

Research Gap Analysis Workshop

National Animal Disease Center

Ames, Iowa

April 5-7, 2016

Purpose: Identify strategic research initiatives for agricultural animals, plants, and food safety that will enable the development of alternatives to antibiotics that could reduce the use of medically important antibiotics.

The intent of the workshop is to identify gaps in knowledge associated with alternatives to antibiotics. The goal of the research gap analysis will be to identify diseases in animal and plant production that will be the most affected by the reduction of antibiotic usage in agriculture; either because they no longer work due to antimicrobial resistance, or because of regulatory restrictions on their use to safeguard medically important antibiotics for veterinary and human use. Importantly, the workshop will provide a forum to discuss and identify alternative antimicrobial strategies and their mechanisms of action for disease prevention, treatment, and agricultural production. This information will be useful to identify strategic areas of research for maintaining a healthy and safe food supply for the agricultural communities and consumers of agricultural products in North America. This workshop will include representation from government and academic scientists, food animal and plant commodity groups, and regulatory and funding agencies (FDA, APHIS-CVB, and USDA-NIFA).

This workshop is organized with the support of the Center for Food Security and Public Health (Iowa State University), PROCINORTE (Inter-American Institute for Cooperation on Agriculture), and USDA Agricultural Research Service (ARS) and National Institute of Food and Agriculture (NIFA).

Organizing Committee: Shawn Bearson; Crystal Loving; Hyun Lillehoj; John Lippolis; Virginia Stockwell; Caird Rexroad; Deb Fravel; Gene Lester; Charlie Walthall; Marcus Kehrl; Jim Roth; Dawne Buhrow; Gary Sherman; Mervalin Morant; Cyril Gay.

Preliminary Program

DAY 1 TUESDAY AFTERNOON

APRIL 5, 2016

	Opening: 1:00-2:15 PM	
	<i>Welcome Address</i> Marcus Kehrli, Director, National Animal Disease Center (NADC), Agricultural Research Service (ARS), USDA	
	<i>USDA's Extramural Investments in Sciences Supporting Development of Alternatives to Antimicrobials for Livestock</i> Gary Sherman, National Program Leader National Institute of Food and Agriculture, USDA	
	<i>Program Review – Workshop Objectives and Expected Outcomes</i> Cyril G. Gay, National Program Leader Office of National Programs Agricultural Research Service, USDA	
	<i>Keynote Presentation: Imrestor™: The journey of a novel antibiotic alternative from hypothesis to product</i> Peter Canning – Director, Bioproduct Innovation, Elanco Animal Health	
	Break 2:15-3:00 pm (long break to encourage interactions)	

Session 1

Industry Perspective

The aim of this session is to identify issues that are affecting agriculture due to the loss of antibiotics and identify needs and expectations for alternatives to antibiotics from the agricultural community.

	<p>Session 1: 3:00-4:15 pm</p> <p>Moderator: Cyril Gay, ARS, USDA</p> 
	<p><i>Beef Cattle</i></p> <p>Kathy Simmons, National Cattlemen's Beef Association (NCBA)</p>
	<p><i>Dairy Cattle</i></p> <p>Leo Timms, Morrill Professor Animal Science & Vet Med, Iowa State University</p>
	<p><i>Swine</i></p> <p>Jennifer Koeman, Director, Producer and Public Health National Pork Board (NPB)</p>
	<p><i>Chickens</i></p> <p>Dave Hermes, Regional Director of Veterinary Services Perdue Foods LLC</p>
	<p><i>Turkeys</i></p> <p>Gretta Irwin, Executive Director / Home Economist Iowa Turkey Federation & Iowa Turkey Marketing Council</p>



Plants
**Rachel B. Elkins, Pomology Farm Advisor, Lake and Mendocino Counties,
University of California**



Aquaculture



Panel discussion with industry speakers: 4:15-4:45 pm




DAY 2 WEDNESDAY ALL DAY

APRIL 6, 2016

Session 2

Alternatives to Antibiotics: Vaccines that could reduce the use of medically important antibiotics

The aim of this session is to identify gaps in vaccines for production diseases. Review the OIE report on vaccines that could reduce the use of medically important antibiotics and identify potential research solutions.




	Session 2: 8:00 – 9:00 am	
	Moderator: Marcus Kehrli, ARS, USDA	
	<i>Current progress and challenges in developing vaccines against Post-weaning diarrhea (PWD)</i> Weiping Zhang, Kansas State University	
	<i>Patented vaccine platform against Pasteurellesae (BRDC in beef cattle)</i> Bob Briggs, National Animal Disease Center (NADC), ARS, USDA	

Session 3

Alternatives to Antibiotics: Lessons from Nature

The aim of this session is to address novel biocontrol approaches for preventing and/or treating bacterial pathogens (and where applicable viral and parasitic pathogens) in food animal production. These novel biocontrol approaches should employ strategies specifically geared to reduce or eliminate drug resistance development. These strategies may include: antimicrobial peptides from nature, probiotics and prebiotics, bacteriophages and lysins, naturally occurring antibacterial lytic enzymes such as bacteriocins that share an added 'no resistance confidence factor' by having co-evolved with their target hosts, recombinant or hyperimmune therapeutic




antibodies, siRNAs, or other novel biotherapeutic alternatives in the pipeline, including demonstrated synergistic approaches that could both reduce costs and increase efficacy while reducing the risk of drug resistance development.

	Session 3: 9:00 – 10:15 am	
	Moderator: Gary Sherman, NIFA, USDA	
	<i>Biological control using beneficial bacteria</i> Virginia Stockwell- Horticulture Crops, ARS, USDA	
	<i>Phytochemicals to prevent and treat poultry diseases.</i> Hyun Lillehoj, Beltsville Area Research Center, ARS, USDA	
	Break: 10:15-10:45 pm	

Session 4

Altering Innate Defense Mechanisms to Enhance Disease Resistance and Treat Animal Infections

This session will address novel drug-free alternative host directed strategies to enhance innate defense mechanisms by modulation of innate immune pathways or activation of conserved innate immune sensing molecules of the host immune system. This session will focus on topics such as regulators of innate signalling derived from natural host defense peptides, and novel biotherapeutics and anti-infectives targeting conserved innate sensing receptors such as TLR, NLR, and RLR as means to activate effector mechanisms against infectious diseases where current therapeutic drug therapy is not working. Examples of technologies involving altering innate defense mechanisms as adjunctive therapies to treat human infectious and inflammatory diseases will be provided. Emphasis will be given to new technologies for enhancing animal production with practical examples from new technologies that have reached commercialization.

	Session 4: 10:45-12:00 pm	
	Moderator: Crystal Loving, ARS, USDA	
	<i>Antimicrobial peptides as alternatives to antibiotics: boom or bust?</i> Glenn Zhang, Oklahoma State University	
	<i>Zelnate, a licensed bacterial-produced plasmid DNA with a liposome carrier that stimulates the innate immune system</i> James Little, Bayer Animal Health	
	Panel discussion with 6 morning speakers: 12:00-12:30 pm	

Session 5

The Gut Microbiome and Immune Development, Health and Disease

Recent advances are demonstrating that the microbiota plays a key role in health and disease. Sequencing and microbiome analysis have enabled a much more precise description of microbial communities in gut ecosystems than has hitherto been possible. The challenge now is to relate description to function, particularly as it relates to health and disease in animals and humans. This session will attempt to capture state-of-the-art results in farm animals and humans to assess how microbiome analysis is helping to solve disease problems. Changes in the microbiome can lead to changes in the host animal's immune response, affecting inflammation. Understanding the microbiome changes that accompany, and possibly cause, inflammation should lead to new methods to medicate disease and improve the health of animals in animal production.

	Session 5: 1:30-2:45 pm	
	Moderator: Shawn Bearson, ARS, USDA	
	<i>Identifying applications from the gastrointestinal microbiota response to antibiotic exposure and Salmonella challenge</i>	
	Heather Allen, National Animal Disease Center (NADC), USDA	
	<i>Microbial communities in the chicken/turkey gastrointestinal tract related to health and development</i>	
	Timothy Johnson, University of Minnesota	
	Break: 2:45-3:15 pm	

Session 6

Alternatives to Antibiotics to Promote Growth in Livestock, Poultry, and Aquaculture Production

The aim of this session is to explore novel approaches that can be used as alternatives for antibiotic growth promoters in poultry, swine, ruminant, and aquaculture production. Although data on field performances are of importance, a key aim of this session is to improve knowledge on mechanisms of action of the growth-promoting characteristics of the proposed approaches. Approaches to be discussed can be of any nature, and can affect either the host's function or the host's microbiota, but should be sustainable and developed in a scientifically sound way. Emphasis will be put on the development of novel methods and compounds and on the identification of the mechanism of action of available strategies.

	Session 6: 3:15-4:30 pm	
	Moderator: Hyun Lillehoj, ARS, USDA	
	<i>Mechanism of Action and Efficacy of Biochanin A: A Phytochemical Antimicrobial Growth Promoter</i>	
	Michael D. Flythe, USDA-ARS Forage-Animal Production Research Unit, Lexington, Kentucky	
	<i>Dietary feed additives that influence growth performance of swine</i>	
	Joel DeRouchey, Kansas State University	
	Panel discussion with four afternoon speakers: 4:30-5:00 pm	

DAY 3 THURSDAY UNTIL EARLY AFTERNOON

APRIL 7, 2016

SESSION 7

Regulatory Pathways to Enable the Licensing of Alternatives to Antibiotics

This session will review the regulatory pathways in the United States to license alternatives to antibiotics. The particular regulatory challenges that are faced in taking new molecules from discovery to commercial production will be addressed. This session will also cover how to seek approval for labeling claims that are new with specific focus on claims that a product is able to reduce the use of antibiotics.

	Session 7: 8:00-9:30 am	
	Moderator: Renee Wagner, ARS, USDA	
	<i>FDA's innovation initiative to evaluate novel emerging technologies and international cooperation in the area of innovation</i>	
	Cindy L. Burnsteel, Center for Veterinary Medicine, FDA	
	<i>Center for Veterinary Biologics regulatory program applicable to alternatives to antibiotics</i>	
	Bryon Rippke, Center for Veterinary Biologics, APHIS, USDA	
	<i>Industry perspective on implementation</i>	
	Michael Roof, Boehringer-Ingelheim	
	Panel discussion with three speakers: 9:00-9:30 pm	

SESSION 8
Breakout Sessions
Gaps and Solutions

	<p>Session 8: 9:30 am – 2:00 pm</p> <p>Box Lunch: 11:30-12:30</p> 
	<p>Guidance for breakout sessions and go right into breakout rooms</p> <p>Cyril Gay, National Program Leader, ARS, USDA</p>
	<p>Swine</p> <p>Moderators: Jennifer Koeman, National Pork Board Susan L. Brockmeier, ARS, USDA</p>
	<p>Cattle</p> <p>Moderators: Kathy Simmons, National Cattlemen’s Beef Association John Lippolis, ARS, USDA</p>
	<p>Poultry</p> <p>Moderators: Dave Hermes, Perdue Foods LLC Hyun Lillehoj, ARS, USDA</p>
	<p>Aquaculture</p> <p>Moderators: Craig Shoemaker, ARS, USDA Timothy Welch, ARS, USDA</p>
	<p>Plants</p> <p>Moderators: Rachel B. Elkins, University of California Virginia Stockwell, ARS, USDA</p>
	<p>Gap Analysis results: 12:30-2:00</p>

Conclusion

Conclusions/Summary of Key Recommendations/Next Steps

Cyril Gay, National Program Leader, ARS, USDA

