

**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**

**INITIAL STATEMENT OF REASONS**

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 livestock 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.

The proposed adoptions and revisions described below will achieve improved consistency with federal requirements and enhanced product traceability.

**SECTIONS AFFECTED**

California Code of Regulations (CCR) Title 3, Division 4, Chapter 2, Subchapter 2, Articles 1, 2, and 4, Sections 2675.1, 2681, and 2694.

**PROBLEM STATEMENT**

Food and Agricultural Code (FAC) Section 14903 states that the secretary shall establish, by regulation, good manufacturing practices, hazard analysis, and preventive control measures and that those regulations shall be based upon federal food and drug laws and regulations. Based on this statutory mandate to align with federal law, the proposed regulations incorporate provisions of the Food Safety Modernization Act (FSMA) from Code of Federal Regulations, Title 21, Part 507 (21 CFR 507), Subparts A, B, C, E, and F.

Feed manufacturing facilities are already required by federal law to comply with these requirements. However, the Department cannot currently inspect manufacturing facilities for compliance with federal requirements unless performing a contract inspection on behalf of the U.S. Food and Drug Administration (FDA), with each facility receiving an inspection every two to seven years. The Department is well positioned to inspect California facilities for compliance with federal requirements during annual routine state inspections.

In addition, current regulation includes an incomplete reference to the CFR concerning the manufacture, distribution and use of commercial feed containing protein derived from prohibited mammalian tissues. Additional revisions are needed to ensure all relevant sections of the CFR are referenced.

Current regulation requires the individual batch or production run number, code, date or other suitable identification to be included on a medicated feed label, but not on a formula feed label. This inconsistency limits the ability of industry and the Department to trace formula feed that may be contaminated or adulterated, potentially jeopardizing animal health.

## **BENEFITS**

The proposed regulations will incorporate FSMA provisions from 21 CFR 507, 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 FDA once every 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 identify distribution more quickly and accurately 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.

## **SPECIFIC PURPOSE AND NECESSITY**

The following paragraphs provide the specific purpose, rationale, and summaries of these proposed changes to the CCR related to commercial feed.

### **ARTICLE 1. DEFINITIONS AND GENERAL PROVISIONS**

#### **Section 2675.1. General Provisions.**

**Section 2675.1(b)** is being adopted to clarify that the manufacture, distribution and use of commercial feed shall comply with the requirements of 21 CFR 507, Subparts A, B, C, E, and F and that the enumerated subparts pertaining to commercial feed are incorporated by reference. The section also clarifies that the term “animal food” as used

in the incorporated language 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.

FAC Section 14903 states that the secretary shall establish, by regulation, good manufacturing practices, hazard analysis, and preventive control measures. FAC Section 14903 also states that the regulations established shall be based upon federal food and drug laws and regulations. The proposed change is necessary to clarify the specific federal good manufacturing practices, hazard analysis, and preventive control measures that are being established.

The most straightforward way to establish the good manufacturing practices, hazard analysis, and preventive control measures mandated by FAC Section 14903 is by incorporating federal requirements by reference. Restating federal requirements in the CCR violates the nonduplication standard described in Government Code Section 11349(f) and would be cumbersome, unduly expensive, or otherwise impractical. Restating federal requirements in the CCR would also be more time consuming for Department staff to update if the CFR changes and could increase the possibility for accidental inconsistencies. Incorporating by reference will allow the Department to promulgate regulations updating the new effective date if changes are made to the CFR, rather than making individual changes to the text, and will minimize the risk for error. Incorporation by reference is appropriate because the CFR is reasonably available to the affected public from a commonly known or specified source.

Developing unique regulations specifying good manufacturing practices, hazard analysis, and preventive control measures would be unnecessarily confusing for industry to comply with, as well as for Department staff to enforce. These federal requirements have been in effect since 2011 and are already well known to industry. Department staff are already fully trained and have been performing inspections for these requirements under FDA authority as part of the Department's Animal Food Inspection Contract. However, the Department conducts a limited number of FDA contract inspections per year, with each facility being inspected every two to seven years. For this reason, FDA has encouraged the Department to adopt 21 CFR 507 and begin conducting additional inspections under state authority. Incorporation of these provisions will not impact the work done under the Department's Animal Food Inspection Contract; rather, it will enable the Department to verify compliance with these food safety provisions annually while conducting routine inspections under State authority.

The Department is participating in its second, five-year cooperative agreement with FDA to implement the Animal Feed Regulatory Program Standards (AFRPS) in California. The goal of the AFRPS is to support development of a uniform and consistent approach to feed regulation by state programs throughout the U.S. As part of implementing the

AFRPS, states must evaluate their laws and regulations and, whenever possible, work to achieve equivalency with federal laws and regulations. Incorporation of 21 CFR 507, Subparts A, B, C, E, and F would help the Department move towards the goal of achieving state equivalency with federal laws and regulations.

Furthermore, the commercial feed industry is very supportive of this effort and has requested the Department incorporate these provisions into the CCR. Commercial feed manufacturing facilities are already required by federal law to comply with the provisions of 21 CFR 507. The addition of these provisions to the CCR will not impose any new requirements; rather, it will allow the Department to address federal compliance issues when conducting routine state inspections. The Department's commercial feed inspectors and investigators have established relationships with the manufacturing facilities in their territories; addressing these requirements during routine visits will be a positive step toward achieving and maintaining compliance.

Incorporation of these provisions into the CCR by reference is necessary to ensure the Department fulfills its statutory mandate to base regulatory requirements on federal standards, help support implementation of the AFRPS by achieving equivalency with federal laws and regulations, ensure the Department fulfills the terms of its cooperative agreement with FDA, as well as enabling the Department to further assist FDA in protecting public and animal health by ensuring the safety of human and animal food.

Specifying that the term "animal food" as used in 21 CFR 507 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 is necessary for clarity. The term "animal food" as used in 21 CFR 507 applies to both commercial feed for livestock as well as pet food. CFRP only has the authority to regulate commercial feed as defined under FAC Section 14925 which specifically exempts "preparations which are manufactured and distributed for feeding to domestic pets, such as dogs, cats, and birds." This distinction is necessary to clarify that CFRP is not seeking to incorporate any regulatory provisions for products that fall outside its statutory authority.

**Authority and Reference:** FAC Section 14903 is being added to the authority and reference section because it gives the Department authority to establish regulations defining good manufacturing practices, hazard analysis, and preventive control measures and the proposed regulations implement, interpret, or make specific the measures authorized by FAC 14903.

## **ARTICLE 2. COMMERCIAL FEED CONTAINING DRUGS, FOOD ADDITIVES, OR HARMFUL SUBSTANCES**

### **Section 2681. Animal Proteins Prohibited in Ruminant Feed.**

**Section 2681(a)** is being amended to incorporate the requirements of 21 CFR 589.2001 and update the version date to 2022. This CFR regulation describes the cattle materials prohibited in feed to prevent the transmission of bovine spongiform encephalopathy (BSE). This change is necessary to correct the inadvertent omission of 21 CFR 589.2001 and will ensure all relevant sections of the CFR pertaining to animal proteins prohibited in ruminant feed are referenced in the CCR.

The addition of this provision to the CCR does not impose any new requirements; rather, it will ensure the Department conducts inspections that are fully equivalent to federal BSE requirements. Incorporation of this provision into the CCR is necessary to ensure the Department fulfills its statutory mandate to base regulatory requirements on federal standards, help support implementation of the AFRPS by achieving equivalency with federal laws and regulations, ensure the Department fulfills the terms of its cooperative agreement with FDA, as well as enabling the Department to further assist FDA in protecting public and animal health by ensuring the safety of human and animal food.

#### **ARTICLE 4. LABELING AND USE REQUIREMENTS**

##### **Section 2694. Label Statements.**

**Section 2694(q)** is being adopted to clarify 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 that is adequate to facilitate the tracing of the complete manufacturing and distribution history of the product. The proposed language clarifies that bulk feed shall have this information stated on the label, invoice, or shipping document, and that sacked or packaged feed shall have the lot number applied to the label, sack, or package. The proposed language is consistent with 3 CCR Section 2701(g) which already requires batch or production run identification information for medicated feed. Also requiring this identifying information for formula feed is necessary to facilitate product traceback/traceforward in the event of a recall or consumer complaint. Without batch or production run identification, the ability to trace dangerous adulterated formula feed is limited, potentially jeopardizing animal and human health.

Including batch or production run identification information is already a common practice used by the majority of the feed industry. Department observations of traceback capability made during federal contract inspections estimate that approximately 15 to 20 manufacturers in California do not currently maintain batch or production run identification information, meaning about 5% of total feed tonnage is not traceable. This proposed addition would help protect public and animal health by ensuring all formula feed is fully traceable. Furthermore, the commercial feed industry is supportive of this effort and has requested the Department incorporate this provision into the CCR.

**Authority and Reference:** FAC Section 14903 is being added to the authority and reference section because it gives the Department authority to establish regulations defining good manufacturing practices, hazard analysis, and preventive control measures and the proposed regulations implement, interpret, or make specific the measures authorized by FAC 14903.

**TECHNICAL, THEORETICAL, AND/OR EMPIRICAL STUDY, REPORTS, OR OTHER DOCUMENTS RELIED UPON**

None.

**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 significant economic impact. The proposed inclusion of batch or production run identification information on formula feed labels is already common practice in the industry; the proposed change is expected to impact a small number of feed manufacturing facilities at minimal cost. The proposed incorporation of 21 CFR 507, Subparts A, B, C, E, and F does not have any associated economic impact because these are existing federal requirements the California commercial feed industry must already comply with.

These proposed regulations will not:

- (1) Create or eliminate jobs within California.
- (2) Create new businesses or eliminate existing businesses within the State of California.
- (3) Affect the expansion of businesses currently doing business within the State of California.
- (4) Affect the health and welfare of California residents, worker safety, and the state's environment.

**EVIDENCE SUPPORTING FINDING OF NO SIGNIFICANT STATEWIDE ADVERSE ECONOMIC IMPACT DIRECTLY AFFECTING BUSINESS**

The Department anticipates there will be no significant statewide adverse economic impact directly affecting business as a result of the proposed regulations.

The sections of the CFR being incorporated by reference are existing requirements of federal law. No new requirements are being imposed; therefore, the proposed

regulations will not require feed manufacturing facilities to incur any additional expense to comply.

The proposed inclusion of batch or production run identification information on formula feed labels is already common practice in the industry; the proposed change is expected to impact a small number of manufacturing facilities at minimal cost. Program observations of traceback capability made during federal contract inspections have determined that the majority of manufacturing facilities already have a mechanism in place for tracing runs of feed. The Department estimates that the formulation software programs utilized by most manufacturing facilities has the capability to generate identifying information that would satisfy the proposed requirement. At most, the Department estimates that approximately 15 to 20 manufacturing facilities in California do not currently have the capability to maintain batch or production run identification information, accounting for less than 5% of total feed tonnage. To comply with the proposed regulation, some manufacturing facilities may choose to update their formulation software, while others may choose to utilize something as simple as a date stamp label. The proposed regulation does not prescribe what mechanism must be utilized, so long as this identification is maintained. The individual cost impact will vary depending on how each manufacturing facility chooses to comply; however, the Department estimates the cost would average about \$100 per facility for a total statewide economic impact of \$2,000. This cost is negligible in comparison to the potential adverse economic impacts that could result from a feed safety incident where product traceability is limited.

#### **REASONABLE ALTERNATIVES TO THE REGULATIONS AND THE DEPARTMENT'S REASONS FOR REJECTING THOSE ALTERNATIVES**

The Department considered restating 21 CFR 507, Subparts A, B, C, E, and F in the CCR instead of incorporating by reference. This alternative was rejected because restating federal requirements in the CCR violates the nonduplication standard described in Government Code Section 11349(f) and would be cumbersome, unduly expensive, or otherwise impractical. Restating federal requirements in the CCR would also be more time consuming for Department staff to update if the CFR changes and could increase the possibility for accidental inconsistencies.

The Department considered developing its own unique regulations specifying good manufacturing practices, hazard analysis, and preventive control measures. This alternative was rejected because it would be unnecessarily confusing for industry to comply with, as well as for Department staff to enforce. The requirements of 21 CFR 507 have been in effect since 2011; they are already well known to industry and Department staff are fully trained to perform inspections for these requirements.

The Department considered not adopting regulations specifying good manufacturing practices, hazard analysis, and preventive control measures. This alternative was

rejected because FAC Section 14903 requires the Department to develop these regulations. This alternative was also rejected because the Department has been tasked with achieving equivalency with federal law as part of its participation in the AFRPS cooperative agreement with FDA. In addition, this alternative was rejected because the commercial feed industry has requested the Department incorporate these provisions into the CCR.

The Department considered not requiring the addition of batch or production run identification information to formula feed labels. This alternative was rejected because the ability to trace dangerous adulterated formula feed is critical to protecting animal and human health.

### **DUPLICATION OR CONFLICT WITH FEDERAL REGULATIONS**

The proposed regulations do not duplicate or conflict with federal regulations. The proposed regulations merely incorporate a reference to existing federal regulations, rather than duplicating the text.