

WEST VIRGINIA
SECRETARY OF STATE
KEN HECHLER
ADMINISTRATIVE LAW DIVISION

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FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 8, 1991
ADMINISTRATIVE LAW DIVISION

Form #8

Effective Date

Aug. 12, 1991

NOTICE OF AN EMERGENCY AMENDMENT TO AN EMERGENCY RULE

AGENCY: Agriculture TITLE NUMBER: 61

DATE EMERGENCY RULE WAS ORIGINALLY FILED: June 26, 1991

IS THIS THE FIRST EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:
yes

IS THIS THE SECOND EMERGENCY AMENDMENT TO THE ORIGINALLY FILED EMERGENCY RULE:

DATE OF FIRST EMERGENCY AMENDMENT: _____

SERIES NUMBER OF RULE: 5 TITLE OF RULE: Commercial Feed
(repeal and replace)

THE ATTACHED IS AN EMERGENCY AMENDMENT TO AN EXISTING EMERGENCY RULE. THIS EMERGENCY AMENDMENT BECOMES EFFECTIVE AFTER APPROVAL BY SECRETARY OF STATE OR 35TH DAY AFTER FILING, WHICHEVER OCCURS FIRST.

THE FACTS AND CIRCUMSTANCES CONSTITUTING THE EMERGENCY AMENDMENT ARE AS FOLLOWS:
See attached sheet

Use Additional Sheets If Necessary.


Signature

COMMERCIAL FEED REGULATIONS

STATEMENT OF FACTS AND CIRCUMSTANCES REQUIRING THE FILING OF AN AMENDMENT TO THE EMERGENCY

The Commercial Feed Regulations originally filed as an emergency on June 26, 1991, and effective on this date, were amended due to written comments received during the public comment period. The agency wishes to enforce the rule in as amended.

The major revisions of the rule are that the requirement for mineral guarantees to be made only on feeds that contain a minimum amount of minerals, instead of all feeds. The revision will allow the use of tentative AAFCO definitions for feed (the previous rule prohibited this), the mandatory requirement for embargo of feed on the first notice was removed, and the requirements for good manufacturing practices were amended. Other minor revisions were made for clarity and are technical in nature.

APPENDIX B

FISCAL NOTE FOR PROPOSED RULES

Rule Title: Commercial Feed

Type of Rule: XX Legislative Interpretive Procedural

Agency Department of Agriculture Address Guthrie Agricultural Center
Charleston, West Virginia 25312

1. Effect of Proposed Rule	ANNUAL		FISCAL YEAR		
	Increase	Decrease	Current	Next	Thereafter
Estimated Total Cost	\$	\$	\$	\$	\$
Personal Services					
Current Expense		-\$16,950			
Repairs and Alterations					
Equipment					
Other Test Charges*	+\$16,950				

2. Explanation of above estimates:

Rules will allow the Department of Agriculture to recover costs incurred for analyzing non-official samples at the request of individuals.

3. Objectives of these rules:

The objective of these rules is to establish guidelines for permits and registrations, label format and good manufacturing practices for commercial feeds. Labeling provisions are not substantially different from previous practice and should not increase manufacturing expenses.

*Based on average \$56.50 charge per sample times 300 samples analyzed during 1990-91 fiscal year.

4. Explanation of Overall Economic Impact of Proposed Rule.

A. Economic Impact on State Government.

The Department of Agriculture will see a recovery of testing expenses for non-official samples submitted by individuals.

B. Economic Impact on Political Subdivisions; Specific Industries; Specific groups of citizens.

1. Farmers will see an estimated initial cost of \$30.00 for re-use of feed feed bags in the manufacture of customer-formula feed. Number of farmers is unknown.

2. Good manufacturing practices established by law are equivalent to FDA Medicated Feed Program. Most mills in state have been on this program in previous years and were able to comply; therefore, the cost to each mill is expected to be minimal.

C. Economic Impact on Citizens/Public at Large.

Individuals who submit samples for analysis shall be required to pay a fee as established by rules. Samples throughout the 1990-91 year were tested for protein, fat, fiber, moisture, calcium and phosphorus. Individuals shall pay an average of \$56.50 per sample, if the previously-mentioned elements are requested.

Date: _____

June 26, 1991

Signature of Agency Head or Authorized Representative

Clare Bennett

TITLE 61
LEGISLATIVE RULE
STATE DEPARTMENT OF AGRICULTURE

SERIES V
COMMERCIAL FEED

§61-5-1. General.

1.1. Scope - These regulations establish guidelines for permits and registrations, label format and good manufacturing practices for commercial feeds. These are Legislative regulations.

1.2. Authority - Code of West Virginia §19-14.

1.3. Filing Date -

1.4. Effective Date -

1.5. Repeal of former rule: This legislative rule repeals and replaces WV 61CSR5 "West Virginia Commercial Feed Law Regulations" filed June 1, 1976 and effective July 1, 1976.

§61-5-2. Incorporation by Reference.

2.1. The following are hereby adopted in their entirety:

2.1.a. Official Definitions of Feed Ingredients as published in the 1991 Official Publication of the Association of American Feed Control Officials, Incorporated.

2.1.b. Official Pet Food Regulations as published in the 1991 Official Publication of the Association of American Feed Control Officials, Incorporated.

2.1.c. Federal Food, Drug, and Cosmetic Act (August 1985), Sections 360(b), 406, 408(a), 409, 512, 706.

2.1.d. Title 21 Code of Federal Regulations, Parts 225, 226, 501, 510, 558, 570, 573, 582, and 584 et seq. (April 1, 1990) adopted pursuant to the Federal Food, Drug, and Cosmetic Act (August 1985).

2.1.e. Title 40 Code of Federal Regulations Parts 185 and 186 et seq. (July 1, 1990) adopted pursuant to the Federal Food, Drug, and Cosmetic Act (August 1985).

2.1.f. Federal Virus, Serum and Toxins Act of 1913 as amended December 23, 1985.

§61-5-3. Policy.

3.1. All persons distributing or using commercial feed, including retailers, wholesalers, jobbers and brokers are equally responsible for full compliance with the provisions of West Virginia Code §19-14 et seq. Any person who has in his possession any unlawful commercial feed is responsible for compliance, including registration, payment of the tonnage fee, labeling and any other legal requirement, if not performed by another person.

3.2. The following persons shall also comply with all provisions of this article and regulations issued hereunder:

3.2.a. Each person who sells or intends to sell commercial feed directly to a purchaser located within this state via mail-order catalog;

3.2.b. Each person who travels out of this state to purchase commercial feed for distribution or resale within this state; or

3.2.c. Each person who contacts a final purchaser located within this state, either verbally or in writing, to sell commercial feed.

3.3. All human food, stale human food or garbage used as feed shall be exempt from the registration, labeling, inspection fees provisions of this article; however, they shall be subject to inspection, sampling and analysis provisions of this article.

§61-5-4. Permits; Registration.

4.1 Applications:

4.1.a. The following shall be required to be completed on a "Commercial Feed Manufacturer Permit" application: company name; location; mailing address, if different; phone number; manager name; owner name; information relevant to the manufacture of a commercial feed.

4.1.b. The following shall be required to be completed on a "Commercial Feed Distributor Permit" application: company name; location(s); mailing address; phone number; contact person; owner name; source(s) of commercial feed distributed (i.e., manufacturer, previous distributor).

4.1.c. The following shall be required to be completed on a commercial feed registration application: corporate name; location; mailing address; phone number; contact person; owner name; brand and product name.

4.1.c.A. A label for each product listed on a commercial feed registration application shall accompany such application.

4.1.d. Each application for permit or registration shall be signed and dated under sworn statement by an authorized representative of such company.

4.1.e. The commissioner may request additional information on a case-by-case basis when necessary to carry out the provisions of the article or rules.

4.2. Commercial feeds generally manufactured for and categorized for non-pet use (i.e., horses, pigs, sheep, goats, trout, duck and others) or for wild animal use (i.e., wild bird food) shall not be considered as pet foods.

4.2.a. The category of other products shall be determined on a case-by-case basis as the commissioner deems necessary.

4.3 A pet food biscuit or rawhide chew manufactured in different sizes (small, medium, large) or a commercial feed manufactured in different forms (pellets, crumbles or mash) shall not be registered as different products; however, the registrant must indicate sizes and/or forms the product is manufactured in and provide labels for each product.

4.4 A person who cancels a permit or registration before the expiration date shall not be entitled to a refund of the permit or registration fee previously paid.

4.5 A person whose application for permit or registration has been refused shall receive a refund of the registration fee. A person whose permit or registration has been suspended or revoked shall not receive a refund of the previously submitted application fee.

4.6 A registrant shall give notice to the commissioner when a product shall be discontinued or removed from distribution in this state. A product no longer distributed in this state shall be registered for one additional registration period to allow for removal of product on shelves, unless the product is voluntarily withdrawn from distribution in this state by the registrant. After that period, responsibility for compliance with this article may be charged to other interested parties.

4.7 Registrations for commercial feeds distributed in packages over ten pounds and bulk on file with the commissioner before May 28, 1991 shall remain registered under provisions of this article, unless registration is cancelled by registrant or registration is revoked or suspended for cause by the commissioner.

4.8 Revisions to commercial feeds in packages over ten pounds and bulk registered before May 27, 1991 shall be reviewed and processed according to the provisions of this article.

4.9 Prior to approval of a registration application or approval of a label for commercial feed which contains additives (including drugs, other special purpose additives, or non-nutritive additives), the commissioner may require the registrant to submit evidence to prove the safety and efficacy of the commercial feed when used according to the directions furnished on the label.

4.10. Pet foods and specialty pet foods:

4.10.a. If a pet food or specialty pet food requires minor label revision(s) to conform to labeling requirements, the product shall be registered conditionally for the current registration period; however, if a label requires major revisions, the product shall be withheld from registration pending revision of labeling. An opportunity for a hearing in this matter shall be given to the applicant pursuant to West Virginia Code §19-14-7.

4.10.a.A. Minor revisions are those items that are necessary to conform to this article, but, without correction, are not likely to cause the purchaser of the product to be misinformed, such as the guaranteed analysis being listed out of order.

4.10.a.B. Major revisions may include, but are not limited to, misleading and/or contradictory claims on the label, misleading product name or other revisions that may mislead or misinform a purchaser.

4.10.b. Revisions to pet food and specialty pet food labels registered shall require a new application for registration, except that there will be no fee for a revision that involves a change in the net weight or a change in the list of ingredients.

4.10.c. All pet chews, bones, toys and exercisers (of any shape or size) made of rawhide, wood or man-made material, whether flavor-coated or unflavored, shall be exempt from registration and labeling, unless the manufacturer, in its product label or labeling, makes a claim that the product is intended for use as an animal food, or that the product provides anything of nutritional value to the animal.

§61-5-5. Labeling.

5.1. The information required in West Virginia Code §19-14-8(b)(1)-(5) must appear in its entirety on one side of the label or on one side of the container. The information required by West Virginia Code §19-14-8(b)(6)-(7) shall be displayed in a prominent place on the label or container but not necessarily on the same

side as the above information. When the information required by West Virginia Code §19-14-8(b)(6)-(7) is placed on a different side of the label or container, it must be referenced on the front side with a statement such as "See back of label for directions for use." None of the information required by West Virginia Code §19-14-8 shall be subordinated or obscured by other statements or designs.

5.1.a. The guaranteed analysis of the commercial feed as required under the provisions of West Virginia Code §19-14-8(b)(3) shall include the following items, unless exempted in part 4.1.a.L of these rules, and shall be listed in the following order:

5.1.a.A. Minimum percentage of crude protein.

5.1.a.B. Minimum or maximum percentage of equivalent protein from non-protein nitrogen, if present, as required in subsection 6.5 of these rules.

5.1.a.C. Minimum percentage of crude fat.

5.1.a.D. Maximum percentage of crude fiber.

5.1.a.E. Minerals in formula feeds, to include in the following order: minimum and maximum percentages of calcium; minimum percentage of phosphorus; minimum and maximum percentages of salt; and other minerals.

5.1.a.F. Minerals in feed ingredients as specified in the Official Definitions of Feed Ingredients.

5.1.a.G. Vitamins in such terms as specified in subsection 6.3 of these rules.

5.1.a.H. Total sugars as invert on dried molasses products or products being sold primarily for their sugar content.

5.1.a.I. Viable lactic acid producing micro-organisms for use in silages in terms specified in subsection 6.7 of these rules.

5.1.a.J. Fat products, guaranteed in the following order:

5.1.a.J.(a) minimum percentage of total fatty acids;

5.1.a.J.(b) maximum percentage of unsaponifiable matter; and

5.1.a.J.(c) maximum percentage of insoluble matter;

5.1.a.K. Guarantees as specified by the Official Definitions of Feed Ingredients.

5.1.a.L. Exemptions:

5.1.a.L.(a) Guarantees for minerals are not required when there are no specific label claims and when the commercial feed contains less than 6-1/2% of Calcium, Phosphorus, Sodium and Chloride.

5.1.a.L.(b) Guarantees for vitamins are not required when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.

5.1.a.L.(c) Guarantees for crude protein, crude fat, and crude fiber are not required when the commercial feed is intended for purposes other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.

5.1.a.L.(d) Guarantees for microorganisms are not required when the commercial feed is intended for a purpose other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, and when no specific label claims regarding these microorganisms are made.

5.2. Pet food labels, excluding specialty pet foods, shall conform to the Official Pet Food Regulations.

5.3. Specialty pet food labels shall conform to West Virginia Code §19-14-8.

5.4. The use of claims stating improvement or newness (i.e., new, improved, introducing, better tasting, more taste than before) should be sufficiently substantiated by the manufacturer and shall be limited to six months' production. For registration purposes, a label shall be submitted for a six-month period, with a revised label submitted after six months. No additional application or registration fee shall be required for that product during the registration period as indicated on the registration certificate.

5.5. If a customer-formula feed is sold in bags, rather than bulk, each bag is not required to be labeled, Provided that an invoice accompanies the customer-formula feed and is supplied to the purchaser at the time of delivery pursuant to West Virginia Code §19-14-8(d).

§61-5-6. Brand and Product Names.

6.1. The brand or product name must be appropriate for the intended use of the feed and must not be misleading. If the name indicates the feed is made for a specific use, the character of the feed must conform therewith. A commercial feed labeled "Dairy Feed," for example, must be suitable for that purpose.

6.2. Commercial, registered brand or trade names are not permitted in guarantees or ingredient listings and are permitted only in the product name of feeds produced by or for the firm holding the rights to such a name.

6.3. The name of a commercial feed shall not be derived from one or more ingredients of a mixture to the exclusion of other ingredients and shall not be one representing any components of a mixture unless all components are included in the name: Provided, That if any ingredient or combination of ingredients is intended to impart a distinctive characteristic to the product which is of significance to the purchaser, the name of that ingredient or combination of ingredients may be used as a part of the brand name or product name if the ingredients or combination of ingredients is quantitatively guaranteed in the guaranteed analysis, and the brand or product name is not otherwise false or misleading.

6.4. The word "protein" shall not be permitted in the product name of a feed that contains added non-protein nitrogen.

6.5. When the name carries a percentage value, it shall be understood to signify protein and/or equivalent protein content only, even though it may not explicitly modify the percentage with the word "protein": Provided, That other percentage values may be permitted if they are followed by the proper description and conform to good labeling practice. Numbers shall not be used in such a manner as to be misleading or confusing to the customer.

6.6. Single ingredient feeds shall have a product name in accordance with the designated Official Definition of Feed Ingredients, unless the commissioner designates otherwise.

6.7. The word "vitamin," or a contraction thereof, or any word suggesting a vitamin can be used only in the name of a commercial feed which is represented to be a vitamin supplement, and which is labeled with the minimum content of each vitamin declared, as specified in subsection 6.3 of these rules.

6.8. The term "mineralized" shall not be used in the name of a feed except for "TRACE MINERALIZED SALT." When so used, the product must contain significant amounts of trace minerals which are recognized as essential for animal nutrition.

6.9. The term "meat" and "meat by-products" shall be qualified to designate the animal from which the meat and meat by-products is derived unless the meat and meat by-products are made

from cattle, swine, sheep or goats.

§61-5-7. Expression of Guarantees.

7.1. The guarantees for crude protein, equivalent protein from non-protein nitrogen, crude fat, crude fiber and mineral guarantees shall be in terms of a percentage.

7.2. Commercial feeds containing 6-1/2% or more Calcium, Phosphorus, Sodium and Chloride shall include in the guaranteed analysis the minimum and maximum percentages of calcium (Ca), the minimum percentage of phosphorus (P), and if salt is added, the minimum and maximum percentage of salt (NaCl). Minerals, except salt (NaCl), shall be guaranteed in terms of percentage of the element. When calcium and/or salt guarantees are given in the guaranteed analysis, such shall be stated and conform to the following:

7.2.a. When the minimum is 5.0% or less, the maximum shall not exceed the minimum by more than one percentage point;

7.2.b. When the minimum is above 5.0%, the maximum shall not exceed the minimum by more than 20% and in no case shall the maximum exceed the minimum by more than 5 percentage points.

7.2.c. When required, guarantees for minimum potassium, magnesium, sulfur and maximum fluoride shall be stated in terms of percentage. Other minimum mineral guarantees shall be stated in parts per million (ppm) when the concentration is less than 10,000 ppm and in percentage when the concentration is 10,000 ppm (1%) or greater.

7.3. Guarantees for minimum vitamin content of commercial feeds shall be listed on the label in the order specified and are to be stated in mg/lb unless otherwise specified:

7.3.a. Vitamin A, other than precursors of vitamin A, in International Units per pound.

7.3.b. Vitamin D-3 in products offered for poultry feeding, in International Chick Units per pound.

7.3.c. Vitamin D for other uses, International Units per pound.

7.3.d. Vitamin E, in International Units per pound.

7.3.e. Concentrated oils and feed additive premixes containing vitamins A, D and/or E may, at the option of the distributor, be stated in units per gram instead of units per pound.

7.3.f. Vitamin B-12, in milligrams or micrograms per pound.

7.3.g. All other vitamin guarantees shall express the vitamin activity in milligrams per pound in terms of the following: menadione; riboflavin; d-pantothenic acid; thiamine; niacin; vitamin B-6; folic acid, choline, biotin, inositol; p-amino benzoic acid, ascorbic acid; and carotene.

7.4. Guarantees for drugs shall be stated on the label in terms of percent by weight, except:

7.4.a. Antibiotics, present at less than 2,000 grams per ton (total) of commercial feed shall be stated in grams per ton of commercial feed.

7.4.b. Antibiotics present at 2,000 or more grams per ton (total) of commercial feed, shall be stated in grams per pound of commercial feed.

7.4.c. The term "milligrams per pound" may be used for drugs or antibiotics in those cases where a dosage is given in "milligrams" in the feeding directions.

7.5. Commercial feeds containing any added non-protein nitrogen shall be labeled as follows:

7.5.a. For ruminants:

7.5.a.A. Complete feeds, supplements, and concentrates containing added non-protein nitrogen and containing more than 5% protein from natural sources shall be guaranteed as follows:

Crude protein, minimum, _____ %
(This includes not more than _____ %
equivalent protein from non-protein
nitrogen).

7.5.a.B. Mixed feed concentrates and supplements containing less than 5% protein from natural sources shall be guaranteed as follows:

Equivalent Crude Protein from Non-Protein
Nitrogen, minimum, _____ %

7.5.a.C. Ingredient sources of non-protein nitrogen, such as Urea, Diammonium Phosphate, Ammonium Polyphosphate Solution, Ammoniated Rice Hulls, or other basic non-protein nitrogen ingredients defined by the Association of American Feed Control Officials shall be guaranteed as follows:

Nitrogen, minimum, _____%
Equivalent Crude Protein from Non-Protein
Nitrogen, minimum, _____%

7.5.b. For non-ruminants:

7.5.b.A. Complete feeds, supplements and concentrates containing crude protein from all forms of non-protein nitrogen, added as such, shall be labeled as follows:

Crude protein, minimum, _____%
(This includes not more than _____%
equivalent crude protein which is not
nutritionally available to (species of
animal for which feed is intended).

7.5.b.B. Premixes, concentrates or supplements intended for non-ruminants containing more than 1.25% equivalent crude protein, from all forms of non-protein nitrogen, added as such, must contain adequate directions for use and a prominent statement:

WARNING: This feed must be used only in accordance with directions furnished on the label.

7.6. Mineral phosphatic materials for feeding purposes shall be labeled with the guarantee for minimum and maximum percentage of calcium (when present), the minimum percentage of phosphorus, and the maximum percentage of fluorine.

7.7. Guarantees for microorganisms shall be stated on the label in colony forming units per gram (CFU/g) when directions are for using the product in grams, or in colony forming units per pound (CFU/lb) when directions are for using the product in pounds. A parenthetical statement following the guarantee shall list each species in order of predominance.

7.8. The sliding-scale method of expressing guarantees (for example, "Protein 15-18%") is prohibited.

§61-5-8. Ingredient Statement

8.1. The name of each ingredient must be shown in letters or type of the same size.

8.2. No reference to quality or grade of an ingredient shall appear in the ingredient statement.

8.3. The term "dehydrated" may precede the name of any product that has been artificially dried.

8.4. A single ingredient product defined by the Official Definitions of Feed Ingredients is not required to have an ingredient statement.

8.5. Tentative definitions for ingredients as listed in the 1991 Official Publication of the Association of American Feed Control Officials shall not be used until adopted as official by the Association unless no official definition exists, or the ingredient has a common accepted name that requires no definition, (i.e., sugar).

8.6. When the word "iodized" is used in connection with a feed ingredient, the feed ingredient shall contain not less than 0.007% iodine, uniformly distributed.

8.7. When water is added in the preparation of canned pet foods, water must be listed as an ingredient.

8.8 Food additives and ingredients generally recognized as safe pursuant to 21 CFR Parts 573, 582 and 584, respectively, shall be permitted in the ingredient statement.

§61-5-9. Directions for Use and Precautionary Statements.

9.1. Directions for use and precautionary statements on the label or labeling of all commercial feeds and customer-formula feeds containing additives (including drugs, special purpose additives, or non-nutritive additives) shall:

9.1.a. Be adequate to enable safe and effective use for the intended purposes by users with no special knowledge of the purpose and use of such articles; and,

9.1.b. Include, but not be limited to, all information described by all applicable regulations under 21 CFR, Parts 501, 510 and 558.

9.2. If the commercial feed contains more than 8.75% of equivalent crude protein from all forms of non-protein nitrogen, added as such, or the equivalent crude protein from all forms of non-protein, added as such, exceeds one-third of the total crude protein, the label shall bear adequate directions for the safe use of feeds and a precautionary statement: "CAUTION: USE AS DIRECTED." The directions for use and the caution statement shall be in type of such size so placed on the label that they will be read and understood by ordinary persons under customary conditions of purchase and use.

9.3. Adequate directions for use and precautionary statements necessary for safe and effective use are required on commercial feeds distributed to supply particular dietary needs or for

supplementing or fortifying the usual diet or ration with any vitamin, mineral, or other dietary nutrient or compound.

9.4. On labels, such as those for medicated feeds which bear adequate feeding directions and/or warning statements, the presence of added non-protein nitrogen shall not require a duplication of the feeding directions or the precautionary statements as long as those statements include sufficient information to ensure the safe and effective use of this product as formulated.

§61-5-10. Non-Protein Nitrogen

10.1. Urea and other non-protein nitrogen products defined in the Official Definitions of Feed Ingredients are acceptable ingredients only in commercial feeds for ruminant animals as a source of equivalent crude protein.

10.2. Non-protein nitrogen defined in the Official Definitions of Feed Ingredients, when so indicated, are acceptable ingredients in commercial feeds distributed to non-ruminant animals as a source of nutrients other than equivalent crude protein. The maximum equivalent crude protein from non-protein nitrogen sources when used in non-ruminant rations shall not exceed 1.25% of the total daily ration.

§61-5-11. Evidence of Safety and Efficacy

11.1 The commissioner shall accept the following as satisfactory evidence of safety and efficacy of a commercial feed:

11.1.a. When the commercial feed contains additives, the use of which conforms to the requirements of 21 CFR Parts 570, 573 and 584 or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use.

11.1.a.A. "Additive" is defined as an ingredient or combination of ingredients added to the basic feed mix or parts thereof to fulfill a specific need. Additives are usually used in micro quantities and require careful handling and mixing for safe and effective use.

11.1.b. When the product is itself a drug as defined in West Virginia Code §19-14-2(j) and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Federal Food, Drug, and Cosmetic Act, Section 360(b).

11.1.c. When one of the purposes for feeding 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.

11.1.d. When the commercial feed is a direct fed microbial product and:

11.1.d.A. The product meets the particular fermentation product definition; and

11.1.d.B. The microbial content statement, as expressed in the labeling is limited to the following: "Contains a source of live (viable) naturally occurring microorganisms." This statement shall appear on the label; and

11.1.d.C. The source is stated with a corresponding guarantee expressed in accordance with subsection 6.7 of these rules.

§61-15-12. Adulteration.

12.1 A commercial feed shall be deemed to be adulterated:

12.1.a. If it bears or contains any poisonous or deleterious substance which may render it injurious to health; but in case the substance is not an added substance, such commercial feed shall not be considered adulterated under this subsection if the quantity of such substance in such commercial feed does not ordinarily render it injurious to health; or

12.1.b. If it bears or contains any added poisonous, added deleterious, or added nonnutritive substance which is unsafe within the meaning of Section 406 of the Federal Food, Drug, and Cosmetic Act (other than one which is a pesticide chemical in or on a raw agricultural commodity or a food additive); or

12.1.c. If it is, or it bears or contains any food additive which is unsafe within the meaning of Section 409 of the Federal Food, Drug, and Cosmetic Act; or

12.1.d. If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408(a) of the Federal Food, Drug and Cosmetic Act; Provided, That where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 408 of the Federal Food, Drug and Cosmetic Act and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed feed shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and

the concentration of such residue in the processed feed is not greater than the tolerance prescribed for the raw agricultural commodity unless the feeding of such processed feed will result or is likely to result in a pesticide residue in the edible product of the animal, which is unsafe within the meaning of Section 408(a) of the Federal Food, Drug and Cosmetic Act; or

12.1.e. If it is, or it bears or contains any color additive which is unsafe within the meaning of Section 706 of the Federal Food, Drug and Cosmetic Act; or

12.1.f. If it is, or it bears or contains any new animal drug which is unsafe within the meaning of Section 512 of the Federal Food, Drug and Cosmetic Act.

12.1.g. If any valuable constituent has been in whole or in part omitted or abstracted therefrom or any less valuable substance substituted therefore.

12.1.h. If it contains a drug and the methods used in or the facilities or controls used for its manufacture, processing, or packaging do not conform to current good manufacturing practices to assure that the drug meets the requirements of this article as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess.

12.1.i. If it contains the following poisonous, deleterious or nonnutritive substances as herein defined:

12.1.i.A. Fluorine and any mineral or mineral mixture which is to be used directly for the feeding of domestic animals and in which the fluorine exceeds 0.20% for breeding and dairy cattle; 0.30% for slaughter cattle; 0.30% for sheep; 0.35% for lambs; 0.45% for swine; and 0.60% for poultry.

12.1.i.B. Fluorine bearing ingredients when used in such amounts that they raise the fluorine content of the total ration (exclusive of roughage) above the following amounts: 0.004% for breeding and dairy cattle; 0.009% for slaughter cattle; 0.006% for sheep; 0.01% for lambs; 0.015% for swine and 0.03% for poultry.

12.1.i.C. Fluorine bearing ingredients incorporated in any feed that is fed directly to cattle, sheep or goats consuming roughage (with or without) limited amounts of grain, that results in a daily fluorine intake in excess of 50 milligrams of fluorine per 100 pounds of body weight.

12.1.j. If it is or contains soybean meal, flakes or pellets or other vegetable meals, flakes or pellets which have been extracted with trichlorethylene or other chlorinated solvents.

12.1.k. If it contains sulfur dioxide, sulfurous acid, and salts of sulfurous acid when used in or on feeds or feed ingredients which are considered or reported to be a significant source of vitamin B1 (Thiamine).

12.1.l. All screenings or by-products of grains and seeds containing weed seeds, when used in commercial feed or sold as such to the ultimate purchaser, shall be ground fine enough or otherwise treated to destroy the viability of such weed seeds so that the finished product contains no viable weed seeds per pound.

12.1.m. If it is packaged in bags which are not adequately cleaned to remove residues of potential adulterants which may be harmful to animals.

12.2. Tolerances for pesticide residues in commercial feed shall be those specified in 40 CFR Parts 185 and 186.

§61-5-13. Laboratory services.

13.1 Laboratory facilities are available for analysis of feed, hay, grass or silage samples for interested persons on a non-official basis.

13.2. Charges for such non-official tests shall be those in Table 61-5-A.

13.3. No charge will be assessed to a person for an official sample taken by the commissioner in the course of carrying out the powers and duties under §19-14-3 of the article.

§61-5-14. Powers and Duties of the commissioner.

14.1 When sample collection by the commissioner destroys the saleability of the product (for example, when an entire package must be collected for analysis), the commissioner shall offer to pay the custodian of the product an amount no more than the wholesale cost of that product to that retailer.

§61-5-15. Enforcement Policy.

15.1. First Notice -- If the sample is found to be violative, a first notice shall be issued and an embargo ordered for the lot of commercial feed may be issued to the custodian of the lot sampled. A resample of a different lot shall be taken by the commissioner.

15.2. Second Notice -- If the resample is found to be violative, a second notice shall be issued and an embargo ordered

for the lot of commercial feed shall be issued to the custodian of the lot sampled. A resample of a different lot shall be taken by the commissioner.

15.3. Third Notice -- If the resample is found to be violative, a third notice shall be issued and general embargo order issued to the registrant. A general embargo order shall require all commercial feed of the same brand and product to be removed from sale or distribution within the state until released.

15.4. If a resample indicates the commercial feed is in compliance, the violation will be closed.

15.5. A series of violations will be assessed based on a twelve-month period.

§61-5-16. Good Manufacturing Practices.

16.1. For the purposes of enforcement of West Virginia Code §19-14-10, the commissioner adopts the following regulations as current good manufacturing practices:

16.1.a. The regulations prescribing good manufacturing practices for Type B and Type C medicated feeds as published in the 21 CFR 225.1-225.115 for which a medicated feed application is required by the Food and Drug Administration.

16.1.b. The regulations in 21 CFR 225.2 and 225.120 through 225.202 shall apply to facilities manufacturing solely medicated feeds for which approved medicated feed applications are not required.

16.2. Feed bags may be re-used for a customer-formula feed, Provided that only the customer furnishes the used bags to the manufacturer and that the re-use of these bags will not adulterate the commercial feed pursuant to West Virginia Code §19-14-10.

16.3. The re-use of bags that have been adequately cleaned, so that the use of such bags is not likely to cause adulteration of the feed, shall be permitted.

APPENDIX

TABLE 61-5-A

Charges for tests on non-official samples

Alflatoxin (screen test)	\$25.00	per sample
Ash	\$7.60	per sample
Calcium	\$7.90	per sample
Crude fat	\$6.30	per sample
Crude fiber	\$10.10	per sample
Magnesium.....	\$7.90	per sample
Moisture - oven	\$4.40	per sample
Phosphorus.....	\$12.60	per sample
Protein - Kjeidahl	\$7.30	per sample
Total Digestible Nitrogen	\$46.60	per sample

KEN HECHLER
Secretary of State

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Special Assistant

(Plus all the volunteer
help we can get)

August 12, 1991

NOTICE OF EMERGENCY RULE DECISION BY THE SECRETARY OF STATE

AGENCY: Agriculture

RULE: Amendments, Series 5, Commercial Feed

DATE ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991

FILED AS FIRST EMERGENCY AMENDMENT: August 8, 1991

DECISION NO. 70-91

Following review under WV Code 29A-3-15a, it is the decision of the Secretary of State that the above emergency rule be approved. A copy of the complete decision with required findings is available from this office.

A handwritten signature in cursive script that reads "Ken Hechler".

KEN HECHLER
Secretary of State

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 12, 1991
ADMINISTRATIVE LAW DIVISION

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Secretary of State

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DECISION EMERGENCY RULE DECISION (ERD 70-91)

AGENCY: Agriculture
RULE: Amendments, Series 5, Commercial Feed
ORIGINALLY FILED AS AN EMERGENCY RULE: June 26, 1991
FILED AS EMERGENCY AMENDMENT: August 8, 1991

- par. 1 The Department of Agriculture (Department) has filed the emergency amendments to the above emergency rule.
- par. 2 West Virginia Code 29A-3-a requires the Secretary of State to review all emergency rules filed after March 8, 1986. This review requires the Secretary of State to determine if the agency filing such emergency rule: 1) has complied with the procedures for adopting an emergency rule; 2) exceeded the scope of its statutory authority in promulgating the emergency rule; or 3) can show that an emergency exists justifying the promulgation of an emergency rule.
- par. 3 Following review, the Secretary of State shall issue a decision as to whether or not such an emergency rule should be disapproved [(29A-3-a(a))].
- par. 4 (A) Procedural Compliance: WV Code 29A-3-15 permits an agency to adopt, amend or repeal, without hearing, any legislative rule by filing such rule, along with a statement of the circumstances constituting the emergency, with the Secretary of State and forthwith with the Legislative Rule-Making Review Committee (LRMRC).
- par. 5 If an agency has accomplished the above two required filings with the appropriate supporting documents by the time the emergency rule decision is issued or the expiration of the forty-two day review period, whichever is sooner, the Secretary of State shall rule in favor of procedural compliance.

par. 6 The Department filed this emergency rule with supporting documents with the Secretary of State August 8, 1991 and with the LRMRC August 8, 1991.

par. 7 It is the determination of the Secretary of State that the Department has complied with the procedural requirements of WV Code §29A-3-15 for adoption of an emergency rule.

par. 8 (B) Statutory Authority -- WV Code §19-14-10 reads:

Commercial feed or feed ingredients is adulterated:

(a) If it contains any poisonous, deleterious or nonnutritive substance, including pesticide chemical residues, food additives, color additives or drugs which is or may be injurious to animals when fed such feed in accordance with the directions, or to humans who consume the resultant food product of the animal;

(b) If its composition of quality falls below or differs from what is stated on the label or by its labeling;

(c) If it contains viable weed seeds exceeding the limits set by the commissioner by rules;

(d) If the facilities, controls, or methods used in the manufacture, processing or packaging do not conform to industry standards set by the commissioner by rules; or

(e) If it was manufactured or held under conditions whereby it became contaminated by dust, dirt, insects, birds, rodents or animal excretion thereby rendering it injurious to animal health.

par. 9 It is the determination of the Secretary of State that the Department has not exceeded its statutory authority in promulgating this emergency rule.

par. 10 (C) Emergency WV Code 29A-3-15(g) defines "emergency" as follows:

(g) For the purposes of this section, an emergency exists when the promulgation of a rule is necessary for the immediate preservation of the public peace, health, safety or welfare or is necessary to comply with a time limitation established by this code or by a federal statute or regulation or to prevent substantial harm to the public interest.

par. 11 There are essentially three classes of emergency broadly presented with the above provision: 1) immediate preservation; 2) time limitation; and 3) substantial harm. An agency need only document to the satisfaction of the Secretary of State that there exists a nexus between the proposal and the circumstances creating at least one of the above three emergency categories.

par. 12 The facts and circumstances as presented by the Department are as follows:

The Commercial Feed Regulations originally filed as an emergency on June 26, 1991, and effective on this date, were amended due to written comments received during the public comment period. The agency wishes to enforce the rule as amended.

The major revisions of the rule are that the requirement for mineral guarantees to be made only on feeds that contain a minimum amount of minerals, instead of all feeds. The revision will allow the use of tentative AAFCO definitions for feed (the previous rule prohibited this), the mandatory requirement for embargo of feed on the first notice was removed, and the requirements for good manufacturing practices were amended. Other minor revisions were made for clarity and are technical in nature.

par. 13 It is the determination of the Secretary of State that this proposal qualifies under the definition of an emergency as defined in §29A-3-15(g). . . "prevent substantial harm to public interest."

par. 14 This decision shall be cited as Emergency Rule Decision 70-91 or ERD 70-91 and may be cited as precedent. This decision is available from the Secretary of State and has been filed with the Department of Agriculture, the Attorney General and the Legislative Rule Making Review Commission.



KEN HECHLER
Secretary of State

FILED IN THE OFFICE OF
THE SECRETARY OF STATE
THIS DATE Aug 12, 1991
ADMINISTRATIVE LAW DIVISION

Entered _____