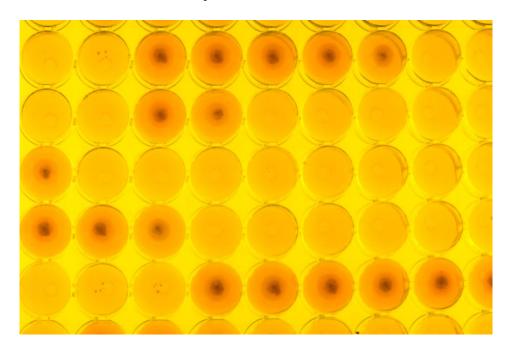


Antibiotic Resistance Workshop Executive Summary

George Washington Carver Center Beltsville, Maryland

May 15–17, 2012



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Cover photo by Peggy Greb for the Agricultural Research Service. The darker-orange wells show growth of antimicrobial-resistant bacteria. The lighter-orange wells show no growth, meaning the bacteria were susceptible to the antimicrobials.

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I. OVERVIEW AND BACKGROUND

Concerns over antibiotic resistance are driving policies to ensure appropriate use of antibiotics in human medicine and on animal farms worldwide. The availability of medical interventions to prevent and control animal diseases on the farm will directly impact global food security, the Feed the Future Initiative, and the health of animals and humans alike. To address these issues, the U.S. Department of Agriculture (USDA) sponsored a three-day workshop (May 15–17, 2012) to assess steps that could be taken to address the issue of antibiotic use and resistance. The objectives of the workshop were as follows:

- To review current antibiotic use and resistance monitoring,
- To review management practices to reduce antibiotic resistance, and
- To review alternatives to the use of antibiotics to treat and prevent diseases or to enhance production in food animals.

To achieve the objectives, the first day of the meeting was devoted to listening to stakeholders' concerns. The second day was devoted to discussing antibiotic resistance with other Federal agencies, including the Food and Drug Administration (FDA), Centers for Disease Control and Prevention (CDC), and National Institutes of Health (NIH).

Based on input from stakeholders and Federal partners, the third day of the workshop was devoted to examining ways that USDA might achieve the meeting objectives and to begin outlining appropriate roles for USDA agencies to confront the issue of antimicrobial resistance. These roles include conducting surveillance to document trends in drug use and antimicrobial resistance over time; carrying out research on alternative medical interventions (vaccines, immune enhancers, bacteriocins, probiotics, etc.), alternative strategies (management practices) to prevent and control disease, and alternative strategies to promote animal growth; economic analyses of policy changes and the use of antimicrobial alternatives; and outreach/education activities on surveillance and research initiatives.

Sponsoring USDA agencies included the Animal and Plant Health Inspection Service (APHIS), Food Safety and Inspection Service (FSIS), Agricultural Research Service (ARS), Economic Research Service (ERS), and National Institute of Food and Agriculture (NIFA).

The workshop included representatives of 35 stakeholder organizations, 3 non-USDA Federal partner organizations, and 28 USDA employees representing APHIS, FSIS, ARS, ERS, NIFA, and the Foreign Agriculture Service. A list of meeting participants appears in the appendix.

The purpose of this report is to summarize the key points that emerged from the workshop. An overview of input received from stakeholders and Federal partners appears in parts II and III of the report, respectively. Part IV contains a summary of next steps for USDA after hearing from stakeholders and Federal partners. These steps include an assessment of current antibiotic use and resistance monitoring; management practices to reduce antimicrobial resistance; alternatives to antibiotics for treating and preventing diseases or for enhancing production in food animals; alternative medical interventions; and revisions to education, training, and extension and outreach practices.

II. INPUT FROM STAKEHOLDERS

The first day of the meeting was devoted to listening to stakeholders' concerns about antimicrobial resistance and to obtain information that would assist USDA in addressing the issue of antibiotic use and resistance.

Stakeholders representing public health providers and policy-making organizations, consumer organizations, veterinary practitioner organizations, agricultural commodity producers, and veterinary pharmaceutical companies were invited to participate in a listening session and submit written statements to address three broad areas of antimicrobial resistance:

1. Current antibiotic use and resistance monitoring

- Where are the substantial gaps in our knowledge of antimicrobial use and resistance in animal agriculture? What types of additional data need to be collected and analyzed?
- How would you prioritize these data needs given resource limitations?
- What role do you see for your organization or others in collaborating with USDA to meet these needs?

2. Management practices to reduce antibiotic resistance

- Where are the gaps in understanding how both producers' management decisions (on farms) and post-harvest interventions (at plants) affect the risk of antimicrobial resistance or the risk of transfer of antimicrobial resistance?
- What additional practices are being investigated or proposed that could also be recommended? (Consider national and international practices.)
- How can we measure the effectiveness of current and proposed management practices?

3. Alternative medical interventions

- What specific research is needed to address antibiotic resistance and how will this research address the problem?
- How would alternatives to antibiotics for treating and preventing animal diseases help reduce the use of antibiotics in animal agriculture and what would be the incentive for farmers to use them?
- How would you prioritize these research needs given limited resources?

Much of the discussion that occurred during the stakeholder listening sessions focused on the need for additional basic science/research and surveillance data on which to base Federal policy decisions and to support the identification of alternative approaches to control disease.

There was consensus that antibiotic use selects for antibiotic-resistant bacteria and that action is needed by all participants to address the issue in both human and veterinary applications.

Stakeholders also agreed that current data on drug sales is a poor surrogate for actual drug use data and that collection of species-specific drug use data should be a top priority.

The primary point of disagreement among stakeholders is whether reducing veterinary antibiotic use will have an effect on public health. In general, many stakeholders from the public health and consumer sectors agreed that the public health issue can be best addressed by reducing the overall amounts of antibiotics used in food animal production and that a reduction in total antibiotic use should be the ultimate goal. In contrast, stakeholders from the agricultural sector believe that identifying control points along the entire farm-to-fork continuum could prevent or reduce transmission of antibiotic resistance from animals to humans and advocated for strategies that would be most effective in reducing the transmission of antibiotic-resistant bacteria to humans and thus improve public health. Several stakeholders strongly stated the need for data-driven risk assessments to inform policy decisions and to evaluate the effectiveness of interventions.

Current antibiotic use and resistance monitoring is seen as a foundation for building better data collection systems that are timely and transparent. Stakeholders recommend the continuation and expansion of the National Animal Health Monitoring System (NAHMS) and the National Antimicrobial Resistance Monitoring System (NARMS), with an emphasis on adding farm and slaughter samples to fill current knowledge gaps. Stakeholders suggested coordinating sample collection strategies and independently validating those methods. Several stakeholders expressed the need that research and regulatory functions related to surveillance should remain separate from each other.

Many stakeholders talked about the need for management practices to reduce antibiotic resistance and many who work in agriculture are interested in seeing research initiated that could quantify the impacts of specific management practices on antibiotic resistance. This issue includes working out details of dosing and treatment regimens of specific antibiotics for food-producing animals as well as impacts of routine daily activities (i.e., general management and nutrition) on carriage, shedding, and transmission of antibiotic resistance. Because agricultural systems are diverse and complex even within a specific commodity group, concern exists regarding the transferability of results between different systems. Almost all stakeholders outside of agricultural settings expressed concern about the hygiene of current systems and advocated for better hygiene as a means of ultimately reducing the transfer of antibiotic resistance from animals to humans.

Many stakeholders said they are interested in alternative medical interventions. There was great interest from agricultural producers for systems to evaluate the efficacy of alternative (i.e., non-antibiotic) treatments and prevention technologies (e.g., vaccines and probiotics), and both producers and companies strongly advocated for streamlined and coordinated efforts from university, government, and industry to develop and bring to market new alternative treatments and preventions.

III. INPUT FROM FEDERAL PARTNERS

The purpose of the second day of the meeting was to have USDA scientists meet with other Federal agency partners to assess what stakeholders had said the day before to address the issue of antibiotic use and resistance, and to identify and share potential current and future actions that would enable USDA to lead and support all stakeholders and partners in addressing antibiotic use and resistance.

Discussions with Federal partners revealed the need for USDA to play a supporting role, primarily to the U.S. Food and Drug Administration, and particularly in the areas of research and surveillance, as FDA moves forward with the actions announced in April 2012 to restrict medically important antibiotics for use in the treatment, control, and prevention of disease. The FDA actions will restrict the use of medically important antibiotics for growth promotion and will require oversight by a veterinarian.

A. Food and Drug Administration

Representatives of the FDA discussed the recently published Guidance for Industry "The Judicious Use of Medically Important Antimicrobial Drugs in Food-Producing Animals" (Final Guidance 209, Draft Guidance 213, and proposed draft regulation; April 13, 2012). The Guidance aims to ensure the judicious use of existing products that predate FDA's Guidance for Industry 152 (used for assessing the safety of new animal drugs) through restricting the labeled use of medically important antimicrobial drugs to therapeutic uses and assuring veterinary oversight of antimicrobial drug use in food animals. The FDA plans to implement changes over a 3-year period and welcomed the opportunity to work with USDA to help the animal agriculture industry adjust to the changes. The FDA is also assessing ways to collect accurate drug use information and is modifying the animal arm of the National Antimicrobial Resistance Monitoring System. Changes to the system likely will include the type of samples obtained at slaughter and partnerships with universities to obtain on-farm isolates.

B. Centers for Disease Control and Prevention

Representatives of the Centers for Disease Control and Prevention emphasized the need to study the ecology, epidemiology, and microbiology of antimicrobial resistance in concert, especially the ecological disruptions that can lead to emerging zoonoses and antimicrobial resistance. CDC representatives stated that the antimicrobial ecosystem is complex, nonlinear, and dynamic. Antimicrobial resistance and use monitoring and surveillance are challenging to conduct,

¹ The Final Guidance 209 document is available at this address: http://www.fda.gov/downloads/AnimalVeterinary/GuidanceComplianceEnforcement/GuidanceforIndustry/UCM216936.pdf

analyze, and interpret but can provide valuable data as snapshots of the current state and evidence of trends.

C. National Institutes of Health

Representatives of the National Institutes of Health (NIH) discussed current activities within three broad categories: 1) basic research; 2) translational research/product development; and 3) clinical research. Investigator-initiated grants concentrate on mechanisms of resistance; antimicrobial, diagnostic, and vaccine target identification and characterization; and the discovery of new chemical entities with antimicrobial activity. NIH scientists and administrators are exploring the benefit of new therapeutics through a number of small business grants and partnership programs and conducting targeted clinical trials to reduce the risk from antimicrobial resistance.

IV. NEXT STEPS FOR USDA

A. An Assessment of Current Antibiotic Use and Resistance Monitoring

While antibiotic use and resistance monitoring is occurring at some level in both the private and public sectors, better information would improve our understanding of the role of agriculture in antimicrobial resistance. Currently, USDA participates in national resistance monitoring activities; however, participation is limited and may become more limited if funding remains constrained. With additional funding, the USDA may be able to coordinate more prospective onfarm and in-plant studies to enhance monitoring for antibiotic use and resistance.

Stakeholders identified four types of information gaps associated with antibiotic use and resistance monitoring: 1) data deficits; 2) communication gaps; 3) defined metrics; and 4) funding gaps. These are discussed in more detail below.

1. Data Gaps

Three distinct categories of data deficits exist: a) antibiotic use and resistance measures; b) ecologic assessments; and c) economic impact assessments. These are outlined below, followed by a summary of what might occur by correcting the deficits.

Stakeholders identified four specific deficits associated with antibiotic use and resistance measures:

- 1. Lack of specific quantitative data on antimicrobial drug use in animals (for an animal species in a particular production environment by reason for use)
- 2. Lack of specific quantitative data on antimicrobial drug use in people
- 3. Lack of specific data on antimicrobial resistance in animals (for an animal species in a particular production environment by organism)
- 4. Lack of specific data on human illnesses and outbreaks due to antimicrobial resistant versus susceptible microbes

Three specific ecologic assessment deficits were identified:

- 1. Lack of understanding how various microbial communities resident to specific eco-niches (e.g., animals, people, environmental locations) are related with particular reference to the transfer of resistant organisms or resistance genes among the niche environments
- 2. Lack of understanding of the amount of risk posed by antimicrobial drug use in animals versus other risk factors such as the ecologic spread of resistance genes and the impact of various risk factors on public health
- 3. Lack of understanding of relationships between virulence and drug resistance

Finally, two deficits associated with economic impact assessment were identified:

- 1. Lack of data on the true economic benefit of antibiotic use for health and production
- 2. Lack of data on the potential impacts of antibiotic policy changes

Correction of these data deficits would allow standardized comparisons to be made across production systems, a refinement in prudent use guidelines, an ability to monitor the impacts of antibiotic policy changes, antibiotic resistance control efforts with a better focus, and better predictions of the consequences of policy changes.

2. Communication Gaps

Gaps in communication include a limited understanding among stakeholder communities of the roles, responsibilities, and efforts of various government agencies related to antibiotic use and resistance; a lack of standardized terminology, which leads to confusion and disagreement (e.g., terms for the purpose of drug use and terms used in data interpretation such as "trend"); and a limited understanding among stakeholders of how data from antibiotic use and resistance monitoring can and will be used.

Addressing these communication gaps would allow more meaningful dialogue among various stakeholder groups, more appropriately focused efforts for antibiotic use and resistance monitoring, and greater "buy in" among stakeholder groups for the monitoring efforts and their resulting actions.

3. Defined Metrics

Few useful metrics exist for gauging progress toward stated goals or to define the need for action as a result of changes from historic baselines. Having defined metrics available would allow more appropriately focused efforts for antibiotic use and resistance monitoring and greater "buy in" among stakeholder groups for the monitoring efforts and their resulting actions.

4. Funding Needs

There is not enough sustained, supportive funding to fill the critical information gaps. A sustained source of funding to address the issue of antimicrobial resistance would allow meaningful, longer-term progress in filling the gaps that would result in appropriate and effective policies.

5. Addressing the Gaps

Stakeholders suggested the following activities, which might help alleviate the deficits outlined above:

- Take a holistic approach to assessing risks associated with antimicrobial resistance, partly by considering the entire microbiome and resistome.
- Strengthen the NARMS program by improving data accessibility and understandability and improve the representation of the data (organisms, sources, genes vs. phenotypes).

- Strengthen the NAHMS program by increasing the frequency of studies and incorporating prospective monitoring.
- Conduct research via a long-term plan, devise a strategic focus to fill critical gaps in ecologic understanding, and evaluate the economic issues associated with antimicrobial resistance.
- Conduct outreach and education activities to better deliver existing USDA information and by supporting the stewardship of antimicrobial drugs.

B. Management Practices to Reduce Antibiotic Resistance

Assuring the health and productivity of livestock and poultry populations is the key to sustaining an adequate food supply and will contribute to an expansion of international trade. Antibiotics are one tool that has been used to achieve these goals. Other tools are also available and, in some cases, the use of alternative strategies or tools can have a sparing effect on the use of antibiotics. As such, use of these alternatives may have a role in dealing with the antibiotic resistance issue. Currently, the USDA collects information on management practices that can affect the development of antibiotic resistance. With additional funding, USDA could conduct coordinated, prospective sampling for microbes with simultaneous collection of management information to capture changes over time and temporal relationships to inform appropriately targeted risk management decision-making.

There are gaps in our understanding that hinder making effective and appropriate tradeoff decisions among the alternatives. Some of these include:

- a. Lack of understanding of the effects of preharvest strategies and management practices at slaughter on outcomes at slaughter and beyond
- b. Lack of consistent sampling over time to capture reasons for shifts in microbial populations
- c. Lack of understanding of the mechanisms by which antibiotics enhance production and thus what unintended consequences may be for various policy decisions
- d. Lack of understanding of the interchangeability of management practices or strategies
- e. Lack of metrics for assessing the success of specific management practices such as the removal of antibiotic drug use in animals to improve public health
- f. Lack of consideration of trade impacts of management decisions, such as the withdrawal of antibiotics

Addressing these gaps would allow informed trade-off decisions at all levels from production management to policy. Stakeholders suggested two activities to help alleviate the gaps:

- 1. Conduct ecologic studies to simultaneously evaluate management practices and strategies, and
- 2. Sample consistently over time to capture reasons for microbial shifts.

C. Alternative Medical Interventions

In view of the emerging global concerns over antibiotic resistance, there is a pressing need to have a scientific forum to discuss alternatives to antibiotics in food animal production. The global increase in antibiotic resistance among bacterial pathogens is believed to be due in part to the use of antibiotics in animal production. Consequently, there is a growing concern that the potential development of antibiotic-resistant strains within food animal production facilities and among food-borne bacteria could seriously compromise current medical interventions and public health. Some countries such as those in the European Union have discontinued the use of antibiotic growth promoters (AGPs), and some Asian countries are planning to follow the European Union in banning AGPs. These restrictions are not limited to developed countries with intensive animal production systems. They are also being considered in developing countries where people are dependent on the production of livestock and poultry for their livelihood. It is clear that the continued reliance on antibiotics in animal production will inevitably result in further restrictions, including the international trade of food animal products. There is also increasing scientific evidence that implicates certain antibiotics with disrupting the normal flora of the gut of animals and humans, yielding negative consequence on the immune system, disease resistance, and health. As we move into the 21st century and the demands for animal food products increase to meet the nutritional needs of a growing world population, alternative medical interventions to prevent and control animal diseases is a global issue and a critical component of efforts to alleviate poverty and world hunger.

1. Problem 1

There is a shortage of antimicrobials, either commercially available or under development for treating microbial infections of animals and, in particular, products that are effective against pathogens with antibiotic-resistant genes. There are concerns that the effectiveness of many or all antibiotics produced will eventually be confounded by resistance development in the target pathogens.

Potential Solutions: Develop innovative antimicrobials that provide alternatives to conventional antibiotics and that are refractory to resistance development. Numerous alternative strategies have been proposed and should be explored: prebiotics; probiotics; bacteriophages; bioactive phytochemicals; essential oils; lytic enzymes; host antimicrobial peptides; bacteriocins; immune enhancers; transgenic expression of antimicrobial proteins; vaccines; and selective breeding paradigms that take advantage of naturally occurring disease resistance.

Priorities: With the goal of implementing alternative strategies as quickly as possible, the following four strategic objectives should be implemented as soon as possible: 1) research to discover and develop alternatives to antibiotics; 2) develop alternatives that more readily fit into current management practices and have efficacy in reducing resistant strain development; 3) develop alternatives that face the fewest hurdles to both public perception and regulatory agency approval; and 4) develop alternatives to antibiotics that can treat as broad a range of target pathogens as possible while maintaining as low a level of resistance development as possible. A

top priority should be to work with regulatory agencies to ensure regulatory pathways are in place to support the development of alternatives to antibiotics. Exploring novel antibiotics for synergy with existing antibiotics as a means to enhance or prolong the useable lifetime of existing antibiotics should also be given serious consideration. Longer-term goals should include verification that a novel alternative to an antibiotic is refractory to resistance development.

2. Problem 2

Commensal bacteria can serve as a reservoir of resistance genes for eventual transfer to pathogenic strains. One strategy to avoid selecting for resistance genes in commensal bacteria is to develop alternative antimicrobials that are limited in their target pathogen range (e.g., bacteriophages are usually limited to killing those bacteria that are within a narrow host range). However, this limits the efficacy of the antimicrobial against a wide range of pathogens and often demands expensive diagnostics to identify the specific attributes of the pathogen to be treated.

Potential Solutions: Consider identifying multiple agents that can work synergistically; for example, the production of phage cocktails that would target numerous pathogens simultaneously.

Priorities: A need exists for studies to identify those animal pathogens that confer the highest negative impact on several levels: animal health, human health, food quality, food safety, cost of not treating vs. cost of treatment, and maintenance of resistance gene reservoirs.

These studies should be highly specific to account for the many factors that can affect the findings (e.g., geography, climate, species of livestock, livestock management practices to allow for accurate interpretation and focused risk management).

3. Problem 3

Eliminating the use of antibiotics for animal production may have adverse consequences on the production, health, and welfare of animals.

Potential Solutions: Although the mechanisms by which antibiotics enhance animal production and health have not been fully investigated, scientific advances resulting from new research tools such as metagenomics and other genome-enabled technologies are providing insights into the ecology of the gut microbiome, host-pathogen interactions, immune development, nutrition, and health. These new research tools provide new opportunities to develop feed additives to enhance the production and health of livestock, poultry, and fish.

Priorities: Invest in basic research projects that will further our understanding of the gut microbiome and gut health. Investigate the effectiveness of new feed additives in enhancing feed conversion, weight gain, and other production parameters. Identify and characterize the mechanisms associated with enhanced animal production. Identify and develop alternatives to

antibiotics that do not disrupt the normal flora of the gut of animals but rather enhance the immune system, disease resistance, and health.

D. Education, Training, and Extension/Outreach

1. Problems/Gaps

Several workshop attendees remarked that the general public and many policymakers have prematurely and incorrectly concluded that the important questions have already been answered about 1) the causes of antibiotic resistance development (i.e., the use of antimicrobials in animals is the principle source of this threat to efficacy in humans) and 2) the best ways to identify and manage or control the actual sources of increased risk. The remarks suggest that insufficient training in the animal production process remains a challenge. Some participants predicted a new training demand for veterinarians will occur should the FDA's two new guidances and the veterinary feed directive rule be approved. The apparent loss of support for the CDC's "Get Smart on the Farm" program may leave an outreach gap that USDA could seek to reenergize. Finally, State Veterinary Practice Acts need to be considered as many have evolved over the years to lessen the need for involvement of a veterinarian in the purchase and use of antimicrobial agents and other drugs.

2. Potential Solutions

Workshop participants proposed that USDA needs to better educate the public and policymakers on several matters related to agricultural animal production and antimicrobial resistance if sound policy on this important issue is to prevail. To change general public and policymaker misperceptions about antimicrobial resistance, fundamental solutions will require a significant increase in (new) resources devoted to the development and distribution of high-quality, sciencebased antimicrobial resistance information. One mechanism to support such an effort would be to develop an antimicrobial resistance— and extension education—focused Request for Applications (RFAs) under NIFA's integrated program authority. To achieve a goal as ambitious as described, one or more multi-institutional Coordinated Agricultural Project (CAP)-scale, multiyear (i.e., 5year) grants could be considered in order to give the best chance for success. Such a new initiative would attract the best applicant teams, and the most effective ones would likely tap into and strongly leverage the significant extension agent and extension specialist human resources already working within the nationwide system of Cooperative Extension offices and Land Grant Universities. Given necessary additional resources, NIFA could use similar approaches to encourage the development of innovative, top-quality formal classes or curricula for postsecondary, postgraduate, and professional (veterinary) educational levels to bolster the antimicrobial resistance literacy of subsequent generations of Americans. The RFAs could be worded such that among the topic areas defined as eligible would be those that would attract proposals and teams prepared to address the most serious education and outreach gaps first. Other important steps to filling education, training, and outreach gaps relative to antimicrobial resistance are 1) sustained strong support for extension, and 2) the development of education

programs aimed at delivering science-based information to state legislators who control the language in their respective Practice Acts.

3. Priorities

Absent reliable, science-based information disseminated widely, strategically, convincingly, and engagingly, the prospects for evolution of effective antimicrobial resistance policy are greatly reduced. Therefore, among the higher priority issues for implementation should be 1) basic educational program for users of the products to ensure judicious use, and 2) identification of new funding to support new multi-award—capacity, CAP-scale, competitive grants (Agriculture and Food Research Initiative) opportunities. Sufficiently well funded, these CAP awards could reach targeted audiences, from grades K–12 to adults to legislators, in a coordinated campaign to spread validated, science-based information about the true relative risks and benefits of various antimicrobial resistance policy options.

APPENDIX: PARTICIPANTS

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