

AGRICULTURAL EXPERIMENT STATION
(Amendment)

12 KAR 2:051. Manufacturing conditions.

RELATES TO: KRS 250.501, 250.511, 250.541, 250.551, 250.581(1), 21 C.F.R. 225.1-225.202, 226.1-226.115

STATUTORY AUTHORITY: KRS 250.541(c), 250.571(1), 21 C.F.R. 225.1-225.202, 226.1-226.115

CERTIFICATION STATEMENT: This certifies that this administrative regulation complies with the requirements of 2025 RS HB 6, Section 8.

NECESSITY, FUNCTION, AND CONFORMITY: KRS 250.571(1) authorizes the Director of the Agricultural Experiment Station to promulgate administrative regulations necessary for the efficient enforcement of KRS 250.491 to 250.631, regarding commercial feeds. KRS 250.541(2)(c) requires the promulgation of an administrative regulation that establishes the current good manufacturing practices for the manufacturing, processing, and packaging of commercial feed. This administrative regulation establishes current good manufacturing practices, hazard analysis, and risk-based preventive controls for facilities engaged in holding and distribution of animal feed.

Section 1. The current good manufacturing practices published in the Code of Federal Regulations for Type B and Type C medicated feeds ~~are~~ governed by 21 C.F.R. 225.1 through 225.202 are adopted by reference.

Section 2. The current good manufacturing practices published in the Code of Federal Regulations for Type A medicated articles ~~are~~ governed by 21 C.F.R. 226.1 through 226.115 are adopted by reference.

Section 3. The current good manufacturing practices, hazard analysis, and risk-based preventive controls for food for animals published in the Code of Federal Regulations for facilities engaged in the holding and distribution of animal food ~~are~~ governed by 21 C.F.R. 507.1 through 507.215 are adopted by reference.

DR. JAMES MATTHEWS, Director

APPROVED BY AGENCY: September 10, 2025

FILED WITH LRC: September 11, 2025 at 10:50 a.m.

PUBLIC HEARING AND COMMENT PERIOD: A public hearing on this administrative regulation shall be held on November 24, 2025, at 9:00 a.m., at the offices of the Division of Regulatory Services, 1600 University Court, Lexington, Kentucky 40546. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing was received by that date, the hearing may be cancelled. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through November 30, 2025. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person.

CONTACT PERSON: G. Alan Harrison, Feed & Milk Director, University of Kentucky Division of Regulatory Services, 103 Regulatory Services Building, Lexington, Kentucky 40546, phone (859) 257-2785, fax (859) 323-9931, email alan.harrison@uky.edu.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person:G. Alan Harrison

Subject Headings:Agriculture, Animals: Livestock and Poultry, Equine and Horses, Consumer Protection

(1) Provide a brief summary of:

(a) What this administrative regulation does:

This administrative regulation establishes current good manufacturing practices, hazard analysis, and risk-based preventive controls for facilities engaged in holding and distribution of animal feed.

(b) The necessity of this administrative regulation:

Establishes good manufacturing practices for companies manufacturing commercial feeds.

(c) How this administrative regulation conforms to the content of the authorizing statutes:

Pursuant to KRS 250.501(1)(a) the Director of the Agricultural Experiment Station is required to promulgate an administrative regulation to achieve efficient enforcement of KRS 250.491 to 250.631, regarding commercial feeds.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:

Establishes proper manufacturing practices for the safe manufacture of commercial feeds.

(2) If this is an amendment to an existing administrative regulation, provide a brief summary of:

(a) How the amendment will change this existing administrative regulation:

Establishes proper manufacturing practices based on the Food Safety Modernization Act put forth in 2011.

(b) The necessity of the amendment to this administrative regulation:

Updates standards previously established in this regulation.

(c) How the amendment conforms to the content of the authorizing statutes:

Updates the existing regulation.

(d) How the amendment will assist in the effective administration of the statutes:

Brings this regulation up to current standards.

(3) Does this administrative regulation or amendment implement legislation from the previous five years?No

(4) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation:

Firms which manufacture commercial feeds in Kentucky will be affected by this administrative regulation.

(5) Provide an analysis of how the entities identified in question (4) will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:

(a) List the actions that each of the regulated entities identified in question (4) will have to take to comply with this administrative regulation or amendment:

Follow current good manufacturing practices.

(b) In complying with this administrative regulation or amendment, how much will it cost each of the entities identified in question (4):

It will depend on how much they have to do to meet the requirements established by FSMA.

(c) As a result of compliance, what benefits will accrue to the entities identified in question (4):

They will meet federal standards and be sure of producing safe products.

(6) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:

(a) Initially:

Depends on how much needs to be done.

(b) On a continuing basis:

Minimal once standards are met.

(7) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation or this amendment:

Annual budget of the Division of Regulatory Services.

(8) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment:

No increase in fees.

(9) State whether or not this administrative regulation establishes any fees or directly or indirectly increases any fees:

No new fees and no increase in existing fees.

(10) TIERING: Is tiering applied?

No, this administrative regulation treats all regulated entities the same.

FISCAL IMPACT STATEMENT

(1) Identify each state statute, federal statute, or federal regulation that requires or authorizes the action taken by the administrative regulation:

KRS 250.571

(2) State whether this administrative regulation is expressly authorized by an act of the General Assembly, and if so, identify the act:

KRS 250.571

(3)(a) Identify the promulgating agency and any other affected state units, parts, or divisions:

University of Kentucky Division of Regulatory Services

(b) Estimate the following for each affected state unit, part, or division identified in (3)(a):

1. Expenditures:

For the first year:No fiscal impact

For subsequent years:No fiscal impact

2. Revenues:

For the first year:No fiscal impact

For subsequent years:No fiscal impact

3. Cost Savings:

For the first year:No fiscal impact

For subsequent years:No fiscal impact

(4)(a) Identify affected local entities (for example: cities, counties, fire departments, school districts):

No impact on local entities

(b) Estimate the following for each affected local entity identified in (4)(a):

1. Expenditures:

For the first year:No impact

For subsequent years:No impact

2. Revenues:

For the first year:No impact

For subsequent years:No impact

3. Cost Savings:

For the first year:No impact

For subsequent years:No impact

(5)(a) Identify any affected regulated entities not listed in (3)(a) or (4)(a):

No impact on other entities

(b) Estimate the following for each regulated entity identified in (5)(a):

1. Expenditures:

For the first year:No impact

For subsequent years:No impact

2. Revenues:

For the first year:No impact

For subsequent years:No impact

3. Cost Savings:

For the first year:No impact

For subsequent years:No impact

(6) Provide a narrative to explain the following for each entity identified in (3)(a), (4)(a), and (5)(a)

(a) Fiscal impact of this administrative regulation:

The University of Kentucky Division of Regulatory Services anticipates no fiscal impact from the proposed amendment to the regulation. The update simply incorporates by reference the good manufacturing practices outlined in the Food Safety Modernization Act (FSMA).

(b) Methodology and resources used to reach this conclusion:

Manufacturers of animal feed are already held to good manufacturing practices as outlined in FSMA.

(7) Explain, as it relates to the entities identified in (3)(a), (4)(a), and (5)(a):

(a) Whether this administrative regulation will have a "major economic impact", as defined by KRS 13A.010(14):

No

(b) The methodology and resources used to reach this conclusion:

Minor changes in regulation affect only manufacturers of animal feed.

FEDERAL MANDATE ANALYSIS COMPARISON

(1) Federal statute or regulation constituting the federal mandate.

Federal Food, Drug, and Cosmetic Act and C.F.R. 21

(2) State compliance standards.

In harmony with federal standards.

(3) Minimum or uniform standards contained in the federal mandate.

This administrative regulation aligns with FMSA, creating harmony between state and federal standards.

(4) Will this administrative regulation impose stricter requirements, or additional or different responsibilities or requirements, than those required by the federal mandate?

No

(5) Justification for the imposition of the stricter standard, or additional or different responsibilities or requirements.

NA