CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE (Department)

FEED INSPECTION ADVISORY BOARD (FIAB)
CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE
2399 Gateway Oaks Drive, Sacramento, CA 95833 / HYBRID

October 3, 2024
4:00 PM – 5:00 PM

MINUTES

BOARD MEMBERS	CDFA STAFF	INTERESTED PARTIES
Alejandro Hernandez	Brittnie Williams	Allen Bridges
Dan Rice	Erika Lewis	Chris Zanobini
Eric Benziger	Jenna Leal	Doug Miller
Jed Asmus	Natalie Krout-Greenberg	Michael Boccadoro
Jeremy Banducci	Rachelle Kennedy	
Dr. Marit Arana	Roberta Franco	
Michael DeGroot	Samantha Moran-Defty	
	Ted Bert	
	KC Gutenberger	
BOARD MEMBERS ABSENT	Valerie White	
Michael Koewler		
Shay Rambur		

INTRODUCTIONS AND ANNOUNCEMENTS

Dr. Marit Arana, Chair, called the meeting to order at 4:03 PM. Self-introductions were made, and a quorum was established.

VOTE AND APPROVE BOVAER IN CALIFORNIA

Jenna Leal stated the Feed Technical Advisory Subcommittee (TASC) meeting held earlier today was a productive discussion. TASC has offered technical support over the years in reviewing processes of feed ingredient definitions and helping with regulation development. Based on the motion made at the August 14, 2024 FIAB meeting, the Feed program formalized a detailed process with TASC. The process will begin with product acknowledgement allowing market access or enforcement discretion from FDA and Feed program internal evaluation (program will defer to the Food and Drug Administration (FDA) for safety reviews) and prepare documentation for TASC evaluation. TASC will be provided with several different documents and labeling to ensure proper use and labeling in California and then provide feedback on evaluation and make a recommendation to the FIAB. FIAB will determine whether to make a recommendation to the Secretary. Once recommendations are made to the Secretary, the Feed program will submit all supporting documentation, then the Department will draft a letter memorializing the evaluation and publish it to the Department's webpage.

Leal presented the three TASC motions/recommendations to the FIAB, which include Process Approval, Bovaer Authority, and Bovaer Labeling Requirements.

1) Process Proposal: “TASC recommends the FIAB support the CFRP’s proposed process to evaluate products/ingredients under FDA enforcement discretion for safe and effective labeling and use in California."

Jed Asmus asked if it is only products that must go through the FDA process. Leal responded, stating yes, for example, processed animal waste was a recent product where FDA or the Association of American Food Control Officials (AAFCO) in the past have approved feed ingredients that do not fit the California market. The TASC took part in formulating those definitions. In this case, FDA’s discretion letter may change, and it comes with labeling that is to be evaluated by TASC through this process.

MOTION: Jeremy Banducci moved to approve Process Proposal recommended by TASC to the Secretary; Michael DeGroot seconded. The motion passed unanimously by all members present with a vote of 7 to 0.

2) Bovaer Authority: “TASC recommends the FIAB recommend to the Secretary that Bovaer®10 falls under Feed Program authority as prescribed in Food and Agricultural Code Sections 14902.1 and 15011."

Leal mentioned the importance of this motion because this product falls under this area submitted as a feed additive but went through scrutiny of a new animal drug process so the FIAB and the Department must acknowledge regulation of this product under Feed program authority. The Feed program has authority through Senate Bill 780 that states “notwithstanding any other law, any commercial feed additive or drug approved by the United Stated Department of Agriculture or US Food and Drug Administration that is fed to livestock shall be under the oversight of the department as the primary state regulatory agency, including but not limited to, products that make environmental and health claims.” In addition, Food and Agricultural Code, Section 15011, states the Secretary shall fix the standards for commercial feed ingredients, including drugs, tolerances for agriculture, chemicals and any additives used in the manufacture of feed to ensure the safety of animals and the products of animals which are used for human consumption. The Secretary shall enforce all medicated feed withdrawal periods as set by regulation. Leal stated Bovaer does not have any withdrawals so that the latter part would not be applicable.

Michael DeGroot verified if Bovaer is a non-approved drug from FDA. Leal reiterated it is not approved as a drug from FDA and that there is no medicated labeling requirement, and it will not have new drug application number or permit.

Rachelle Kennedy added that Bovaer went through FDA’s drug office for environmental food safety residues then through FDA’s animal feed office for animal safety, effectiveness, and manufacturing.

DeGroot further commented that there may be other products like this that are called a non-approved drug from FDA that go through the drug side feed side. DeGroot confirmed that the product is going to be labeled as a feed and mentioned would move the motion. Leal stated when the Innovative Feed Act is approved, this would fall into the zootechnical substance category to be reevaluated.

Allen Bridges responded, stating there would be no reevaluation of the data package. Elanco worked with CVM to provide all the data required for the enforcement direction decision. Bridges stated an administrative process will be required but no re-review of data will occur.

Asmus clarified if the regulation of this product means enables market access. Leal responded, stating that the Feed program would operate under the authority of our Feed laws and regulations for this product and defer to FDA for safety. The Feed program authority has far more thorough due process with its administrative penalties and labeling requirements.

Asmus further confirmed that FIAB/the Department are not intentionally or unintentionally going into the carbon side of this transaction or any of the claims associated with that. Leal stated no, this is simply to allow product market access as FDA states in their letter and that it will be regulated under Feed program authority. The Feed program has no authority for methane reductions.

MOTION: Michael DeGroot moved to approve the Bovaer Authority recommendation to the Secretary; Eric Benziger seconded. The motion passed unanimously by all members present with a vote of 7 to 0.

The Feed program, Elanco and TASC have had discussions about the labeling requirements of the product, the product would not be sold dairy direct through Elanco, and that the product must go through a licensed distributor to be fed on farm for program to capture the necessary data for regulatory enforcement on labeling. There are a lot of label requirements and to ensure the proper use of the product, per the label requirements, the product must go through licensed facilities.

3) Bovaer Labeling Requirements: ""“TASC recommends the FIAB recommend to the Secretary requirements for labeling of commercial feeds containing Bovaer®10 to be in compliance with FDA and California Commercial Feed Laws and Regulations and must include, at minimum; all guarantees, indications for use, limitations, warnings, caution statements and other statements which appear on the Bovaer®10 label; a statement of the concentration of 3-NOP in the commercial feed in units of mg/lb; and adequate directions for use which are capable of being followed and likely to be followed in usual feeding practices including, at minimum, directions to further manufacture the feed to achieve a rate of 27.2-36.3 mg 3-NOP per pound (60-80 mg per kilogram) of DM in the total mixed ration.”

Jeremy Banducci asked for clarification if meant by guaranteed analysis and not methane reduction guarantees. Leal stated it is guaranteed analysis purported on the label under the active ingredient.

Chair Arana commented, stating that the3-NOP and silicon dioxide in the bag, if it's a premix or blend or if it's added to proteins, vitamins and minerals – all would be listed in the guarantee according to California and/or AAFCO labeling requirements.

MOTION: Jeremy Banducci moved to approve the Bovaer Labeling Requirements recommendation to the Secretary; Eric Benziger seconded. The motion passed unanimously by all members present with a vote of 7 to 0.

Leal concluded the three TASC recommendations to the FIAB, stating that the Feed program will gather all documents, including a memo describing the outcomes of this meeting to the Secretary. The Department will draft a letter outlining the product being classified under the Feed Laws and regulations labeling requirements which will be published on the Feed program's webpage for reference.

Asmus requested a copy of the documentation and recording of this meeting. Leal requested board liaison, Brittnie Williams, to send a copy of the recording to the FIAB.

Dan Rice asked if the California Air Resources Board (CARB) will attend the next FIAB meeting in November. Leal stated that the Feed program has not yet been in communication with CARB but that Tawny Mata, Director of the Department's Office of Environmental Farming and Innovation and Scientific Advisor to the Secretary, has been in communication with CARB. Leal will confirm that CARB is aware of this and invite CARB to the next FIAB meeting.

PUBLIC COMMENTS

No public comments were made.

ADJOURNMENT

The meeting was adjourned at 4:31 PM.

ORIGINAL SIGNED BY JENNA LEAL 10/03/2024
Jenna Leal, Environmental Program Manager II Date
Feed, Fertilizer, and Livestock Drugs Regulatory Services