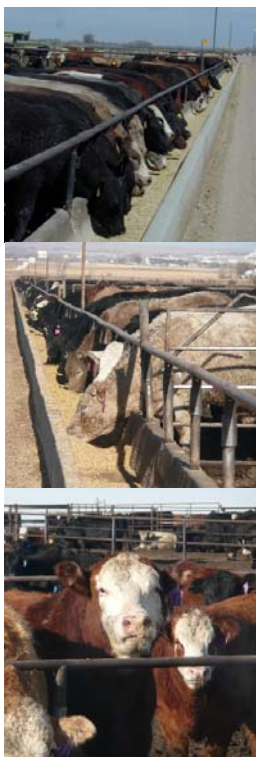




United States Department of Agriculture

Veterinary Services



Challenges in Managing Antimicrobial Drug Use in Food Producing Animals

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Proposed Initiatives from the USDA Antimicrobial Resistance Action Plan

In December 2014, the U.S. Department of Agriculture (USDA) released an Antimicrobial Resistance Action Plan to guide future activities related to antimicrobial resistance (AMR). The Action Plan outlines USDA's current activities and proposes a comprehensive, integrated approach for future activities that includes surveillance; research and development; and education, extension, and outreach. This info sheet briefly describes initiatives proposed in the USDA's Antimicrobial Resistance Action Plan that the USDA's Animal and Plant Health Inspection Service's (APHIS) National Animal Health Monitoring System (NAHMS) might be involved in and provides a tentative timetable for implementing the proposed initiatives.

Background

Antimicrobial resistance is one of the most serious threats to the health of animals and humans worldwide. As such, everyone has a shared responsibility to limit the impact of AMR. Antimicrobial resistance is a multifaceted issue that requires a One Health¹ approach, which recognizes that the health of animals and humans is irrevocably linked and closely connected to the environment.

The USDA is not the lead regulatory agency with respect to antibiotic use and AMR. It does, however, play an important role in addressing the challenges presented by AMR by developing partnerships with stakeholders and via the missions of several of its key agencies.² In addition, the USDA possesses in-depth

knowledge of the management practices and technologies associated with animal health, welfare, productivity, and food safety. As such, the USDA is uniquely positioned to contribute to the body of scientific knowledge about AMR and the role of antimicrobial use and other factors that play a part in the health of livestock.

For nearly two decades, the USDA has actively conducted surveillance, basic and applied research, and education and outreach programs related to AMR. Through these efforts, effective mitigation strategies for AMR were developed, and animal producers were advised on how to implement these strategies. The USDA's AMR activities have made important contributions to better understanding the role of animal management in AMR and to reducing its development and spread of AMR. Considerable work remains, however, and there is a growing sense of urgency throughout the world to address the AMR issue.

Proposed initiatives

The Action Plan proposes several initiatives that would enable USDA to address recognized knowledge gaps in AMR and develop effective, practical mitigation strategies to help prolong the effectiveness of antibiotics for animals and humans. The USDA proposes to obtain and disseminate science-based, actionable, information about antibiotic use and resistance and relate this information to livestock management practices. To achieve the greatest impact, the proposed initiatives would build upon existing activities and be integrated across USDA agencies. Since all of these proposed activities are voluntary, collaborations with stakeholders and producers will be established to leverage expertise and resources in the most efficient and effective ways.

The USDA wants to ensure that stakeholders have an opportunity to review the components of its AMR Action Plan and provide feedback before moving forward with the proposed AMR initiatives in the plan. Accordingly, the remainder of this info sheet offers a brief synopsis of initiatives proposed in the Action Plan and a timetable for implementing the initiatives in which USDA, APHIS might be involved.

¹The One Health Initiative is a movement to forge co-equal, all inclusive collaborations between physicians, osteopaths, veterinarians, dentists, nurses, and other scientific-health and environmentally related disciplines, including the American Medical Association, American Veterinary Medical Association, American Academy of Pediatrics, American Nurses Association, American Association of Public Health Physicians, the American Society of Tropical Medicine and Hygiene, the Centers for Disease Control and Prevention (CDC), the United States Department of Agriculture (USDA), and the U.S. National Environmental Health Association (NEHA). Additionally, more than 800 prominent scientists, physicians, and veterinarians worldwide have endorsed the initiative.

²Agricultural Research Service (ARS), APHIS, Economic Research Service (ERS), Food Safety and Inspection Service (FSIS), the National Agricultural Statistics Service (NASS), the National Institute of Food and Agriculture (NIFA), as well as other agencies.



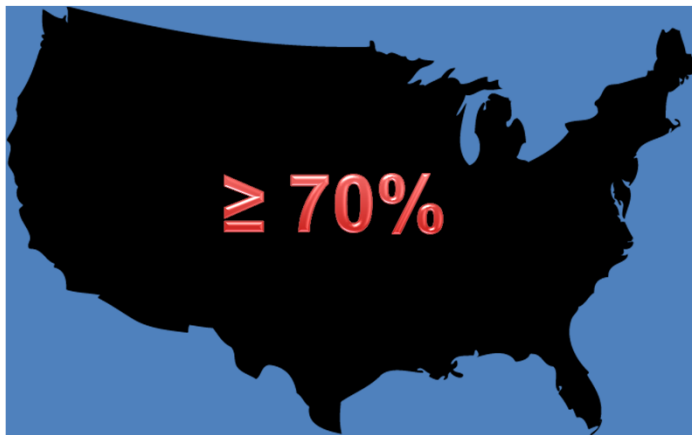
NAHMS Commodity Surveys

- Periodic (every 5-7 years)
- Cross-sectional
 - Snapshot of health and management practices at the time of the study
- 1-2 questionnaires are administered along with collection of biological samples
- Stakeholder driven
- Confidential and voluntary
- Statistically based for population estimation



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National Studies



– Animal population

– Operations





Limitations of NAHMS Antimicrobial Use Data

- Provides information in terms of percent of animals receiving or percent of operations using a specific antibiotic and purpose for use
- Does not provide total kilograms used or animal daily doses
- Data are collected every 5-7 years for each species



Enhancements to NAHMS studies

- Analysis of retrospective data from past NAHMS Studies
 - fully utilize existing data to meet current information needs.
- Use data currently unavailable in the U.S.
 - National estimates are needed to assess effects of FDA policy changes.
- Annual survey
 - to provide national estimates of antibiotic use in feed or water for feedlot cattle, broilers, swine, and, potentially, turkeys.
- NASS surveys
 - Questions could be added to existing and proposed.

A sufficient number of operations could be sampled and tested for the presence of zoonotic pathogens (e.g., *Salmonella*, *Campylobacter*) and commensals (e.g., *Enterococcus*, *E. coli*) to provide national, population- based estimates on prevalence and antimicrobial resistance in these organisms.



Enhancements to Economic Research Service Surveys

- Economic impacts at the farm level of FDA-GFI #213 to be assessed
- Costs, productivity, and production practices
- Likely swine and broilers.



On-farm Longitudinal Studies

- These studies can assess relationships between antibiotic use, AMR patterns, and management practices on farms over time.
- Assess relationships between antibiotic use (and other factors) and the development of resistance in zoonotic pathogens and commensals on farms.
- Due to cost limitations, the number of operations would likely be insufficient to provide national or regional population estimates.
- Data would be protected from Freedom of Information Act (FOIA) requests.



Targeted Studies

- There is currently no mechanism within the USDA for conducting as-needed investigations into clusters of AMR pathogens.
- Enable the investigation of clusters of AMR pathogens identified through NAHMS studies or FSIS sampling.
- Would be a nonregulatory activity performed at the request of producers and slaughter plants.
- Limited-scope studies could focus on specific, critical issues related to AMR or antibiotic use for the commodity of interest



Proprietary Data

- Easier method of obtaining data on antibiotic use than using a questionnaire.
- Could complement NASS surveys to obtain national estimates of antibiotic use in feed for feedlot cattle, broilers, swine, and turkeys.
- Data would remain confidential and protected from FOIA requests due to NAHMS statistical unit status within USDA.



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National Veterinary Services Laboratories / National Animal Health Laboratory Network

laboratory diagnostics, genomics, data

- AMR testing on samples from clinically ill animals
 - A centralized database would allow for collating AMR data across labs.
 - Monitor the continued usefulness of antibiotics against animal pathogens.
 - Inform producers' and veterinarians' when making treatment decisions.
- MED-VET-NET / Pulse NET
 - Genetic resistance (genomics)
 - Sample testing methodologies and standardization of techniques
 - Identify pathogens of interest



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National Veterinary Accreditation Program

Veterinary Accreditation is a part of the veterinary education curriculum

- Judicious use
- Veterinary Feed Directive training
- Potential data stream

Study type	Proposed Initiative	Phase	CY2015				CY2016				CY2017			
			Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Longitudinal studies	On-farm longitudinal studies	Design		X	X									
		Office of Management and Budget (OMB)*			X	X	X	X						
		Data collection						X	X	X	X	X	X	X
		Analysis							X	X	X	X	X	X
		Reporting								X		X		X
	Collation of AMR data from veterinary diagnostic laboratories	Stakeholder discussions		X	X	X								
		Design			X	X	X							
		Data collection					X	X	X	X	X	X	X	X
		Analysis						X	X	X	X	X	X	X
		Reporting								X		X		X
National cross-sectional studies	Annual Antibiotic Use Survey (Including Proprietary Data)	Design	X	X										
		OMB*		X	X	X	X							
		Data collection					X			X	X			X
		Analysis					X	X			X			
		Reporting						X	X			X	X	
	ERS Surveys	Design		X	X	X								
		OMB*		X	X	X	X							
		Data collection					X	X						
		Analysis						X	X	X				
		Reporting									X	X		
	Analysis of Retrospective Data from Past NAHMS Studies	Analysis		X	X	X	X							
		Reporting			X	X	X	X						
	Enhancements to NAHMS studies: Equine 2015	Data collection		X	X	X								
		Analysis			X	X	X	X						
		Reporting					X	X	X	X				
	Enhancements to NAHMS studies: Beef (stockers) 2017	Info needs assessment			X	X								
		Design			X	X	X	X	X					
		OMB*							X	X	X	X		
		Implementation											X	X
		Analysis												
		Reporting												
Targeted studies	As-needed epidemiological investigations	Stakeholder discussions			X	X	X	X						
		Design, data/sample collection, analysis, reporting (short-term, not national, no OMB package)												
	Focused NAHMS Studies (performed annually)	Design				X	X							
		OMB*					X	X	X	X	X			
		Implementation									X	X		
		Analysis											X	X
		Reporting												
Proprietary data	This was not a proposed initiative in the USDA AMR Action Plan	Stakeholder discussions			X	X	X	X						

*Includes preparation of the OMB package as well as analysis and approval of the package by OMB. Data collection cannot begin until after OMB approval. At least 11 months are needed after submission of the OMB package to obtain OMB approval.

X=Work will occur during this quarter, depending on resources.



Challenges

- NARMS data not linked with use practices, on-farm data.
- Measures of appropriate use may not indicate reduced use.
- Management practices, key organisms, dosages, indications, temporal data, sampling techniques, collection,
 - May not be easy to gather data.
- Whole genome sequencing
 - Analysis of data may take time.
- Use estimation is different from use monitoring.
 - The objective is to inform decisions and policy formulation.
- Market dynamics, consumer urgency
- Meeting expectations



Other Initiatives

- Economic analysis
 - Policy analysis
 - Impact analysis
- Data sharing
 - Data access, management, quality, analysis of metadata

Research needs

- Identification and communication
- Reporting
- Communication
 - Not education and outreach

Resource intensive activities



Getting Started

- Because proposed activities are *voluntary*, USDA must closely cooperate with Federal, industry, commodity, and academic partners to implement any sort of plan.
- Regulatory and budgetary process in the US.
- Support by producers, veterinarians, commodity groups, others.
- Long term outlook
- Funding



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Thank You