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

Stanislaus County Farm Bureau 1201 L Street Modesto, CA 95353 (209) 522-7278

> **April 5, 2018** 9:00 AM MINUTES

MEMBERS CDFA STAFF INTERESTED PARTIES

Doug Stabelfeld Amadou Ba John Walth, Chair Angelia Johnson Marit Arana, Vice Chair Brittnie Sabalbro Michael Koewler Carla Sanchez Paul Parreira Jenna Areias Shay Rambur Jessica Valdez Tim Riordan Killeen Sanders Tom Prokop

Maryam Khosravifard

Mike Davidson

Natalie Krout-Greenberg MEMBERS ABSENT

John Silva Rachelle Kennedy Samantha Moran

INTRODUCTIONS AND ANNOUNCEMENTS

Mr. John Walth, Chair, called the meeting to order at 9:02 a.m. He informed the interested parties that per the Bagley-Keene Open Meeting Act, they are not required to sign in or identify themselves. Self-introductions were made, and a guorum was established. Mr. John Silva was absent.

Ms. Jenna Areias, Environmental Program Manager I (EPM I), announced that the Department's Legal office advised that 'Public Comment [Items Not on the Agenda]' be added to future board agendas. The 'public comment' agenda item will be placed at the end of future meeting agendas to allow interested parties to make comments.

Ms. Natalie Krout-Greenberg, Division Director, stated that the public comments will not be up for board discussion for any subject not on the meeting agenda; however, the board will decide whether the issue brought before the board has relevancy to be included on the next agenda.

APPROVE OCTOBER 5, 2017 MEETING MINUTES

Chair Walth requested the board review the minutes of the October 5, 2017 FIAB meeting.

MOTION: Mr. Tom Prokop moved to approve the meeting minutes; Dr. Marit Arana seconded. The motion passed unanimously with a vote by all Board members present of 8 - 0.

DEPARTMENT / DIVISION / BRANCH UPDATE

Ms. Krout-Greenberg reported that while the secretary feels that three, three-year terms (a consecutive period of nine years) is appropriate, she focuses primarily on three factors when reviewing and approving the recommendations for board appointments.

- Diversity within the industry the board represents to ensure all stakeholders are at the table so that the board has the opportunity to look at all sectors of the industry.
- Balancing longevity with bringing in new members to be able to maintain and pass on the knowledge of members that have served long term to ensure continuity.
- 3) Appointing new members to bring a fresh perspective.

Ms. Krout-Greenberg reported the main purpose of Senate Bill (SB) 1383, which passed on September 19, 2016, is undertaking various actions to reduce emissions of short-lived climate pollutants (SLCP). The Department's science advisor to the secretary is working with the Office of Environmental Farming and Innovation (OEFI) to address components to this bill such as dairy digesters, methane emissions, and enteric fermentation. Ms. Krout-Greenberg met with the California Air Resources Board (CARB) to see their long term vision of addressing SLCP.

CARB will release a literature review available to the public that focuses on feed sources typical to the industry and feed sources specific to California. CARB has also created three public working groups to focus on digester, non-digester, and research. The research working group issued a Request for Information (RFI) that is available until May 31, 2018. The purpose of the RFI is to collectively gather information from the industry's knowledge and experience to fill the existing voids. CARB will identify what is important, what is covered, and where there are gaps between the literature review, scientific community, and industry. These phases of work will embody what is to come if regulations are feasible prior to the January 1, 2024 deadline.

Ms. Krout-Greenberg educated CARB about how the Department works closely with the Food and Drug Adminsitration (FDA) and Association of American Food Control

Officials (AAFCO) with the feed ingredient approval process. She provided information regarding California's uniqueness of ingredient sources and use of co-products.

Ms. Krout-Greenberg gave an SB 27 update. SB 27 addresses the use of medically important antimicrobial drugs (MIADs) in livestock, and the Antimicrobial Use and Stewardship (AUS) program was established to implement SB 27 mandates. The Feed program is responsible for the regulated use component pertaining to Veterinary Feed Directives (VFDs). VFDs continue to be a highly focused topic between the Department, the Governor's Office, and stakeholders. The Department looks at VFDs very closely and must stick to the letter of the law.

AUS responsibilities are split between the Animal Health Branch, which has the components of stewardship and studies and the Feed, Fertilizer, and Livestock Drugs Branch, which under the Feed program has the component of regulated use where data is collected from retailers, distributers, and feed mills. The survey data will be compiled into a published report to the legislature in 2019.

Ms. Krout-Greenberg stated it is important for the industry and Department's Feed program, in coordination with the board, to implement internal strategic planning this year due to all the upcoming changes through the Food Safety Modernization Act (FSMA) and all that is impacting the Feed industry.

Chair Walth asked if there is an AUS board. Ms. Krout-Greenberg stated that there is not an advisory board appointed per the letter of the law in SB 27 but that there is an AUS stakeholder group that is comprised of industry associations, veterinarians, medical boards, academia, and consumer advocacy groups.

Dr. Amadou Ba also reported on SB 1383. This bill establishes methane emission reduction targets that will impact not only the Department, but multiple agencies such as the State Water Resources Control Board, California Department of Resources Recycling and Recovery (CalRecycle), and CARB. CalRecycle is looking to avoid landfill methane emmissions and is holding scoping meetings for implementation of regulations to address organic waste that could potentially impact the Feed program and rendering industry. CalRecycle received substantial comments to the draft regulations from industry, and the Department has provided a general framework for the exemption language since animal feed is deemed to be a recovery not a disposal. CalRecycle regulations will result in major changes for all entites that handle organic waste. The next scoping meeting will be on May 8, 2018.

Dr. Ba gave a database update. For the past three years, the program has worked with the Office of Information Technology to enhance the database for those who pay the fertilizer mill assessment, feed tonnage tax, and license fee via paper check. The accounting process is more susceptible to errors with each check transaction and the payment process is handled by multiple program and financial services staff. The

program is working on implementing a new "E check" payment process to begin in 2019 that will allow industry to complete check transactions through the database.

Dr. Ba reported the secretary agreed with the board's recommendation made at the last FIAB meeting. The recommended decrease in tonnage tax from \$0.12 to \$0.10 cents became effective January 1, 2018.

The University of California Davis (UCD) published an article on a nitrogen oxides (NO_x) emmissions study that shows agricultural land is a large NO_x emmitter. The issue with UCD's widely published article is that the UC researcher's findings published in the recent article do not align with CARB and other previous results.

SB 623, increasing the mill assessment fees to \$0.06 cents, has been converted into a trailer bill. The agricultural sector supports the bill, but the water purveyors have some reservations due to the amount of costs coming from a water tax.

Dr. Ba provided Branch updates. Ms. Areias, Feed program supervisor, was promoted to an EPM I; Ms. Casey Dykier and Ms. Jessica Valdez were newly appointed as an Environmental Scientists (ES) and Mr. Trevor Morgan, who was an ES for AUS, has returned to the private sector. The Branch Office Support Staff is looking to backfill a seasonal Agricultural Aide/Agricultural Technician position. The Fertilizer program appointed three new ES positions: two registration staff for the Sacramento office, Ms. Kathryn Coke and Ms. Yanhong Li, and one field staff for the Fresno area, Ms. Kim Schneider. After 30 years of state service, Mr. Charlie Nelson, Special Investigator, retired on January 31, 2018. Mr. Mark Cady, Fertilizer Research and Education program (FREP) Senior Environmental Scientist (SES)(Specialist), promoted to SES (Supervisor). FREP has recently interviewed for the vacant SES (Specialist) position and hopes to make an offer to a potential candidate soon.

BOARD VACANCIES

Dr. Ba stated the Feed program received five applications for the board terms expiring on April 30, 2018.

Chair Walth asked the board its appointment recommendations for the secretary. Mr. Koewler commented that all candidates are acceptable and well qualified, but recommended that Dr. Marit Arana, Mr. Paul Parreira, and Ms. Shay Rambur fill the three vacated positions.

Ms. Areias announced that in January's California Grain and Feed Association (CGFA) meeting, she was informed by Mr. John Silva that he will no longer be able to serve on the board as he is leaving TPi Nutra Blend. Ms. Areias asked him for a resignation letter; the program has yet to receive the letter and will reach out to TPi Nutra Blend to confirm that he is no longer with the company. Ms. Areias stated the program will

advertise the one vacancy when it becomes open. Ms. Arana asked if the board can keep the other applicants when Mr. Silva's position becomes vacant. Chair Walth recommended the program reach out to the two other applicants, inform them of the new vacancy, and encourage them to reapply.

MOTION: Mr. Michael Koewler moved to approve recommendations of Dr. Marit Arana, Mr. Paul Parreira, and Ms. Shay Rambur for the board vacancies; Mr. Tim Riordan seconded. The motion passed unanimously with a vote by all board members present of 8-0.

FUND CONDITION / TONNAGE REPORTING

Ms. Areias reported, as of July 1, 2017, the total combined funds for the Feed and the Safe Animal Feed and Education (SAFE) programs were \$4,118,539. Revenue, which included tonnage tax, feed and livestock drugs (LD) license, and restricted livestock drug (RLD) registration, was \$2,534,481; expenditures were \$1,841,400; encumbrances were \$63,764; and the total ending adjusted balance was \$4,747,676. Ms. Areias announced that there are no recoveries for bovine spongiform encephalopathy (BSE) and Tissue Residue (TR) but there will be on the next fund condition report. She stated TR assignments have reduced; therefore, there are no numbers to report. The recoveries for Animal Feed Regulatory Program Standards (AFRPS) were \$193,813. The total adjusted balance for LD was \$249,522 and AUS was \$567,805.

Ms. Areias addressed Chair Walth's financial concerns about the program revenue in the last FIAB meeting. The Department worked thoroughly to identify and summarize the revenue of the LD split from Feed and SAFE. She stated the total Feed revenue was verified in documents for fiscal year (FY) 2014-15; however, the LD split was not what was reported to the board, which was an error on the Department's end. The program did not report the LD in the revenue because it was split from Feed and SAFE.

Ms. Areias discussed the importance of showing the board how the program tracks all employee time spent with AUS, AFRPS, and federal contracts, and charges each program based on the work being done. The costs associated with each program can vary from travel, vehicle, equipment, and hours spent.

The program gave a detailed breakdown of employee time and tracked expenditures. Ms. Krout-Greenberg also reported the program is aligned with the 2013 strategic plan. She announced that a line item for the FSMA cooperative agreement (CA) might be added to the Feed program. Currently, the National Association of State Departments of Agriculture (NASDA) is working on a model, like the Produce Safety Rule, for states that have accomplished the 11 standards. States that meet the 11 standards will have the opportunity of work through a CA. NASDA will release the plan in May and those interested will have the opportunity to apply this fall. This will offset the cost directly to the Feed program; however, it is work done on behalf of the federal government to

reach feed compliance and the board will need to decide if they want the program to apply once the CA is in place. She stated the purpose of providing the financial revenue documentation is to ensure the program has enough revenue to support the budget. Chair Walth stated the documentation is transparent and applauded the program for providing the information to the board.

Ms. Areias announced this is the last year of the TR contract as FDA is ending the enforcement contract and adding the Judicious Drug Use Program Cooperative Agreement (JDUP-CA), an agreement for \$525,000. The program sent a Letter of Intent and plans to move forward with the agreement. She stated the JDUP-CA is VFD related work; it requires inspectors to visit feed mills to inspect VFDs, onsite assessments, on farms whom feed VFDs, and follow up violations to issue TR violators. JDUP-CA covers Feed and LD law, and AUS due to the outreach component. She stated JDUP-CA work will be directly related to feed mill, distributors, and on farm inspections.

Ms. Areias presented the FY 2018-19 revenue projections handout. The FY 2018-19 revenue projection is calculated at \$0.10 cents with 21 million tons with a total projected revenue of 3.0 million for FY 2017-18; and total remaining reserves to be \$3.3 million. Chair Walth stated the program can add a couple hundred thousand to the total remaining reserves to be \$3.9 million indicating that the program is in good standing.

Ms. Areias informed the board that the 'Program Cost Account – Commercial Feed Program Revenue' document was included in error. This document is typically used for audits by the Department's Audit Office (AO). Chair Walth asked if there are other Department funded programs that have an audit committee within their board. Ms. Krout-Greenberg replied there is not, but a program can request a financial audit by the AO. She stated an audit completed every five years, to ensure all money is accounted for, would be valuable to the Division and to the industry funded programs.

Chair Walth asked the program to gather cost information and to possibly add a financial audit line item to the FY 2019-20 budget. Ms. Areias stated a line item can be added to a revised FY 2018-19 budget for the next FIAB meeting.

FEED, LIVESTOCK DRUGS, AUS, AND SAFE PROGRAM UPDATES

Ms. Areias announced program staff updates. Ms. Casey Dykier and Ms. Jessica Valdez, ES for Feed and AUS, started in December 2017. Both have a wealth of knowledge in agriculture, animal science, and laboratory setting, and have been great additions to the program. The program is working strategically to fill vacant positions for the benefit of the program.

The Feed program has fully implemented seven of the 11 AFRPS Standards. The 11 Standards implementation clearly defines the inspection rules by creating a standard inspection checklist for routine inspections, violation follow-up inspections, complaints,

enforcement actions, and compliance standards and enforcement matrix. The program is now required to put a numerical value of firm history, nature and severity of violation, in every violation. All are to be documented for auditing purposes. Per the 2013 strategic plan, the program was successful in meeting the 60/40 split goal of feed and food safety versus label compliance.

FEED AND LIVESTOCK DRUGS FIELD ACTIVITIES

Mr. Mike Davidson, Supervising Special Investigator I, reported the program discovered over 3,000 bags of damaged Whey Protein Concentrate where Salmonella detected positive. All bags were shipped to Southern California for radiation and then re-tested negative for Salmonella. The food plant is working with the Department on proper reworking of the product.

Ms. Areias stated that at the July 2016 FIAB meeting, the board recommended a Regulation Working Group to draft regulations. The working group met to discuss AAFCO definitions, analytical variations, FSMA, and the VFD rule. The group also discussed developing a penalty matrix to clarify the assessment of fines for violations, including minor, moderate, and severe violations, for fairness and consistency in compliance with laws and regulations. Ms. Areias stated while a penalty matrix is the goal, the Commercial Feed Administrative Penalty language must be imbedded in the Feed law first. She requested that the board discuss and provide recommendation for the program to move forward.

MOTION: Mr. Tim Riordan moved to approve developing a feed penalty matrix; Mr. Paul Parreira seconded. The motion passed unanimously with a vote by all board members present of 8-0.

Mr. Tim Riordan asked if the board needed to create a subcommittee to help develop a penalty matrix. Ms. Areias replied that the program has prepared the administrative penalty language to add to the Feed law and that once the language is imbedded into the Feed law, the program will have the authority to develop a penalty matrix. The program will need a subcommittee's input to help identify enforcement actions, the level of enforcement, and the penalty fine.

Ms. Krout-Greenberg advised the board to begin forming a work group to draft regulatory framework for enforcement actions. She reminded the board, that per the Bagley Keene Act, the work group meetings must be noticed with an agenda to the public. Mr. Paul Parreira advised the board to form a work group at this meeting. Chair Walth suggested Mr. Parreira, Ms. Shay Rambur, and Mr. Tim Riordan be members of the work group.

MOTION: Mr. Paul Parreira moved to approve a Regulation Working Group of Mr. Parreira, Ms. Rambur, and Mr. Riordan; Mr. Tim Riordan seconded. The motion passed unanimously with a vote by all board members present of 8-0.

Ms. Areias gave FDA contract updates, reporting there were 17 TR investigations, 24 BSE inspections, 2 FSMA Current Good Manufacturing Practices (CGMP) inspections, and 0 VFD inspections. A discussion took place with Research Microbiologist Dr. Yudhbir Sharma from US FDA, the United States Department of Agriculture (USDA), and the Department regarding the TR enforcement contract work.

Draft regulations pertaining the application of a RLD licensee should be published on July 1, 2018. Ms. Areias provided a product registration update reporting as of January 1, 2018, 908 label registrations, and of those, 149 are Restricted Drugs.

Ms. Rachelle Kennedy, SES (Specialist), provided AUS updates, reporting that the draft regulations of the RLD licensee application will be paired with regulations for the Sales of California Prescription Drugs which is to be published July 1, 2018.

Ms. Kennedy reported the FDA's JDUP-CA will replace the TR contract. AUS will apply for the JDUP-CA in mid-May and will begin September.

AUS conducted a VFD survey by identifying VFDs. The program visited VFD feed manufacturers, distributors, and any facilities that filed a FDA Letter of Intent. AUS is collecting all VFDs and tonnage of medicated feed for manufacturers. AUS is also redacting VFDs required information of farm name and address, and leaving only the veterinarians name. Chapter 4.5 Livestock: Use of Antimicrobial Drugs Section 14407 states "notwithstanding the California Public Records Act (PRA), any information provided pursuant to this chapter, shall be held confidential, and shall not be disclosed to any person or governmental agency, other than the department or the Veterinary Medical Board, for the purposes of enforcing the Veterinary Medicine Practice Act, unless the data is aggregated to prevent the identification of an individual farm or business." All VFD information is held confidential and is not subject to a PRA. AUS is only obtaining the information needed in the VFD surveys by collecting and redacting information, and then providing it to surveys and studies.

Discussion ensued regarding the gathering of VFDs.

Ms. Areias stated AUS has a three-phase approach: contacting firms with a Letter of Intent, conducting a focus study, and performing ongoing survey and enforcement action. Chapter 4.5 gives the program the authority to enforce the VFD rule and gather information for surveys and studies. A checklist was developed for compliance and information gathering.

SAFE AND AFRPS

Ms. Samantha Moran-Defty, ES, stated SAFE hosted three Food Safety Preventive Control Alliance (FSPCA) Qualified Individual (QI) training in 2017 to reach various regions (Modesto, Sacramento, and Tulare) in the industry. A SAFE Listserv was developed in December 2017 to allow for industry to communicate with the program and amongst each other, and for notification of upcoming trainings. In March, SAFE sent out a survey via SAFE Listserv to discover the need for the program to host another Preventive Controls Qualified Individual (PCQI) training. SAFE performed and completed FSMA CGMP readiness inspections at Priority 1 firms; inspections at Priority 2-4 firms started this year. Based upon the results of the FSMA CGMP readiness inspections at Priority 1 firms, SAFE identified sections for industry to focus on which include meeting training requirements and recordkeeping of personnel, general preventative maintenance on plant and grounds, plant operations, and general housekeeping of the facility.

Ms. Moran-Defty reported the breakdown of 2017 sample tracking by number and type of samples collected. She reported SAFE plans to perform CGMP readiness inspections at the remaining firms that manufacture textured feed, except single ingredient manufacturers. Four field program staff will be completing FSMA GMP regulators training in June; bringing the total to seven program staff having FSMA CGMP Regulatory training. Ms. Moran-Defty stated the field program staff will also be required to attend and participate in the Hazard Analysis training. She will continue to work with firms for development and compliance with CGMPs and Food Safety Plans.

FDA conducted an AFRPS audit on July 10-11, 2017; SAFE met six of the 11 standards: inspection program, feed-related illness or death and emergency response, outreach activities, self-assessment, lab services, and sampling program. SAFE completed Standard 6 Enforcement Program in February 2018.

CENTER FOR ANALYTICAL CHEMISTRY LAB REPORT UPDATES

Ms. Krout-Greenberg introduced Ms. Maryam Khosravifard, EPM I for the Center for Analytical Chemistry lab, who replaced Ms. Elaine Wong, former EPM I for the lab. Ms. Khosravifard started with the Department as an Agricultural Chemist.

Ms. Khosravifard reported the lab had an 11 percent reduction in the total number of samples received, a 24 percent reduction in the number of rush samples; however, a 32 percent increase in partial rush samples. Sample turnaround time improved 14 percent (15-21 days) over last year. Ms. Khosravifard reported she is evaluating the program to enhance methodologies for accuracy and efficiency in the lab to ensure timely reporting of sample results. The lab is remodeling space and working with contractors for the delivery and installation of the Liquid Chromatography Mass Spectrometry (LCMS) triple

quadrupole. The LCMS was approved by the board and is expected to arrive in June 2018.

Mr. Riordan asked if the program will add the equipment to the replacement schedule. He also asked if a new Inductively Coupled Plasma Optical Emission Spectrometry (ICP-OES) equipment would potentially increase the speed and accuracy for mineral analysis. He asked about the importance of ICP-OES, and the approximate costs. Ms. Khosravifard replied stating the lab's goal is to switch the metal and mineral analysis to ICP. The LCMS has a more efficient turnaround time of one hour versus one day with the ICP-OES. Ms. Khosravifard is working with vendors to evaluate types of products, the associated costs, and determining what would be the best fit for the lab.

Chair Walth asked the status on the Near Infrared Spectroscopy (NIR) equipment. Ms. Areias replied stating she spoke with Mr. Stan Kobata, SES (Supervisor) of the lab, who has started to validate samples in almond hulls against NIR results. Mr. Kobata hopes to continue validating the samples.

AGENDA ITEMS FOR FUTURE MEETINGS

Chair Walth asked the Board for agenda items for the next meeting and advised the Program to add the strategic planning group to the agenda. Chair Walth asked the length of the strategic plan process. Ms. Krout-Greenberg stated the Division and Branch have been brainstorming on internal processes of key importance. She stated the process can be done in three sessions where the group meets to discuss recommendations that will be presented at the Spring 2019 FIAB meeting.

Mr. Riordan asked for an update on the Technical Advisory Subcommittee (TASC) to be added to the agenda. Ms. Areias stated TASC is a top item on the strategic plan that needs to address the future. TASC has a critical role in the implementation of internal processes. In the Feed bylaws, the board recommended that TASC members with a conflict of interest can no longer serve on the TASC. Therefore, the program must meet with the remaining TASC members to address recommendations for new TASC members; then TASC can move forward with the items identified in the strategic planning.

Dr. Arana asked what the conflict of interest is. Ms. Areias stated that Department employees cannot serve as TASC members.

Mr. Riordan added that TASC expects continuity to remain in place between the program and board. Ms. Krout-Greenberg stated there is an evolving need to have a robust scientist to interface with the program and external sister agencies, and for TASC to help inform on these needs for direction on what is to come for the feed industry in California. Ms. Areias suggested TASC be an agenda item for the next FIAB meeting. Ms. Krout-Greenberg agreed, stating the board may suggest having members from

academia, and emphasized the importance of the vision and purpose of TASC to define the key objectives of undefined feed ingredients and hazard analysis.

NEXT MEETING

Chair Walth stated the next meeting will be held in June 2018. 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 12:04 p.m. by Chair Walth.

Respectfully Submitted By

| ORIGINAL SIGNED BY JENNA AREIAS | 04/05/2018 |
|---|------------|
| Jenna Areias, Feed Program Supervisor | Date |
| Feed, Fertilizer, and Livestock Drugs Regulatory Services | |