

CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE (Department)

**FEED INSPECTION ADVISORY BOARD (FIAB)
STANISLAUS COUNTY FARM BUREAU / HYBRID**

**August 14, 2024
9:00 AM – 12:00 PM**

MINUTES

BOARD MEMBERS

Alejandro Hernandez
Dan Rice
Eric Benziger
Jed Asmus
Jeremy Banducci
Dr. Marit Arana, Chair
Michael DeGroot
Michael Koewler
Shay Rambur, Vice Chair

CDFA STAFF

Angelia Johnson
Ashley James
Brandi Alston
Brittnie Williams
Elizabeth Moseby
Erika Lewis-Ortega
Jenna Leal
KC Gutenberger
Mike Davidson
Natalie Krout-Greenberg
Rachelle Kennedy
Samantha Moran-Defty
Ted Bert
Valerie White

INTERESTED PARTIES

Chris Zanobini
James Langston
Jessica Lawrence
Sean Runyon
Tad Bell

INTRODUCTIONS AND ANNOUNCEMENTS

Dr. Marit Arana, Chair, called the meeting to order at 9:02 AM. Self-introductions were made, and a quorum was established.

APPROVE APRIL 15, 2024 MEETING MINUTES

Chair Arana requested the FIAB review the minutes from the April 15, 2024, FIAB meeting.

MOTION: Jed Asmus moved to approve the April 15, 2024 minutes as presented; Jeremy Banducci seconded. The motion passed unanimously by all members present with a vote of 9 - 0.

DEPARTMENT / DIVISION / BRANCH UPDATES

Natalie Krout-Greenberg, Inspection Services Division Director, announced negotiations for Bargaining Unit (BU) 10 were made the past year. BU 10 includes the Environmental Scientist classifications that are widespread throughout the Department. A preliminary agreement was settled for BU 10 which will impact the budgets with salary increases. The Division will work through the process by looking at the affects to several other programs across the Division.

Krout-Greenberg mentioned the importance of this impact and the 8% budget reduction that will affect all program fund sources. The budget reduction can affect the continuously appropriated Ag Fund, Budget Act Agricultural funded programs, and general funds. The Division is awaiting clarity from the Department of Finance about exemptions. The Secretary continues engagement with industry leadership and transparency through this process. Division will look at how the 8% budget reduction will also affect operations and the requirements from day-to-day standpoints in several of the Division's programs. With this, the state must also achieve a 10,000 position reduction. The Division waits for additional directions on what positions may be affected. The reductions are permanent for staffing and in overall budget allocation. More clarification to what it will look like for the Feed program will be provided at the next FIAB meeting.

Krout-Greenberg announced Dr. Amadou Ba, Branch Chief for the Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch, will retire in November 2024. The Division is working quickly to backfill the position by going through the interview process prior to Dr. Ba's retirement.

PROGRAM UPDATES

Jenna Leal, Environmental Program Manager for the Feed program, presented two current vacancies illustrated on the Branch org chart that have not been filled due to budget constraints and workload. One of the vacancies is currently advertised but awaiting grant funding approval before moving forward with filling the position. Chris Hansen, Special Investigator for Fresno County, is retiring in September 2024.

Leal welcomed the new FIAB member, Eric Benziger, Quality Assurance and Compliance Manager of Associated Feed and Supply Company and acknowledged Chair Marit Arana and Vice Chair Shay Rambur reappointments as FIAB members.

FUND CONDITION / FEED TONNAGE

Leal reported the beginning balance as of July 1, 2023, for Feed and Safe Animal Feed Education Program (SAFE) was \$3,784,224. Revenue for Feed and SAFE was \$3,967,034; expenditures were \$3,191,452 and encumbrances were \$1,137,123. Leal noted prior the lab was a line item in the budget; now the lab line items are contracts through University of California (UC) system and external to the Department. and show as money was encumbered. The ending adjusted balance for Feed was \$3,645,514 and \$914,292 for SAFE. The ending combined adjusted balance for Feed and SAFE was \$3,422,683. Tonnage decreased but reserves held strong due to tonnage increase from \$0.10 to \$0.12 cents. Total recoveries of \$720,546 were received: \$229,940 was from the Food Safety contract and \$490,606 was from the Animal Feed Regulatory Program Standards (AFRPS) grant.

Chair Arana requested a breakdown of the encumbrances for lab, facilities, etc.

Leal reported the tonnage increase from \$0.10 to \$0.12 cents on the table illustrating feed tonnage breakdown by fiscal year, noting tonnage decrease of 2 million tons from

previous reporting years. Notably, tonnage revenue has remained steady due to the tonnage tax increase. Although tonnage revenue is strong, tonnage is slipping. The Feed program continues to look at tonnage auditing, ensuring that firms pay their fair share of tonnage. The Feed program now has an overall picture of tonnage revenue breakdown which has provided more clarity and transparency in reporting with incentivized tonnage and tonnage per feed type.

Valerie White, Environmental Scientist for the Feed Program, reported the current tonnage revenue breakdown illustrates 2024 quarters one and two. White announced the \$0.12 cent non-diversion tonnage rate was raised to \$0.13 cents that became effective July 1, 2024. Non-diversion tonnage of 7,705,754.24 generates a total revenue of \$924,690.51. With a diversion tonnage rate of \$0.06 cent multiplied by the diversion tonnage of 594,786.45 generates a total revenue of \$33,584.25. White presented a table representing current 2024 tonnage per feed type in tons, reporting the majority were byproducts (oilseed meals/hulls/etc.), grains (rolled/crimped/ground) and seeds, and mixed/formula feed (2 or more ingredients).

Dan Rice asked when the incentivized tonnage became effective. Leal responded, stating the incentivized tonnage rate took effect in regulations on October 1, 2022. Rice commented that with the incentivized tonnage rate in place it does not appear that additional funds are being brought into the program.

Chair Arana suggested looking into who holds the incentive license and is reporting less than 1000 tons as well as who hold the regular license and is paying the incentivized tonnage rate.

TONNAGE AUDITS

Leal presented phase two in development of an auditing program. A big gap in tonnage reporting was firms selling to integrators who were not paying tonnage. Majority of integrators are licensed in California but are under the integrator exemption. With the phase two approach, firms will be selected at random from the ExtraView database. Selected firms will receive a notice of Tonnage Audit letter via email, comprehensive guidance documents on what should and should not be paying on tonnage tax and a request for information on tonnage, sales, commodities, toll manufacturing, etc. All completed audits will be confirmed with a closeout letter.

Leal mentioned that the Feed program discovered discrepancies between manufacturers and integrators reporting tonnage of feed going to integrators. It has shown that manufacturers are not paying, and neither are the integrators for that feed. Leal suggested a subcommittee meeting to discuss tonnage and different methodologies of categorizing different levels of payment of tonnage.

Dan Rice commented, stating with the focus on the Feed program's vision of allocated time to audits and integrated facilities, FIAB should revisit a potential regulatory pathway.

Leal presented at the California Grain and Feed Association (CGFA) Board meeting in July 2024 about tonnage auditing and reporting as well as the integrator issue. CGFA made a motion to encourage FIAB to ensure that integrators pay their fair share in tonnage. The motion led Erika Lewis-Ortega, the Feed Program's regulatory specialist, to draft a legal referral to the Department's Legal Office to address whether the program has authority to move forward through regulations and if it will require a bill to change the Food and Agricultural Code. The Feed program anticipates Legal's feedback on September 1, 2024. Leal advises a potential regulatory subcommittee meeting with members Jeremy Banducci, Dan Rice, Shay Rambur and Alejandro Hernandez.

Jed Asmus asked for the legal definition of an integrator. Leal responded, stating there is no legal definition in the Food Safety Modernization Act (FSMA) or in California Feed law and regulations; however, FSMA exempts those who own their own animals and are under the same management. The Feed program adopted the FSMA language by reference; however, it will be a challenge to define the term "integrator" properly to not exclude those currently eligible under FSMA regulations.

Leal gave an update on an ongoing livestock drugs case involving a digestive aid product. This case has been referred to the Attorney General's Office.

FIELD ACTIVITIES, FUNDING OPPORTUNITIES AND FEDERAL CONTRACTS

Samantha Moran-Defty, Senior Environmental Scientist (SES) (Specialist) for the Feed program, gave an overview of efforts and activities as of today. The Feed program has issued 42 notices of warnings for 11 unlicensed feed firms, 8 delinquent tonnage, 3 feed inspection findings, 1 veterinary feed directive, and 19 restricted livestock drugs related. Six feed complaints were received and violation inspection reports consisted of 76 sample violations and 30 regulatory notes.

The Feed program has completed a total of 19 federal contract inspections: 3 visits, 12 full scope preventive controls (PC) inspections, 2 licensed PC inspections, 2 non-licensed PC inspections, 1 training audit, 1 Food and Drug Administration (FDA) audit and 3 veterinary feed directive (VFD)/Bovine spongiform encephalopathy inspections. The AFRPS agreement expires in June 2025; no funding option has been shared with states. The FDA AFRPS final year agreement is July 1, 2024, to June 30, 2025, with \$525,000 for year five. The United States Department of Agriculture Natural Resources Conservation Service (USDA NRCS) Conservation Innovation Grant submitted in October 2023 for \$4,998,821 over a three-year period was not awarded to California. The USDA NRCS Regional Conservation Partnership Program (RCPP) was submitted in June 2024 for a \$25,000,000 over a five-year period.

Leal added, the Feed program would receive a percentage of those funds, but the rest would be passed through the University of California, Davis CLEAR Center partners where the majority of the work will be conducted.

Moran-Defty reported program sampling updates as of July 15, 2024. A total of 361 samples; 22% violation rate and 68% food safety. The Feed program will start the

sampling for the Food Emergency Response Network. The essential sampling was the majority from corn (50) and distillers dried grains (3).

Moran-Defty and Mike Davidson attended the Association of American Feed Control Officials (AAFCO) meeting in Texas. The FDA is not renewing their Memorandum of Understanding (MOU) with AAFCO that is set to expire on October 1, 2024, that recognized AAFCO ingredient definitions. The FDA plans to release guidance documents outlining a proposed Animal Food Ingredient Consultation (AFIC) process to evaluate animal food ingredients. FDA will evaluate the animal Food Additive Petition and Generally Recognized as Safe (GRAS) Notification Programs to determine if changes are needed to promote the efficient development and review of new animal food ingredients. FDA will utilize enforcement discretion for certain ingredients reviewed using the AFIC process.

REGULATIONS

Lewis reported the Feed Program's administrative penalty regulations were approved by the Office of Administrative Law and become effective October 1, 2024. The regulations packet regarding ingredient modernization (Article 14) was expected to go for public comment in August when we received word the AAFCO/FDA MOU would not be renewed. This proposed regulation packet incorporates AAFCO's Official Publication (OP) Chapter 6 ingredient definitions by reference and calls out the ingredients determined to have additional requirements for California. This packet is on hold until the Feed program sees what FDA's guidance documents state. The best path forward would be to take the text of AAFCO's OP ingredient definitions and place it into our Feed regulations.

Leal mentioned FDA will honor and recognize definitions published in the 2024 OP.

The Feed program's regulations in development are for Livestock Drugs registration, tiered tonnage, species specific guarantees, adequate feeding directions, customer formula feed changes, guarantee standards, integrator licensing/tonnage and products with environmental claims.

Mike Davidson, Supervising Special Investigator for the Feed program, presented California formula feed labeling guaranteed requirements. AAFCO has developed over the last 20 years guaranteed analysis for species and the class of animals expanded beyond what the Feed program requires. Davidson asked if FIAB wants to modernize guarantee requirements for every mineral, or species specific or class of animals. Advantages to this would be consumer obtaining more information and if program standardizes guaranteed requirements for species of class or animals, products could move interstate commerce.

The Feed program has taken steps to acknowledge some of these requirements in Feed laws and regulations and allowing a little flexibility to allow for interstate commerce but by doing so this would standardize and provide consistency with other states that

register every single label that is not a customer formula feed, and this is what is requested on their labels.

Discussion ensued regarding interstate commerce and nutrient guarantees on formula feed labels.

Leal commented that nutrient guarantees would align California with other states. The program would not move forward with a potential regulation change without the FIAB direction and support. Leal suggested this could be a topic of discussion for the Feed Regulatory Subcommittee to determine if the program should propose updated species-specific labeling regulations

Davidson also mentioned several firms have horse feed with an ingredient listed outside of the list of the ingredients. Under Article 4 Labeling and Use regulations of the California Code of Regulations (CCR), Section 2691, require firms to provide a percentage of any ingredient listed outside of the list of ingredients. These are mostly for marketed retail products.

Leal stated the Feed program can repeal CCR Section 2691 in the next proposed regulation packet if the FIAB agrees.

MOTION: Jed Asmus moved to approve Section 2691 of the CCR be strikethrough in regulations to effectively align California with other states; Eric Benziger seconded. The motion passed unanimously by all members present with a vote of 9 - 0.

Moran-Defty reported the Carl Fisher equipment has been transferred from the Department's Center for Analytical Chemistry to AN lab. AN lab also has the Near-Infrared Spectroscopy (NIR) equipment that was purchased by the Feed program in 2019. Moran-Defty asked if FIAB wanted to donate the NIR to UC Davis.

Leal added that any equipment given by the Feed program to UC Davis is considered a gift. The Feed program no longer owns the equipment. Leal asked if FIAB wants to transfer the NIR to UC Davis.

MOTION: Dan Rice moved to approve the Feed program transfer the NIR equipment to UC Davis AN lab; Michael DeGroot seconded. The motion passed unanimously by all members present with a vote of 9 - 0.

LABORATORY

Jim Langston, California Animal Health and Food Safety Lab (CAHFS), reported 2023 samplings for minerals, metals, ionophores, tetracycline, mycotoxin, pesticides and various vitamins. Most samples were tested for minerals and metals. CAHFS is on track for sampling this year. Langston announced a new Vitamin D3 method, noting mycotoxins are tested for FDA laboratory Flexible Funding Model (LFFM) program; majority were corn, distillers dried grains and soybean. International Organization for Standardization 17025:2017 accreditation was renewed in April. CAHFS added

mycotoxin to accreditation currently under scope. Vitamin D3 method development is now available for the Feed program and was part of the method development work for the LFFM grant. CAHFS is planning to develop two new methods for the upcoming year. Langston reported CAHFS is fully staffed. The new hire starts September 3, 2024. CAHFS is adding one additional lab analyst position to the team.

CAHFS purchased a Retsch Ultracentrifugal Mill to replace RAS Mill. During this transition of the new Mill, AN lab assisted in sample grinding. CAHFS attended the FDA LFFM Annual meeting in March 2024 and presented topics inter-lab comparison of Monensin analyses and method for removal of interferences with analysis of aflatoxins in feed. Langston announced that he will be presenting lessons learned from analysis of feed samples at the upcoming American Association of Veterinary Laboratory Diagnosticians meeting in October 2024.

SAFE ANIMAL FEED EDUCATION PROGRAM ACTIVITIES

KC Gutenberger, SAFE SES Specialist, announced the Spanish versions of Commercial Feed video tutorials for licensing and reporting tonnage are now available. SAFE strategic plan is what the next five years will look like with a focus on FSMA and providing more detailed educational resources on food safety topics and outreach such as workshops and webinars. SAFE program hosted a Preventive Controls Qualified Individual (PCQI) Training July 17-18, 2024, with 22 participants in attendance. Some industry members have shared interest in a PCQI refresher to go over topics or gain education to improve food safety plans. SAFE is publishing a label guarantee guidance regarding species specific guarantees. A mixer study guide is also in development to outline how to set up a study and review the results.

Gutenberger announced SAFE will be hosting a FDA webinar next month for industry regarding the process of ingredients approvals and Food Use Authorizations.

The 2023 crop year mycotoxin report illustrates 66 samples of various feed types were obtained and analyzed by the Feed program for mycotoxins. Majority of samples were corn and a few mixed feeds; 85% of those samples had no mycotoxins detected. Gutenberger reported 10 samples had mycotoxins, but all were below acceptable limits. Corn samples have levels of fumonisin below 5ppm and two samples had aflatoxin below 20ppm.

Leal reported that the Department's Office of Environmental Farming and Innovation did not have any other updates other than working with their livestock enteric methane emissions reduction research project recipients on authorizations.

ENTERIC ACTIVITIES UPDATE

Leal reported FDA's Center of Veterinary Medicine (CVM) published a letter to Elanco regarding their product, Bovaer® 10. The letter stipulated that FDA identified Bovaer® 10 as an unapproved drug of which they reviewed through both the new feed additive process as well as the new animal drug process and will allow market access of the product while using enforcement discretion. The CVM branch of FDA approves feed

ingredients and new animal drugs. The Center for Food Safety and Applied Nutrition (CFSAN) branch at FDA is the entity at the FDA that oversees all the pasteurized milk ordinance requirements for Grade A milk sold across state lines and interstate commerce. Leal has met with Dr. Stephen Beam, Branch Chief for the Department's Milk and Dairy Food Safety (MDFS) Branch, to discuss whether the FDA CVM letter would allow for the product to be fed to California dairy cattle. Dr. Beam stated that the pasteurized milk ordinance and therefore the MDFS prohibits unapproved drugs in Grade A milk system in the United States and approximately 95% of milk in CA falls under these requirements. CVM has been working with CFSAN to change the Public Milk Ordinance (PMO) to allow for this unapproved drug to be fed to lactating dairy cattle while also allowing the milk to be shipped in commerce accordance to the federal rules. The National Conference on Interstate Milk Shipments (NCIMS) Executive board has requested written documentation from CFSAN explaining they will allow milk products from cattle fed Bovaer® 10 to be enter into the Grade A milk system in California.

While awaiting these statements from FDA, it brings issues because it is not a one product issue. Leal and Dr. Beam have discussed whether California would be okay to completely defer to FDA to allow market access, or if the Feed program authority to regulate these products from Senate Bill 780 and existing CCR Section 2676 titled Safety and Efficacy of Drugs and Food Additives would be the appropriate path for oversight. If that latter is the case, what would regulatory oversight look like, and what resources are needed to regulate such products. Leal stated the risks and benefits with deferring to FDA and expressed the importance of validating the use and inclusion of these products through inspections to assist in the state meeting its SB1383 climate goals. Leal suggested that once FDA CFSAN publishes a letter, an option for the Feed program to take is by using regulation development process for label requirements on these feed additives. Leal requested FIAB discussion and guidance reiterating that either direction the board takes today will result in a formalized process for all products, not just one.

Asmus asked if the California Air Resources Board (CARB) has provided any guidance, or what offsets the percentage reductions will be, and if the Feed program wants the responsibility of reporting the transactions for methane. Leal responded, stating CARB has not provided guidance but believes that they are waiting for the Department to come up with a plan. Leal stated that it would not be a lot of additional work for the program to look at a formula and identify what methane reducing product is included the formula.

Discussion ensued regarding whether other states have approved Bovaer® 10 through their state processes or deferred to FDA. Discussion ensued regarding the concern of the product going dairy direct and its safety requirements. Additionally, the concern of consumer acceptance with this new product and potential impacts negative consumer response would have on the feed and dairy industries. Several members of the FIAB agreed to not defer to FDA completely.

Leal requested a motion from the FIAB indicating the plan to build program's own review process and not to completely defer to FDA's enforcement discretion letter.

Asmus asked if there is a process for program approval in state. Leal stated there is no current process for feed additives, but the program has provisionally approved a livestock drug product in state that was not approved by FDA. Discussion ensued regarding the gray area with Bovaer® 10 market access of whether this product is a feed additive or a drug.

Davidson suggested the Department can work on language and develop a proposed process then present it to the Technical Advisory Subcommittee (TASC) for review but at this point, the Feed program will not say whether the Bovaer® 10 product will be allowed, but that it will be evaluated first for use and labeling in California.

Leal shared that several meetings have occurred with the Department's Legal office and Dr. Beam who have collaboratively drafted a letter including above and beyond some of the program's requirements with safety and efficacy data, label requirements, reporting.

Chair Arana asked if FIAB can maintain where the program is now and revisit this topic at the next FIAB meeting.

Chris Zanobini commented, stating the Feed program may need some level of confidence from the FIAB that they are taking the right approach with the pressures that have major impact on the Feed program. Zanobini commented that there should be some type of position from FIAB to provide some level of assurance that the Feed program is taking the right approach, and it is timely that those decisions happen today.

Asmus asked the Feed program if a motion is needed to uphold the current Feed laws and regulations. Leal stated CVM is treating the product like a feed additive so the Feed program has the authority for the feed additive petition process, or the program can treat it like a drug, and it would be unapproved. The Feed program has more authority on quarantine violations, administrative penalties, food safety, and due process than the Livestock Drugs Program.

Rice recommended TASC review the product for further evaluation. Leal added, that only products that have received enforcement discretion letters from FDA could be evaluated through Feed's TASC and evaluated within the Feed program before allowing market access in California. Leal mentioned potential involvement of MDFS for milk safety.

Asmus asked what if TASC agrees with the plan, but the product is still an unapproved drug. Leal stated the program could look at existing authority while waiting for changes at the federal level. Leal stated this could help the FIAB/Feed program in developing the whole process. Leal proposes when FDA issues letters from CVM and CFSA that the product will be evaluated through TASC and that a process will be developed and

presented to the FIAB for evaluation and ultimate recommendation to the secretary for approval as a feed additive in California.

MOTION: Michael Koewler moved to approve the product to be acknowledged and evaluated through TASC for FIAB recommendation to the secretary for approval as a feed additive for the next 12 months; Jeremy Banducci seconded. The motion passed unanimously by all members present with a vote of 9 - 0.

UNIVERSITY OF CALIFORNIA DAVIS LAB UPDATE

Leal mentioned there are no UC Davis lab updates aside from what was mentioned by Moran-Defty/Langston earlier in the agenda.

ALMOND ALLIANCE UPDATE

Leal reported the Almond Alliance is conducting a whole feeding trial funded by a Specialty Crop Block grant.

CALIFORNIA GRAIN AND FEED ASSOCIATION

No updates were made other than the recommendation of integrators.

PUBLIC COMMENTS

No public comments were made.

AGENDA ITEMS FOR FUTURE MEETINGS

Leal stated an update on enteric activities, TASC and Feed Regulatory Subcommittee update will be on the agenda for the next FIAB meeting as well as the Feed, SAFE, Livestock Drugs and AUS programs proposed FY 25/26 budgets. Leal suggested CARB will be invited to attend the next FIAB meeting to provide an update on enteric methane.

NEXT MEETING

The next FIAB meeting will be on Tuesday, November 5, 2024, in Sacramento, California.

A virtual Feed Regulatory Subcommittee meeting will be on September 5, 2024, in the afternoon. All are welcome to attend.

ADJOURNMENT

MOTION: Jed Asmus moved to adjourn the meeting; Michael Koewler seconded. The meeting was adjourned at 12:25 PM.

ORIGINAL SIGNED BY JENNA LEAL

Jenna Leal, Branch Chief
Feed, Fertilizer, and Livestock Drugs Regulatory Services

8/14/2024

Date