AGRICULTURAL EXPERIMENT STATION
(Amendment)

12 KAR 2:041. Drug and feed additives.

RELATES TO: KRS 250.501, 250.511, 250.541(1)(a), (b), (c), (d), (e), (f), (j), (2)(c), (d), (e), 21 C.F.R. 570.3(1), 570.30, 582, 21 U.S.C. 151-158, 360(b)

STATUTORY AUTHORITY: KRS 250.571(1)

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 provides that a commercial feed or a material exempted from the definition of commercial feed shall be considered adulterated if it meets the conditions established in KRS 250.541. KRS 250.551(1) and (2) prohibit the manufacture or distribution of an adulterated product as animal feed. This administrative regulation establishes the requirements to ensure the safe and effective use of commercial feeds containing additives.

Section 1. Before approval of a registration application or approval of a label for a commercial feed containing an additive, including a drug, another special purpose additive, or non-nutritive additive, the distributor shall, upon request by the director, submit evidence to prove the safe and effective use of the commercial feed when used according to the directions furnished on the label.

Section 2. Satisfactory evidence of safe and effective use of a commercial feed shall be one (1) of the following:

(1) When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in Title 21, Code of Federal Regulations, or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use;

(2) A commercial feed that is a drug as defined in KRS 250.501(7) and is generally recognized by the Food and Drug Administration as safe and effective for its labeled use or is marketed subject to an application approved by the Food and Drug Administration under Section 512 of the Federal Food, Drug, and Cosmetic Act;

(3) When one (1) of the purposes for a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913 as amended;

(4) When the commercial feed is a direct-fed microbial product and:

(a) The product is defined as a fermentation product in the Official Publication of the Association of American Feed Control Officials; and

(b) The microbial content statement:

1. Appears on the label; and

2. States "Contains a source of live (viable), naturally occurring microorganisms"; and

3. The source is stated with a corresponding guarantee expressed in accordance with 12 KAR 2:021, Section 7; or

(5) When the commercial feed is an enzyme product and is:

(a) Defined as an enzyme in the Official Publication of the Association of American Feed Control Officials; and

(b) Guaranteed according to the provisions of 12 KAR 2:021, Section 8.

Section 3. Incorporation by Reference.

(1) "2025 Official Publication", 2025~~[2018]~~ Edition, Association of American Feed Control Officials, is incorporated by reference.

(2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Division of Regulatory Services, 103 Regulatory Services Building, College of Agriculture, University of Kentucky, Lexington, Kentucky 40546-0275, Monday through Friday, 8 a.m. to 4:30 p.m.

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 the requirements to ensure the safe and effective use of commercial feeds containing additives.

(b) The necessity of this administrative regulation:
Provides clarification on the proper way to label 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 define official feed ingredients and feed terms.

(d) How this administrative regulation currently assists or will assist in the effective administration of the statutes:
Establishes proper labeling of feeds containing drugs or other feed additives.

(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:
The amendment updates usage of the Official Publication of the American Association of Feed Control Officials (AAFCO) from the 2018 Edition to the 2025 edition.

(b) The necessity of the amendment to this administrative regulation:
Use of AAFCO language provides consistency between states.

(c) How the amendment conforms to the content of the authorizing statutes:
Updates terms and definitions used to regulate the feed industry.

(d) How the amendment will assist in the effective administration of the statutes:
These updates are beneficial to both the regulatory body and the regulated industry as it brings in new terms and definitions that have been developed since 2018.

(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 register 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:

No action required by distributors of animal feed. No significant action required by manufacturers of animal feed.

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

No cost.

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

No significant benefit to distributors of animal feed. Manufacturers of animal feed may benefit from additional ingredients available for use in products and more descriptive ingredient definitions.

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

(a) Initially:

No cost.

(b) On a continuing basis:

No cost.

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

The Division of Regulatory Services regular annual budget is the source of funding.

(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:

(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:

This regulation is being updated to reference the latest recommendations from the Association of American Feed Control Officials with regards to definitions of ingredients used in the manufacturing of animal feed.

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

Minor changes in regulation affect only manufacturers of animal feed.

(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.
Standards developed by the Association of American Feed Control Officials are in harmony with 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.
N/A