

California Department of Food and Agriculture

Antimicrobial Use and Stewardship Strategic Plan

Calendar Year 2017

A Message from Dr. Annette Jones, Director and State Veterinarian, Animal Health and Food Safety Services, and Natalie Krout-Greenberg, Director, Inspection Services

The California Legislature passed and Governor Brown signed into law Senate Bill 27: Livestock: Use of Antimicrobial Drugs (Hill, Chapter 758, Statutes of 2015). Effective January 1, 2016, the law places a significant mandate on the California Department of Food and Agriculture (CDFA). Specifically the law requires CDFA, in consultation with the Veterinary Medical Board, the California Department of Public Health, universities, and cooperative extensions, to develop antimicrobial stewardship guidelines and best management practices on the proper use of medically important antimicrobial drugs. The law also requires the department to gather information on medically important antimicrobial drug sales and usage, antimicrobial resistant bacteria, and livestock management practice data. Beginning January 1, 2018, California law will prohibit the administration of medically important antimicrobial drugs to livestock, unless ordered by a licensed veterinarian through a prescription or veterinary feed directive pursuant to a veterinarian-client-patient relationship, and will prohibit the administration of a medically important antimicrobial drug to livestock solely for purposes of promoting weight gain or improving feed efficiency, and includes some limits on prophylactic use.

Besides supporting compliance with legislated antimicrobial use restrictions, the Antimicrobial Use and Stewardship Program (AUS) within CDFA will gather information on antibiotic use, development of resistance, animal husbandry practices, and related health and economic outcomes. Working closely with livestock and poultry producers, retailers, veterinarians, health experts, and other interested parties, AUS will function as a catalyst for the development and adoption of meaningful antibiotic stewardship practices for more than 20 different species and livestock production types important to California. Stewardship best practices will continue to evolve as new information is gathered, with the intention of providing livestock and poultry owners and veterinarians updated tools to make optimal investment and treatment decisions that protect the health of animals under their care while mitigating the rate of the development of antimicrobial resistance to medically important antibiotics.

Mission Statement

To provide leadership to California's livestock industry toward the mutual effort to mitigate practices contributing to the expansion of antimicrobial resistance, to reduce potentially harmful impacts from the use of antibiotics, to promote and protect animal health by preserving existing veterinary antimicrobial drugs for veterinary use, and to ensure a clean and wholesome food supply through sound science, education, stewardship, and proficient management.

Vision Statement

The CDFA Antimicrobial Use and Stewardship program will collaboratively partner with the California livestock industry and stakeholders in collecting information to help inform and develop the nation's first comprehensive antimicrobial stewardship model. This program will be recognized as the leader in innovative approaches to antibiotic resistance and responsible antibiotic use.

Who We Are

The mandates of SB 27 significantly impact three of CDFA's regulatory programs: the Animal Health and Food Safety Services (AHFSS) Division, the California Animal Health and Food Safety Laboratory System (CAHFS), Inspection Services (IS) Division: Feed, Fertilizer, and Livestock Drugs Regulatory Services (FFLDRS) Branch.

Animal Health and Food Safety Services

In 1899, the California Legislature established the office of the California State Veterinarian to "protect the health of all domestic animals of the state." While the mission of the State Veterinarian has remained the same, changes in agriculture and public health have influenced the responsibilities and functions of the Animal Health Branch (AHB) to diversify. AHB is the state's organized professional veterinary medical unit that protects livestock populations, consumers, and California's economy from catastrophic animal diseases and other health or agricultural problems to help ensure available, affordable, and wholesome food. The staff focuses on diseases and problems that cannot be successfully controlled on

an individual animal or herd level, but rather require statewide coordinated resources and work with the CAHFS on rapid diagnostic testing in the case of large-scale animal health outbreaks.

California Animal Health and Food Safety Laboratory System

CAHFS is the state entity responsible for providing rapid diagnostic testing for animal health diseases and those diseases that also affect humans. The laboratory is part of the National Animal Health Laboratory Network, which has been included as a component of national surveillance efforts in the current federal Action Plan¹ for combating antimicrobial resistance.

Feed and Livestock Drugs Program

The primary focus of CDFA's Feed and Livestock Drugs Program is to ensure a clean and wholesome supply of meat, milk, and eggs. The laws and regulations define two very distinct and individual programs that the program staff work to carry out.

The Livestock Drugs program regulates over-the-counter livestock drugs and assures that such drugs are available to livestock producers for their use in protecting the health of California's livestock population, and that such use will in turn benefit the general public by providing an abundant supply of wholesome food and fiber. More specifically, livestock drugs intended for food production animals shall not be used to cause a drug residue in food products derived from these animals. These responsibilities are performed through review and registration of livestock drug labels, and licensure of all retail facilities that sell restricted livestock drugs.

The Feed Inspection Program enforces the laws and regulations that govern the manufacture and distribution of livestock feed including medicated livestock feed that may contain Veterinary Feed Directives (VFDs). The Feed Inspection Program along with the feed manufacturing industry ensure that the product received by the consumer is the quality and quantity purported by the manufacturer.

¹ National Action Plan for Combating Antibiotic-Resistance Bacteria, March 2015

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Program Administration

Senate Bill 27, Hill, Livestock: Use of Antimicrobial Drugs (SB 27), establishes an entirely new and progressive program in California. As such, the 2017 Strategic Plan must address establishing adequate program administrative infrastructure to implement the forward thinking expectations outlined in this law.

Goal:

Establish administrative infrastructure required to implement SB 27, considering a two year implementation period and maximizing the use of existing private, academic, federal, and state infrastructure (2016 and 2017 Goal).

Objectives:

- Develop and support State funding proposals including a Budget Change Proposal for fiscal year 2016-2017 workload, and a Budget Change Proposal for additional workload that begins in fiscal year 2017-2018.

Performance Measure: Requested Phase I funds in FY 2016-17 budget with additional phase II funds in FY 2017-18 budget

- Seek direct federal funding support, or USDA and FDA cooperation if no federal funds can be obtained.

Performance Measure: FDA/USDA grant or structure for cooperation in place

- Recruit, hire, and train program staff in accordance with approved funding.

Performance Measure: Training program developed and documented; All positions filled for FY 2016-17. Begin the recruitment and hiring for FY 2017-18.

- Establish business administrative capability
 - Facilities (adequate space and furnishings for staff)
 - Equipment (computers, telecom, etc)
 - Budget management (budget tracking and projection capability)
 - Contracting and purchasing
 - Personnel management
 - Information management (files, shared drives, databases)

- Information security (policy and procedures)
- Public relations, website, outreach support and document editing
- Project management and meeting coordination (contact lists, project assignment and tracking system, meeting coordination procedure and check list, etc.)
- Legal support/Regulation development

Performance Measure: Listed capabilities are acquired/assigned, assessed and have demonstrated adequate functionality per IS and AHFSS Division Directors review

- Develop and implement a communication plan including:
 - SB 27/AUS Ad Hoc Stakeholder Advisory Committee
 - SB 27/AUS Interagency Committee
 - Website
 - Annual report
 - Regional “town hall” or stakeholder meetings
 - Business and professional organization updates

Performance Measure: Completed plan with listed elements described in sufficient detail to implement; published annual report; stakeholder year end communication satisfaction survey

California Animal Health Monitoring System

CDFA will partner with stakeholders and subject matter experts to gather information on antibiotic sales, antibiotic usage, antibiotic resistant bacteria, and livestock management practice (FAC Section 14405 Monitoring and Surveillance). Information gathered will help inform producers and veterinarian decision making and the development of antibiotic stewardship guidelines for individual production types.

Goal:

Develop and begin to implement an overall strategy for collecting representative information from California's major livestock segments, regions with considerable livestock production, and representative segments of the food production chain to include retrospective trends and impacts of the recently implemented Food and Drug Administration (FDA) rules and the SB 27.

Objectives:

- Implement a plan to involve stakeholders and technical experts in Monitoring and Surveillance project development and prioritization.
Performance Measure: Diagram projects and illustrate stakeholder engagement; year-end stakeholder satisfaction survey
- Establish data security policy and capability that ensures information gathered is held confidential and will not be disclosed to any person or government agency unless the data are aggregated to prevent the identification of an individual farm or business (FAC 14407) , including memorandums of understanding or data sharing agreements with cooperators.
Performance Measure: Policy and detailed standard operating procedures approved by CDFA legal; sample MOU/data sharing agreement approved by legal.
- Establish data security policy procedures to assure that information shared by participating agencies is protected per their requirements and per FAC 14407.

Performance Measure: Policy and detailed standard operating procedures to protect information provided by other agencies are reviewed and approved by CDFA and sharing agency's legal counsel

- Ensure the California Animal Health and Food Safety Laboratory System procures equipment and hires and/or trains staff necessary to support resistance pattern studies

Performance Measure: equipment in place, laboratory protocol review complete and testing method competency demonstrated and documented.

- Conduct a literature review to analyze reports and data related to antibiotic use and resistance monitoring, which will include published studies that can provide insight into surveillance/monitoring study design.

Performance Measure: Summary report that includes recommendations for study design

- Evaluate availability and quality of baseline data from existing sources including:
 - Retrospective (prior to 2017) antimicrobial sales data from CDFA and Board of Pharmacy licensed or registered retailers and distributors.
 - Antimicrobial on-farm use and management practice information from National Animal Health Monitoring System reports, university studies, etc.
 - Antimicrobial resistance surveillance from National Antimicrobial Resistance Monitoring System, laboratory reports, California Department of Public Health investigations, etc.

Performance Measure: List sources of potential relevant baseline data; data gathering initiated and documented. Summary report that includes gap analysis related to data quality, geographic distribution and production type

- Develop and initiate or participate in studies intended to gather farm or other relevant data

Performance Measure: Three studies described and initiated

- Complete information sharing plan that will provide producers, veterinarians, and other stakeholders with updates on antibiotic sales and use findings and other disease management practices and health outcomes.

Performance Measure: Documented information sharing plan; year-end stakeholder survey

Stewardship

CDFA will consult with the Veterinary Medical Board (VMB), the California Department of Public Health, universities, and cooperative extensions, to develop antimicrobial stewardship guidelines and best management practices for veterinarians, as well as livestock owners and their employees who are involved in administering medically important antimicrobial drugs, on the proper use of medically important antimicrobial drugs for disease treatment, control, and prevention. The guidelines will include scientifically validated practical alternatives to the use of medically important antimicrobial drugs, including but not limited to the introduction of effective vaccines and good hygiene and management practices (FAC 14404).

Goal:

Develop and implement comprehensive antibiotic stewardship guidelines and best management practices (BMP) for approximately three different livestock and poultry species/production types in 2017.

Objectives:

- Establish and implement an organized process for evaluating and approving suggested BMPs, including:
 - How stakeholders participate in the evaluation process, including but not limited to the establishment of species or production type specific technical working groups
 - Determine the scope of production types that are important to California agriculture (i.e., Aquaculture, Broiler Grower, Calf Ranch, Cattle Feedlot, Cattle Stocker, Cow-calf Ranch, Cow Dairy, Emu Production, Equine, Gamebird, Hatchery, Heifer Raiser, Goat Dairy, Goat Meat, Indoor Swine Grower, Poultry Breeder/multiplier (various types), Pullet Ranch, Turkey Grower, Layer Facility, Mixed Hobby, Ostrich Production, Outdoor Poultry, Outdoor Swine Grower, Sheep Dairy, Sheep Feedlot, Sheep Ranch, Show or Exhibition, and Swine Breeder. *Note that this list is not comprehensive nor does it imply any sort of prioritization*)
 - Prioritization method for BMP development

Performance Measure: List of potential California species or production types requiring unique guidelines listed in priority order for development.

- Conduct extensive literature review for alternative treatment, sanitation, vaccination, and other preventive methods, and implement a process for evaluating and reporting findings.

Performance Measure: Summary report and analysis of existing literature

- Review existing stewardship guidance used for developing antimicrobial stewardship programs in California hospitals and other entities in California public health where stewardship is practiced.

Performance Measure: Report on BMPs and other guidance used in human stewardship programs that can be adapted to animal stewardship programs

- Develop core recommendations and components of BMPs that apply across all species/production types.

Performance Measure: Model BMP structure that includes common elements

- Veterinary Shortage: Conduct regional listening sessions with livestock producers, veterinarians, consumer and special interest groups, local government, and other key stakeholders to discuss and agree upon the infrastructure and protocol for providing timely and economical treatment and care of animals in remote areas where the number of veterinarians is limited.

Performance Measure: Identification and characterization of California regions with limited access to appropriate veterinary service and/or antimicrobials; Summary report and recommendations from two regions (others in 2018)

- Complete three production type specific, scientifically validated BMPs intended to reduce the reliance on medically important antimicrobials while supporting good animal health outcomes on economically viable farms and ranches, that:
 - May include research and development through the competitive contract award process
 - Priority will be to leverage existing producer quality assurance programs to incorporate and deliver new antimicrobial stewardship guidelines and BMPs
 - Incorporate prioritization and input from the species or production type specific technical working group that includes producers, veterinarians, university

experts, staff from agencies with appropriate expertise, and animal health experts.

- Provide guidance on selecting the most appropriate antimicrobial drug, dose, duration, and route of administration and minimizing duration of use and number of animals treated.
- Assess impacts of therapy recommendations on animal health outcomes to assure changes in therapy recommendations will not be deleterious to animal health
- Includes most effective preventative health recommendations

Performance Measure: Three guidance documents describing BMPs for a specific species/production type that is supported by a technical working group as described

- Begin the planning for outreach and education for BMPs
 - With stakeholders, determine goals and metrics for outreach/education campaign.
 - Identify partners (agencies, universities, organizations) to team up with in the distribution of outreach.
 - Identify agencies/organization that will be responsible for training of veterinarians and producers.
 - Conduct outreach and education to private and public sector veterinarians, producers, and allied industries.

Performance Measure: Prepare the initial outreach and education BMP plan

Regulated Use

Beginning in 2018, allowed uses of medically important antimicrobials in Livestock include treating or controlling the spread of a disease or infection, in relation to surgery or a medical procedure, or to prevent the contraction of a particular disease known to occur in a specific situation, and specifically prohibits use for the purposes of growth promotion and feed efficiency (FAC 14401 and 14402). Further, all use of medically important antimicrobials must be under the direction of a licensed veterinarian with a valid veterinarian-client-patient relationship using a prescription or veterinary feed directive (VFD). In order to ensure antimicrobial drugs continue to be accessible, antibiotics deemed by the federal government (FDA) to be sold over-the-counter may continue to be sold at CDFA licensed retail stores and CDFA licensed feed mills. As such, 2017 activity will focus on regulation development, and education and outreach to ensure optimal compliance in 2018. CDFA must also have baseline compliance data to evaluate the first in the nation policies on use when they come into effect.

Goal:

Ensure that the statutes involving 2018 regulated use of antibiotics are supported as needed via regulations, that those impacted by these new provisions have access to outreach and training, that baseline compliance data gathering is initiated, and that agencies with shared jurisdiction agree on outreach and enforcement cooperative roles and responsibilities.

Objectives:

- Review existing and new statutes and impacts to current regulatory framework, identifying potential gaps in regulations and promulgate program regulations to clarify statute and allow for streamlined and cohesive program activities, including:
 - Meet with agencies with relevant jurisdiction including the Veterinary Medical Board and Board of Pharmacy, and agree on potential updates to regulations
 - List and prioritize areas where clarifying regulations will be proposed
 - Seek stakeholder input through the regulatory process
 - Finalize regulations before 2018

Performance Measure: 100% of needed regulatory updates identified and adopted before 2018 with supporting comments from coordinating agencies and most impacted parties

- Develop material explaining the legal requirements coming into effect in 2018 related to antimicrobial use in livestock including:
 - Brochures,
 - Handouts/Guidance Documents
 - Presentations
 - Videos
 - Website information
 - Other as appropriate

Performance Measure: Completed materials as described; effectiveness assessment

- Deliver outreach and education related to 2018 regulated antimicrobial use to:
 - CDFA licensed feed mills, distributors, and retail stores to review VFD and prescription requirements and current compliance.
 - Drug sponsors (manufacturers) and distributors
 - Licensed veterinarians
 - Livestock and poultry owners
 - Relevant organizations (California Veterinary Medical Association, California Grain and Feed Association, California Cattlemen's Association, Pacific Egg and Poultry Association, California Poultry Federation, Western United Dairymen, Milk Producers Council, California Wool Growers Association, California Pork Producers Association, California Farm Bureau Federation, 4-H, FFA, etc.)
 - Regulatory staff

Performance Measure: 80% penetration of target audience

- Gather baseline compliance data from feed mills and feed distributors, veterinarians and livestock and poultry owners/managers relative to the new FDA VFD Rule and antimicrobial label changes that came into effect in 2017.

Performance Measure: Report summarizing the findings in all CDFA licensed feed mills, distributors, and retail stores selling products containing medically important antimicrobials.

AUS Stakeholders

California State Board of Pharmacy
California Animal Health and Food Safety Laboratory
California Department of Public Health
California Veterinary Medical Board
Consumer Advocates
Feed Mills and Feed Industry Organizations
Food Processors, Distributors, Retailers and Business Organizations
Food Security Advocates
Livestock and Poultry Owners and Business Organizations
Natural Resource Advocates
Pharmaceutical Companies and Business Organizations
Physicians and Physician Professional Organizations
Retail Stores Distributing or Potentially Distributing Antibiotics
Schools of Veterinary Medicine
United States Centers for Disease Control and Prevention
United States Department of Agriculture
United States Food and Drug Administration
Veterinarians and Veterinary Professional Organizations