

**CALIFORNIA CODE OF REGULATIONS  
TITLE 3. FOOD AND AGRICULTURE  
DIVISION 4. PLANT INDUSTRY  
CHAPTER 2. FIELD CROPS  
SUBCHAPTER 2. COMMERCIAL FEED  
ARTICLE 9. MISBRANDING AND ADULTERATION**

**INITIAL STATEMENT OF REASONS**

**DESCRIPTION OF THE PUBLIC PROBLEM, ADMINISTRATION REQUIREMENT, OR OTHER CONDITION OR CIRCUMSTANCE THE REGULATION IS INTENDED TO ADDRESS**

The proposed regulation changes are intended to correct an inconsistency in the meaning of aflatoxins in the California Code of Regulations and the Federal Food and Drug Administration (FDA) Compliance Policy Guide (CPG) 7126.33 and remove a potential food safety hazard by eliminating a source of high aflatoxin in the Imperial County. Aflatoxins are a highly potent human carcinogen and when fed to dairy cattle can be transferred from animal feed sources to milk.

**SPECIFIC PURPOSE AND FACTUAL BASIS**

Section 15041 of the Food and Agricultural Code states that a commercial feed is adulterated if it bears or contains any poisonous, deleterious, or nonnutritive substance in amount, which are specified as being unsafe by the Secretary by regulations.

Adopting Section 2675, subsection (i) of the California Code of Regulations defines "aflatoxins" to include the aflatoxin components B<sub>1</sub>, B<sub>2</sub>, G<sub>1</sub> and G<sub>2</sub> collectively, which aligns the meaning of aflatoxin in the CCR with the meaning of aflatoxins in FDA CPG 7126.33.

The specific purpose of amending Section 2734(a)(6), and Sections 2735, 2735(a)(2), 2735(b), and 2735(d) is to reflect the proposed regulation changes in Section 2675(i).

Amend Section 2734(c) by removing the references to the revision date and the name of the specific form because it is no longer necessary to incorporate by reference.

Repealing CCR Section 2735(e) eliminates the exemption that allows cottonseed meal containing more 20 ppb but less than 300 ppb aflatoxin B<sub>1</sub> to be fed to beef cattle in Imperial County feed lots.

**FACTUAL BASIS FOR THE DEPARTMENT DETERMINING THE NEED FOR THE AMENDMENT OF THESE REGULATIONS:**

The Secretary of the Department has proposed these regulation changes based upon the recommendation of the Feed Inspection Advisory Board (FIAB). The FIAB is advisory to the Secretary and may make recommendations on all matters including, but not limited to,

the inspection and enforcement program, research and education, the annual budget, necessary fees to provide adequate inspection services, and regulations required to accomplish the purposes of the statutes in the Food and Agricultural Code (FAC). The FIAB is comprised of eight members who are commercial feed licensees and one public member.

**Defining the Term “Aflatoxins:”** The California Code of Regulations (CCR) and Federal Food and Drug Administration (FDA) Compliance Policy Guide (CPG) differ in their meaning of aflatoxins. This results at times in the inconsistent enforcement of the aflatoxins limit in livestock feed. The proposed regulation changes will align the meaning of aflatoxin in the CCR with the FDA CPG 7126.33 and would result in the uniform enforcement of adulterated livestock feed when livestock feed exceeds the limit for aflatoxins.

**Removing the Reference to the Revision Date:** Section 2735(a)(1) states that the form that is to accompany each lot, truck, railcar, ship barge, container, air transport, or any other means of transportation of cottonseed products originating outside California is to be furnished by the secretary, and is incorporated by reference. Section 2735(a)(1) identifies the form as the Certificate of Movement of Cottonseed Products, Rev. 5-97. Because section 2735(a)(1) specifies all the regulatory content that is required on the form, the Department realizes that the form does not also need to be incorporated by reference. By incorporating the form by reference, this further requires the Department to go through the “change without regulatory effect” process of title 1, CCR, section 100, each time there is a nonsubstantive change to the form, and the revision date of the form changes. Incorporating the form by reference is not necessary and is not required pursuant to the APA; therefore, the Department proposes to delete the name and revision date of the form, and delete the incorporation by reference status of the form. The Department acknowledges that if any regulatory provisions are added or deleted from the form, then such changes are subject to the rulemaking process of the APA. The most recent version of the Certificate of Movement of Cottonseed Products (currently Rev. 5-97) is available by contacting the Department at 916-445-0444.

**Repealing the Exemption for Feeding Cottonseed Meal with Up to 300 ppb Aflatoxin B<sub>1</sub> in Imperial County:** The exemption in the regulations creates an unsafe food situation in Imperial County. The proposed change in the California Code of Regulations would remove the exemption that currently allows the feeding of otherwise adulterated cottonseed meal with more than 20 ppb but less than 300 ppb of aflatoxin B<sub>1</sub> to beef cattle in Imperial County. The accidental feeding of cottonseed meal with 300 ppb aflatoxin to dairy cows would cause the milk to be adulterated with a human carcinogen, aflatoxin M<sub>1</sub>. The removal of this exemption would substantially lessen the chance of an accidental feeding of high levels of aflatoxins to dairy cows and would provide consistency in enforcement and safety throughout the state. The proposed changes will provide added assurance that milk produced in Imperial County is equally as safe from aflatoxin as milk produced throughout the state.

## **DOCUMENTS RELIED UPON**

- Minutes from the June 26, 2008 Feed Inspection Advisory Board Meeting
- Example of the Certificate of Movement of Cottonseed Products Form
- FDA CPG 7126.33
- Email from Dr. Michael Henry of US Food and Drug Administration

## **ALTERNATIVES**

The Department must determine that no reasonable alternative considered by the Department, or that has otherwise been identified and brought to the attention of the Department, would be more effective in carrying out the purpose for which these regulations are proposed, or would be as effective as and less burdensome to affected private persons than the proposed regulations.

## **ESTIMATED COSTS OR SAVINGS TO PUBLIC AGENCIES OR AFFECTED PRIVATE INDIVIDUALS OR ENTITIES**

The Department has initially determined that no savings or increased costs to any state agency, no costs under "Part 7 (commencing with Section 17500) of Division 4" of the Government Code to local agencies or school districts requiring reimbursement, no other non-discretionary costs or savings imposed on local agencies, and no costs or savings in federal funding to the State will result from these proposed regulations. The Department has also determined that these proposed regulations do not impose a mandate on local agencies or school districts.

## **SMALL BUSINESS IMPACT STATEMENT**

The Department has initially determined that the proposed changes in the regulations would result in no added costs to small businesses affected by these proposed changes. No new reporting or administrative requirements and no new or additional fees are associated with the proposed regulations. The potential savings to mitigate a contaminated milk incident outweigh the costs incurred to comply with the proposed change of the meaning of aflatoxin and the removal of the exemption.

## **ECONOMIC IMPACT ON AFFECTED BUSINESSES**

The Department has initially determined that the proposed regulations would result in no significant costs to private businesses or individuals affected by these proposed regulations. This is based on the fact stated in the "SMALL BUSINESSES IMPACT STATEMENT."