CALIFORNIA DEPARTMENT OF FOOD AND AGRICULTURE

CALIFORNIA CODE OF REGULATIONS
TITLE 3. FOOD AND AGRICULTURE
DIVISION 4. PLANT INDUSTRY
CHAPTER 2. FIELD CROPS
SUBCHAPTER 2. COMMERCIAL FEED

FINDING OF EMERGENCY

The Secretary of the California Department of Food and Agriculture (Department) has determined that the proposed emergency regulations are necessary to address a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, and general welfare of Californians.

EMERGENCY DEFINED

Pursuant to Government Code Section 11342.545, "emergency" means a situation that calls for immediate action to avoid serious harm to the public peace, health, safety, or general welfare. If a state agency makes a finding that the adoption of a regulation is necessary to address an emergency, the regulation may be adopted as an emergency regulation pursuant to Government Code Section 11346.1(b)(1). This document provides the necessary specific facts demonstrating the existence of an emergency and the need for immediate action to prevent serious harm to the general welfare of the citizens of California, pursuant to Government Code Section 11346.1(b)(2).

Government Code Section 11346.1(a)(2) requires that, at least five working days prior to submission of the proposed emergency action to the Office of Administrative Law, the adopting agency provides a notice of the proposed emergency action to every person who has filed a request for notice of regulatory action with the agency. After submission of the proposed emergency to the Office of Administrative Law, the Office of Administrative Law shall allow interested persons five calendar days to submit comments on the proposed emergency regulations as set forth in Government Code Section 11349.6.

The Department has complied with the requirement to provide notice of the proposed emergency rulemaking action at least five days prior to submitting the proposed rulemaking action to the Office of Administrative Law, pursuant to Government Code Section 11346.1(a)(2). The information contained within this finding of emergency also meets the requirements of Government Code Sections 11346.1 and 11346.5.

SPECIFIC FACTS DEMONSTRATING THE NEED FOR IMMEDIATE ACTION

The Department's Commercial Feed Regulatory Program (CFRP) is responsible for the enforcement of California state law and regulations pertaining to the manufacturing, distribution and labeling of commercial feed while preventing adulterated feed from being consumed by livestock. Inspectors and investigators located throughout the state conduct routine feed sampling and inspections, quality assurance inspections of feed

manufacturing facilities, respond to consumer complaints, and enforce the laws and regulations that govern the manufacturing, distribution, and labeling of commercial feed for livestock. The work of the CFRP helps to ensure a clean and wholesome supply of meat, milk, and eggs, as well as providing assurance that the product received by the consumer is the quality and quantity purported by the manufacturer.

On August 2, 2024, the US Food and Drug Administration (FDA) announced the expiration of its longstanding memorandum of understanding (MOU) with the Association of American Feed Control Officials (AAFCO) on October 1, 2024. Since 2007, FDA has maintained MOU 225-07-7001 with AAFCO to facilitate collaboration and clarify responsibilities related to the animal food ingredient definition request process, which establishes common or usual names for ingredients that are required on feed labels by both federal law and state regulations.

FDA is the primary federal agency with authority to regulate ingredients and additives used in animal food. AAFCO is a voluntary membership organization comprised of state, federal, and international government agencies responsible for the enforcement of laws and regulations pertaining to the production, labeling, distribution, use, and sale of animal food. AAFCO’s ingredient definition request process works to identify the safety, utility, and identity of ingredients used in animal food and establishes a common or usual name for the ingredients, with scientific and technical assistance provided by FDA. Since 1920, AAFCO has maintained the AAFCO Official Publication (OP), which contains a comprehensive list of common or usual animal food ingredient names established through this collaborative ingredient definition request process. Under the previous AAFCO ingredient definition request process, all ingredients were voted on by AAFCO membership prior to inclusion in the OP. The Department maintains a voting member at AAFCO meetings to have input regarding any new ingredients. However, it is unclear whether states will continue to have a role in the new ingredient definition request process.

While most other states recognize AAFCO’s ingredient names in their statutes, California does not; this is primarily due to differences in how livestock feed and pet food are regulated in this state. In other states and at the federal level, livestock feed and pet food are typically regulated by the same agency. However, in California, livestock feed is regulated by the California Department of Food and Agriculture pursuant to Food and Agricultural Code Division 7, Chapter 6 and California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2, while pet food is regulated by the California Department of Public Health pursuant to Health and Safety Code Division 104, Part 6, Chapter 10 and California Code of Regulations Title 17, Division 1, Chapter 5, Subchapter 2, Group 2, Article 16.

Although the Food and Agricultural Code does not specifically recognize AAFCO, the Department has historically accepted the common or usual ingredient names listed in AAFCO's OP in addition to those specified in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2 because they are recognized by FDA. The basis for

California's acceptance of AAFCO's list of common or usual ingredient names is FDA's recognition of the AAFCO ingredient definition request process memorialized by MOU 225-07-7001. With the expiration of MOU 225-07-7001, the Department believes there is no longer sufficient authority to permit the acceptance of feed ingredients which are defined in the AAFCO OP, but which are not defined in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2.

Since announcing the expiration of the MOU, FDA's Center for Veterinary Medicine has released two draft guidance for industry (GFI) documents; GFI #293 - FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients, which states that FDA does not intend to initiate enforcement action in response to animal food ingredients listed in the 2024 AAFCO OP, and GFI #294 - Animal Food Ingredient Consultation (AFIC), which describes an interim process for reviewing new ingredients while FDA evaluates the animal Food Additive Petition and GRAS Notification programs. However, FDA's guidance documents do not establish legally enforceable responsibilities. The Department is adopting the common or usual animal food ingredient names from the 2024 AAFCO OP into the California Code of Regulations to maintain consistency with FDA through state authority while FDA develops a new animal food ingredient approval process. It is unclear whether states will be involved in FDA's AFIC process, as they have historically been under the AAFCO process. It is critical to ensure the Department maintains oversight of ingredients allowed for use in California because the Department may no longer have a vote in the approval of new ingredients at the national level. Due to California's unique livestock industry, there are products that may be allowed either by AAFCO or FDA that the Department would not accept due to potential safety or feeding concerns.

Food and Agricultural Code Section 14992(e) requires the "recognized official name" of ingredients to be used in feed labeling. The existing commercial feed ingredient definitions specified in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2 have not been comprehensively updated since 1982, with only minor revisions made since 2002. The Department recently conducted an extensive comparison of its regulations against the AAFCO OP and determined numerous unintentional inconsistencies. These inconsistencies are a source of confusion for industry, complicate interstate commerce, and impede the Department's ability to enforce feed labeling requirements. The expiration of MOU 225-07-7001 will only exacerbate these issues because the Department must require the industry to comply exclusively with the outdated and incomplete provisions of California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2. Using enforcement discretion to temporarily deal with this administrative issue would establish a dangerous precedent, particularly with the recent increase of novel and not currently approved feed and livestock drug products and commercial feed additives with drug claims (reference CDFA notices to commercial feed and livestock drug industries linked below). Without using enforcement discretion in this situation, the Department would be forced to take enforcement action against an anticipatedly large portion of California's 2,046

commercial feed licensees. The Department does not have the resources needed to pursue widespread enforcement action against firms, and does not believe it would be appropriate or justified to assess administrative penalties against firms for what is essentially an administrative issue caused by the expiration of MOU 225-07-7001.

Immediate action is needed to update California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2 for consistency with the common ingredient names listed in chapter six of the AAFCO OP, with slight modifications that are necessary to accommodate California's unique feed industry and alignment with the Department's regulatory authority. These ingredient definitions have been thoroughly vetted through the exhaustive AAFCO ingredient definition request process which, until October 1, 2024, included scientific review and concurrence by FDA. Failure to take immediate action impedes the ability of California's 2,046 commercial feed licensees to conduct business, jeopardizes the health and welfare of the state's livestock population and, by extension, consumers nationwide that depend on California to produce a safe and wholesome supply of milk, meat, and eggs.

FACTS EXPLAINING THE FAILURE TO ADDRESS THE SITUATION THROUGH NONEMERGENCY REGULATIONS

The Department had already developed regulations to incorporate the feed ingredient definitions in chapter six of the AAFCO OP by reference through the regular, non-emergency rulemaking process. The notice of a 45-day comment period had just been approved by the Department's Executive Office for submission to OAL and publication in the California Regulatory Notice Register when FDA announced that MOU 225-07-7001 would not be renewed. Prior to FDA's August 2 announcement, no indication had been given that the MOU with AAFCO would be allowed to expire; the MOU has been renewed numerous times and has been in place for the past 17 years.

Following the August 2 announcement, the Department began evaluating how FDA's change in policy would impact the proposed regulations. The Department informed the Feed Inspection Advisory Board (FIAB) of the issue during its August 14 public meeting. Pursuant to Food and Agricultural Code Sections 14971 and 14975, the FIAB is authorized to represent and further the interest of the commercial feed industry as intended to serve the public interest and advises/makes recommendations to the Department's Secretary on all matters pertaining to commercial feed, including inspection and enforcement, CFRP budget, fees, and regulations. The FIAB requested that the Department begin drafting emergency regulations in consultation with the FIAB's Regulatory Subcommittee and a public meeting was scheduled pursuant to Bagley-Keene Open Meeting Act requirements. The following day on August 15, Department staff met to discuss regulatory approach in light of the expiration of MOU 225-07-7001 and direction from the FIAB. It was determined that the preferred course of action would be to copy the ingredient definitions from chapter six of the AAFCO OP into the Department's regulations rather than incorporating the document by reference. This would enable to the Department to avoid incorporating provisions applicable only to

pet food, to omit ingredients determined to be unacceptable for use in California, and to impose stricter ingredient standards where appropriate while maximizing clarity and ease of reference for the regulated industry. In addition, this approach maintains the Department's alignment with FDA, as AAFCO's continued role in the ingredient development process going forward remains unclear. The Department presented its revised approach to the FIAB Regulatory Subcommittee at a public meeting held on September 5, 2024. Following the meeting, the Department worked to incorporate AAFCO OP chapter six – nearly 86,000 words – into draft regulation text, incorporating the FIAB Regulatory Subcommittee's recommendations and modifications needed for state-specific requirements.

With the limited notice provided by FDA, notice period requirements for FIAB meetings required per Food and Agricultural Code Section 14975, and the length and complexity of AAFCO OP chapter six, it would not have been possible for the Department to address this situation through nonemergency regulations before the expiration of MOU 225-07-7001 on October 1, 2024.

ALTERNATIVES CONSIDERED OTHER THAN THIS PROPOSED EMERGENCY REGULATION

No alternative exists for the Department other than this emergency rulemaking action. The only viable option for the Department is to pursue an emergency rulemaking action to ensure the common or usual ingredient names found in AAFCO OP chapter six and accepted by FDA can continue to be lawfully used on feed labels in California after October 1, 2024. Any delay would result in the Department being forced to either (1) use enforcement discretion to allow common or usual feed ingredient names that are not defined in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2, or (2) take enforcement action against these otherwise safe and federally recognized ingredients solely due to the expiration of MOU 225-07-7001.

The Department has a statutory mandate to enforce the provisions of California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2. Using enforcement discretion to allow ingredients that are not defined in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2 could set a dangerous precedent that the Department will enforce the commercial feed law and regulations inconsistently. This is unfair to the industry as well as to the consumers these laws and regulations were enacted to protect. Furthermore, with the recent wave of interest in novel and not currently approved products and additives with drug claims, it is more important than ever to ensure that all ingredients used in commercial feed are safe and approved to protect the health of our livestock and the security of our food supply.

However, taking enforcement action against industry regarding common or usual feed ingredients listed in AAFCO OP chapter six but not currently defined in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2 would impede the ability of California's 2,046 commercial feed licensees to conduct business and potentially lead to

a shortage of viable feed options for California's livestock population. There are approximately 600 ingredients included in AAFCO OP chapter six that are not currently defined in California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2. These ingredients have been through the rigorous AAFCO/FDA ingredient definition request process and are determined to be safe and suitable for use in commercial feed, within the defined parameters. The Department has historically permitted the use of these ingredients because of FDA's recognition of the AAFCO OP in MOU 225-07-7001.

Adding the common or usual feed ingredient names from the AAFCO OP to the California Code of Regulations will allow the Department to maintain consistency with FDA requirements while upholding our statutory mandate to enforce the commercial feed law and regulations.

AUTHORITY AND REFERENCE

The Department is proposing to adopt this emergency rulemaking under the authority provided in Sections 407, 14902, 14903, and 14992 of the Food and Agricultural Code. These proposed modifications implement, interpret, or make specific Sections 14902, 14902.1, 14903, 14925, 14930, 14938, 14991, 14992, 14993, 14994, 15011, 15021, 15041, 15042, 15051, 15053, 15061, 15062, 15071, 15071.5, 15072, and 15073 of the Food and Agricultural Code.

INFORMATIVE DIGEST / POLICY STATEMENT

CFRP is proposing the emergency modifications to 3 CCR, Division 4, Chapter 2, Subchapter 2 described below.

Sections 2675(d) is being amended to update the term "official name" to "recognized official name."

Section 2675(g) is being amended to add the phrase "including but not limited to."

Section 2675(p) is being adopted to define the term "complete feed."

Section 2675(q) is being adopted to define the term "low nutrition ingredients."

Section 2675(r) is being adopted to define the term "premix."

Section 2675(s) is being adopted to define the term "common foods."

Section 2675.1(c) is being adopted to reiterate that, pursuant to Food and Agricultural Code Section 15021, the Department shall have free access at reasonable times to all premises or conveyances used in the manufacture, transportation, importation, distribution, storage, or feeding of any commercial feed and to define "free access," "reasonable times," and "all premises or conveyances."

Section 2675.1(d) is being adopted to reiterate that, pursuant to Food and Agricultural Code Section 14902.1, notwithstanding any other law, any commercial feed, feed additive, or drug approved by FDA that is fed to livestock shall be under the oversight of the Department. This section is also being adopted to define “approved by FDA” as an ingredient, additive, or drug that is listed in the Code of Federal Regulations (CFR) or that has received a generally recognized as safe (GRAS) letter from FDA, and clarify that the Secretary may also consider an ingredient, additive, or drug that has completed a safety review and received a letter from FDA documenting enforcement discretion, no objection to use or sale, no questions to safety, and/or allowing market access.

Section 2680 is being amended to update tolerances for heavy metals.

Section 2683 is being amended to use the term “recognized official name” and correctly spell non-protein nitrogen.

Section 2688 is being amended to use the term “recognized official names.”

Section 2691 is being repealed.

Section 2694(d) is being amended to accept salt in lieu of sodium and replace the term “present” with “added.”

Section 2694(e) is being adopted to specify that all guarantees shall be on an “as-fed” (as-is) basis, rather than on a 100 percent dry matter basis.

Section 2694(e) is being renumbered to Section 2694(f) and amended to remove requirements regarding descriptive terms and prohibit the use of collective terms other than those identified under Section 2778.

Section 2694(f) is being renumbered to Section 2694(g) and amended to remove the phrase “Definitions and Standards.”

Section 2694(g) is being renumbered to Section 2694(h).

Section 2694(h) is being renumbered to Section 2694(i).

Section 2694(i) is being renumbered to Section 2694(j) and amended to remove “no.”

Section 2694(j) is being renumbered to Section 2694(k) and amended to accept salt in lieu of sodium.

Section 2694(k) is being renumbered to Section 2694(l).

Section 2694(l) is being renumbered to Section 2694(m) and amended to remove the moisture limit for mixed feed containing dried animal waste.

Section 2694(m) is being renumbered to Section 2694(n).

Section 2694(n) is being renumbered to Section 2694(o).

Section 2694(o) is being renumbered to Section 2694(p).

Section 2694(p) is being renumbered to Section 2694(q).

Section 2694(q) is being renumbered to Section 2694(r).

Section 2694(s) is being adopted to require any feed ingredients exceeding the maximum moisture specified in the ingredient definition to be labeled as “high moisture.”

Section 2695 is being repealed. Provisions regarding collective terms are proposed to be adopted in Article 14.

Section 2696(d) is being adopted to clarify that all guarantees stated on the label shall accurately represent the composition and/or quality of the commercial feed.

Section 2697(b) is being amended to replace specific sections with a reference to labeling in accordance with Article 14.

Section 2697(e) is being amended to remove an unnecessary comma.

Sections 2702(d) and (e) are being amended to replace International United States Pharmacopoeia (U.S.P.) units with International Units (I.U.).

Section 2702(i) is being adopted to specify unit requirements for mineral guarantees.

Section 2702(j) is being adopted to specify unit requirements for products labeled with a quantity statement.

Section 2702(k) is being adopted to specify unit requirements for lysine, methionine, and other amino acids.

Section 2704 is being repealed. Provisions regarding screenings are proposed to be adopted under Article 14.

Section 2705 is being repealed. Provisions regarding screenings are proposed to be adopted under Article 14.

Section 2706 is being repealed.

Section 2707(a) is being repealed.

Section 2707(b) is being renumbered to Section 2707(a).

Section 2707(c) is being renumbered to Section 2707(b) and amended to correctly spell “non-protein nitrogen.”

Section 2707(d) is being renumbered to Section 2707(c) and amended to add a comma and correctly spell “non-protein nitrogen.”

Section 2707(e) is being renumbered to Section 2707(d).

Section 2734 is being renumbered to Section 2734(a).

Section 2734(a)(4) is being amended to correctly spell “pesticide.”

Section 2735 is being renumbered to Section 2735(a) and amended to remove an unnecessary comma.

Section 2735(a) is being renumbered Section 2735(b) and amended to specify acceptable sampling methods and update a section reference.

Section 2735(b) is being renumbered Section 2735(c) and amended to remove unnecessary commas.

Section 2735(c) is being renumbered to Sectio 2735(d) and amended to replace the term “mailed” with “submitted.”

Section 2735(d) is being renumbered to Section 2735(e) and to remove an unnecessary comma.

Section 2750(e) is being amended to add the term “eligible,” remove the reference to Section 2804, and to list the recognized official names of eligible human food by-products.

Section 2751(c) is being amended to add the term “eligible” and replace the reference to Section 2804 with a reference to Section 2750(e)(1).

Section 2760(d) is being amended to correctly spell “the.”

The title of **Article 14** is being amended to Recognized Official Names.

Sections 2770-2804 are being repealed.

Section 2770 is being adopted to create a section for general provisions and define the abbreviations used in Article 14.

Section 2771 is being adopted to create a section for Alfalfa Products, define general provisions for Alfalfa Products, and specify recognized official names and definitions for acceptable Alfalfa Products.

Section 2772 is being adopted to create a section for Almond Hull Products, define general provisions for Almond Hull Products, and specify recognized official names and definitions for acceptable Almond Hull Products.

Section 2773 is being adopted to create a section for Amino Acids and Related Products, define general provisions for Amino Acids and Related Products, and specify recognized official names and definitions for acceptable Amino Acids and Related Products.

Section 2774 is being adopted to create a section for Animal Products, define general provisions for Animal Products, and specify recognized official names and definitions for acceptable Animal Products.

Section 2775 is being adopted to create a section for Barley Products and specify recognized official names and definitions for acceptable Barley Products.

Section 2776 is being adopted to create a section for Brewers Products and specify recognized official names and definitions for acceptable Brewers Products.

Section 2777 is being adopted to create a section for Citrus Products and specify recognized official names and definitions for acceptable Citrus Products.

Section 2778 is being adopted to create a section for Collective Terms, prohibit the use of Collective Terms other than those specified, and specify recognized official names and definitions for acceptable Collective Terms.

Section 2779 is being adopted to create a section for Corn Products and specify recognized official names and definitions for acceptable Corn Products.

Section 2780 is being adopted to create a section for Cottonseed Products and specify recognized official names and definitions for acceptable Cottonseed Products.

Section 2781 is being adopted to create a section for Distillers Products and specify recognized official names and definitions for acceptable Distillers Products.

Section 2782 is being adopted to create a section for Enzymes, define general provisions for Enzymes, and specify recognized official names and definitions for acceptable Enzymes.

Section 2783 is being adopted to create a section for Fats and Oils, define general provisions for Fats and Oils, and specify recognized official names and definitions for acceptable Fats and Oils.

Section 2784 is being adopted to create a section for Fermentation Products and specify recognized official names and definitions for acceptable Fermentation Products.

Section 2785 is being adopted to create a section for Grain Sorghums, define general provisions for Grain Sorghums, and specify recognized official names and definitions for acceptable Grain Sorghums.

Section 2786 is being adopted to create a section for Human Food By-Products, define general provisions for Human Food By-Products, and specify recognized official names and definitions for acceptable Human Food By-Products.

Section 2787 is being adopted to create a section for Lespedeza Products and specify recognized official names and definitions for acceptable Lespedeza Products.

Section 2788 is being adopted to create a section for Marine Products and specify recognized official names and definitions for acceptable Marine Products.

Section 2789 is being adopted to create a section for Milk Products and specify recognized official names and definitions for acceptable Milk Products.

Section 2790 is being adopted to create a section for Mineral Products, define general provisions for Mineral Products, and specify recognized official names and definitions for acceptable Mineral Products.

Section 2791 is being adopted to create a section for Miscellaneous Products and specify recognized official names and definitions for acceptable Miscellaneous Products.

Section 2792 is being adopted to create a section for Molasses and Molasses Products and specify recognized official names and definitions for acceptable Molasses Products.

Section 2793 is being adopted to create a section for Non-Protein Nitrogen and specify recognized official names and definitions for acceptable Non-Protein Nitrogen Products.

Section 2794 is being adopted to create a section for Oat Products and specify recognized official names and definitions for acceptable Oat Products.

Section 2795 is being adopted to create a section for Other Oilseed Products and specify recognized official names and definitions for acceptable Other Oilseed Products.

Section 2796 is being adopted to create a section for Preservatives, define general provisions for Preservatives, and specify recognized official names and definitions for acceptable Preservatives.

Section 2798 is being adopted to create a section for Processed Animal Waste Products, define general provisions for Processed Animal Waste Products, and specify recognized official names and definitions for acceptable Processed Animal Waste Products.

Section 2799 is being adopted to create a section for Rice Products and specify recognized official names and definitions for acceptable Rice Products.

Section 2800 is being adopted to create a section for Rye Products and specify recognized official names and definitions for acceptable Rye Products.

Section 2801 is being adopted to create a section for Screenings, define general provisions for Screenings, and specify recognized official names and definitions for acceptable Screenings.

Section 2802 is being adopted to create a section for Sesame Products and specify recognized official names and definitions for acceptable Sesame Products.

Section 2803 is being adopted to create a section for Soybean Products and specify recognized official names and definitions for acceptable Soybean Products.

Section 2804 is being adopted to create a section for Special Purpose Products and specify recognized official names and definitions for acceptable Special Purpose Products.

Section 2805 is being adopted to create a section for Technical Additives, define general provisions for Technical Additives, and specify recognized official names and definitions for acceptable Technical Additives.

Section 2806 is being adopted to create a section for Vitamins and specify recognized official names and definitions for acceptable Vitamins.

Section 2807 is being adopted to create a section for Wheat Products, define general provisions for Wheat Products, and specify recognized official names and definitions for acceptable Wheat Products.

Section 2808 is being adopted to create a section for Whole Grains, define general provisions for Whole Grains, and specify recognized official names and definitions for acceptable Whole Grains.

Section 2809 is being adopted to create a section for Yeast and specify recognized official names and definitions for acceptable Yeast ingredients.

Section 2810 is being adopted to create a section for CFR Listed Feed Ingredients, which are ingredients listed in the Code of Federal Regulations.

Section 2811 is being adopted to create a section for GRAS Notified Substances Intended for Animal Food, which are substances that FDA has evaluated and determined that it had no questions regarding the conclusion that the notified animal food substance is generally recognized as safe (GRAS) under the intended conditions of use.

ANTICIPATED BENEFITS OF THE PROPOSED REGULATIONS

Anticipated benefits of the proposed regulations include increased consistency with national standards. The proposed regulations will permit the continued acceptance of common or usual feed ingredient names from the AAFCO OP after the expiration of MOU 225-07-7001, rather than requiring industry to comply with the outdated and incomplete provisions of California Code of Regulations Title 3, Division 4, Chapter 2, Subchapter 2. This will ensure the Department remains consistent with FDA requirements and result in increased clarity for the regulated industry. This will also ensure there are no disruptions to interstate commerce resulting from the expiration of MOU 225-07-7001, as well as reducing the burden on industry resulting from inconsistent labeling requirements among states.

In addition, specifying all ingredient names in regulation will give the Department additional oversight to ensure that any feed safety or consumer protection concerns are addressed through the inclusion of additional requirements for ingredients, as well as the exclusion of ingredients determined to be unacceptable for use in California. This will also ensure the Department avoids setting a bad precedent that we will not take enforcement action against unapproved or recognized products that are being marketed. Additionally, utilizing enforcement discretion in this situation would create confusion for firms regarding what is and is not allowed because the Department has historically imposed additional requirements for California-specific products.

DETERMINATION OF INCONSISTENCY/INCOMPATIBILITY WITH EXISTING REGULATIONS

None.

DUPLICATION OR CONFLICTS WITH FEDERAL REGULATION

The proposed emergency regulations include substances that are defined in the Code of Federal Regulations and the federal Food, Drug, and Cosmetic Act. These duplications are necessary for clarity, consistency, and to maximize ease of reference for the regulated industry.

PLAIN ENGLISH REQUIREMENT

The Department prepared the proposed regulations pursuant to the standard of clarity provided in Government Code Section 11349 and the plain English requirements of Government Code Sections 11342.580 and 11346.2, subdivision (a)(1). The proposed regulations are written to be easily understood by the individuals that will use them.

DISCLOSURES REGARDING THE PROPOSED ACTION

The Department has made the following initial determinations:

Mandate on local agencies and school districts: None.

Cost or savings to any state agency: The proposed action will result in cost savings for the Department. Without these emergency regulations, the Department would incur substantial costs pursuing enforcement action against products with ingredients listed in the AAFCO OP but not currently listed in regulation.

Cost to any local agency or school district which must be reimbursed in accordance with Government Code Sections 17500 through 17630: None.

Other nondiscretionary costs or savings imposed upon local agencies: None.

Cost or savings in federal funding to the state: None.

Significant, statewide adverse economic impact directly affecting business including the ability of California businesses to compete with businesses in other states: The proposed action will not have an adverse economic impact; however, without these emergency regulations, commercial feed manufacturers in California will not be able to maintain their level of production with the limited number of ingredients currently listed in regulation.

Cost impacts on a representative person or business: The Department is not aware of any cost impacts that a representative private person or business would necessarily incur in reasonable compliance with the proposed action. The proposed action would reduce cost impacts on businesses by not requiring label and formulation changes that would be needed for compliance with the limited number of ingredients listed in regulation.

Significant effect on housing costs: None.

RESULTS OF THE ECONOMIC IMPACT ASSESSMENT/ANALYSIS

California Government Code Section 11346.3 requires state agencies to assess the potential economic impacts on California businesses and individuals when proposing to adopt or amend any administrative regulation. The Department has initially determined that the proposed regulatory action will not have a broad economic or fiscal impact on the commercial feed industry. The proposed regulations will not:

(1) Require any additional ongoing expenses for compliant individuals or businesses.

(2) Create or eliminate jobs within the state.

(3) Create new businesses or eliminate existing businesses within the State of California.

(4) Affect the expansion of businesses currently operating within the State of California.

(5) The proposed regulations will benefit the health and welfare of California residents utilizing feed for their livestock by adding clarity to the regulated industry terminology, compliance expectations and subsequent consequences for industry licensees as it pertains to tonnage type, reporting, and payments; tax and licensure responsibilities, providing subsampling results, and defining severity of consequences by violation type.

(6) The proposed regulations are not expected to affect worker safety, or the state's environment.

SMALL BUSINESS DETERMINATION

The Department has determined that the proposed regulations will affect small businesses but will not have an economic impact on those businesses. The proposed actions do not involve any area that would increase fees or result in any increased costs to these businesses.

DOCUMENTS RELIED UPON

Association of American Feed Control Officials Official Publication
https://www.aafco.org/resources/official-publication/

MOU 225-07-7001: Memorandum of Understanding between the United States Food and Drug Administration and the Association of American Feed Control Officials
https://www.fda.gov/about-fda/domestic-mous/mou-225-07-7001

FDA Letter to Stakeholders: Acknowledgment of Expiring FDA-AAFCO MOU
https://www.fda.gov/animal-veterinary/animal-food-feeds/fda-letter-stakeholders-acknowledgment-expiring-fda-aafco-mou

FDA Center for Veterinary Medicine Draft GFI #293 - FDA Enforcement Policy for AAFCO-Defined Animal Feed Ingredients
https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-293-fda-enforcement-policy-aafco-defined-animal-feed-ingredients

FDA Center for Veterinary Medicine Draft GFI #294 - Animal Food Ingredient Consultation (AFIC) https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-294-animal-food-ingredient-consultation-afic

CDFA Notice to Commercial Feed and Livestock Drug Industries: Novel and Not Currently Approved Feed and Livestock Drug Products
https://www.cdfa.ca.gov/is/ffldrs/pdfs/nti_novel_products.pdf

CDFA Notice to Commercial Feed and Livestock Drug Industries: Commercial Feed Additives with Drug Claims

https://www.cdfa.ca.gov/is/ffldrs/pdfs/20240730_NTI_Commercial_Feed_Additives_with_Claims.pdf

CONTACT PERSONS

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