# **California Department of Food and Agriculture**

## **Antimicrobial Use and Stewardship Strategic Plan**

Calendar Year 2018

#### **Forward**

This document constitutes the 2018 Strategic Plan for the Antimicrobial Use and Stewardship Program (AUS) of the California Department of Food and Agriculture. Included is an introduction to AUS that was also provided in the 2017 Strategic Plan, followed by the aims of each component of the program for 2018 and list of AUS stakeholders. Calendar year 2018 marks the second year of this program; please reference the 2017 Strategic Plan for the goals, objectives, and performance measures that were laid out for the first year.

# A Message from Dr. Annette Jones, Director and State Veterinarian, Animal Health and Food Safety Services, and Natalie Krout-Greenberg, Director, Inspection Services March 2017

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 (MIAD's). The law also requires the department to gather information on MIAD sales and usage, antimicrobial resistant bacteria, and livestock management practice data. Beginning January 1, 2018, California law will prohibit the administration of MIAD's 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 MIAD 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 antimicrobial 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**

AHFSS protects public and animal health while enhancing stewardship of the environment. AHFSS employs veterinarians, food safety experts, inspectors, scientists, analysts, and other professionals in programs that protect the safety and security of meat, poultry, dairy products, and other foods of animal origin, assuring consumers and trading partners that California products are consistently safe. They also protect public health and animal health through the prevention, detection, and eradication of livestock and poultry diseases. They maintain the emergency response capabilities necessary to mitigate threats from catastrophic disease outbreaks in livestock or poultry that jeopardize the food supply or human health. They also

respond to food contamination events involving food from animal origin, including implementation of mandatory recalls.

#### California Animal Health and Food Safety (CAHFS) Laboratory System

CAHFS is the state entity responsible for providing rapid diagnostic laboratory 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 Plan<sup>1</sup> for combating antimicrobial resistance.

#### Feed and Livestock Drugs Program

The primary focus of CDFA's Feed and Livestock Drugs Program is to reinforce 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 in such a way as 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 of the quality and quantity purported by the manufacturer.

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<sup>&</sup>lt;sup>1</sup> 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, although the 2017 Strategic Plan and effort addressed most infrastructure needs, the 2018 Strategic Plan must address additional needs as determined during the first year of operation.

#### Goal:

Finalize CDFA infrastructure required to effectively support full implementation of SB 27 mandates, incorporating information gained through initial implementation phases and continuing to maximally leverage existing private, academic, federal, and state resources.

## **Objectives:**

- Fully fund the final phase of implementation via FY 2018-2019 Budget Change Proposal (BCP) (submitted in 2017) to meet workload requirements identified by the initial team.
  - Performance Measure: Inclusion of the BCP for FY 2018-19 in the State budget.
- 2. Continue to seek direct federal funding support, or United States Department of Agriculture (USDA) and Food and Drug Administration (FDA) cooperation if no federal funds can be obtained.
  - Performance Measure: Direct federal funding sought or advocated for; USDA/FDA grants obtained; documentation in place of a structure for cooperation; documentation maintained of grants that are supported by CDFA but were written by other researchers and address California Antimicrobial Resistance (AMR) issues.
- 3. Recruit, hire, and train program staff in accordance with approved funding.

  Performance Measure: Training program developed and documented; all positions filled for FY 2017-18; and recruitment and hiring initiated for additional 2018-2019 positions.
- 4. Finalize implementation of the AUS communication plan including:
  - a. SB 27/AUS Ad Hoc Stakeholder Advisory Committee
  - b. SB 27/AUS Interagency Committee
  - c. Website

- Report of 2018 program activities incorporated into the report for the Legislature as described in the Law
- e. Regional "town hall" or stakeholder meetings
- f. Business and professional organization updates

Performance Measure: Plan completed and described in sufficient detail to implement all listed elements; report submitted to Legislature; and stakeholder year-end communication satisfaction survey administered.

### **Surveys and Studies**

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

#### Goal:

Continue strategic development and implementation of procedures 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 FDA rules and SB 27.

## **Objectives:**

1. Continue to involve stakeholders and technical experts in AUS surveys, studies, project development, and task prioritization.

Performance Measure: Documented stakeholder engagement in report; and, year-end stakeholder satisfaction survey administered.

- 2. Continue to maintain data security policies and capabilities, ensuring that the 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). Such policies extend to include memorandums of understanding and/or data sharing agreements with cooperators. Performance Measure: Data confidentiality maintained; and, standard operating procedures (SOPs) for data handling, access, and sharing reviewed by CDFA legal team or other experts and approved by the State Veterinarian.
- Continue to maintain data security policies and procedures to assure that information shared by participating agencies is protected per their requirements and per FAC 14407.
  - Performance Measure: Data confidentiality maintained; and, standard operating procedures (SOPs) for data handling, access, and sharing reviewed by CDFA legal team or other experts and approved by the State Veterinarian.
- 4. Support CAHFS resistance pattern studies

  Performance Measure: Utilize CAHFS resources in at least two studies to characterize
  pathogens and their resistance to antibiotics; and, preliminary samples received from
  private practitioners, characterized for resistance, and initial future sampling targets
  developed from this information
- 5. Continue to develop and improve study designs and performance metrics based on scientific literature and in collaboration with experts in antimicrobial use and resistance.

  Performance Measure: Maintain an annotated list of references for each study; and, summarize lessons learned in the report.
- 6. Continue to collaborate with state, federal, and research institution partners to identify relevant data collected through external efforts and utilize such data as appropriate.

  Performance Measure: List of data collected through external or cooperative efforts maintained and updated; data sharing documented or agreements in place with at least 3 partners; and, utilization of shared data described in the report.
- 7. Develop and initiate or participate in studies intended to gather farm or other relevant data.

- Performance Measure: Gather data on farm practices or other relevant information from 5 identified production systems and/or other sources by initiating and maintaining ongoing studies as needed to address gaps in knowledge and statistical validity.
- 8. Complete sampling survey of MIAD sales in CA before Jan 2019 to gain sufficient benchmark data so as to be meaningfully interpreted in conjunction with other, more indepth, on-farm studies, both in CA and nationally.
  - Performance Measure: Complete at least one data collection project for VFD feed sales and one for prescription medications.
- Share gathered information in a way that provides producers, veterinarians, and other stakeholders with timely updates on findings regarding antibiotic sales and use, other disease management practices, and health outcomes.
  - Performance Measure: Generate brief summaries of the findings of each AUS-funded study for participants and other stakeholders within 6 months of study completion; summarize the findings of completed or published AUS-funded studies and surveys in the report; and, year-end stakeholder satisfaction survey administered.

## **Stewardship**

CDFA will continue to 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 MIADs. These guidelines will focus on the proper use of MIADs for disease treatment, control, and prevention and will include scientifically validated practical alternatives to the use of MIADs, including but not limited to the introduction of effective vaccines and good hygiene and management practices (FAC 14404).

#### Goal:

Develop, and encourage producer adoption of, comprehensive antibiotic stewardship guidelines and best management practices (BMP) for at least two different livestock and/or poultry production types in 2018.

## **Objectives:**

- Continue to refine recommended antimicrobial judicious use practices.
   Performance Measure: Judicious use principles developed and updated annually by AUS under the guidance of the expert working group and approval of the State
  - Veterinarian.
- 2. Develop clinical resources that facilitate the practice of identified principles for the judicious use of antimicrobials.
  - Performance Measure: Provide further education and promotion of CAHFS lab services related to AMR to veterinarians through at least four venues and via at least two methods (i.e. web resource, in person, accreditation, etc.).
- 3. Develop specific stewardship guidelines for all livestock and poultry production types and components of BMPs based on surveys performed on relevant production groups. Performance Measure: Initiate production of guidelines and BMP for at least two livestock and/or poultry production types; and, set timelines for completion of these guidelines.
- Continue targeted literature review to assess viable vaccination, sanitation, and biosecurity measures to support ongoing development and refinement of AUS stewardship guidelines and BMPs.
  - Performance Measure: Integrate new and emerging information into the development and revision of AUS' stewardship guidelines.
- 5. Initiate relationship with the programs and channels identified to have the greatest penetration to producers in each production type in order to disseminate stewardship guidelines and BMPs for relevant stakeholders in a timely and effective manner.
  - Performance Measure: Establish means to estimate penetration of programs for each

- production class in order to identify best channels for dissemination of stewardship guidelines and BMPs; disseminate materials as the content is finalized; and, record and report outreach activities.
- 6. Identify and assess underserved communities to better understand and to support expanding access to veterinary services within the state.
  Performance Measure: Hold at least two "town hall" or similar meetings in underserved areas to better understand gaps in veterinary service access and potential solutions; and, develop and maintain a list of underserved areas that includes the criteria used for categorizing an area as underserved (e.g. species expertise, remote, etc.); share summary information on underserved community needs with veterinarians.
- 7. In collaboration with USDA, VMB, and CVMA, support expansion of veterinary services in underserved communities by providing resources to veterinarians to assist them in expanding their practice to meet the needs of the community.
  Performance Measure: Provide information to veterinarians on available sources of education on species cross-training and in the skills needed to meet community needs.
- 8. Continue outreach and education to producers and veterinarians regarding stewardship, judicious use, and SB 27 antimicrobial use allowances.
  - a. Maintain communication via email and phone to help with questions.
  - b. Develop tools to address common problems.
  - c. Distribute educational materials through relevant stakeholder organizations.

Performance Measure: Year-end stakeholder survey administered; documentation of questions, problems, and responses maintained; a system to track outreach and distribution of educational materials established; and, 2018 outreach performance adequately captured.

## **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; use for the purposes of growth promotion and feed efficiency are specifically prohibited (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). Drugs administered through feed with a valid VFD may be purchased from a facility that has filed a letter of intent with the FDA. As such, 2018 activity will continue to focus on education and outreach, and inspection and enforcement to ensure compliance with the sale and use of Medically Important Antimicrobial Drugs.

#### Goal:

Ensure that those impacted by these new provisions have access to outreach and that programs and agencies with shared jurisdiction collaborate on outreach and enforcement cooperative roles and responsibilities. Assess the need for clarifying regulations and complete the regulatory process for retail sale of California prescription MIADs.

## **Objectives:**

- Continue to collaborate with other state agencies, including Board of Pharmacy, to find solution sets to ensure producer access to California prescription MIADs for purchase. Performance Measure: Solution sets are identified and documented; and, resolutions initiated
- 2. Complete the regulatory process further defining CDFA regulatory oversight of retail sales of California prescription MIADs.
  - Performance Measure: The roles of the Board of Pharmacy and CDFA are clarified; and, the needed regulations are adopted.
- 3. Assess the need for further regulations clarifying SB 27 and initiate the indicated regulatory processes.

#### Performance Measure: Analysis summarized; and, identified regulations initiated.

- 4. Develop material explaining the legal requirements including prescription and VFD requirements related to antimicrobial use in livestock including:
  - a. Brochures,
  - b. Handouts/Guidance Documents
  - c. Presentations
  - d. Videos/Webinars
  - e. Website information
  - f. Other formats as appropriate

Performance Measure: Complete new materials; update existing materials as needed; and, year-end stakeholder satisfaction survey administered.

- 5. Deliver outreach and education related to 2018 regulated antimicrobial use to:
  - a. CDFA licensed feed mills, distributors, and retail stores
  - b. Drug sponsors (manufacturers) and distributors
  - c. Relevant organizations (i.e. 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.)
  - d. Regulatory staff
  - e. Producers of all applicable livestock and poultry types, livestock markets, custom harvest and USDA exempt poultry harvest facilities, CA licensed veterinarians, feedlots, and others engaged in applicable livestock and poultry production and harvest in California.

Performance Measure: 80% penetration of identified audience outlets and venues.

6. Inspect, monitor, and ensure VFD compliance at feed mills and feed distributors manufacturing or distributing VFD feeds. Gather information relative to the FDA VFD Rule and antimicrobial label changes that came into effect in 2017. Gather VFD data to support surveys and studies. Performance Measure: Findings and compliance activities in all CDFA licensed feed mills selling products containing MIADs summarized and established as benchmark for future compliance improvement activities.

- 7. Inspect, monitor, and ensure livestock drug retailers' compliance.

  Performance Measure: Findings and compliance activities at CDFA licensed retailers, including those related to promulgated regulations, summarized and established as benchmark for future compliance improvement activities.
- 8. Enhance collaboration with State and Federal agency partners in order to optimally enforce the provisions for antimicrobial use.
  - Performance Measure: Annual work plan developed and implemented that leverages outreach and jurisdictional enforcement authority as appropriate to include VMB, FDA, USDA, CDFA- Inspection Service and Animal Health and Food Safety Divisions.

#### **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