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

2800 Gateway Oaks Drive, Room 101 Sacramento, CA 95833 (916) 900-5022

June 10, 2014 9:00 AM to 12:00 PM

MINUTES

MEMBERS

John Walth, Chair John Kauffmann, Vice Chair Marit Arana Paul Parreira Thomas Prokop **CDFA** Amadou Ba Gary Castro Giancarlo LaGiusa Elaine Wong Jenna Areias Jennifer Goucher Maria Tenorio Marilyn Boehnke Mike Davidson Nirmal Saini Vanessa Jivan

INTERESTED PARTIES

Asif Maan Doug Stabelfeld Kelly Covello Tad Bell

INTRODUCTIONS AND ANNOUNCEMENTS

Chairperson, Mr. John Walth called the meeting to order at 9:10 a.m. Self-introductions were made and a quorum was established.

Mr. Walth requested a moment of silence for the passing of board member Mr. Tom Daly.

REVIEW AND APPROVE MINUTES

Mr. Walth requested the board review the minutes from the March 4, 2014 meeting.

MOTION: Mr. Thomas Prokop moved to approve the March 4, 2014 minutes as submitted. Mr. John Kauffmann seconded; the motion passed unanimously.

BOARD VACANCIES

Mr. Walth reported there are currently four vacancies on the FIAB, one from the unexpected passing of Mr. Daly. Five applications were received for the four vacancies. Mr. Walth specified the term for Mr. Daly's position would be for the remainder of that term and not the standard 3-year term.

Mr. John Kaufmann, the nominating working group, reported the working group had reviewed and discussed the qualifications of the nominees. Two of the candidates were previous board members, Mr. Michael Koewler and Mr. Timothy Riordan. The other candidates were Mr. Bob Berczynski, Mr. John Silva, and Mr. Doug Stabelfeld. Mr. Kaufmann noted all five candidates were worthy of a position on the board, and urged the applicant who was not recommended for appointment to apply for future vacancies. The nominating group recommended the appointment of Mr. Riordan as a public member and Mr. Koewler, Mr. Silva, and Mr. Berczynski as regular members, and further recommended Mr. Berczynski to serve the remainder of Mr. Daly's term.

Mr. Walth requested input or a motion from the board regarding the nominating working group's recommendation.

MOTION: Mr. Thomas Prokop moved to accept the working group's recommendations to appoint Mr. Timothy Riordan as a public member; Mr. Michael Koewler, Mr. John Silva as regular board members; and Mr. Bob Bercyzynski to serve a partial term as a regular member in place of Mr. Tom Daly. Mr. Paul Parreira seconded the motion; the motion passed unanimously.

Mr. Walth informed the board the Secretary has the final decision on the appointments. The program will prepare the appointment packet and submit it for her review and approval.

DEPARTMENT / DIVISION / BRANCH UPDATES

Dr. Amadou Ba provided the board with Division and Branch updates. He reported that Mr. Kevin Masuhara, the previous Division Director of Marketing Services, is now the Department's Deputy Secretary for Administration and Finance. This position was previously held by Mr. Nate Dechoretz, who recently retired.

Dr. Ba reported the Branch has several new staff; Ms. Marilyn Boehnke had replaced Ms. Maria Tenorio and is the liaison to the Fertilizer and Feed advisory boards; Ms. Jennifer Goucher, previously the Office Technician for the Fertilizer program, accepted a training and development assignment as a Research Analyst for the Safe Animal Feed and Education (SAFE) Program; Mr. Giancarlo LaGiusa promoted to Office Technician for the Feed program; and Ms. Andrea Cano replaced Mr. LaGiusa as the Branch Office Assistant. Dr. Ba reported the branch has been actively recruiting to fill seven new positions the program received for the Fertilizer Program through the Budget Act of 2013. He stated four of the seven positions had been filled, and interviews were underway for the remaining three positions.

Ms. Jenna Areias introduced the Feed Program team members. Ms. Vanessa Jivan handles the program's federal contracts, works with the Food and Drug Administration (FDA), and assists with special projects for SAFE; Mr. LaGiusa handles the Feed Program licensing functions; Ms. Goucher conducts outreach and education in the SAFE program; and Mr. Gary Castro is the lead on Animal Feed Regulatory Program (AFRP) Standards.

FUND CONDITION

Ms. Areias stated, as of March 31, 2014, in the CDFA account total funds for the Feed program were \$1,300,382; total funds for SAFE were \$149,751. The total combined funds were \$1,450,133. Revenue was \$2,623,168; expenditures were \$2,467,662; the adjusted ending balance was \$1,605,639.

Ms. Areias reported the total tonnage for the first three quarters in fiscal year 2013/14 was approximately 15.6 million. Approximately six million tons is usually reported for the fourth quarter; the program is on track with tonnage reporting and revenue.

FEED PROGRAM UPDATES

Ms. Areias stated the regulation packet to increase the feed license fee from \$400 to \$500 is under review by the Department and should be in effect for the July 1, 2015 renewal period.

Mr. Castro stated the packet had to be approved by the Office of Administrative Law (OAL) and received in the Secretary of State's office by March 2015. The OAL has 30 working days to approve or disapprove a regulation once it has been received for review.

Mr. Walth asked if the board could decide to maintain the license fee at \$400 and not move forward with the increase if at the September 2014 budget meeting the board finds the additional revenue is no longer needed.

Dr. Ba confirmed the board would be able to stop the increase in September 2014. He said the proposal was still being reviewed internally, and had not yet been submitted to OAL for review.

Ms. Areias stated she and Mr. Mike Davidson attended two Association of American Feed Control Officials (AAFCO) events this year; the 2014 Midyear Meeting was in New Orleans and the Feed Administrator Seminar (FAS) in May was in Montana. Ms. Areias reported a great deal of information was brought back to the program.

Ms. Areias reported on the AAFCO FAS, stating the seminar consisted of closed sessions for regulators and FDA only. A main topic was the Food Safety Modernization Act (FSMA); there were concerns regarding the conflicting definitions of "farm" in the Bioterrorism Act and the proposed FSMA rule; the FDA was exploring changing the definition. Over 2,600 comments were received and the FDA was reviewing the National Grain and Feed Association (NGFA), the American Feed Industry Association (AFIA), CDFA, and state regulatory program comments first. The program invested a significant amount of time working on CDFA's comments for the FSMA regulations; it was an important group effort that provided valuable feedback to the board.

Mr. Prokop stated CDFA's comments are thorough and impressive. Ms. Areias thanked him and said she would pass on his message to Ms. Natalie Krout-Greenberg.

Ms. Areias stated cooperative agreements were also discussed at the seminar. California does not have a cooperative agreement with the FDA, but the program will consider it for upcoming FSMA work. The benefit of using cooperative agreements rather than contracts is they have more latitude and flexibility. They can also encompass longer terms, such as 10-years, and can be renegotiated yearly.

Ms. Areias stated the FDA was interested in working with the states and discussion should start now. She attended a division meeting and questions were developed pertaining to produce and feed rules for the Secretary's June 19, 2014 meeting with the FDA. A main question was how the funding mechanism would be structured and whether it would be a contract or cooperative agreement; another question addressed was the role of CDFA versus the role of the California Department of Public Health (CDPH). A detailed overview of the programs restructure and the working group's efforts was provided to the Secretary.

Ms. Areias informed the board another main topic at the seminar was the 11 AFRP Standards, which are:

- 1. Regulatory Foundation
- 2. Training
- 3. Inspection Program
- 4. Auditing
- 5. Feed-Related Illness or Death and Emergency Response
- 6. Enforcement Program
- 7. Outreach Activities
- 8. Planning and Resources
- 9. Assessment and Improvement
- 10. Laboratory Services
- 11. Sampling Program

Ms. Areias reported Mr. Castro was lead for the 11 Standards project; he has completed a risk assessment and prioritized the 11 AFRP Standards. The program started with Standard 4, Auditing, which includes observing the inspectors in the field, making sure inspections are uniform throughout the state, auditing field processes, and performing a desk audit of field staff. The second area of focus is Standard 1, Regulatory Foundation. The program will be looking at regulatory changes that may be needed to ensure inspections performed under state authority are equivalent to inspections performed under federal authority.

Ms. Areias stated funds for Standard 9, Assessment and Improvement, were included in the program's contract with the FDA for next year; the program will receive \$10,000 to conduct the self-assessment. The program will submit a form to the FDA certifying the program has evaluated whether it meets, partially meets, or does not meet each of the 11 Standards. The program must also provide a timeline of when the program will meet each standard that it has not met or has only partially met; the FDA will audit the program against those timelines.

Ms. Areias stated an inspection schedule will be created with information on how often the high-, medium-, and low-risk firms will be visited; how many samples will be taken; and whether the samples will be food and feed safety-related or label compliant. Day-to-day activities of field staff will be documented. She said a full self-assessment takes approximately 3,000 hours, about 12 months. The program's self-assessment started in April 2014; the goal is to complete it within 12 months. Ms. Areias stated Mr. Pat Kennelly, had agreed to work with the program on the assessment.

Mr. Tad Bell asked if the Division Director and the Secretary needed to be briefed on this issue, so that when implemented, there would not be several inspectors going through a single facility, when it can and should be done by one inspector. It would be beneficial to industry for an entire facility to only have one inspection, performed by one inspector, especially since some feed facilities also handle pet food. Mr. Bell suggested the program begin talking about the single inspection issue with Mr. Kennelly and the Secretary. Ms. Areias stated the program would discuss it with Mr. Rick Jensen and Mr. Kennelly.

Ms. Kelly Covello commented state agencies should create the best and most efficient plan for the industry that clearly justifies the reasons why one inspection for state and federal regulations would be the most efficient method, and present it to the FDA.

Ms. Areias agreed with both Mr. Bell and Ms. Covello. A question on single inspections was included in the program's questions to the FDA, including what makes a state inspection equivalent; what are the qualifications; and what do we need to do to make sure our industry does not have a multitude of different inspectors at the same facility.

Ms. Areias reported that Senate Bill (SB) 835 was in the Appropriations Committee and appeared to be moving forward with no obstacles. The FDA proposed its Guidance for Industry #209 as the overall strategy for antibiotic use, and Guidance #213 for the direct manufacturer.

Ms. Areias reported a California Senator used guidance #209 and #213, as well as the Veterinary Feed Directive to write SB 835, which would mandate the FDA's voluntary guidance in California law. If this bill becomes law, there is an exemption in the Livestock Drugs regulations that will have to be removed or amended.

Mr. Bell asked if Mr. Jim Houston, CDFA's Deputy Secretary for Legislation and Public Engagement, was aware of changes would have to be made to the regulations due to SB 835. Ms. Areias stated the program included that information in the bill analysis; Mr. Jensen met with Mr. Houston to further discuss the potential issue.

Ms. Areias reported the feed contract had been submitted; 20 good manufacturing practice (GMP) inspections were included in the contract. The FDA will pay for inspections at 20 of the 55 high-risk firms and the program will receive \$200 for verifying whether or not a company, reported as no longer in business, is still doing business. The 2014 feed contract amount is \$112,078.40 and now has three option years. The current tissue residue (TR) contract is in effect though the end of October 2014, and the new contract is being negotiated.

Ms. Areias reported that many of the program's current activities correlate to meeting the 11 AFRP Standards. The program is required to have Standard Operating Procedures (SOPs) for inspections, sampling, and report writing; essentially all program activities. Ms. Samantha Moran is updating the Inspector Manuals and SOPs for field operations.

Ms. Areias stated the SAFE Program is becoming more technical with outreach and educational activities, and working with academia. Ms. Goucher will be working with the

Technical Advisory Subcommittee (TASC) and UC Davis on new feed ingredients, and other functions such as FEED/SAFE Outreach, updating the program website, and uploading the FSMA feed safety plan to the website.

Ms. Areias stated for the Feed Program there is uncertainty about whether there will be an intern this year. If there is, the intern will be working with Ms. Goucher to gather data on undefined feed ingredients for the TASC. Dr. Marit Arana stated several individuals at Chico State may be interested in an internship; information will be posted to the A.L. Gilbert website.

Ms. Covello asked if program staff are uploading the commercial feed reports to firm accounts on the Branch's Extraview database, and whether the firms had been notified. Ms. Areias stated the reports are uploaded and the firms have been notified.

Ms. Covello suggested the program schedule a webinar to show the feed industry how to use the database since a lot of industry are not aware the reports are available through the Extraview database. Dr. Ba informed the board there is a video with voiceover on the Department's website to assist the industry with database processes.

Ms. Areais reported the program's Analytical Variation Data, which had been collected over the past 50 years, would soon be digitized and accessible electronically.

FIELD ACTIVITIES REPORT

Mr. Davidson informed the board that the program quarantined whole cottonseed imported from Mexico that had alflatoxin levels over 20 ppb. Samples taken at locations where it had been delivered were also over 20 ppb. All of the contaminated cottonseed has been returned to Mexico. Ms. Areias stated the FDA was very supportive with the cottonseed issue; CDFA took lead and the FDA remained involved. Coordination is currently disjointed among the US Department of Agriculture, Animal and Plant Health Inspection Service ((USDA-APHIS); the FDA; and the CBP. The Department is working to develop more open communications with the US Customs and Border Protection (CBP); because they are a federal agency, the CBP does not collect any documentation required by the State. She noted relationships will need to improve when the Foreign Supplier Verification regulations are released.

Mr. Bell asked if the licensee used a broker. Ms. Areias stated the guarantor, who brought the product into California, was from Minneapolis. The firm used a trans-loading facility that was nine miles from the border, and used California brokers to disperse the product into the Central Valley.

Mr. Davidson reported the program has been conducting an annual corn survey for several years to test for twelve mycotoxins; this year's survey was the cleanest corn in years.

Mr. Walth asked how many acres of corn were in this year's Imperial Valley Corn program. Ms. Areias stated only one grower because of the drought, the price of corn decreasing, and the closure of National Beef; the 7,000-acre goal is no longer being discussed. Harvest will be completed by the next board meeting, and the board will be provided with an update. Mr. Davidson stated the FDA received a tip about a feed store in Visalia selling illegal drugs manufactured in Mexico. The FDA was gravely concerned because the majority of the drugs were highly powerful antibiotics, and asked the program for help using CDFA's Livestock Drug authority. Field staff went to Visalia to quarantine the drugs, but the owner was uncooperative. He refused to sign any documentation; he agreed to take the drugs off the shelf. Staff returned the next day with a Deputy from the Tulare County Sheriff's Department and the owner allowed them to take possession of the drugs. Mr. Davidson reported the program has rapport with the FDA and the Center for Veterinary Medicine; the Visalia drug quarantine was a successful joint effort between the program and the FDA.

Ms. Covello asked the status of the case that was with the District Attorney (DA). Ms. Areias stated the program presented an almond hull case to the Fresno DA. The firm had product quarantined twice within the last harvest season. After being released from the second quarantine, the firm had four consecutive crude fiber violations. The DA is very interested in the case and supportive of moving forward. Lead investigator, Mr. Chris Hansen, has been checking with the DA's office regularly, but has no new information to report.

Mr. Paul Parreira asked if CDFA has to inspect documentation from grain elevators to the field level to meet FSMA requirements, or if activities would be limited to feed mills and grain elevators. He also asked how CDFA would coordinate having one inspector per facility, such as a food-grade processing facility like a rice mill versus a cotton gin, and what the differences would be in the regulation activities. Mr. Davidson stated all activities will be risk-based starting with the 55 high-risk firms. While humans do not consume cottonseed, it is related to food; a cotton gin may have issues with human food because of the possibility of alflatoxin in milk. Ms. Areias stated a food and feed safety plan must be in place no matter what is processed; all hazards need to be identified and documented, whether or not a hazard is likely to occur.

Mr. Bell stated coordinated training for inspectors is an item that should be addressed at the Secretary's meeting with the FDA; the board should assist the program in coordinating trainings for the FDA inspectors. He commented that if the program inspectors are required to have annual training, FDA inspectors should also go through training every year.

Ms. Areias stated UC Davis received a \$3 million grant for FSMA outreach, and will be providing information to industry. Additionally, the Feed Safety Alliance's curriculum will be released soon; SAFE will play an important role to ensure consistency. Mr. Walth suggested the Feed Safety Alliance reach out to Mr. Chris Zanobini because he is a Davis alumnus.

LAB REPORT/UPDATES

Ms. Elaine Wong reported that from January to April 2014, 230 samples were received at the Center for Analytical Chemistry (CAC); 126 were routine, 6 were priority, 14 were partial rush, and 84 were rush samples. The average number of assays per sample was 4.71. Ms. Elaine Wong reported that the lab was at 80% of sample analyses completed in 14 days, and 97% of total sample analyses completed in 21 days.

Mr. Parreira asked for an update on the almond hullers and processors request for assistance in comparing analyses between labs. Ms. Areias stated approximately 50 samples will be split. The split sampling had started and Ms. Covello and Ms. Wong are sharing information. Ms. Wong stated 13 samples have been split so far, and about five or six more split samples are in the lab, and will be sent out. The CAC recently received lab analyses from private labs that tested the split samples; Ms. Wong plans to compare those analyses to CAC's analyses. She stated the CAC would be glad to work with industry to resolve any discrepancies.

Ms. Covello informed the board the program is not paying the shipping costs and any other private lab costs; Almond Hullers and Processors Association (AHPA) is paying them. She then asked Mr. Nirmal Saini and Ms. Wong for their professional opinion whether 50 samples would be enough to approach other labs with a variance. Ms. Wong stated it is enough to show a little bit of trending, and is a good place to start; but overall, because the almond industry is huge, 50 is not enough.

Mr. Davidson informed the board the labs are only sampling the assay, as the samples are already ground and dried, so any variance in sampling and preparation techniques is gone. Mr. Parreira commented since preparing the samples was an issue, the CAC is preparing all samples. If the labs results are all within a range of tolerance, the problem must be in the preparation. The CAC can invite the private labs to Sacramento for preparation training.

ADDITIONAL ITEMS / NEXT MEETING

Mr. Bell asked Ms. Areias if it is standard protocol for the program to issue a Notice of Violation and to recover costs from violators for lab services and investigative services for federal cases, such as the cottonseed and livestock drugs situations. Ms. Areias stated there was no lab work involved in the livestock drug case; a Notice of Violation was issued and the firm was required to submit a disposal plan. If the firm failed to submit a plan, the program would have to do the disposal and civil penalties in the Food and Agricultural Code would apply.

Mr. Bell encouraged the program to bill violators for costs and services. Ms. Areias stated, in the future, the program plans to create a civil penalty matrix and incorporate it into the Feed regulations that will detail violations and the severity of the penalty similar to the matrix in the Fertilizer program regulations.

Mr. Bell commented the Feed Inspection program goes through the county DAs because it is not able to collect money for violations; reimbursement is purposely not a fine, so the Feed program will never be a program that survives by collecting fines. The DAs are able to go after violators based on Food and Agriculture statues or on bad business practices. He noted the money collected does not come back to the program, it stays with the county. Mr. Davidson stated the DA reimburses the program for investigative time when a settlement is received.

Mr. Parreira asked Dr. Ba if a lab analysis was required for compost, or manure that is sold. Dr. Ba stated a lab analysis is not required for dairy manure and compost, as long as no claims or guarantees are made, such as organic or nutritional guarantees; it is a soil amendment.

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Mr. Parreira requested Ms. Areias provide the board with contact telephone numbers for topic-specific questions, such as licensing, as well as an organizational chart at the next board meeting, as there have been several new positions and a lot of movement in the Branch. Ms. Areias stated the program would email the information to the board.

The next meeting will be on September 9, 2014, at the Stanislaus County Farm Bureau building in Modesto at 9:00 a.m.

MOTION: Dr. Marit Arana moved to adjourn the meeting at 11:30 a.m.; Mr. John Kauffmann seconded. The motion passed unanimously.

The meeting was adjourned at 11:30 a.m. by Mr. Walth.

Respectfully submitted by:

Jenne Marcias

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

<u>6/10/14</u> Date