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 (Notice Published July 1, 2022)

NOTICE OF PROPOSED RULEMAKING

NOTICE IS HEREBY GIVEN that the Department of Food and Agriculture (Department) proposes to adopt and amend regulations as described below within the California Code of Regulations, Title 3 (3 CCR), Division 4, Chapter 2, Subchapter 2. The Department is issuing this notice to meet requirements set forth in Government Code Section 11346.4.

PUBLIC HEARING

Any interested person or his or her duly authorized representative may request a public hearing on this proposed action by submitting a written request no later than 15 days before the close of the written comment period noted below.

WRITTEN COMMENT PERIOD

Any interested person, or his or her authorized representative, may submit written comments relevant to the proposed regulatory action to the Department by mail or email. The written comment period will close on August 15, 2022. The Department will only consider comments received by that date. Submit written comments to:

Erika Lewis, Research Data Specialist II California Department of Food and Agriculture Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch 1220 N Street Sacramento, CA 95814 Email: <u>feed_lvstk@cdfa.ca.gov</u>

Following the written comment period or public hearing, if one is requested, and after considering all comments, objections, and recommendations regarding the proposed actions, the Department, at its own motion or at the request of any interested person, may adopt the proposal substantially as set forth without further notice.

AUTHORITY AND REFERENCE

The Department is proposing to adopt changes to 3 CCR, Division 4, Chapter 2, Subchapter 2 pursuant to the authority vested by Sections 407, 14902, 14903, and 14992 of the Food and Agricultural Code (FAC) to adopt, implement, and enforce these regulations. The proposed regulations will implement, interpret, or make specific FAC Sections 14903, 14925, 14991, 14992, 15011, 15041, and 15042.

Notice of Proposed Rulemaking Commercial Feed FSMA Incorporation 3 CCR Sections 2675.1 - 2694 Page 2 of 6

INFORMATIVE DIGEST / POLICY STATEMENT

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. The work of the CFRP helps to ensure a clean and wholesome supply of milk and meat, as well as providing assurance that the product received by the consumer is the quality and quantity purported by the manufacturer.

CFRP is proposing the adoptions and revisions to 3 CCR, Division 4, Chapter 2, Subchapter 2 described below.

The proposed adoption of Section 2675.1(b) specifies that the manufacture, distribution, and use of commercial feed shall comply with the requirements of Code of Federal Regulations Title 21, Part 507, Subparts A, B, C, E, and F, April 1, 2022, and clarifies that the enumerated subparts pertaining to commercial feed are incorporated by reference. This section clarifies that the term "animal food" as used in the Code of Federal Regulations refers only to commercial feed as defined in FAC Section 14925 and that any requirements applicable to processed, fresh, or frozen pet food are not incorporated.

The proposed revision to Section 2681(a) adds a reference to Code of Federal Regulations Title 21, Part 589.2001, April 1, 2022, and clarifies the existing reference to Part 589.2000 and the proposed reference to Part 589.2001 are incorporated by reference.

The proposed adoption of Section 2694(q) specifies that each batch or production run of formula feed shall be identified with its own individual batch or production run number, code, date, or other suitable identification adequate to facilitate the tracing of the complete manufacturing and distribution history of the product.

Anticipated Benefits of the Proposed Regulations:

The proposed regulations will incorporate provisions of the Food Safety Modernization Act (FSMA) from the Code of Federal Regulations, as well as requiring batch or production run identification to be added to formula feed labels. The anticipated benefits of the proposed regulations include improved consistency with federal requirements and enhanced product traceability. The proposed changes will benefit industry, consumers, and the public by enabling the Department to conduct enhanced inspections at commercial feed manufacturing facilities. Currently, these facilities receive a contract inspection performed on behalf of the U.S. Food and Drug Administration once every Notice of Proposed Rulemaking Commercial Feed FSMA Incorporation 3 CCR Sections 2675.1 - 2694 Page 3 of 6

two to seven years; incorporating federal requirements will allow the Department to inspect these facilities for compliance with federal requirements as part of routine state inspections conducted annually. The proposed regulations will also benefit industry, consumers, and the public by strengthening product traceforward/traceback capability through the addition of batch or production run identification for formula feed. This will allow industry and the Department to more quickly and accurately identify distribution in the event of a contaminated or adulterated product, ultimately enhancing consumer protections. The overall benefit of these regulations is to protect the health of the livestock population of the state, which will benefit the general public by maintaining an abundant and safe supply of wholesome food and fiber.

Determination of Inconsistency/Incompatibility with Existing Regulations:

The Department evaluated the proposed regulations and made several determinations required by Government Code Section 11346.5(a)(3)(A) to 11346.5(a)(3)(D). The Department determined that there are no existing state laws or regulations related directly to the proposed action and the effect of the proposed action; the proposed regulations are not inconsistent or incompatible with existing state regulations.

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: None.

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

Other nondiscretionary cost 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: None.

Notice of Proposed Rulemaking Commercial Feed FSMA Incorporation 3 CCR Sections 2675.1 - 2694 Page 4 of 6

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.

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 following is a summary of results from the economic impact analysis:

- The proposed regulatory action would not have a broad economic or fiscal impact to the commercial feed industry.
- The requirement to add batch or production run identification to formula feed labels may impact an estimated 20 manufacturers; the cost per firm will vary but is estimated at a one-time cost of \$100 per firm, for a statewide total of \$2,000.
- The proposed regulatory action would not require any additional ongoing expenses to individuals or businesses.
- The proposed regulatory action would not result in the creation or elimination of jobs within the state.
- The proposed regulatory action would not require the creation of new businesses or the elimination of existing businesses.
- The proposed regulatory action would not affect the expansion of businesses currently operating within the state.
- The proposed regulatory action will benefit the health and welfare of California residents by enabling the Department to conduct enhanced inspections at commercial feed manufacturing facilities as well as strengthening product traceability, ultimately enhancing consumer protections.
- The proposed regulatory action would not affect worker safety or the state's environment.

SMALL BUSINESS DETERMINATION

The Department has initially determined that the proposed regulations will impact small business; however, these costs are not expected to be significant. The Department anticipates that at most, a small business could expect to incur \$100 in initial and \$0 in annual ongoing costs to comply with this regulation.

Notice of Proposed Rulemaking Commercial Feed FSMA Incorporation 3 CCR Sections 2675.1 - 2694 Page 5 of 6

CONSIDERATION OF ALTERNATIVES

In accordance with Government Code Section 11346.5(a)(13), the Department must determine that no reasonable alternative it has considered or that has otherwise been identified and brought to its attention would be more effective in carrying out the purpose for which the action is proposed, would be as effective and less burdensome to affected private persons than the proposed action, or would be more cost-effective to affected private persons and equally effective in implementing the statutory policy or other provision of law. The Department invites interested persons to present statements or arguments with respect to alternatives to the proposed regulations at the scheduled hearing or during the written comment period.

CONTACT PERSONS

Written comments and inquiries concerning the substance of the proposed regulation, initial statement of reasons, proposed actions, location of the rulemaking file, or a request for a public hearing should be directed to:

Erika Lewis, Research Data Specialist II California Department of Food and Agriculture Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch 1220 N Street Sacramento, CA 95814 Email: <u>feed_lvstk@cdfa.ca.gov</u> Phone: 916-900-5022

The backup contact person for these inquiries is:

Ashley James, Research Data Analyst II California Department of Food and Agriculture Feed, Fertilizer, and Livestock Drugs Regulatory Services Branch 1220 N Street Sacramento, CA 95814 Email: <u>feed_lvstk@cdfa.ca.gov</u> Phone: 916-900-5022

AVAILABILITY OF STATEMENT OF REASONS, TEXT OF PROPOSED REGULATIONS, AND RULEMAKING FILE

The Department will have the entire rulemaking file available for inspection and copying throughout the rulemaking process. A copy of this notice, the proposed regulation text, and the initial statement of reasons may be obtained by contacting Erika Lewis at the address provided in the "Contact Persons" section.

AVAILABILITY OF DOCUMENTS ON THE INTERNET

Notice of Proposed Rulemaking Commercial Feed FSMA Incorporation 3 CCR Sections 2675.1 - 2694 Page 6 of 6

Copies of the notice of proposed action, the initial statement of reasons, and the proposed regulation text in underline and strikethrough can be accessed through the Department's website: <u>https://www.cdfa.ca.gov/is/Regulations.html</u>.

AVAILABILITY OF CHANGED OR MODIFIED TEXT

After considering all timely and relevant comments received during the written comment period, the Department may adopt the proposed regulations substantially as described in this notice. If the Department makes modifications which differ, but are sufficiently related to the originally proposed text, it will make the modified text (with the changes clearly indicated) available to the public for at least 15 days prior to amendment. Please send requests for copies of any modified regulations to the attention of Erika Lewis at the address provided in the "Contact Persons" section. The Department will accept written comments on the modified regulations for 15 days after the date on which they are made available.

AVAILABILITY OF THE FINAL STATEMENT OF REASONS

Upon its completion, copies of the final statement of reasons may be obtained by contacting Erika Lewis at the address provided in the "Contact Persons" section.