

**CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE (CDFA)
FEED INSPECTION ADVISORY BOARD (FIAB) MEETING**

**California Department of Food and Agriculture
2800 Gateway Oaks Drive, Room 267
Sacramento, CA 95833
(916) 900-5022**

**October 25, 2016
9:00 AM**

MINUTES

MEMBERS

John Walth, Chair
John Kauffmann, Vice Chair
Doug Stabelfeld
John Silva
Marit Arana
Paul Parreira
Tim Riordan
Michael Koewler

MEMBERS ABSENT

Thomas Prokop

CDFA STAFF

Amadou Ba
Angelia Johnson
Brittnie Sabalbro
Carla Sanchez
Elaine Wong
Gary Castro
Jenna Areias
Maria Tenorio
Mike Davidson
Natalie Krout-Greenberg
Nirmal Saini
Samantha Moran
Shelly King

INTERESTED PARTIES

Chris Zanobini
Kelly Covello
Tad Bell

INTRODUCTIONS AND ANNOUNCEMENTS

Mr. John Walth, Chair, called the meeting to order at 9:15 a.m. Introductions were made, and a quorum was established. He informed the interested parties they are not required to sign in or identify themselves, per the Bagley-Keene Open Meeting Act. Mr. Thomas Prokop, Board member, was absent.

APPROVE MEETING MINUTES

Chair Walth requested the board review the minutes of the July 13, 2016 FIAB meeting. Dr. Marit Arana requested an amendment to the minutes regarding the terms "acid detergent fibers" and "neutral detergent fibers."

MOTION: Mr. Tim Riordan moved to approve the meeting minutes as amended; Mr. John Silva seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

DEPARTMENT / DIVISION / BRANCH UPDATE

Ms. Natalie Krout-Greenberg provided Department and Division updates. The Inspection Services Division hosted six Food and Drug Administration (FDA) staff tours of the produce and almond hullers industry. Dr. Stephen Ostroff, FDA Deputy Commissioner of Foods and Veterinary Medicine, provided insight on the diversity of California's produce and challenges regarding the implementation of the Food and Safety Modernization Act (FSMA). CDFA was recently awarded \$11.7 million through a five-year cooperative agreement for state-level implementation of the Produce Safety Rule under FSMA. The Division will develop a strategic plan for inventory and will identify the authority needed to hire new staff to implement the program and develop program enforcement. Ms. Krout-Greenberg announced Ms. Carla Sanchez, previously the Special Assistant of the Office of Environmental Farming and Innovation, was appointed as Special Assistant of the Inspection Services Division.

Ms. Krout-Greenberg reported the Inspection and Compliance Branch is hosting an Organic Working Group to ensure the State Organic Program is capturing data in order to create a report that is informative to industry, and to align the Branch with recently passed legislation. The Office of Farm to Fork's Nutrition Incentive Program submitted a Request for Proposal to provide federal matching dollars for communities to have access to fresh fruits and vegetables.

Proposition 64, if passed, would impact the Medical Cannabis Cultivation Program (MCCP). It would allow adults over 21 to possess and use marijuana for "adult use." The measure would create two new taxes, one levied on cultivation and the other on retail. Revenue would be spent on drug research, treatment, enforcement, health, and safety grants addressing marijuana-related concerns, youth programs, and preventing environmental damage from illegal marijuana production. CDFA is working closely with the Department of Finance (DOF) to analyze the economic impact and is advertising several positions to prepare for the outcome of the Proposition.

MCCP conducted eight scoping sessions throughout the State in September 2016. This provided the public an opportunity to discuss environmental impacts, program regulations, and industry challenges.

Ms. Kelly Covello asked if CDFA commented on the draft guidance documents released by FDA regarding Good Manufacturing Practices (GMP) for Animal Food. Ms. Krout-Greenberg confirmed the Inspection Services Division did comment on the guidance document.

Dr. Amadou Ba provided Branch and program updates. He stated Assembly Bill (AB) 2511 and AB 1811 were signed by the Governor and will be effective January 1, 2017. AB 1811 pertains to organic input material (OIM) inspections and provisional registrations, and allows the Department to promulgate regulations for a revised fertilizing mate-

rials registration cycle. AB 2511, initiated by the Governor's Office of Planning and Research, defined biochar as a fertilizing material, requiring product label registration and mill assessment payment.

Senate Bill (SB) 27 was also signed by the Governor. This bill addresses the administration of medically important antimicrobial drugs to livestock. Through a Budget Change Proposal (BCP), the Feed program received \$550,000 in general fund dollars and 3.5 positions for fiscal year (FY) 16/17. The program is advertising positions to hire staff in order to implement the new Antimicrobial Use and Stewardship Services (AUSS) Program. The program submitted a BCP for additional positions and general fund dollars for FY 17/18.

An additional BCP was sent to DOF requesting one Environmental Scientist position to address biochar, based on AB 2511. Nine BCPs were submitted by the Department; two will impact the Branch.

The Fertilizer Research and Education Program (FREP) conference was held October 26 - 27, 2016 in Modesto, California. FREP funded \$1.9 million in research projects to address nitrate in ground water; \$500,000 was funded for biochar research. FREP received a Specialty Crop Block Grant for \$282,000 for a three-year period to conduct additional outreach.

FEED, LIVESTOCK DRUGS, AND SAFE PROGRAM UPDATES

Ms. Jenna Areias stated Ms. Cathryn McCandless, Research Analyst II for the Safe Animal Feed Education (SAFE) Program, started a Ph.D. program at UC Davis. She will continue to develop regulations related to the Technical Advisory Subcommittee (TASC), but on a reduced time base. TASC regulations will define new feed ingredients on a provisional basis, while they go through the formal approval process with FDA, to obtain a "generally recognized as safe" (GRAS) determination.

FUND CONDITION

Ms. Areias reported, at the last FIAB meeting, there was discussion regarding splitting the Feed and Livestock Drugs (LD) program's budget authority. Prior to the split, as of June 30, 2016, total combined funds for the Feed and SAFE programs were \$1,796,684; revenue was \$3,910,422; expenditures were \$2,994,187; and encumbrances were \$121,490; the total ending adjusted balance was \$2,591,429.

As of September 30, 2016, the Feed program's total fund balance was \$2,470,489; SAFE balance was \$33,683; LD balance was \$242,430; and AUSS balance was \$550,000; for a combined total of \$3,296,602. Revenue received for Feed was \$1,295,291; SAFE revenue was \$95,968; LD revenue was \$8,500; for a combined total revenue of \$1,399,759. Expenditures for Feed were \$640,808; SAFE was \$46,218; LD was \$9,302; and AUSS was \$27,264; for a combined total of \$723,592. Encumbrances

mainly impacted the Feed program at \$66,764, due to vehicle purchases for the next FY; the combined total of encumbrances was \$68,998. The total adjusted balance was \$3,058,208 for Feed; \$81,600 for SAFE; \$241,628 for LD; \$522,335 for AUSS; with a combined total of \$3,903,771.

Mr. John Silva asked if AUSS will be funded annually by the Governor and if there will be any additional expenses that will need to be covered. Ms. Areias stated the Governor approved a BCP for 2016 of \$550,000 to fund AUSS activities mandated by SB 27. AUSS is split between CDFA's Inspection Services and Animal Health Divisions; \$550,000 is only part of a greater number of general fund dollars received for AUSS within CDFA. The program developed an activity tracker for staff to track AUSS activities; the Feed and LD programs' expenditures are not included in AUSS.

Ms. Krout-Greenberg stated every CDFA program has a different Program Cost Account (PCA) code to track its expenditures. Ms. Areias stated the second BCP submitted for FY 17/18, which requested an additional five positions, must be approved by DOF and the Governor. SB 27 also requires the program to identify other funding sources; the program is seeking federal grant dollars.

Mr. Chris Zanobini asked what will happen if the BCP does not get approved by the Governor. Ms. Krout-Greenberg stated if the BCP is not approved, AUSS activities will not be done. The Feed program funds are only to be used specific to Chapter 4 in the Livestock Drugs Law, aside from Chapter 6 of the Feed Law which specifies no funds will be used for Chapter 4.5. Dr. Ba stated SB 27 is funded by general fund dollars because antimicrobial resistance is a public health issue, not only an animal health issue.

Dr. Marit Arana asked which program the Veterinary Feed Directive rule (VFD) falls within. Ms. Areias stated SB 770, the Mendoza bill, states all medicated feed, including VFD's, shall fall under CDFA's oversight. CDFA is in the process of drafting a legal referral to clarify SB 27's mandate, due to an exemption of VFD's in Chapter 4 of the Livestock Drugs law. Mr. Mike Davidson stated the program will promulgate regulations for VFD's in the near future. Ms. Areias added that CDFA's main concern is to ensure the mandate does not overlap with the oversight of the Board of Pharmacy.

MOTION: Dr. Marit Arana moved the Feed and LD funds be split into two separate accounts, with the LD account to start with a beginning balance of \$242,430; Mr. Tim Riordan seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

TONNAGE REPORTING

Ms. Areias reported the Feed tonnage looks to be on track with prior years. Mr. Riordan asked if the program had ever considered adjusting tonnage based on moisture. Discussion ensued regarding the program's method of assessing tonnage and tonnage reporting by firms.

PROPOSED FY 17/18 PROGRAM BUDGET

Ms. Areias presented the proposed Feed and SAFE budget for FY 17/18 to the board, highlighting the personnel services combined total for Feed and SAFE is \$1,631,485, and the operating expenses combined total is \$665,121. She stated the program will continue to utilize the Memorandum of Understanding (MOU) between the program and the Pest Exclusion Branch. She underlined out-of-state travel increased for the Feed program's proposed budget for FY 17/18. The Animal Feed Regulatory Program Standards (AFRPS) grant was added as a line item under the total program costs; however, the Tissue Residue recovery (TR) line item was not included in either program budgets. TR investigations involve drugs in tissue; therefore, the program moved the TR line item to the LD program budget, where it is more appropriate. The total proposed program costs for both programs for FY 17/18 are \$4,168,870.

Mr. Tad Bell stated the training budget seems low, and requested the program confirm there will be sufficient funds to cover the program's training needs. He also asked why the Governor's budget does not match with the actual proposed budget. Ms. Areias stated under the AFRPS grant, there is a large amount of funds allocated to cover training needs; therefore, the budget does not need to reflect the total amount of the program's training needs. She stated the Governor's budget is CDFA's authority, and actual budgets are a working budget, and are less than the authority.

MOTION: Mr. Michael Koewler moved to approve the combined Feed and SAFE revised FY 16/17 budget of \$3,996,248, and the combined proposed FY 17/18 budget of \$4,168,870; Mr. John Kauffmann seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

Ms. Areias presented program budgets for the LD program and AUSS for FY 16/17. She highlighted the AUSS budget includes the 3.5 positions that were received through the BCP that was approved by DOF. Total combined proposed program costs for FY 16/17 are \$701,645.

Ms. Areias also presented program budgets for the LD program and AUSS for FY 17/18; the AUSS program budget includes the additional 5 positions awaiting approval from DOF. Total combined program costs for FY 17/18 are \$1,576,267.

Discussion ensued regarding whether this board should approve the AUSS budget since it is a separate program, funded through General Fund dollars, and the FIAB does not make any recommendations to the Governor for that program. Ms. Areias explained the AUSS budget was simply provided to the board as informational.

Mr. Bell recommended the program include a display of the funding source in future budgets, and stated a fiscal distribution would also be informative.

MOTION: Mr. John Silva moved to approve the LD program's revised FY 16/17 budget and the proposed FY 17/18 budget; Mr. Michael Koewler seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

REGULATION WORKING GROUP

Ms. Areias stated at the previous board meeting, the board formed a Regulation Working Group. It was created due to federal and state law changes; the need for guidance in drafting regulations; and mandates by California State Law, enforcement activities, and industry demand.

The working group met to discuss several objectives and issues for the Feed program, including developing a penalty matrix; evaluating selenium and prohibited materials by adopting the Code of Federal Regulations (CFR) in the LD program for product safety; and more. The working group also recommended adopting FSMA GMP regulations into the California Code of Regulations (CCR), developing regulations that parallel the American Association of Feed Control Officials (AAFCO) Official Publication feed ingredient recognition, developing a penalty matrix, and adopting FDA's VFD guidance by reference.

Chair Walth requested the TASC provide a recommendation to the FIAB at the next board meeting related to CDFA adopting AAFCO required guarantees.

Mr. Silva asked CDFA to explain the basis and foundation of the penalty matrix. Ms. Areias stated CDFA plans to increase fines for violations. Ms. Krout-Greenberg added the penalty matrix will also clarify how to assess fines for violations, including minor, moderate, and severe violations, for fairness and consistency in compliance with laws and regulations.

MOTION: Mr. John Kauffmann moved to approve the recommendations regarding the LD and Feed programs, as proposed by the Regulation Working Group; Mr. Tim Riordan seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

FIELD ACTIVITIES

Mr. Mike Davidson stated the program has been focusing on LD registration compliance, and developing a restricted LD inspection checklist to document inspections and inform retail stores about feed required VFD's. Additionally, the program started a corn survey for the 2016 crop year to check protein, fat, and 12 mycotoxins, and will be performing mixer studies and flush verification testing at firms who manufacture medicated feed or concentrated mineral mixes. Mr. Davidson presented an overview of program enforcement activities, such as Commercial Feed License revocation, repeat drug residue violations, unregistered livestock drugs, etc.

Ms. Areias provided the board with AUSS program updates. She highlighted the program meets with the Animal Health Division on a bimonthly basis to address program planning and has also been working diligently with the Human Resources Branch to hire staff for the vacant AUSS positions. Ms. Areias presented the Branch's proposed organizational charts for FY 16/17 and 17/18. Ms. Areias stated legal referrals will be submitted to CDFA's Legal Office for clarification on VFD's and oversight on medically important antibiotics on LD.

SAFE AND AFRPS

Ms. Samantha Moran, Feed, Fertilizer, and Livestock Drugs (FFLD) Inspector, provided the board with SAFE program activity updates. SAFE is currently focusing on FSMA outreach. The program is also working with the Food Safety Preventive Controls Alliance to host Lead instructor training. Ms. Moran stated SAFE has been tracking all sample data collected by the Feed program staff. The data is compiled and used to determine industry trends, feed safety and label compliance issues, and firm violation rates. Additionally, the program is conducting outreach at all medicated feed mills, with mill managers and staff, in California to discuss FDA's FSMA staggered implementation approach, and state and federal guidance. Mixer studies and flush verifications are also being performed at feed mills who handle livestock drugs to determine the effectiveness of the mixing times and flushes being used.

Ms. Moran informed the board the SAFE website was recently updated to be more user friendly. The website now also includes FDA's guidance documents and materials regarding GMP requirements, Human Food By-Products, and VFDs.

Ms. Moran provided an AFRPS update, stating the program's first grant year ended September 30, 2016. The program completed Standard 1: Regulatory Foundation, and Standard 5: Animal Illness or Death and Emergency Response. The program is currently working on Standard 11: Sampling, and Standard 3: Inspection Program, and it anticipates it will be completed around December 2016. Visits from FDA's Office of Partnership will begin November 2016 for review of the program's process improvements through AFRPS. Ms. Areias stated the program will receive its first FDA audit during the last week of July 2017, through the Office of Management and Budget.

CAC LAB REPORT UPDATE

Ms. Elaine Wong stated due to a retirement and the absence of lab staff, the sample processing time at the lab was delayed; however, CAC is now caught up on sample turnaround time. Mr. Nirmal Saini added the lab will soon be fully staffed, as they are scheduling interviews now.

Ms. Wong announced the lab stopped reporting Acid Detergent Fiber (ADF) analyses and started reporting Neutral Detergent Fiber (NDF), but data has yet to be collected. In the previous FIAB meeting, the board requested costs on the Near-infrared (NIR) equipment; NIR costs approximately \$40,000 - \$45,000. Mr. Paul Parreira asked if the

board still wants the CAC to purchase NIR equipment. Dr. Arana stated purchasing NIR equipment early would be beneficial because it would allow the lab sufficient time to learn to use the equipment, specifically because it may become a regulatory standard. Chair Walth agreed the lab should purchase NIR equipment.

Discussion ensued regarding NIR equipment use.

MOTION: Mr. Michael Koewler moved to approve the lab's purchase of the NIR equipment; Mr. Paul Parreira seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

Chair Walth suggested the board revisit the FY 17/18 proposed budget to increase the equipment line item. Mr. Bell concurred, stating the board should approve the appropriate spending authority for equipment to meet the lab's needs.

MOTION: Mr. Paul Parreira moved to amend the proposed FY 17/18 budget from \$4,168,870 to \$4,368,870 by increasing the lab equipment line item to \$300,000; Mr. John Kauffmann seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

Mr. Bell suggested it would be helpful if Ms. Wong and Mr. Nirmal Saini implement a standard timeline, before the lab begins using NIR equipment, to discuss an expectation of exact costs and what it will take to analyze NDF.

Mr. Riordan also suggested Ms. Wong and Ms. Covello contact commercial labs to discuss their procedures, equipment, and methodologies to help validate the NIR equipment.

AGENDA ITEMS FOR FUTURE MEETINGS

Chair Walth asked the board for agenda items for the next meeting, including TASC providing a recommendation to the board on if the program should adopt AAFCO guarantees. Mr. Koewler announced three terms will expire on April 30, 2017. Ms. Krout-Greenberg stated mycotoxin data trends will be presented. Mr. Riordan suggested CDFA provide information on feed and food safety violations.

NEXT MEETING

Chair Walth stated the next meeting will be in February 2017. The board members will be polled to select a date.

MOTION: Mr. Michael Koewler moved to adjourn the meeting; Mr. Doug Stabelfeld seconded. The motion passed unanimously with a vote by all board members present of 8 - 0.

The meeting was adjourned at 12:10 p.m. by Chair Walth.

Respectfully Submitted By



Jenna Areias, Feed Program Supervisor
Feed, Fertilizer, and Livestock Drugs Regulatory Services

10/25/2016
Date