S. poultry industry's effort to develop an on-farm antibiotic use survey and its plan to share aggregate survey data with APHIS and FDA, as discussed above. Additionally, FDA is actively engaging stakeholders to leverage public-private partnerships and collaboration to collect farm-specific data, according to FDA officials. However, the United States has no practice comparable to benchmarking. According to APHIS officials, benchmarking and measuring producers' use and veterinarians' prescriptions of antibiotics would require major infrastructure and technological investments for data capture, analysis, and reporting, and for educating producers and veterinarians regarding use of the data. According to representatives from an animal health company, it may not be feasible for the United States to adopt practices from the Netherlands because it would require similar or equal veterinary practice laws across all states.

Canada

The Canadian government is working toward integrating federal and province-level policies on antibiotic use and collects farm-specific antibiotic use and resistance data on some species. The 2015 Canadian national action plan on antibiotic use and resistance calls for integration of federal-level and province-level policies and lists specific activities along with completion dates. Officials we interviewed from a Canadian food safety agency told us that Canada is developing a framework to align national and province-level veterinary oversight efforts and increase collaboration between these levels of government. Additionally, officials from a Canadian agency that regulates medical products told us that the federal government is working on a policy initiative to increase veterinary oversight over all medically important antimicrobials used in food animal production and that, as part of this initiative, they are working with provinces to ensure the streamlined transition of over-the-counter medically important antibiotics to prescription status.

The national action plan also identifies the need for continued government support of industry-led quality assurance programs that address judicious use of antibiotics in food animals. For example, the Chicken Farmers of Canada's On-Farm Food Safety Assurance program

requires producers to keep records, called flock sheets, on each chicken flock. These sheets capture information related to animal health, including any antibiotics given to the bird during production, and must be presented prior to slaughtering. This differs from the United States where the poultry industry is vertically integrated—meaning that individual poultry companies own or contract for all phases of production and processing. Because of this integration, flock health information and production practices in the United States, including antibiotics used in feed or administered by a veterinarian, are maintained by the poultry company and not individual farmers. The national action plan also states that Canada is working toward removing growth promotion claims on antibiotics labels, similar to the U.S. approach, and that the pharmaceutical industry has voluntarily committed to comply by December 2016.

According to one Canadian government official, data on antibiotic use in food animals have improved in recent years as a result of refinements to antibiotic sales data as well as farm-specific monitoring of antibiotic use in chickens, which has allowed officials to observe a relationship between changes in antibiotic use and resistance. For example, current data from the Canadian Integrated Program for Antimicrobial Resistance Surveillance show changes in resistant bacteria, isolated from chickens, associated with an intervention led by the poultry industry that focused on reducing the preventative use of a type of antibiotic called cephalosporin, according to Canadian government documents.⁵⁶ According to an official from the Canadian Integrated Program for Antimicrobial Resistance Surveillance that we interviewed, the Canadian system is similar to the National Antimicrobial Resistance Monitoring System in the United States; however, unlike the U.S. system, the Canadian system has a farm surveillance component that captures information on antibiotic use, antibiotic resistance, and farm characteristics. The 2013 annual report from the Canadian Integrated Program for Antimicrobial Resistance Surveillance states that Canada initiated this surveillance component in a sample of farms in five major pork-producing provinces and in four major poultry-producing provinces in 2006 and 2013, respectively.⁵⁷ In 2014, a

⁵⁶Cephalosporins are widely used in human and veterinary medicine, and there are two currently approved to treat and control certain diseases in food animals, including respiratory disease in cattle, swine, sheep, and goats.

⁵⁷Veterinarians use questionnaires to collect data on farm demographics, animal health, and antimicrobial use. The Canadian government receives anonymized data and is unaware of the identity of the participating producers.

total of 95 swine farms and 143 chicken farms participated in this voluntary program, according to the most recent (2014) annual report. The Canadian government compensates veterinarians to collect samples and gather data from each participating farms, according to a Canadian government official. Representatives from a veterinary organization we interviewed told us that surveillance data are good for looking at trends but that such data are limited and not appropriate to determine whether a producer is misusing antibiotics. One representative of the swine industry similarly told us that data collected from sample pig farms are limited and, to be more statistically representative of the industry, should be broadened to be more geographically representative and cover all types of pig production. While the Canadian farm surveillance program does not currently monitor antibiotic use and resistance in beef cattle on farms, the Canadian beef industry has funded research to develop an on-farm data collection framework and would welcome the addition of farm-specific antibiotic use and resistance surveillance to the program, according to representatives from a Canadian beef industry group we interviewed. Similar to the Canadian farm surveillance program, United States producers voluntarily participate in periodic surveys to provide antibiotic use data at the farm level, as part of National Animal Health Monitoring System; however, no U.S. program conducts longitudinal studies to collect data across time on antibiotic use, as noted above.

Denmark

Since we reported on Denmark's actions to regulate antibiotic use in 2011, Denmark has developed a variety of policies focused on both producers' and veterinarians' use of antibiotics and has continued to monitor levels of antibiotic use, according to Danish government documents we reviewed and officials we interviewed.⁵⁸ For example, officials from the Danish Veterinary and Food Administration explained that in 2013, they implemented a tax on the sale of antimicrobials, including antibiotics, and other drugs used in veterinary medicine.⁵⁹ They told us that the initiative aims to strengthen veterinarians' and producers' incentive to choose alternatives to antimicrobial, including antibiotic, treatment or to choose the most responsible antimicrobial or antibiotic

⁵⁸GAO-11-801.

⁵⁹The tax level varies depending on the type of antibiotic, with critically important antibiotics being taxed the highest, at 10.84 percent. The tax is collected when pharmacies and other distributors sell veterinary medicines.

treatment—using antibiotics judiciously. One Danish industry representative told us that it is yet to be determined if the tax will be effective in reducing use, and that a high tax may lead to the illegal import of antibiotics. Officials from the Danish Veterinary and Food Administration also explained that other actions since 2011 include the introduction of legislation in 2014 on the treatment of swine herds. They stated that when veterinarians prescribe antibiotics to be administered through feed or water for respiratory or gastrointestinal infections, veterinarians must take samples from the herd for laboratory testing to verify the clinical diagnosis. Officials from the Danish Veterinary and Food Administration also indicated that Denmark has leveraged voluntary industry initiatives to manage the use of antibiotics, such as the cattle industry’s ban on the use of an antibiotic deemed critically important to human medicine. Denmark continues to collect farm-specific antibiotic use data through veterinary prescriptions and reports results along with resistance data annually via the Danish Integrated Antimicrobial Resistance Monitoring and Research Program, according to Danish government documents and officials. The most recent report states that antibiotic consumption was 47 percent lower in 2015 than in 1994 and decreased slightly from 2014 through 2015.⁶⁰ As we previously reported, the lower levels of antibiotic beginning after 1994 coincide with changes to government policies on growth promotion and veterinarians’ sales profits.⁶¹ Representatives of U.S. industry and veterinary organizations we interviewed questioned whether the actions taken by Denmark were successful. They said while antibiotic use decreased, Denmark experienced issues with animal welfare, such as greater levels of disease, and increased the use of antibiotics for disease treatment. Danish officials acknowledged the concerns for animal welfare associated with reductions in antibiotic use, but documents they provided stated that they have not seen any evidence of decreased animal welfare or increases in infection prevalence. Representatives from a U.S. food industry organization and a veterinary organization told us that actions taken by Denmark are not feasible in the United States because of differences between the countries. For example, the food production industries in Denmark are different in size and production volume when

⁶⁰Danish Integrated Antimicrobial Resistance Monitoring and Research Program, *DANMAP 2015-Use of Antimicrobial Agents and the Occurrence of Antimicrobial Resistance in Bacteria from Food Animals, Food and Humans in Denmark* (Denmark: Nov. 2016).

⁶¹[GAO-11-801](#).

compared with those in the United States, according to representatives from the U.S. poultry industry.

EU

Since 2011, when we last reported on the EU's efforts,⁶² the EU has developed an antibiotic-resistance action plan, reported reductions in sales of antibiotics, and made associations between antibiotic use and resistance in a new report. The EU action plan calls for various actions to strengthen judicious use, oversight, and surveillance of antibiotics. According to EU documents, steps taken to implement the plan include, publishing guidelines for prudent use of antibiotics in veterinary medicine in 2015, enacting an animal health law in March 2016 that emphasizes prevention of disease rather than cure, and revising legislation for veterinary medicinal products and for medicated feed. In 2011, we reported on EU efforts to collect sales data; at that time only nine European countries had submitted data. For the 2016 report on EU sales, 29 European countries had submitted data, and the data show that from 2011 to 2014 sales of antibiotics for use in animals fell by approximately 2 percent in 25 European countries.⁶³ One difference between the United States and the EU is the classification of certain antimicrobials, including antibiotics, in sales reports; for example, in the EU a group of medications called ionophores are not included in antimicrobial sales reports, but in the United States ionophores are included.⁶⁴

According to EU documents we reviewed, other actions since 2011 include activities to promote the collection of on farm data, mainly through developing guidance and a pilot project. For example, a report from the European Medicines Agency, an agency within the EU, describes a trial conducted in 2014 to test a protocol and template for data collection on antimicrobial use in pigs. The report states that based on results from the

⁶²[GAO-11-801](#).

⁶³There were insufficient data to determine increases or decreases in the three remaining countries. For more information see, European Medicines Agency, *European Surveillance of Veterinary Antimicrobial Consumption, 2016. Sales of veterinary antimicrobial agents in 29 EU/EEA countries in 2014* (Oct. 14, 2016).

⁶⁴In 2014, ionophores accounted for 31 percent of domestic antimicrobial sales. They are used only in veterinary medicine and are not generally associated with antimicrobial resistance issues, according to the FDA. For more information see, Food and Drug Administration, *2014 Summary Report on Antimicrobials Sold or Distributed for Use in Food-Producing Animals* (December 2015).

trial the agency is preparing guidance, including a protocol and template, for member states on antibiotic use data collection.⁶⁵ Additionally, the EU agency began a pilot study to collect antibiotic use data from twenty pig farms per country, but there was insufficient support among member states to continue the study, according to EU documents. Officials from the European Medicines Agency told us that the pilot project underscored the challenges in collecting farm-specific data which include producer confidentiality and resource constraints. However, these officials also told us that they have limited access to farm-specific data from certain countries, including Denmark, the Netherlands, and Norway. The EU also took steps to compare surveillance data on antibiotic use and resistance in pathogens in humans, food, animals, and environment. Specifically, in 2015 three EU agencies published the first integrated analysis report that found a positive association between the use of certain antibiotics in food animals and resistance in humans. For example, the report cited that a positive association was observed between fluoroquinolone resistance in *E. coli* from humans and the total consumption in animals.⁶⁶ The report also explains that the agencies analyzed existing data from five separate monitoring systems, including sales data, to create the integrated report. In the United States, no such comparisons in surveillance reports have been made, in part because antibiotic use data are limited, as previously discussed.

The Netherlands and Denmark Set Reduction Targets and the EU Called for Measurable Goals and Indicators

The Netherlands and Denmark set antibiotic use reduction targets to help manage the use of antibiotics in food animals.⁶⁷ According to government officials in both countries, the targets were a critical component of their

⁶⁵European Medicines Agency, *Report on ESVAC Trial for Collecting Data on Consumption of Antimicrobial Agents in Pigs* (London, United Kingdom: May 20, 2016).

⁶⁶The three EU agencies that published this report are the European Center for Disease Prevention and Control, the European Food Safety Authority, and the European Medicines Agency. For more information, see *ECDC/EFSA/EMA First Joint Report on the Integrated Analysis of the Consumption of Antimicrobial Agents and Occurrence of Antimicrobial Resistance in Bacteria from Humans and Food-Producing Animals* (Stockholm/Parma/London: Jan. 30, 2015).

⁶⁷Canada did not set reduction targets as part of its approach to address antimicrobial resistance, as outlined in its action plan on antimicrobial resistance and use. For more information, see Public Health Agency of Canada, *Federal Action Plan on Antimicrobial Resistance and Use in Canada* (Ottawa, Canada: March 2015).

strategies to reduce antibiotics use. The Netherlands and Denmark used reduction targets to measure the progress and impact of actions taken, and as existing targets are reached these countries continue to set new targets. Similarly, the EU outlined its next steps for combating antibiotic resistance in a June 2016 document that calls for measurable goals that lead to reductions in infections in humans and animals and reductions in antibiotic use and resistance, among other things. U.S. federal officials and representatives of industry and veterinary organizations whom we interviewed questioned the usefulness of setting antibiotic use reduction targets in the United States, in part, because targets may reduce animal welfare.

Netherlands

The Netherlands policy on reducing antibiotic use, implemented through the public-private partnership discussed above, set the following reduction targets on antibiotics used in food animals: 20 percent reduction in the sales of all antibiotics used in food animal production by 2011, 50 percent by 2013, and 70 percent by 2015. According to Dutch government officials, the first two targets were met and exceeded, but the 70-percent reduction by 2015 was not met; a 58-percent reduction was achieved from 2009 through 2015, according to government documents. Indicators used to measure the policy's impact included antibiotic use and resistance levels in swine, mortality of swine, and veterinary cost per swine. According to a Dutch industry representative, to reduce the use of antibiotics, food animal industries optimized feed, housing, vaccines, and hygiene (see fig. 3).

Figure 3: Pigs in Birthing and Feeding Crate



Pigs from a farm in the Netherlands that increased crate and housing space, stopped castrating animals to reduce infections, enhanced hygiene practices to limit risk the risk of contamination, and did not mix pigs from different litters to prevent the spread of bacteria and infections.

Source: GAO. | GAO-17-192

In a June 2015 letter to parliament, government officials proposed the Netherlands approach to antibiotic resistance for 2015 through 2019, which includes taking additional action to achieve the 70-percent reduction goal and developing species-specific measures and reduction targets. Representatives from veterinary and industry organizations in the Netherlands told us that setting targets has proven to be effective, but that there is concern that further reductions may pose some risk to animal health and welfare. For example, piglets may be at risk of premature death if certain antibiotics are prohibited or fewer antibiotics are used, according to Dutch veterinary and industry representatives. Representatives of veterinary and producer organizations we spoke with in the United States expressed similar concerns that reductions in antibiotic use may compromise animal health and welfare.

Denmark

In 2011, we reported on Denmark's Yellow Card initiative, which set regulatory limits on antibiotic use and subjected pig producers exceeding

limits to increased monitoring by government officials.⁶⁸ The goal of the Yellow Card initiative was to achieve a 10-percent reduction in antibiotic use by 2013 from 2009 levels. According to government officials, the goal was met and exceeded. In 2016, Denmark expanded the Yellow Card initiative in pigs to focus more on antibiotics that are important for human health. It also developed an action plan to address methicillin-resistant *Staphylococcus aureus* (MRSA).⁶⁹ Included in this plan is a new target of a 15 percent reduction in antibiotic use in swine by 2018. According to a representative from a Danish industry organization that represents producers across many food animal production sectors, producers who used antibiotics below the permitted levels began increasing their use to the maximum amounts allowed, and the new reduction target is a response to these increases. The representative also told us that reduction targets are critical because they place the responsibility for reduction on the producer or farmer—the person who determines what farm practices are implemented—and that reducing antibiotic use and setting reduction targets must be done with involvement of producers and veterinarians because the need for antibiotics varies across animals. For example, dairy cattle in different age groups use varying amounts of antibiotics, and setting one target may put the more susceptible age group at greater risk of infection or death, according to industry officials. In addition to the government targets, industry set its own targets to reduce the use of antibiotics. For example, the dairy and beef cattle industries set a target in 2014 to reduce use by 20 percent by 2018. Some U.S. officials and stakeholders question the benefits of antibiotic use targets and reductions in Denmark because while antibiotic use was reduced, changes in resistance are less clear. Representatives from the U.S. swine industry told us that targets based on volume of antibiotics used do not take into account the potency of the antibiotics, and that a mandatory reduction target could take antibiotic use in an unfavorable direction, such as a shift from veterinarians and producers using older drugs that are less potent, to using drugs that are more potent, newer, or important to human health.

⁶⁸GAO-11-801.

⁶⁹MRSA is a bacterium responsible for several difficult-to-treat infections in humans that can affect different parts of the body. MRSA infections are tougher to treat than most strains of *staphylococcus aureus*—or staph—because of MRSA’s resistance to some commonly used antibiotics.

EU

In 2016, the EU Council published a statement of its conclusions on the next steps for its member states to combat antimicrobial resistance including setting goals and targets.⁷⁰ The statement calls for EU member states to have a one-health action plan by 2017 with measureable goals, qualitative or quantitative, that lead to reduction in infections in humans and animals, reductions in antimicrobial use and resistance, and prudent antimicrobial use. The statement also calls for EU officials and member states to jointly develop a new EU action plan on antimicrobial resistance, indicators to assess the progress made on addressing antibiotic resistance, and indicators to assess progress in implementing the new action plan.⁷¹ EU officials told us that the EU is seeking to develop indicators that are easy to measure, are not too costly, and can be applied across its member states. Representatives of U.S. industry and veterinary organizations we interviewed stated that they would support measures and targets that focus on compliance with judicious use policies, but not on reductions.

HHS and USDA Have Not Conducted On-Farm Investigations and No Consensus Exists on When Such Investigations Are Warranted

CDC, APHIS, and FSIS officials told us they have not conducted on-farm investigations during outbreaks from foodborne illness including those from antibiotic-resistant pathogens in animal products. Moreover, there is no consensus about when an on-farm investigation is needed. In 2014, recognizing the importance of the one-health concept (health of humans, animals, and the environment are interconnected) FSIS and APHIS

⁷⁰EU Council, *Council Conclusions on the Next Steps Under a One Health Approach to Combat Antimicrobial Resistance* (Brussels, Belgium: June 2016).

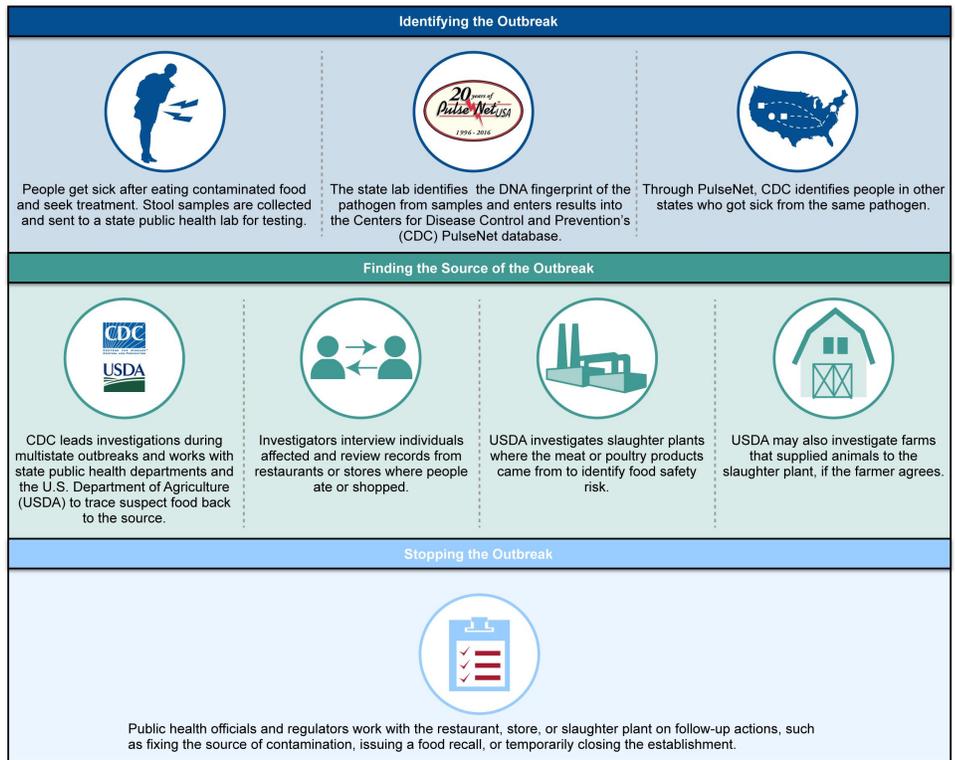
⁷¹Following the EU Council Conclusion, the European Commission requested that the European Center for Disease Prevention and Control, European Food Safety Authority, and European Medicines Agency jointly propose a list of outcome indicators for monitoring and detecting reduction in the levels of antimicrobial consumption and key drug-resistant microorganisms in humans, food animals, and food animal products. For more information see, European Commission, *Request for a Joint ECDC, EFSA, and EMA Scientific Opinion on a List of Outcome Indicators As Regards Surveillance of Antimicrobial Resistance and Antimicrobial Consumption in Humans and Food-producing Animals* (Brussels, Belgium: Oct. 10, 2016).

created a memorandum of understanding and standard operating procedures for APHIS to investigate the root cause of foodborne illness outbreaks, given APHIS's regular interactions with producers on farms and expertise in veterinary epidemiology. Under the memorandum of understanding, APHIS will conduct epidemiological investigations—which includes examining the spread of disease by time, place, and animal as well as the mode of transmission and source of entry of disease—to determine the root cause of foodborne illness, which may be related to factors at the farm level, according to FSIS officials. Such investigations can be used to identify on-farm risk factors for disease occurrence or spread that might be controlled or mitigated by some intervention in current or future situations.

For multistate foodborne illness outbreaks, CDC is to identify the outbreak and lead the investigation by determining the DNA fingerprint of the bacteria that cause the outbreak as well as whether or not the bacteria is resistant to any antibiotics. According to CDC officials, with increasing use of whole genome sequencing—an advanced technique to fingerprint bacteria—federal agencies may prioritize foodborne outbreak investigations from antibiotic-resistant bacteria because they can identify these outbreaks sooner. CDC is to coordinate with state health departments and FSIS if a meat or poultry product is implicated (see fig. 4 for more information on the investigation process for multistate foodborne illness outbreaks).⁷²

⁷²According to FSIS officials, even when FSIS-regulated products are implicated in foodborne illness outbreaks, tracing back meat products, in particular cattle and swine, to specific farms is often difficult; for example, meat products (cattle and swine) from various sources can be comingled during processing causing farm-specific information for the resultant product to be lost and the use of sale barns and independent haulers also increases the difficulty of tracing back processed meat to specific animals or farms.

Figure 4: Example of Multistate Foodborne Illness Outbreak Investigation Process



Sources: Centers for Disease Control and Prevention and GAO. | GAO-17-192

Note: This figure is not intended to represent the full complexity of foodborne illness outbreaks. For example, the Food and Drug Administration is involved in outbreaks related to food products other than USDA-regulated meat, poultry, and processed egg products.

However, APHIS and FSIS did not conduct on-farm investigations in response to a multistate foodborne illness outbreak in 2015 involving an antibiotic-resistant strain of *Salmonella* in roaster pigs, the first attempt to use the 2014 memorandum of understanding. We determined this is because stakeholders—industry, state agencies, and federal agencies—did not agree on whether on-farm investigations were needed as part of the 2015 outbreak investigation. Specifically, FSIS, the pork industry, and a state agriculture agency agreed that the slaughter plant was the source of the outbreak, negating the need for an on-farm investigation in their view, while state public health agencies wanted on-farm investigations to determine whether the pigs from the five farms supplying the slaughter plant were carriers of the outbreak strain and to identify the slaughter plants that received the pigs. CDC and APHIS deferred to FSIS on whether an on-farm investigation was needed. According to FSIS officials, the outbreak was attributed to conditions and practices at the slaughter

plant and the company implemented extensive corrective actions at the plant in response to the 2015 outbreak. However, in July 2016, FSIS issued a public health alert because of concerns about illnesses from another outbreak linked to the *Salmonella* strain from the 2015 outbreak involving whole roaster pigs; the same slaughter plant was implicated in the 2016 outbreak. CDC officials told us that resistance for this specific strain of *Salmonella* has increased for a variety of drugs and that an on-farm investigation would have been useful in the original outbreak to explore whether the outbreak strain was present in pigs while they were still on the farm. FSIS and the Washington State Department of Health investigated the 2016 outbreak, but no on-farm investigations were conducted. The implicated slaughter plant recalled products and the outbreak ended, according to Washington state officials. As of October 2016, FSIS and APHIS were continuing discussions and making plans on how best to address the need to enhance understanding of this *Salmonella* strain in live pigs, especially how to identify on-farm interventions that may prevent future illness, according to FSIS officials.

APHIS and FSIS officials told us that deciding when to conduct investigations on the farm is complex. First, the memorandum of understanding requires producer's consent to conduct an on-farm investigation. The memorandum of understanding outlines the need for producer's consent, in part, because neither APHIS nor FSIS has authority to access farms during foodborne illness outbreaks without the cooperation of the producer.⁷³ APHIS will contact the producer or company involved to discuss the specifics of an investigation and to gain voluntary participation in any investigation. CDC has authority to take actions to prevent the interstate spread of communicable diseases, which, according to CDC legal officials, would include diseases originating on farms that may relate to foodborne illness from antibiotic-resistant pathogens. Specifically, CDC has authority to take measures in the event of inadequate state or local control to prevent interstate

⁷³The Animal Health Protection Act authorizes the Secretary of Agriculture to carry out operations and measures to detect, control, or eradicate pests or diseases of livestock. Pub. L. No. 107-171, tit. X, subtit. E, 116 Stat. 494 (codified as amended at 7 U.S.C. §§ 8301-8317). This authority has been delegated to APHIS. Livestock is defined as all farm-raised animals. Under this authority APHIS can access farms, with or without consent of the producer, in response to animal diseases, but not foodborne illnesses. The Federal Meat Inspection Act, 21 U.S.C. §§ 601-683, and the Poultry Products Inspection Act, 21 U.S.C. §§ 451-472, give USDA responsibility, delegated to FSIS, for ensuring the safety and wholesomeness of meat and poultry products before they enter into commerce, and authority to inspect animal carcasses and meat products. This authority applies to slaughter plants and animal food manufacturers, but does not apply to farms.

communicable disease spread.⁷⁴ To the extent that CDC would use this authority, CDC would generally work with APHIS and FSIS on issues relevant to their expertise, according to CDC officials. Second, deciding whether an outbreak is likely due to on-farm risk factors versus ones that are largely the result of in-plant problems is difficult because every outbreak is unique, according to FSIS officials. FSIS is less likely to request APHIS assistance if there is evidence of insanitary conditions—a condition in which edible meat and poultry products may become contaminated or unsafe—at the slaughter plant. However, the APHIS and FSIS memorandum of understanding does not include a decision-making framework to determine the need for an on-farm investigation; instead it focuses on the procedures for and division of responsibilities in assessing the root cause of an outbreak. In contrast, APHIS uses a decision matrix when determining whether it will pursue epidemiological assessments on the farm during other types of investigations, such as investigations of animal disease outbreaks.

According to FSIS Directive 8080.3, the objectives of foodborne illness investigation include identifying contributing factors to the foodborne illness, including outbreaks, and recommending actions or new policies to prevent future occurrences.⁷⁵ The White House's 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria* includes a 3-year milestone for USDA to begin coordinated investigations of emerging antibiotic-resistant pathogens on the farm and at slaughter plants under the one-health surveillance goal. The objective for this milestone emphasizes coordination among federal agencies, producers, and other stakeholders. Coordination with the stakeholders who have the authority and who control access to the farm could help APHIS and FSIS fully investigate an outbreak. Specifically, CDC has authority to cooperate with and assist state and local governments with epidemiologic investigations

⁷⁴Sections 301 and 311 of the Public Health Service Act give CDC broad authority to cooperate with and assist state and local governments with epidemiologic investigations. See 42 U.S.C. §§ 241, 243. Section 361 of the law authorizes regulations to prevent the introduction and interstate spread of communicable diseases affecting human health. 42 U.S.C. § 264. Under its regulations, the Centers for Disease Control and Prevention can take measures in the event that state or local measures to prevent interstate communicable disease spread are insufficient, including inspection, fumigation, disinfection, sanitation, pest extermination, and destruction of animals or articles believed to be sources of infection. 42 C.F.R. § 70.2.

⁷⁵A foodborne illness investigation is a multifaceted, multidisciplinary undertaking that includes, but is not limited to, collecting and analyzing data from epidemiologic, laboratory, and environmental assessments.

and to take actions to prevent the spread of communicable diseases in the event of inadequate local control, including diseases originating on farms. In addition, involving stakeholders from industry and state departments of agriculture could increase the likelihood of obtaining producers' consent to on-farm investigations. Developing a framework for deciding when on-farm investigations are warranted during outbreaks, in coordination with CDC and other stakeholders, would help APHIS and FSIS identify factors that contribute to or cause foodborne illness outbreaks, including those from antibiotic-resistant pathogens in animal products.

Conclusions

Ensuring the continued effectiveness of antibiotics, particularly those used in human medicine, is critical because the rise of antibiotic-resistant bacteria poses a global threat to public health. Since 2011, HHS and USDA agencies have taken actions to increase veterinary oversight of medically important antibiotics used in the feed and water of food animals and to collect more detailed antibiotic sales, use, and resistance data. However, these actions do not address long-term and open-ended use of medically important antibiotics because some antibiotics do not have defined durations of use on their labels. Without developing a process to establish appropriate durations of use on labels of all medically important antibiotics, FDA will not know whether it is ensuring judicious use of medically important antibiotics in food animals. In addition, FDA officials told us the agency is developing a plan that outlines its key activities over the next 5 years to further support antimicrobial stewardship in veterinary settings, including steps to bring the use of medically important antibiotics administered in other dosage forms (not feed or water) under veterinary oversight. However, FDA was unable to provide us with this plan or provide specifics about the steps outlined in the plan because it was still under development. A published plan with steps is critical to guide FDA's efforts in ensuring the judicious use of medically important antibiotics in food animals.

HHS and USDA agencies continue to move forward with data collection activities including new initiatives, but data gaps remain. For more than a decade, we have reported on the need for HHS and USDA to work together to obtain more detailed farm-specific data on antibiotic use and resistance to address the risk of antibiotic resistance. In 2004, we recommended that HHS and USDA jointly develop and implement a plan for collecting data on antibiotic use in food animals that would support

understanding the relationship between use and resistance, among other things. In 2011, we again recommended that HHS and USDA identify approaches for collecting detailed data on antibiotic use to assess the effectiveness of policies to curb antibiotic resistance, among other things. Although HHS and USDA agreed with these recommendations, they have not developed a joint plan to collect such data. We continue to believe that developing a joint plan for collecting data to further assess the relationship between antibiotic use and resistance at the farm level is essential and will help maximize resources and reduce the risk of duplicating efforts at a time when resources are constrained.

To assess the impact of agency actions to manage the use of antibiotics in food animals, FSIS finalized a performance measure, but FDA and APHIS have not developed any such measures or related targets, which is not consistent with leading practices for federal strategic planning and performance measurement. Without developing performance measures and targets for their actions, FDA and APHIS cannot assess impacts of their efforts to manage the use antibiotics in food animals.

In addition, although APHIS and FSIS established a memorandum of understanding in 2014 to assess the root cause of foodborne illness outbreaks, the memorandum does not include a decision-making framework for determining when on-farm investigations are needed. In the first use of the memorandum in a 2015 outbreak, there was no consensus among stakeholders on when such investigations were needed. Developing a framework for deciding when on-farm investigations are warranted during outbreaks, in coordination with CDC and other stakeholders, would help APHIS and FSIS identify factors that contribute to or cause foodborne illness outbreaks, including those from antibiotic-resistant pathogens in animal products.

Recommendations for Executive Action

The Secretary of Health and Human Services should direct the Commissioner of FDA to take the following three actions:

- Develop a process, which may include time frames, to establish appropriate durations of use on labels of all medically important antibiotics used in food animals.

- Establish steps to increase veterinary oversight of medically important antibiotics administered in routes other than feed and water, such as injections and tablets.
- Develop performance measures and targets for actions to manage the use of antibiotics such as revising the veterinary feed directive and developing guidance documents on judicious use.

The Secretary of Agriculture should take the following three actions:

- Direct the Administrator of APHIS to develop performance measures and targets for collecting farm-specific data on
 - antibiotic use in food animals and
 - antibiotic-resistant bacteria in food animals.
- Direct the Administrator of APHIS and the Administrator of FSIS to work with the Director of CDC to develop a framework for deciding when on-farm investigations are warranted during outbreaks.

Agency Comments

We provided a draft of this report to the Secretaries of Agriculture and Health and Human Services for review and comment. USDA and HHS provided written comments, reproduced in appendixes IV and V, respectively. USDA agreed with our recommendations. The department stated that it will develop performance measures and targets for collecting farm-specific data on antibiotic use in farm animals and antibiotic-resistant bacteria. USDA also agreed that a decision matrix to support multi-agency cooperation and to determine when on farm investigations are warranted, could be a useful addition, and noted that it has similar matrices that can serve as a model for antimicrobial resistance investigations. HHS neither agreed nor disagreed with our recommendations. USDA and HHS also provided technical comments, which we incorporated as appropriate.

As agreed with your offices, unless you publicly announce the contents of this report earlier, we plan no further distribution until 30 days from the report date. At that time, we will send copies to the appropriate congressional committees, the Secretary of Agriculture, the Secretary of Health and Human Services, and other interested parties. In addition, the

report will be available at no charge on the GAO website at <http://www.gao.gov>.

If you or your staff members have any questions about this report, please contact me at (202) 512-3841 or neumannj@gao.gov. Contact points for our Offices of Congressional Relations and Public Affairs may be found on the last page of this report. GAO staff who made key contributions to this report are listed in appendix VI.

A handwritten signature in black ink, appearing to read "John Neumann", with a long horizontal flourish extending to the right.

John Neumann Director, Natural Resources and Environment

Appendix I: Objectives, Scope, and Methodology

This report (1) examines actions the U.S. Department of Health and Human Services (HHS) and U.S. Department of Agriculture (USDA) have taken since 2011 to manage the use of antibiotics in food animals and to assess the impact of their actions, (2) identifies actions that selected countries and the European Union (EU) have taken to manage the use of antibiotics in food animals, and (3) examines the extent to which HHS and USDA have conducted on-farm investigations of outbreaks of foodborne illness from antibiotic-resistant pathogens in animal products.

To examine actions HHS and USDA have taken since 2011 to manage the use of antibiotics in food animals and to assess the impact of their actions, we reviewed relevant statutes and regulations, agencies' plans and guidance, and stakeholders' reports related to managing the use of antibiotics in food animals. We also reviewed USDA's Office of Inspector General report on USDA's actions to manage the use of antibiotics in food animals. We reviewed federal data reports on antibiotic sales, use, and resistance and asked officials about the quality of these data. Based on these steps, we determined that the data were sufficiently reliable for our purpose of illustrating actions taken to improve data collection. We compared information from federal agencies about actions taken to manage the use of antibiotics with federal standards for internal controls.¹ We also reviewed public comments submitted to HHS regarding data collection on farms and changes to the Animal Drug User Fee Act. We interviewed federal officials and representatives of stakeholder organizations about federal actions taken to manage the use of antibiotics since 2011. These stakeholder organizations, represented national food animal industries (National Chicken Council, National Turkey Federation, U.S. Poultry and Egg Association, National Pork Producers Council, National Pork Board, and National Milk Producers Federation); veterinarians (American Association of Avian Pathologists, American Association of Bovine Practitioners, American Association of Swine Veterinarians, and American Veterinary Medicine Association); the pharmaceutical industry (Animal Health Institute and Zoetis); consumer advocates (Keep Antibiotics Working, National Resource Defense

¹GAO, *Standards for Internal Control in the Federal Government*, [GAO-14-704G](#) (Washington, D.C.: Sept. 10, 2014).

Council, and Center for Science in the Public Interest); and others (Cattle Empire, American Feed Industry Association, Farm Foundation, and Pew Charitable Trusts).² In addition, we interviewed representatives of several companies (producers and restaurants) that provide food products from animals raised without antibiotics to obtain a better understanding of production practices; the types of antibiotic use data available at the farm level; and perspectives on federal efforts to educate producers about antibiotics. The views of representatives we spoke with are not generalizable to other companies.³ In addition, we compared federal agencies' actions with relevant goals outlined in the 2015 *National Action Plan for Combating Antibiotic-Resistant Bacteria* and interviewed representatives of stakeholder organizations to obtain views on agencies' efforts taken to date. To examine agencies' efforts to assess the impact of their actions, we reviewed HHS and USDA agencies' strategic plans and we identified any relevant goals, measures, and targets developed by federal agencies. We compared the measures and targets with agencies' goals, *National Action Plan* goals and milestones, and leading practices for improving agency performance—specifically, practices identified in the GPRA Modernization Act of 2010 and our prior work on performance management.⁴

To identify actions that selected countries and the EU have taken to manage the use of antibiotics in food animals since 2011, we reviewed documents, statutes, regulations, published studies, and surveillance reports regarding animal antibiotic use and resistance in Canada, Denmark, the Netherlands, and the EU. We selected these countries and

²Cattle Empire is a beef cattle producer. The American Feed Industry Association represents the interests of the U.S. animal feed industry and its suppliers. Farm Foundation is a non-advocacy organization that provides objective information to foster a deeper understanding of issues shaping the future for agriculture, food systems, and rural regions. The Pew Charitable Trusts is a nonprofit organization that applies an analytical approach to improve public policy, inform the public, and invigorate civic life.

³We selected these companies based on their pledge to provide products from animals raised without antibiotics.

⁴The GPRA Modernization Act of 2010 requires executive agencies to complete strategic plans in which they define their missions, establish results-oriented goals, and identify the strategies that will be needed to achieve those goals. It also requires agencies to complete annual performance plans that establish performance goals—which contribute to the strategic goals—and measure performance toward achieving performance goals. Performance measures, called performance indicators, are important management tools that help agencies monitor and report progress toward their goals. Numerical targets are a key attribute of performance measures because they allow managers to compare planned performance with actual results.

this region because they have taken actions to mitigate antibiotic resistance by managing the use of antibiotics in food animals. Additionally, each country and region met at least one of the following criteria: (1) have food animal production practices similar to those of the United States (Canada); (2) have taken actions over the last 10 years to manage the use of antibiotics in food animals (the EU and Denmark); and (3) have novel practices to manage the use of antibiotics in food animals (the Netherlands). Moreover, Denmark and the Netherlands are EU members that have made changes beyond EU directives to manage the use of antibiotics in food animals. We interviewed government officials either in person or by phone from Health Canada, the Public Health Agency of Canada, Agriculture and Agri-Food Canada, the Canadian Food Inspection Agency, and the Office of the Auditor General of Canada; the Danish Veterinary and Food Administration; the Netherlands Ministry of Health, Welfare and Sport, the Netherlands Ministry of Economic Affairs and Netherlands Food and Consumer Product Safety Authority; and the European Union Directorate General for Health and Food Safety and the European Medicines Agency. Additionally, we visited a swine facility in the Netherlands to learn about production practices. We also interviewed representatives of the Netherlands Veterinary Medicines Authority, an independent agency that monitors the use of antibiotics in food animals, defines antibiotic use benchmarks, and reports on antibiotic use trends, among other things. Finally, we interviewed representatives from veterinary and food animal industry organizations in the United States, Canada, Denmark, and the Netherlands; a U.S. organization that represents pharmaceutical companies that manufacture animal health products; as well as researchers in the field. We did not independently verify statements made about the EU practices or about the selected countries' statutes and regulations. We reviewed the methodologies of the studies provided to us and found them reasonable for presenting examples of the selected countries and the EU efforts.

To examine the extent to which HHS and USDA conducted on-farm investigations of outbreaks of foodborne illness from antibiotic-resistant pathogens in animal products, we reviewed HHS's Centers for Disease Control and Prevention and USDA's Animal and Plant Health Service (APHIS) and Food Safety and Inspection Service (FSIS) documentation, including directives, relevant to investigations of foodborne illness outbreaks, as well as the 2014 APHIS-FSIS memorandum of understanding and corresponding standard operating procedures to access farms for investigations during such outbreaks. We also reviewed documentation on a 2015 *Salmonella* outbreak that we identified as the only outbreak in which APHIS and FSIS used their memorandum of

understanding. We interviewed federal and state officials (Washington and Montana) who investigated the 2015 outbreak. We also interviewed federal officials about the agencies' authority to conduct on-farm investigations during foodborne illness outbreaks, including those involving antibiotic-resistant pathogens.

We conducted this performance audit from August 2015 to March 2017 in accordance with generally accepted government auditing standards. Those standards require that we plan and perform the audit to obtain sufficient, appropriate evidence to provide a reasonable basis for our findings and conclusions based on our audit objectives. We believe that the evidence obtained provides a reasonable basis for our findings and conclusions based on our audit objectives.

Appendix II: Medically Important Antibiotics That Changed Dispensing Status

As of January 2017, medically important antimicrobials, including antibiotics, identified by the U.S. Department of Health and Human Services' Food and Drug Administration (FDA) may only be used in the feed and water of food animals under the supervision of licensed veterinarians, according to FDA officials. Table 3 shows the antibiotics which changed dispensing status to require veterinary oversight.

Table 3: Medically Important Antibiotics Used in the Feed and Water of Food Animals Changed from Over-the-Counter to Veterinary Feed Directive and Prescription Status, as of January 2017

Antibiotic class	FDA ranking of importance of antibiotic class to human medicine	Antibiotic name	Changed to veterinary feed directive	Changed to prescription
Aminoglycosides	Highly important	Hygromycin B	Yes	NA
		Gentamicin, Spectinomycin	NA	Yes
		Apramycin, Neomycin Streptomycin	Yes	Yes
Macrolides	Critically important	Tylosin, Oleandomycin	Yes	NA
		Carbomycin	NA	Yes
		Erythromycin	Yes	Yes
Diaminopyrimidines	Not ranked ^a	Ormetoprim	Yes	NA
Lincosamides	Highly important	Lincomycin	Yes	Yes
Penicillins	Highly important	Penicillin	Yes	Yes
Streptogramins	Highly important	Virginiamycin	Yes	NA
Tetracyclines	Highly important	Chlortetracycline, Oxytetracycline	Yes	Yes
		Tetracycline	NA	Yes
Sulfonamides (Sulfas)	Not ranked ^a	Sulfachloropyrazine, Sulfachlorpyridazine	NA	Yes
		Sulfadimethoxine, Sulfamerazine, Sulfamethazine, Sulfaquinoxaline	Yes	Yes

Legend: ✓ = yes; — = not applicable.

Source: GAO analysis of Food and Drug Administration (FDA) documents. | GAO-17-192

**Appendix II: Medically Important Antibiotics
That Changed Dispensing Status**

Note: *Guidance for Industry #213* recommended that water-soluble products (medicated drinking water) change from over-the-counter to prescription status and that products used in or on feed (medicated feed) change from over-the-counter to veterinary feed directive status. Some antibiotics, not listed, were already veterinary feed directive status prior to January 2017.

^aDrugs in the class of diaminopyrimidines and sulfas are not currently ranked in appendix A of *Guidance for Industry #152*, but FDA is in the process of updating this list, according to FDA officials.

Appendix III: Companies That Sell Products with No Antibiotic Use Claims

Some companies that sell meat and poultry products have taken steps to eliminate or reduce the use of antibiotics in food animals and label products coming from these animals with claims related to “no antibiotic use.” We interviewed representatives of six such companies—specifically, three producers and three restaurants. Representatives of four of the six companies—three producers and one restaurant—told us that consumer demand was one of the main reasons why their companies took action to reduce or eliminate the use of antibiotics in food animals, and representatives of the two other companies—both restaurants—stated that their companies took action for reasons related to human and animal health.¹ As part of their efforts, companies implemented various on-farm practices, such as changing animal housing and using alternatives to antibiotics. For example, according to one company representative, the company provided larger housing to reduce crowding and promoted the use of probiotics to improve animal health. Representatives told us that their companies seek to ensure animal welfare and will use antibiotics to treat sick animals; however, these animals are removed from the product line and sold as conventional products.

Representatives of these companies also shared challenges they face in raising animals and selling food animal products without antibiotics. For example, one producer told us there is a lack of antibiotic alternatives, and that drug companies do not always produce alternatives for all species of food animals. Restaurant representatives with whom we spoke said that a challenge in providing meat and poultry products from animals raised without antibiotics is that supply is limited; for example, companies only buy certain parts of the animal, but the supplier needs to sell all parts, which may limit the availability of suppliers willing to specialize in animals raised without antibiotics. Additionally, company representatives told us that it is more difficult for pork and beef producers than poultry producers to raise animals without antibiotics because the supply chain

¹The producers we spoke with are involved in various aspects of meat and poultry production, processing, and retail. Among other things, companies may raise their own animals, buy animals from independent farmers, and sell meat and poultry products.

for poultry is vertically integrated—meaning that the same company generally owns the animal from birth through processing—but the supply chains for pork and beef are not.

The companies we interviewed use various terms for their label claim related to no antibiotic use, such as “no antibiotics ever,” “no human antibiotics,” “raised without antibiotics,” and “raised without antibiotics important to human health.” To include these or similar claims on their product labels, companies must submit to the U.S. Department of Agriculture’s (USDA) Food Safety and Inspection Service (FSIS) detailed records from the production process that support the accuracy of the claim. All company representatives we interviewed told us their companies collect and report data related to the production practices for their products. For example, one company requires its suppliers to report quarterly on antimicrobials used and the reason for use. Another representative told us that the company collects numerous data points throughout the year, including all medicines used on the farm and feed history, to validate antibiotic use compliance by its suppliers with company policies.

Company representatives we spoke with agreed that there is some confusion among consumers regarding products sold and marketed as being from animals raised without antibiotics. One company representative told us that consumers are unaware that antibiotic use claims refer to animal raising practices rather than the presence of antibiotics in food products and that all meat and poultry products are tested when presented for slaughter to ensure antibiotic residues are below allowable government limits. Under its National Residue Program, FSIS monitors meat, poultry, and processed egg products for chemical residues, including antibiotics. Additionally, the Food and Drug Administration requires, as a condition of use on the product label, withdrawal periods for antibiotics—that is, periods of time prior to slaughter when antibiotics cannot be used. Another company representative told us that there is confusion about the various marketing claims used by companies, such as “no hormones” and “no antibiotics.” FSIS officials told us that the agency is aware of the concerns industry and consumers may have regarding the various claims on products currently in the marketplace. In September 2016, FSIS released labeling guidance that provides information about claims frequently used on products, what they mean, and how they are evaluated for accuracy. In regard to label claims related to antibiotic use, the guidance describes the requirements needed to make a claim, provides examples of terms that may be used, and lists the documentation needed for approval of the

claim. FSIS is also considering rulemaking to define and clarify the varied language used in the “raised without antibiotics” claim, according to officials.

Companies may choose to further differentiate their products in the marketplace through participating in certification, audit, or other programs, such as USDA’s National Organic Program or Process Verified Program.² Products may carry the USDA organic seal if companies and their products are certified by a USDA certifying agent to be in accordance with USDA organic regulations, which include not treating animals with antibiotics.³ Similarly, a company may use the process verified seal on their products if one or more of their agricultural processes, such as raising animals without antibiotics, is verified through an audit by USDA. Unlike the National Organic Program, under the Process Verified Program companies establish their own processes and standards. As a result, processes and standards may vary across the companies. In addition, the constraints on antibiotic use do not need to meet statutory or regulatory requirements, leading to differing standards.⁴ For example, one company may have a process verified program for no antibiotics ever, and another may have a program for no antibiotics important to human health. Representatives from five of the six companies we spoke with told us that for some products they participate in USDA’s Process Verified Program to verify antibiotic use claims.

²USDA’s Agricultural Marketing Service oversees both the National Organic Program and the Process Verified Program. Through the National Organic Program, the Agricultural Marketing Service is responsible for the USDA organic standards and the accreditation of organic certifying agents. According to USDA documents, the USDA Process Verified Program is a verification service that offers applicants a unique way to market their products to customers using clearly defined, implemented, and transparent process points. Applicants choose which process points to adhere to, and these points can vary by industry and product.

³We previously reported on the National Organic Program and described various standards that must be met. [GAO-11-801](#).

⁴In 2015, USDA began approving poultry companies to the School Food Focus Certified Responsible Antibiotic Use standard which seeks, for poultry products used in school meals, to minimize the use of veterinary antibiotics that are identical or closely related to drugs used in human medicine. This program also includes an audit to verify production practices.

Appendix IV: Comments from the Department of Agriculture



United States Department of Agriculture

Office of the Secretary
Washington, D.C. 20250

FEB - 8 2017

Mr. John Neumann, Director
Natural Resources and Environment
Government Accountability Office
441 G Street NW
Washington, DC 20548

Dear Mr. Neumann:

Thank you for providing the United States Department of Agriculture (USDA) the opportunity to comment on the Government Accountability Office's (GAO) Draft Report, "Antibiotic Resistance: More Information Needed to Oversee Use of Medically Important Drugs in Food Animals" (17-192). We have addressed the recommendation made to the Secretary of Agriculture.

Recommendation

The Secretary of Agriculture should direct the Administrator of the Animal and Plant Health Inspection Service (APHIS) to develop performance measures and targets for collecting farm-specific data on (1) antibiotic use in food animals and (2) antibiotic-resistant bacteria in food animals; and the Administrator of APHIS and the Administrator of the Food Safety and Inspection Service (FSIS) to work with the Director of the Centers for Disease Control and Prevention (CDC) to develop a framework for deciding when on-farm investigations are warranted during outbreaks.

USDA Response

USDA agrees with this recommendation. APHIS will develop performance measures and targets for collecting farm-specific data on antibiotic use in farm animals and antibiotic resistant bacteria. APHIS has developed a planned approach for gathering representative data for major commodity groups of concern (e.g., feedlot cattle, swine, and poultry). APHIS' National Animal Health Monitoring System (NAHMS) has a long history of cooperation with the USDA's National Agricultural Statistics Service (NASS) and coordinates with CDC's National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS). NAHMS monitoring of two operation types, feedlot cattle and swine, will begin by May 2017. USDA has developed a Strategic Plan to guide coordinated action and further program buildup pending availability of funds, to include the expansion of data collection through surveys in other commodity groups and industry operation types, epidemiology based investigations, longitudinal studies, and laboratory monitoring for antibiotic resistance in pathogens of concern to public and animal health. APHIS has developed a National Animal Health Laboratory Network (NAHLN) pilot for this latter purpose. APHIS has a Memorandum of Understanding with FSIS, dated April 2014, to conduct on-farm investigations for outbreaks of food origin. APHIS agrees that on farm investigations could include pathogens of animal origin that are resistant to antibiotics.

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Page 2

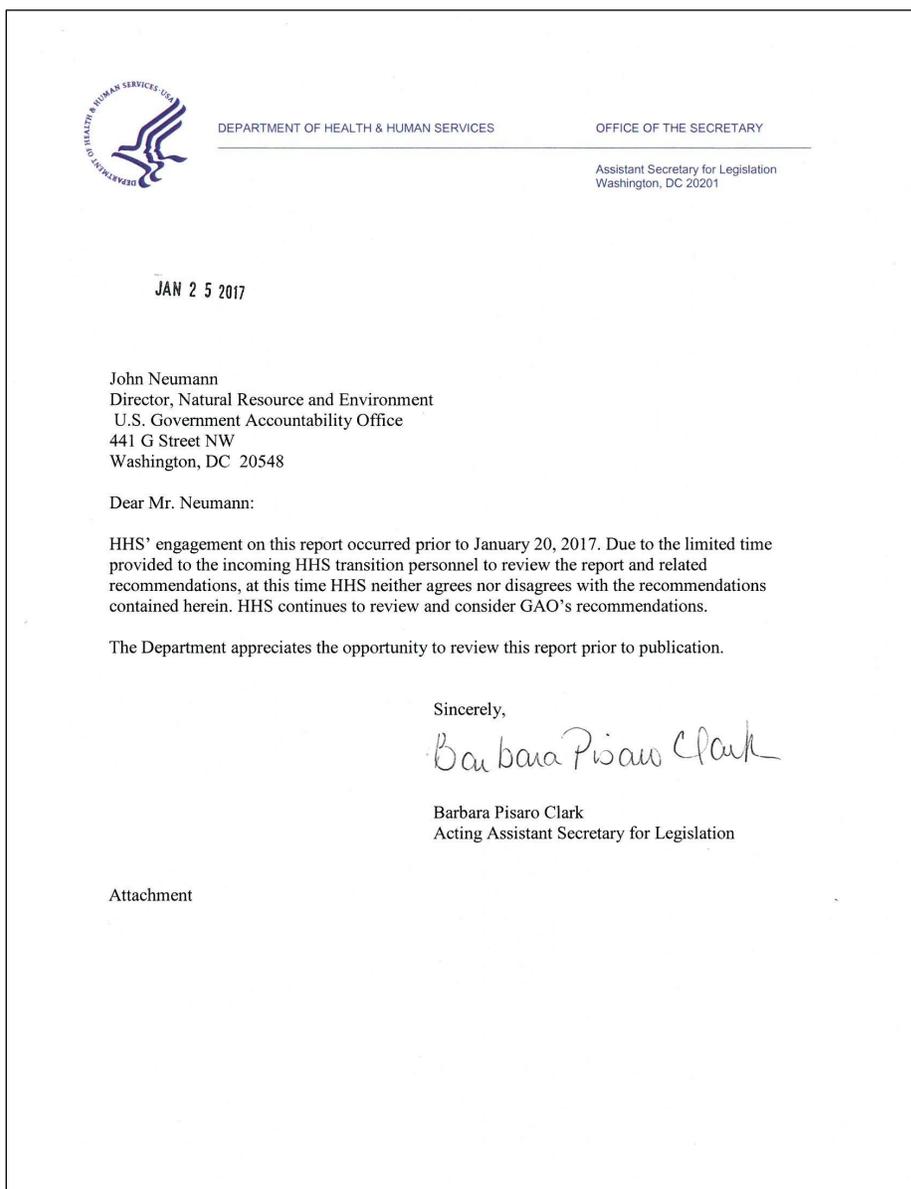
APHIS believes that these investigations should be risk based, and investigations should be designed to increase knowledge useful for minimizing risks.

NAHMS has developed an approach and study design to meet this objective that also maintains producer confidentiality. APHIS agrees that a decision matrix to support multi-agency cooperation and to determine when on-farm Antimicrobial Resistance (AMR) investigative activities are warranted could be a useful addition. APHIS has developed and implemented a decision matrix for investigation of zoonoses and other non-food borne disease outbreak investigations. These matrices can serve as a model for developing a similar matrix for on-farm AMR investigation activities.



Kevin Shea
Acting Deputy Under Secretary
Marketing and Regulatory Programs

Appendix V: Comments from the Department of Health and Human Services



Appendix VI: GAO Contact and Staff Acknowledgments

GAO Contact

John Neumann, (202) 512-3841 or neumannj@gao.gov

Staff Acknowledgments

In addition to the contact named above, Mary Denigan-Macauley (Assistant Director), Nkenge Gibson, Cynthia Norris, Benjamin Sclafani, and Bryant Torres made significant contributions to the report. Also contributing to the report in their areas of expertise were Kevin Bray, Gary Brown, Robert Copeland, Michele Fejfar, Benjamin Licht, Sushil Sharma, and Sara Sullivan.

Appendix VII: Accessible Data

Data Tables

Text for Figure 1: How Antibiotic-Resistant Bacteria Can Develop and Spread

Resistance – animals can carry harmful bacteria in there intestines

- Antibiotics
- Animals
- Antibiotics kill most bacteria
- Resistant bacteria can survive and multiply

Spread – resistant bacteria can spread to

- Animal products
- Produce through contaminated water or soil
- Prepared food through contaminated surfaces
- The environment via animal waste

Exposure – people can get sick with resistant infections from

- contaminated food
- Contaminated environment

Impact – some resistant infections cause

- mild illness
- severe illness and may lead to death

Data Table for Figure 2: National Antimicrobial Resistance Monitoring System Data Collection

	CDC	FDA	USDA
Area Monitored	Human population	Retail meats	Animal population

	CDC	FDA	USDA
Data collected	Physician visits	Random stratified samplings in 14 states (beef, pork, chicken, turkey)	Random samplings of national production at slaughter (beef, dairy, hogs, sows, chickens, turkeys)
Data collection centers	Local lab State lab	Labs in 14 states	Eastern FSIS laboratory

Data Table for Figure 4: Example of Multistate Foodborne Illness Outbreak Investigation Process

Identifying the outbreak

- People get sick after eating contaminated food, and seek treatment. Stool samples are collected and sent to a state public health lab for testing.
- The state lab identifies the DNA fingerprint of the pathogen in the contaminated food and enters results into the Center for Disease Control and Prevention’s (CDC) PulseNet database.
- Through PulseNet, CDC identifies people in other states who got sick from the same pathogen.

Finding the Source of the Outbreak

- CDC leads investigations during multistate outbreaks and works with state public health departments and the U.S. Department of Agriculture (USDA) to trace suspect food back to the source.
- Investigators interview individuals affected and review records from restaurants or stores where people ate or shopped.
- USDA investigates slaughter plants where the meat or poultry products came from to identify food safety risk.
- USDA may also investigate farms that supplied animals to the slaughter plant, if the farmer agrees.

Stopping the Outbreak

- Public health officials and regulators work with the restaurant, store, or slaughter plant on follow-up actions such as fixing the source of contamination, issuing a food recall, or temporarily closing the establishment.

Agency Comment Letters

Text of Appendix IV: Comments from the Department of Agriculture

Page 1

Mr. John Neumann, Director Natural Resources and Environment
Government Accountability Office 441 G Street NW

Washington, DC 20548 Dear Mr. Neumann:

Office of the Secretary Washington , D.C.20250

FEB 8, 2017

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Recommendation

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USDA Response

USDA agrees with this recommendation. APHIS will develop performance measures and targets for collecting farm-specific data on antibiotic use in farm animals and antibiotic resistant bacteria. APHIS has developed a planned approach for gathering representative data for major commodity groups of concern (e.g., feedlot cattle, swine, and poultry). APHIS' National Animal Health Monitoring System (NAHMS) has a long history of

cooperation with the USDA's National Agricultural Statistics Service (NASS) and coordinates with CDC's National Antimicrobial Resistance Monitoring System for Enteric Bacteria (NARMS). NAHMS monitoring of two operation types, feedlot cattle and swine, will begin by May 2017. USDA has developed a Strategic Plan to guide coordinated action and further program buildup pending availability of funds, to include the expansion of data collection through surveys in other commodity groups and industry operation types, epidemiology based investigations, longitudinal studies, and laboratory monitoring for antibiotic resistance in pathogens of concern to public and animal health. APHIS has developed a National Animal Health Laboratory Network (NAHLN) pilot for this latter purpose. APHIS has a Memorandum of Understanding with FSIS, dated April 2014, to conduct on-farm investigations for outbreaks of food origin. APHIS agrees that on farm investigations could include pathogens of animal origin that are resistant to antibiotics.

Page 2

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Kevin Shea

Acting Deputy Under Secretary Marketing and Regulatory Programs

Text of Appendix V: Comments from the Department of Health and Human Services

JAN 25, 2017

John Neumann

Director, Natural Resource and Environment

U.S. Government Accountability Office 441 G Street NW

Washington, DC 20548

Dear Mr. Neumann:

HHS' engagement on this report occurred prior to January 20, 2017. Due to the limited time provided to the incoming HHS transition personnel to review the report and related recommendations, at this time HHS neither agrees nor disagrees with the recommendations contained herein. HHS continues to review and consider GAO's recommendations.

The Department appreciates the opportunity to review this report prior to publication.

Sincerely,

Barbara Pisaro Clark

Acting Assistant Secretary for Legislation

Attachment

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