

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:

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) "Official Publication", 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.

(012 KAR 002:041. AES-2(1973)-8; 1 Ky.R. 1000; eff. 6-11-1975; 23 Ky.R. 1610; eff. 1-10-1997; 25 Ky.R. 1087; 2355; eff. 4-14-1999; 45 Ky. R. 395; eff. 10-10-2018; Crt to Am; filed Am 9-11-2025.)