WELCOME!

to the

National Stakeholder Webinar Listening Session

RESEARCH, EDUCATION & EXTENSION PRIORITY SETTING FOR

Antimicrobial Resistance (AMR)

Hosted Jointly by

USDA NIFA/ARS/Chief Scientist Office

Tuesday July 19, 11:30am-2:30pm EDT

Welcome Stakeholders

The remaining 13 webinar topics are:

- Turkey
- Swine
- Specialty Farm Species
- Beef
- Cross cutting: Animal Well-being
- Poultry – Broiler/Meat

- Dairy
- Aquaculture
- Sheep
- Cross-cutting: Microbiome
- Poultry – Layer/Breeder
- Goats
- Horses

https://nifa.usda.gov/animal-health-stakeholder-webinar-series

Agenda

- Overview of NIFA, ARS and Office of the Chief Scientist
- Goals of today's webinar
- Ground Rules
- AMR Presentation – Discussion Leader, Dr. Morgan Scott
  - Preliminary top 5 priorities
- ~20min in-depth discussion on each priority
- Wrap Up

NIFA Overview

Gary Sherman, DVM, PhD

NIFA National Program Leader (NPL) for Veterinary Science, Acting NPL for Animal Agrosecurity

NIFA's Mission & Vision

- USDA's primary <u>extramural</u> agency to advance food & agricultural sciences
- We <u>lead & fund</u> initiatives that ensure the long-term viability of agriculture by:
  - ➤ Supporting **research**, **education**, & **extension activities** in partnership with institutions and other entities across US *(Land-Grant University System, other universities/colleges, government, private, and non-profit*
- <u>AGENCY BUDGET:</u>
  - $1.49 Billion (2016)
  - $1.88 Billion (2017 Request)
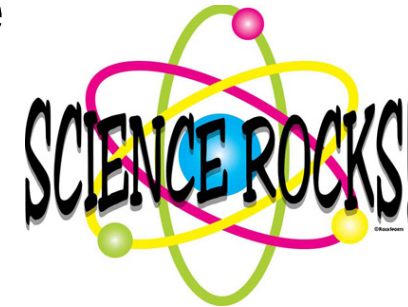
NIFA Provides

- **<u>Competitive grants</u>:**
  - – Basic & applied research, education, & extension activities
  - – Projects that integrate research, education, & extension functions.

- **<u>Capacity grants</u>:**
  - – Distributed by formula to Land-Grant Universities, Schools of vet medicine, & other partners to maintain "capacity" to conduct research & extension.
  - – 25% research funds → <u>Multi-state</u> Research Committees (including animal health topics)

- **<u>Non-competitive grants</u>:** Directed by Congress to designated institutions for research, education, or extension on topics of importance to a state or region.

NIFA Covers Many Topics
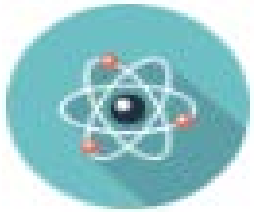
Advanced Technologies
- Bioenergy
- Biotechnology
- Nanotechnology

Animals
- Animal Breeding
- Animal Health
- Animal Production
- Aquaculture

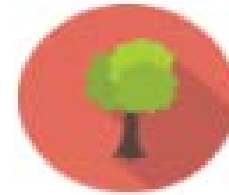## Business and Economics
- Markets and Trade
- Natural Resource Economics
- Small Business

Education
- Minority Serving Institutions
- Teaching and Learning
- Workforce Development

Environment
- Climate Change
- Ecosystems
- Invasive Pests and Diseases

Farming and Ranching
- Agricultural Safety
- Agriculture Technology
- Farmer Education
- Organic Agriculture
- Small and Family Farms

NIFA's Many Topics Cont'd

Food Science
- Food Quality
- Food Safety

Health
- Nutrition
- Obesity
- Wellness

International
- Global Engagement
- Global Food Security

Natural Resources
- Air
- Forests
- Grasslands and Rangelands
- Soil
- Water

People
- Community Vitality
- Family Well-Being
- Youth

Plants
- Crop Production
- Pest Management
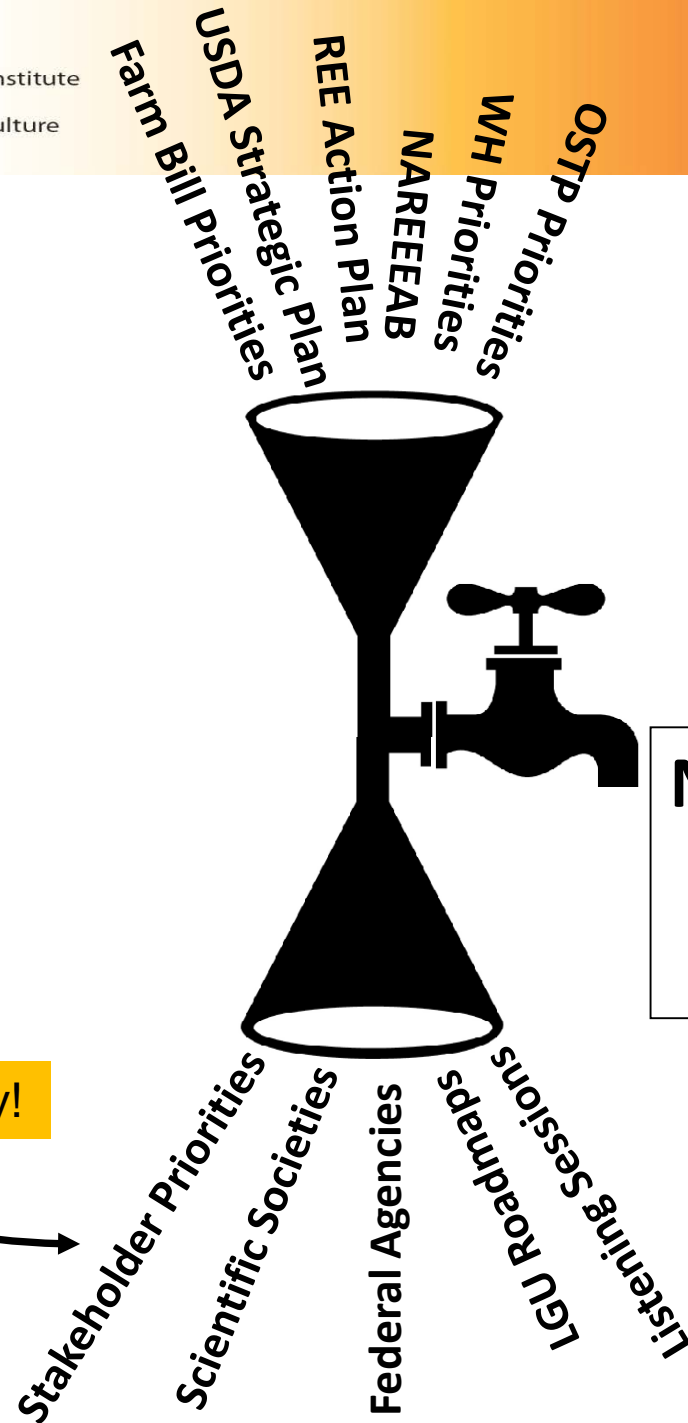- Plant Breeding
- Plant Health

NIFA's Animal Disease Funding
By Categories (2010-2014 Avg/year)*

- Animal Diseases (virus, bacteria, prion, non-infectious) ------ $ 27.7 M / year
- Animal Genome --$ 9.3 M / year
- Zoonotic Diseases & Parasites Affecting Humans --------------$ 4.0 M /year
- Genetic Improvement of Animals (assumed 1/3 for health) ---- $ 2.6 M /year
- Internal Parasites of Animals ---$ 2.2 M / year
- External Parasites of Animals --$ 1.3 M / year
- Toxic Chemicals, Poisonous Plants, Naturally Occurring
  Toxins, & other Hazards Affecting Animals -------------------------$ 1.2 M / year

- **TOTAL INCLUDES <u>ALL</u> AGRICULTURAL ANIMALS----------$48.3 M / year**

* Data Source: NIFA's Data Gateway: https://nifa.usda.gov/data

USDA NIFA — United States Department of Agriculture | National Institute of Food and Agriculture

INVESTING IN SCIENCE | SECURING OUR FUTURE | WWW.NIFA.USDA.GOV

Priority Setting

Farm Bill Priorities
USDA Strategic Plan
REE Action Plan
NAREEEAB
WH Priorities
OSTP Priorities

NIFA Competitive Priorities: Request For Application (RFA) Priorities

Thank you for participating today!

Stakeholder Priorities
Scientific Societies
Federal Agencies
LGU Roadmaps
Listening Sessions

ARS Overview

Cyril G. Gay, DVM, PhD
Senior National Program Leader
Animal Production and Protection

Office of National Programs
Beltsville, Maryland

Agricultural Research Service (ARS)

- <u>In-house/intramural</u> science research arm of USDA
- Farm-to-table research scope
- Information and technology transfer
- Administration and stakeholder priority setting process
- National Programs

- 700+ projects
- 2000+ scientists and post docs
- 90+ laboratories
- $1.1 billion annual budget
- Partnerships NIFA, universities and industry
- International collaborations

Office of National Programs

- Provide Program Planning & Leadership for ARS funding
- Receive input on 'high priority' research needs (relevance)
- Develop Action Plans & research objectives for each research project with the scientists
- Identify opportunities to leverage ARS research activities (intergovernmental, international, national stakeholder groups, regulatory)
- Coordinate research direction across National Programs

ARS National Programs

Natural Resources & Sustainable Agricultural Systems (~20%)	Crop Production& Protection (~35%)	Animal Production & Protection (~15%)	Nutrition, Food Safety & Quality (~30%)
• Water Availability and Watershed Management • Climate Change, Soils, and Emissions • Biorefining • Agricultural and Industrial Byproducts • Pasture, Forage and Rangeland Systems • Agricultural System Competitiveness and Sustainability	• Plant Genetic Resources, Genomics and Genetic Improvement • Plant Diseases • Crop Protection and Quarantine • Crop Production	• Food Animal Production • Animal Health • Veterinary, Medical, and Urban Entomology • Aquaculture	• Human Nutrition • Food Safety (Plant & Animal Products) • Quality and Utilization of Agricultural Products

Animal Health
National Program 103

- 2 National Program Leaders

- FY16 Budget: $70 million

- 37 Research Projects

- 9 Locations

- 100 Scientists

- Laboratories with focus

- Specialized scientific expertise

- Linked to 4 National Programs
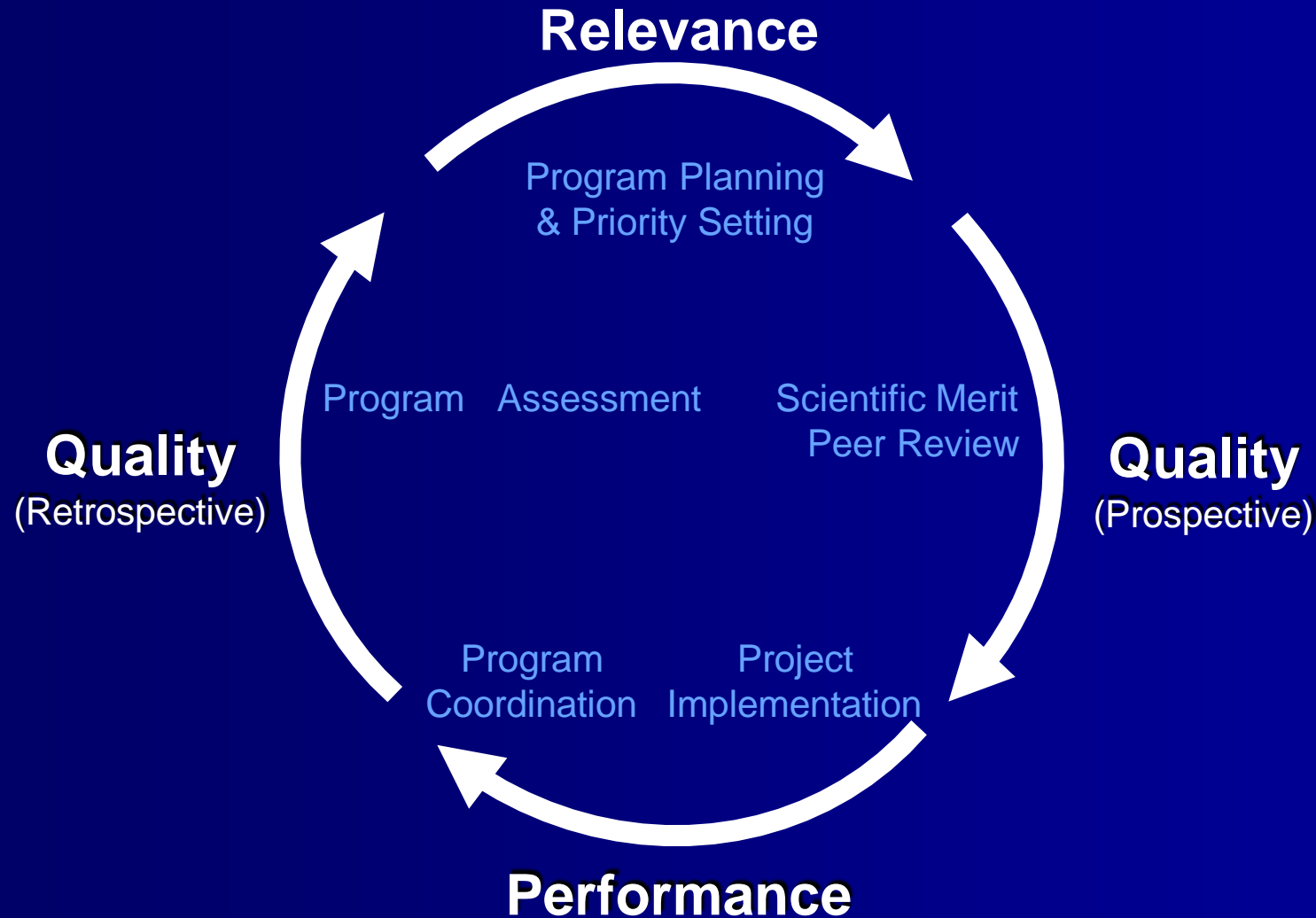
Animal Health
National Program 103

- ## Vision:
  - To be recognized worldwide as a leader in animal health research with an emphasis on delivering effective solutions to prevent and control animal diseases that impact agriculture and public health.

- ## Mission:
  - To deliver scientific information and tools to detect, control, and where feasible, eradicate animal diseases of high national priority.

Animal Health Research Components

1: Biodefense

2: Antimicrobial Resistance

3: Zoonotic Bacterial Diseases

4: Respiratory Diseases

5: Priority Production Diseases

6: Parasitic Diseases

7: Transmissible Spongiform Encephalopathies

ARS National Program Cycle

OMB Research & Development Investment Criteria

Relevance

Program Planning
& Priority Setting

Program   Assessment   Scientific Merit
Peer Review

Quality
(Retrospective)

Quality
(Prospective)

Program   Project
Coordination   Implementation

Performance

USDA
Office of the Chief Scientist Overview

Neena Anandarman, DVM, MPH

Senior Advisor on Animals and Animal Products

USDA's Office of the Chief Scientist

- Strategic coordination of the science that informs the Department's and the Federal government's decisions, policies and regulations that impact all aspects of U.S. food and agriculture and related landscapes and communities
- Departmental coordination across 8 USDA agencies and with federal partners in addressing AMR for the Combating Antibiotic Resistant Bacteria (CARB) National Action Plan (NAP)

USDA's Office of the Chief Scientist

- CARB NAP Goal 4 is research: Input from stakeholders and USG partners for research priority-setting for AMR for the next 5 years is extremely valuable across USDA agencies since all of the activities of USDA are interconnected and viewed through a One Health lens
- Research, surveillance, and education and outreach efforts inform each other
- Information from this workshop will help inform USDA in continually updating its efforts to address AMR while moving forward with our federal partners to implement the CARB National Action Plan.

Animal and Plant Inspection Service Veterinary Services

Larry Granger, DVM

USDA Antimicrobial Resistance Program Lead

Today's Goals

- Identify AMR Research, Education and Extension priorities for the next 5 years **_from the perspective of animal agriculture_**
- By the end of this webinar, identify at least 5 science priorities of greatest importance.
- Express priorities at a level that will effectively inform and guide intramural and extramural science priority setting & solicitation (e.g., not too prescriptive, not too general; see next slide)
- Brainstorm beyond your specific constituency & personal bias
- Along with pre-webinar and post-webinar submitted information, generate core concepts & content of final report

Animal Health & Disease
Program Area Priority Code A1221
Excerpt from 2016 Foundational RFA

Cellular, molecular, genomic/genetic or whole-animal aspects of animal health and disease, especially focusing on one or more of the following:
• Maintenance of homeostasis, including influences of microbiomes on health and disease;
• Disease prevention (e.g., vaccines, diagnostics, enhanced innate or adaptive immunity, disease resistance or susceptibility, or management); or
• Therapeutic interventions for disease reduction/treatment, including alternatives to current antimicrobial treatments.

Ground Rules

- ~20 minutes of discussion on top 5 topics
- ~20 minutes on each topic
  - What specific research questions or initiatives should be prioritized to fill the gaps within each topic?
  - What extension and education needs exist pertaining to the topic?
  - What new tools or methodological innovations are needed to effectively address high-priority knowledge gaps, and/or education/extension needs?
- Keep comments short
- Provide full comments via webchat or email if Notes don't capture your full intent

Animal Health Stakeholder Webinar - Antimicrobial Resistance

USDA-NIFA Division of Animal Systems, USDA-ARS Animal Health USDA Office of the Chief Scientist

June 19, 2016 11:30 EDT

H. Morgan Scott DVM, PhD

College of Veterinary Medicine and Biomedical Sciences

Texas A&M University

College Station, Texas, U.S.A.

hmscott@cvm.tamu.edu

Purpose

- "USDA's Office of the Secretary, USDA-NIFA's Division of Animal Systems & USDA-ARS Animal Protection and Production programs are hosting this webinar to solicit comments on **where USDA can best focus its limited resources and efforts across programs involving antimicrobial resistance in the context of animal health**".
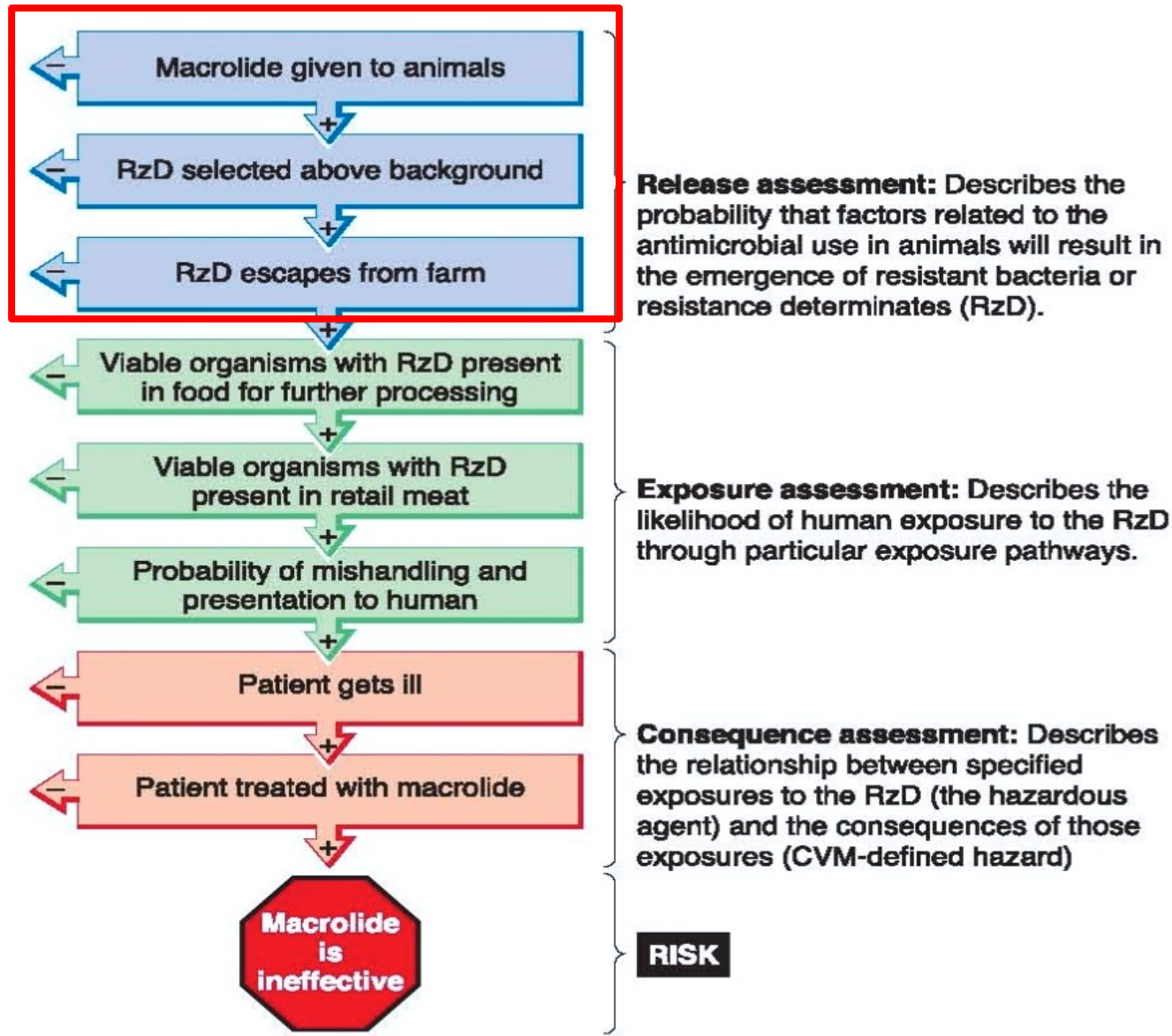
Overview

- Some points for consideration
- Set of slides developed from pre-webinar stakeholder input
  - 5 major themes
    - Research, extension/outreach, education
  - Additional uncategorized themes
- Webinar stakeholder inputs

Points for consideration

- In the context of 'animal health'
  - Generally speaking, focusing on those areas with the potential to impact animal health; either negatively or positively, as efforts are made to mitigate AMR
    - Research, extension/outreach, education efforts to address these areas
  - Focus here is not directly on potential public health risks, though such influence is clearly present

Risk assessment framework

Hurd (Microbe, 2006)

FIGURE 1

Release assessment: Describes the probability that factors related to the antimicrobial use in animals will result in the emergence of resistant bacteria or resistance determinates (RzD).

- Macrolide given to animals
- RzD selected above background
- RzD escapes from farm

Exposure assessment: Describes the likelihood of human exposure to the RzD through particular exposure pathways.

- Viable organisms with RzD present in food for further processing
- Viable organisms with RzD present in retail meat
- Probability of mishandling and presentation to human

Consequence assessment: Describes the relationship between specified exposures to the RzD (the hazardous agent) and the consequences of those exposures (CVM-defined hazard)

- Patient gets ill
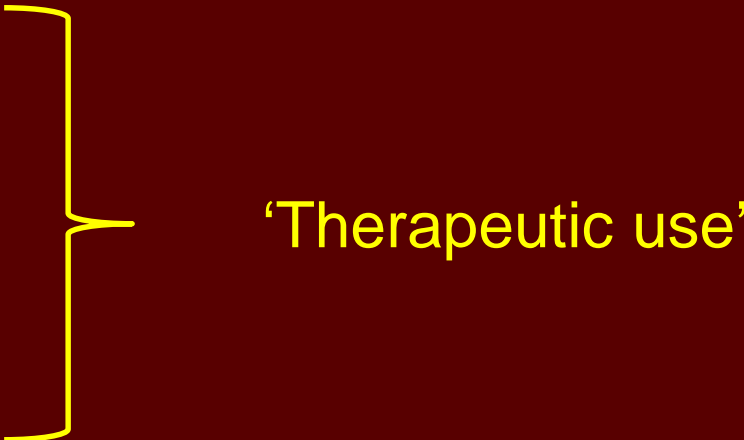- Patient treated with macrolide

RISK

- Macrolide is ineffective

Stepwise risk assessment-based approach for estimating the impact on human health from macrolide resistance that develops on poultry farms.
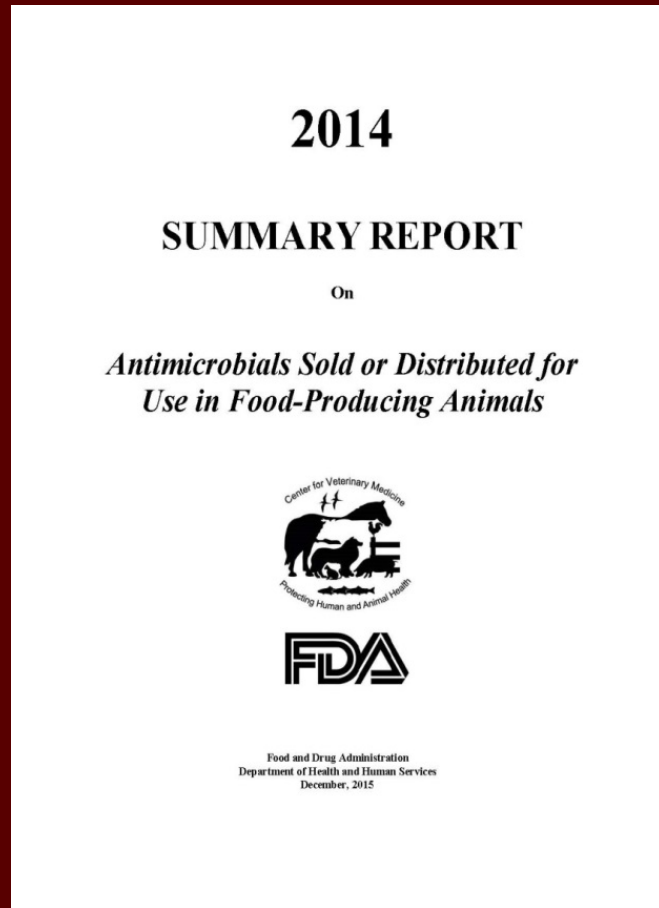
Classification of antibiotic uses in animal agriculture

- Broadly speaking:
  - 1) Treatment,
  - 2) Control,
  - 3) Prevention,
  - 4) Growth promotion / production efficiency
    - Phased out on December 31, 2016 via GFI 209/213
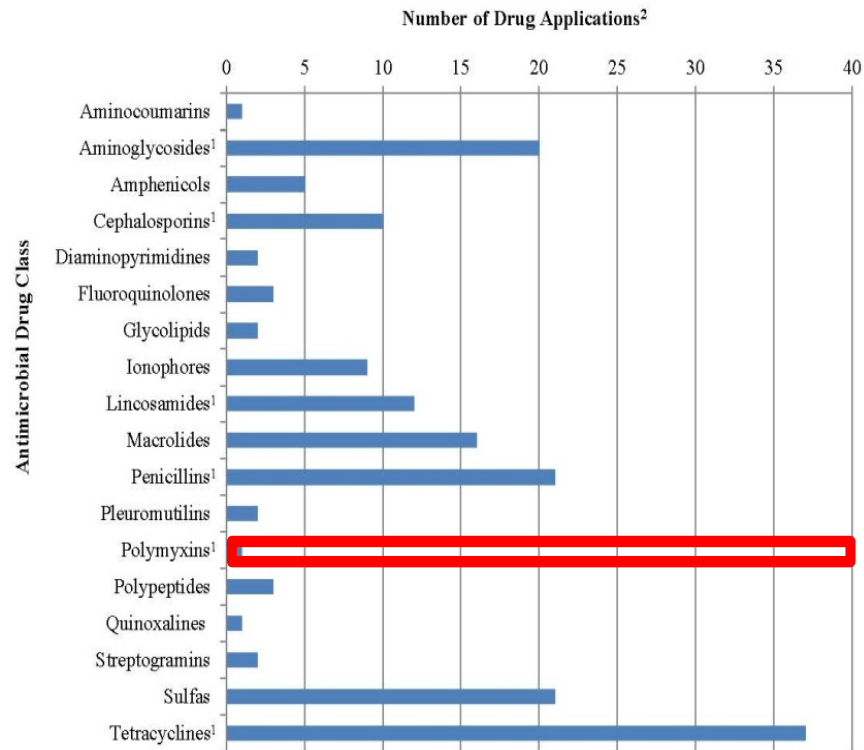
'Therapeutic use'

Antibiotic uses in animal agriculture

2014

SUMMARY REPORT

On

Antimicrobials Sold or Distributed for Use in Food-Producing Animals

Food and Drug Administration
Department of Health and Human Services
December, 2015

ANTIMICROBIAL DRUGS APPROVED FOR USE IN FOOD-PRODUCING ANIMALS[1]
ACTIVELY MARKETED IN 2014
DOMESTIC SALES AND DISTRIBUTION DATA
REPORTED BY MEDICAL IMPORTANCE AND DRUG CLASS

	Drug Class	Annual Totals (kg)[2]	% Subtotal	% Grand Total
Medically Important[3]	Aminoglycosides[1]	304,160	3%	2%
	Cephalosporins[1]	31,722	<1%	<1%
	Fluoroquinolones	17,220	<1%	<1%
	Lincosamides[1]	233,681	2%	2%
	Macrolides	621,769	7%	4%
	Penicillins[1]	885,975	9%	6%
	Sulfas	452,224	5%	3%
	Tetracyclines[1]	6,600,849	70%	43%
	NIR[1,5]	328,389	3%	2%
	Subtotal	*9,475,989*	*100%*	*62%*
Not Currently Medically Important[4]	Ionophores	4,718,650	80%	31%
	NIR[6]	1,163,571	20%	8%
	Subtotal	*5,882,221*	*100%*	*38%*
	Grand Total	*15,358,210*		*100%*

Relevance to U.S. animal agriculture?
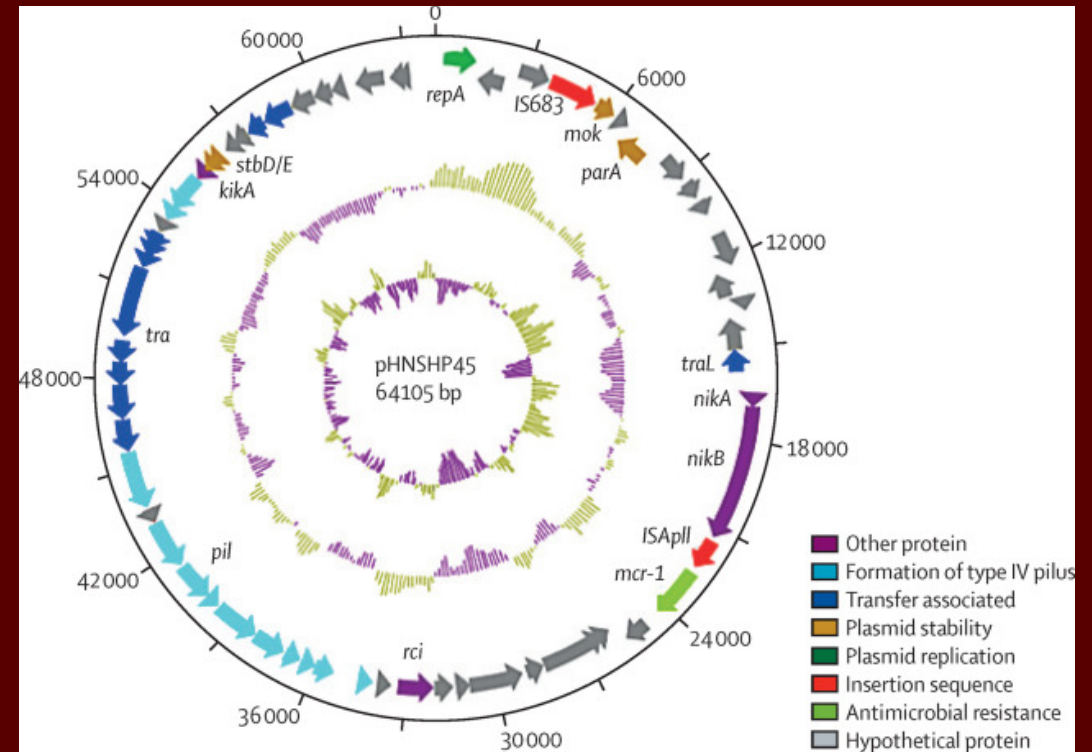
Colistin resistance: mcr-1

#209

Guidance for Industry

**The Judicious Use of Medically Important
Antimicrobial Drugs in Food-Producing Animals**

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. Submit electronic comments on the guidance at http://www.regulations.gov. All written comments should be identified with the Docket No. FDA-2010-D-0094.

Contains Nonbinding Recommendations

#213

Guidance for Industry

**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**

Submit comments on this guidance at any time. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Submit electronic comments to http://www.regulations.gov. All written comments should be identified with the Docket No. FDA-2011-D-0889.

For further information regarding this document, contact William T. Flynn, Center for Veterinary Medicine (HFV-1), Food and Drug Administration, 7519 Standish Place, Rockville,

"To preserve the effectiveness [of antibiotics], we simply must use them as judiciously as possible"

Dr. Joshua Sharfstein, then US FDA deputy commissioner, in
June of 2010 suggesting that antibiotics should only be used
to protect the health of an animal and not to help it grow
faster or more efficiently

Stakeholder input

- **Source**
  - Via website
  - E-mail
  - 3rd party (other USDA efforts)

- **Categorized by theme**
  - Semi-quantitative
  - Overlap

Theme	Count
Communication/Extension/Guidelines on proper use	6
Balanced epidemiologic approach	5
Defining risks of antibiotic use in food animals	4
Emphasis on herd health management practices +/- treatment regimen optimization	4
Need for diverse antibiotic choices (finfish, minor use)	3
Alternative strategies to antimicrobials	3
Public outreach on importance of antibiotic to animal health	3
Optimal duration of exposure to balance efficacy with pressure	2
Balance production efficiency with conservation of Abx	2
Mitigation Steps - Systems level	2
Consumer perception	2
Need for vaccines to avoid Abx use	1
Vector Control	1
Best practices from outside US	1
Model curriculum/Space to share curriculum	1
"Alternative" Commercialization	1
Animal/Pathogen breakpoints	1
Standardized Genomic Indicators	1
Identification of management practices that lead to AMR	1
Selection pressure changes vs. genetic acquisition	1
Environmental Interactions/ Biome	1
Gut Microbiome +/- role of commensals in AMR Emergence & Spread	1
Attributable/validated Risks to Human Health	1
Address Veterinarian Shortages	1
Address Small Producer Challenges	1

Extension/outreach/education - specific themes

- Communication via extension/outreach including guidelines on proper use of antibiotics
  - Stewardship/judicious use/Veterinary Feed Directive
  - QA programs
- Public outreach concerning importance of antibiotics to animal health
  - Efforts to understand consumer perceptions and concerns
- Need for a model curricula to improve awareness and understanding of antimicrobial resistance

Stakeholder input research Theme #1: Risk analysis approaches

- Balanced epidemiologic approach / optimizing varying analytical approaches
  - Multiple ways to evaluate data endpoints
    - Isolate-based AMR prevalence by bacterial species, single/multi-resistance including whole-genome sequencing
    - Microbial ecology (quantitative approaches with indicator species)
    - Meta-genome/resistome approaches
- Defining risks of antibiotic use in food animals
  - Understand risk factors for above, & where in food chain
    - Direct selection by antibiotics
    - Co-selection by antibiotics or alternatives
    - Indirect selection via management/nutrition, etc.

Stakeholder input research Theme #2: Optimize antibiotic therapy

- Optimize antibiotic treatments to minimize resistance while maximizing animal health benefits
  - Develop and employ rapid diagnostics to reduce unnecessary and ineffective treatments
  - Better define risk/benefits of various uses/routes of administration/dosage regimens
  - Ensure optimal duration of exposure to balance selection pressures with efficacy
  - Establish in relation to animal/pathogen breakpoints
  - Consider changing bacterial populations over time (plasmid acquisition, fitness)

Stakeholder input research Theme #3: Alternative approaches to health

- Emphasis on herd health management practices, including treatment regimen optimization, and alternatives
  - Management approaches to minimize need for antibiotics
    - Vaccines, biosecurity, animal handling, weaning, transport, stress
  - Alternatives to antibiotics
    - Non-specific immune modulators, phage therapy, metals, host peptides, etc
- Mitigation strategies employing 'systems approaches'
- Examine 'best practices' from elsewhere

Stakeholder input research Theme #4: 'One Health' challenges

- Expanded from food chain to include environmental interactions / microbiome of within/without host
  - Vector control
- Importance of indicator/commensal organisms versus pathogens in selection and expansion of resistance

Stakeholder input research Theme #5: Underserved/represented groups

- Need for diverse treatment options (including antibiotics) for 'minor species', aquaculture (including finfish), and other persons/groups/regions
  - Address small producer challenges
  - Address veterinarian shortages
  - Alternative commercialization pathways

AMR Discussion

After today?

- Review and analysis of all comments provided via webinar or other mediums

- Final report in 2017

- Use report to inform the development of RFAs and Scientific Priorities

Thank you for Participating!

Having some important after-thoughts?
Remember: you may continue to email input to
animal.health@nifa.usda.gov (AMR in the subject line) until Friday, July 29

Please direct questions or comments related to this AMR webinar to:
Gary Sherman: gsherman@nifa.usda.gov; 202-401-4952