WEST VIRGINIA
SECRETARY OF STATE
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ADMINISTRATIVE LAW DIVISION

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NOTICE OF RULE MODIFICATION OF A PROPOSED RULE

AGENCY: Agriculture TITLE NUMBER: 61

CITE AUTHORITY 19-14-3

AMENDMENT TO AN EXISTING RULE: YES X NO ___

IF YES, SERIES NUMBER OF RULE BEING AMENDED: V

TITLE OF RULE BEING AMENDED: Commercial Feed (repeal and replace)

IF NO, SERIES NUMBER OF NEW RULE BEING PROPOSED: ___

TITLE OF RULE BEING PROPOSED: ___

THE ABOVE PROPOSED LEGISLATIVE RULE, FOLLOWING REVIEW BY THE LEGISLATIVE RULE MAKING REVIEW COMMITTEE IS HEREBY MODIFIED AS A RESULT OF REVIEW AND COMMENT BY THE LEGISLATIVE RULE-MAKING REVIEW COMMITTEE. THE ATTACHED MODIFICATIONS ARE FILED WITH THE SECRETARY OF STATE.

4.00

TITLE 61
LEGISLATIVE RULE
STATE DEPARTMENT OF AGRICULTURE

SERIES V
COMMERCIAL FEED

§61-5-1. General.

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

1.2. Authority - Code of West Virginia §19-14-3.

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 Rules" filed June 1, 1976 and effective July 1, 1976.

§61-5-2. Incorporation by Reference.

2.1. The following documents are 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, also known as 21 United States Code.

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, also known as 21 United States Code 151-159.

§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 WV Code §19-14-1 et seq. Any person who has in his or her possession any unlawful commercial feed is responsible for complying with the law, including registering the commercial feed, paying the tonnage fee, labeling the commercial feed and complying with any other legal requirement, if not met by another person.

3.2. The following persons must also comply with all provisions of WV Code 19-14-1 et seq. and these rules:

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 is exempt from the registration, labeling and inspection fee provisions of WV Code §19-14-5, 8 and 9; however, they are subject to the inspection, sampling and analysis provisions of WV Code §19-14-3.

§61-5-4. Permits; Registration.

4.1. Commercial Feed Manufacturer Permit.

4.1.a. Each manufacturer of commercial feed, including customer-formula feed, within the state, subject to the provisions of WV Code §19-14-5(c), must complete a "Commercial Feed Manufacturer Permit" application with the following information: the corporate or company name; the location; the mailing address; the phone number; the manager's name; the owner's name; and any other information relevant to the manufacture of any commercial feed that the commissioner may request in order the carry out the provisions of WV Code 19-14-1 et seq. or these rules. The manufacturer or his or her authorized representative must sign and date the "Commercial Feed Manufacturer Permit" application under

sworn statement.

4.1.b. The commissioner will not refund the application fee paid by a manufacturer or his or her authorized representative who cancels his or her "Commercial Feed Manufacturer Permit".

4.1.c. The commissioner will refund the application fee paid by a manufacturer when he or she has refused the application for a "Commercial Feed Manufacturer Permit".

4.1.d. The commissioner will not refund the application fee paid by a manufacturer when he or she has suspended or revoked the "Commercial Feed Manufacturer Permit".

4.2. Commercial Feed Distributor Permit.

4.2.a. Each distributor subject to the provisions of WV Code §19-14-5(d) must complete a "Commercial Feed Distributor Permit" application with the following information: the corporate or company name; the location(s); the mailing address; the phone number; the contact person; the owner's name and any other information relevant to the distribution of any commercial feed that the commissioner may request in order to carry out the provisions of WV Code §19-14-1 et seq. or these rules. The distributor or his or her authorized representative must sign and date the "Commercial Feed Distributor Permit" application under sworn statement.

4.2.b. The commissioner will not refund the application fee paid by a distributor or his or her authorized representative who cancels his or her "Commercial Feed Distributor Permit".

4.2.c. The commissioner will refund the application fee paid by a distributor when he or she has refused the application for a "Commercial Feed Distributor Permit".

4.2.d. The commissioner will not refund the application fee paid by a distributor when he or she has suspended or revoked the "Commercial Feed Distributor Permit".

4.3. Commercial Feed Registration.

4.3.a. Each person registering a commercial feed must complete a commercial feed registration application with the following information: the corporate or company name; the location; the mailing address; the phone number; the contact person; the owner's name; and the brand and product name of each feed to be registered. The commissioner may request additional information in order to carry out the provisions of WV Code §19-14-1 et seq. or these rules.

4.3.a.A. A label for each product listed on a

commercial feed registration application must accompany the application.

4.3.a.B. The registrant or his or her authorized representative must sign and date the "Commercial Feed Registration" application under sworn statement.

4.3.b. The commissioner will not consider 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) as pet food. The commissioner will determine the category of other products as pet food or non-pet food on a case-by-case basis.

4.3.c. An individual commercial feed registration is not required for each pet food biscuit or rawhide chew manufactured in different sizes, such as small, medium, large, or a commercial feed manufactured in different forms, such as pellets, crumbles or mash; however, the registrant must indicate the sizes and/or forms in which the product is manufactured and provide labels for each product when applying for registration.

4.3.d. The commissioner will not refund the application fee paid by a registrant or his or her authorized representative who cancels his or her "Commercial Feed Registration" in part or in whole.

4.3.e. The commissioner will refund the application fee paid by a registrant when he or she has refused the application for a "Commercial Feed Registration" in part or in whole.

4.3.f. The commissioner will not refund the application fee paid by a registrant when he or she has suspended or revoked the "Commercial Feed Registration" in part or in whole.

4.3.g. The registrant shall notify the commissioner when a product is discontinued or removed from distribution in this state. The registrant shall maintain registration for a product no longer distributed in this state for one additional registration period to allow for the sale or removal of the product on the shelves or the registrant shall immediately withdraw the product from distribution. After that period, the commissioner may hold the registrant, the distributor or the person offering the product for sale responsible for complying with WV Code §19-14-5(e) and this rule.

4.3.h. The commissioner will maintain registrations for commercial feeds distributed in packages over ten pounds and unpackaged feed (bulk) that have been registered before May 28, 1991 until the registration is canceled by the registrant or the commissioner revokes or suspends the registration for cause.

4.3.i. The commissioner shall review and process revisions to commercial feeds in packages over ten pounds and unpackaged feed (bulk), registered before May 28, 1991, that have been submitted to the commissioner by the registrant subject to the provisions of WV Code §19-14-1 et seq.

4.3.j. 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.

4.3.k. If a pet food or specialty pet food requires minor label revision(s) to conform to labeling requirements, the commissioner shall register the product conditionally for the current registration period; however, if a label requires major revisions, the commissioner shall withhold the product from registration pending revision of labeling. The commissioner shall offer the applicant an opportunity for a hearing in this matter pursuant to WV Code §19-14-7.

4.3.k.A. Minor revisions are those items that are necessary to conform to WV Code §19-14-8, 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.

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

4.3.l. When pet food or specialty pet food labels are changed by the manufacturer of his own accord, the registrant shall submit a new application for a revision to the registration. The commissioner will waive the application fee for any label revision that involves a change in the net weight or a change in the list of ingredients.

4.3.m. The commissioner will not require registration of any pet chew, bone, toy or exerciser (of any shape or size) made of rawhide, wood or man-made material, whether flavor-coated or unflavored, unless the registrant makes a claim on the product label or labeling 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 WV 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 of any commercial feed. The registrant shall display the information required by WV Code §19-14-8(b)(6)-(7) in a prominent place on the label or container but not necessarily on the same side as information required in WV Code §19-14-8(b)(1)-(5). When the information required by WV 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." The registrant shall not subordinate or obscure the information required by WV Code §19-14-8 by other statements or designs.

5.1.a. The guaranteed analysis of the commercial feed as required under the provisions of WV Code §19-14-8(b)(3) shall include the following items, unless exempted in section 5.1.a.I. of these rules, and the registrant shall list the guaranteed analysis in the following order:

5.1.a.A. The minimum percentage of crude protein.

5.1.a.B. The minimum or maximum percentage of equivalent protein from non-protein nitrogen, if present, as required in subsection 7.5 of these rules.

5.1.a.C. The minimum percentage of crude fat.

5.1.a.D. The 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, as incorporated by reference in section 2 of this rule.

5.1.a.G. Vitamins in terms specified in subsection 7.3 of these rules.

5.1.a.H. Other guarantees as specified by the Official Definitions of Feed Ingredients, as incorporated by reference in section 2 of this rule.

5.1.a.I. except that:

5.1.a.I.(a) Guarantees for product sold primarily for their sugar content or on dried molasses products may be expressed as total sugars.

5.1.a.I.(b) Guarantees for product containing viable lactic acid producing micro-organisms for use in silages

shall include the information required by subsection 7.7 of these rules in addition to the requirements of WV Code §19-14-8(b)(3).

5.1.a.I.(c) Guarantees for product sold primarily for their fat content may be expressed as the minimum percentage of total fatty acids the maximum percentage of unsaponifiable matter and the maximum percentage of insoluble matter.

5.1.a.I.(d) 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.I.(e) 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.I.(f) 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 to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.

5.1.a.I.(g) 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 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, as incorporated by reference in section 2 of these rules.

5.3. Specialty pet food labels shall conform to the requirements of WV Code §19-14-8.

5.4. The registrant shall provide information to substantiate claims of improvement or newness (i.e., new, improved, introducing, better tasting, more taste than before) when required by the commissioner. The registrant shall limit the use of these claims to six months' production of the feed and shall submit a revised label within six months of original registration. The commissioner will not require an additional application fee for the submission of a revised label under these circumstances during the current registration period.

5.5. If a manufacturer or distributor sells customer-formula feed in bags, rather than unpackaged feed (bulk), then he or she is not required to label each bag, Provided that an invoice, which supplies all the information required by WV Code §19-14-8(d),

accompanies the customer-formula feed at all times that the feed is distributed.

§61-5-6. Brand and Product Names.

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

6.2. The registrant shall not use a commercial, registered brand or trade name in any guarantee or ingredient listings but may use a commercial, registered brand or trade name in the product name of feeds produced by or for the firm holding the rights to the name.

6.3. The registrant shall not derive the name of a commercial feed from one or more ingredients of a mixture to the exclusion of other ingredients. The name of a commercial feed 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 registrant shall not use the word "protein" 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 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 the registrant may use other percentage values if they are followed by the proper description and conform to good labeling practice. In no case shall the registrant use numbers in the name of the product in a manner that is misleading or confusing to the customer.

6.6. The registrant shall use a name for a single ingredient feed that is in accord with the name of the product designated in the Official Definition of Feed Ingredients, as incorporated by reference in section 2 of these rules, unless the commissioner allows otherwise.

6.7. The registrant may use the word "vitamin," or a contraction thereof, or any word suggesting a vitamin 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 7.3 of these rules.

6.8. The registrant may not use the term "mineralized" in the name of a feed except for its use in the phrase "TRACE MINERALIZED SALT." When this phrase is used, the product must contain significant amounts of trace minerals which are recognized as essential for animal nutrition.

6.9. The registrant shall qualify the terms "meat" and "meat by-products" to designate the animal from which the meat and meat by-products are 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 registrant shall express guarantees for crude protein, equivalent protein from non-protein nitrogen, crude fat, crude fiber and mineral guarantees in terms of percentages.

7.2. For commercial feeds containing 6-1/2% or more Calcium, Phosphorus, Sodium and Chloride, the registrant shall guarantee 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). The registrant shall guarantee minerals, except salt (NaCl), in terms of percentage of the element. When calcium and/or salt guarantees are given in the guaranteed analysis, the guarantee for calcium and/or salt, 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, the registrant shall state guarantees for minimum potassium, magnesium, sulfur and maximum fluoride in terms of percentage. The registrant shall state other minimum mineral guarantees 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. The registrant shall state the guarantees for minimum vitamin content in a commercial feed as mg/lb unless otherwise specified in this subsection and shall list guarantees on the label in the order specified in this subsection:

7.3.a. Vitamin A, other than precursors of vitamin A,

shall be guaranteed in International Units per pound.

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

7.3.c. Vitamin D in products not offered for poultry feeding, shall be guaranteed in International Units per pound.

7.3.d. Vitamin E shall be guaranteed in International Units per pound.

7.3.e. Vitamin B-12 shall be guaranteed in milligrams or micrograms per pound.

7.3.f. Vitamins A, D and/or E that are in concentrated oils and feed additive premixes may be guaranteed, at the option of the registrant, in either units per gram or units per pound.

7.3.g. All other vitamin guarantees shall express the vitamin activity in milligrams per pound and shall be listed in the following order: 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 The registrant shall guarantee drugs on the label in terms of percent by weight, except that:

7.4.a. Drugs, present at less than 2,000 grams per ton (total) of commercial feed shall be guaranteed as grams per ton of commercial feed.

7.4.b. Drugs, present at 2,000 or more grams per ton (total) of commercial feed shall be guaranteed as grams per pound of commercial feed.

7.4.c. Drugs, when incorporated in feed where the feeding directions give a dosage in "milligrams" may be guaranteed as milligrams per pound of commercial feed.

7.5. The registrant shall label and guarantee commercial feeds containing any added non-protein nitrogen 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:

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:

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 in the Official Definitions of Feed Ingredients, as adopted by reference in section 2 of these rules:

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:

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. The registrant shall label mineral phosphatic materials for feeding purposes 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. The registrant shall state the guarantees for microorganisms 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 commissioner will not register any feed that is labeled with the sliding-scale method of expressing guarantees (for example, "Protein 15-18%").

§61-5-8. Ingredient Statement

8.1. The registrant shall label each commercial feed with an ingredient statement with:

8.1.a. The name of each ingredient in letters or type of the same size.

8.1.b. No reference to the quality or grade of any ingredient in the ingredient statement.

8.1.c. The term "dehydrated" permitted only prior to the name of an ingredient that has been artificially dried.

8.1.d. The term "iodized" permitted only prior to the name of an ingredient when the ingredient contains not less than 0.007% iodine, uniformly distributed.

8.1.e. The term "water" appearing in the list of ingredients when water is added in the preparation of canned pet food.

8.2. The registrant may use ingredients that have a tentative official definition listed in the Official Definitions of Feed Ingredients, as adopted in section 2 of these rules, only if no official definition exists.

8.3. The registrant may use the names of food additives and ingredients generally recognized as safe pursuant to 21 CFR Parts 573, 582 and 584, respectively, when these products are added to the commercial feed.

8.4. The registrant is not required to have an ingredient statement for any single ingredient product where the name of the product is the same as the product that is defined by the Official Definitions of Feed Ingredients, as incorporated by reference in section 2 of these rules.

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

9.1. The registrant shall include directions for use and precautionary statements on the label or labeling of all commercial feeds containing additives (including drugs, special purpose additives, or non-nutritive additives). The directions for use and precautionary statements shall be adequate to enable the safe and effective use of the commercial feed for its intended purposes by

the users with no special knowledge of the purpose and use of commercial feeds; and,

9.1.b. Include at a minimum, but not be limited to, all information described by all applicable regulations under 21 CFR, Parts 501, 510 and 558, as incorporated by reference in section 2 of these rules.

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, then the registrant shall include on the label adequate directions for the safe use of the feed and the caution 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. The registrant shall include adequate directions for use and precautionary statements necessary for the safe and effective use of 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 the registrant to duplicate the feeding directions or the precautionary statements as long as the statements that are on the label include sufficient information to ensure the safe and effective use of this product as formulated.

§61-5-10. Non-Protein Nitrogen

10.1. The commissioner will register commercial feeds with urea and other non-protein nitrogen products that are defined in the Official Definitions of Feed Ingredients, as incorporated by reference in section 2 of these rules, as a source of equivalent crude protein only for use in feed for ruminant animals.

10.2. The commissioner will register commercial feeds with non-protein nitrogen products that are defined in the Official Definitions of Feed Ingredients, as incorporated by reference in section 2 of these rules, when these ingredients are used as a source of nutrients other than equivalent crude protein only for use in feed for non-ruminant animals provided that the maximum equivalent crude protein from non-protein nitrogen sources when used in non-ruminant animal rations does 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 the safety and efficacy of a commercial feed:

11.1.a. The use of additives in the commercial feed conforms to the requirements of 21 CFR Parts 570, 573 and 584, as incorporated by reference in section 2 of these rules or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for its indicated 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. The use of any drug that is generally recognized as safe and effective for the labeled use or that is marketed subject to an application approved by the Federal Food, Drug, and Cosmetic Act, Section 360(b), as incorporated by reference in section 2 of these rules.

11.1.c. The use of any immunological agent that has been approved for that purpose through the Federal Virus, Serum and Toxins Act of 1913, as incorporated by reference in section 2 of these rules, when one of the purposes for feeding the commercial feed is to impart immunity (that is, to act through some immunological process the constituents imparting immunity).

11.1.d. The use of any direct fed microbial product, as defined in the Official Definitions of Feed Ingredients, as incorporated by reference in section 2 of this rule, that meets the particular fermentation product definition; where 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 where the source of the microorganisms is stated with a corresponding guarantee expressed in accordance with subsection 7.7 of these rules.

§61-15-12. Adulteration.

12.1 A commercial feed is adulterated:

12.1.a. If it bears or contains any poisonous or deleterious substance which may render it injurious to animal or human health; but in the case where the substance is not an added substance, the commercial feed is not considered adulterated under this subsection if the quantity of the substance in the 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, as incorporated by reference in section 2 of these rules, (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, as incorporated by reference in section 2 of these rules; 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, as incorporated by reference in section 2 of these rules; 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 the raw agricultural commodity has been subjected to processing, such as canning, cooking, freezing, dehydrating, or milling, the residue of the pesticide chemical remaining in or on the processed feed is not considered unsafe if the residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of the residue in the processed feed is not greater than the tolerance prescribed for the raw agricultural commodity unless the feeding of the 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, as incorporated by reference in section 2 of these rules; 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, as incorporated by reference in section 2 of these rules.

12.1.g. If any valuable constituent has been in whole or in part omitted or abstracted from the commercial feed or any less valuable substance substituted for it.

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 the drug meets the requirements of WV Code §19-14-10 and of

this section 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 defined in this subsection:

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 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. If it contains any viable weed seeds in screenings or by-products of grains and seeds containing weed seeds when the product is used in commercial feed or sold as a single ingredient feed. Products containing viable weed seed shall be ground fine enough or otherwise treated to destroy the viability of weed seeds prior to distribution.

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 are those specified in 40 CFR Parts 185 and 186, as incorporated by reference in section 2 of these rules.

§61-5-13. Laboratory services.

13.1 The commissioner shall make available laboratory facilities for the analysis of feed, hay, grass or silage samples for interested persons on a non-official basis.

13.2. Charges for such non-official tests are specified in Table 61-5-A of this rule.

13.3. The commissioner shall not charge a person for an official sample taken by the commissioner in the course of carrying out the powers and duties under WV Code §19-14-3 or these rules.

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

14.1 When sample collection by the commissioner destroys the salability 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 not more than the wholesale cost of that product to that retailer.

§61-5-15. Enforcement Policy.

15.1. First Notice -- If a commercial feed sample does not conform to WV Code §19-14-1 et seq. or these rules, the commissioner shall issue a first notice to the registrant of the commercial feed. The commissioner may also issue an embargo order for the lot of commercial feed to the custodian of the lot sampled. The commissioner will take an additional sample from a different lot.

15.2 Second Notice -- If a commercial feed sample does not conform to WV Code §19-14-1 et seq. or these rules within a twelve-month period of assessing a first notice, the commissioner shall issue a second notice to the registrant of the commercial feed. The commissioner shall also issue an embargo order for the lot of commercial feed to the custodian of the lot sampled. The commissioner will take an additional sample from a different lot.

15.3 Third Notice -- If a commercial feed sample does not conform to WV Code §19-14-1 et seq. or these rules subsequent to the assessment of a second notice and within a twelve-month period of assessing a first notice, the commissioner shall issue a third notice to the registrant of the commercial feed. The commissioner shall also issue a general embargo order to the registrant that will require him or her to remove all lots of that commercial feed from sale and distribution within the state until the embargo is released.

15.4 If a resample indicates that the commercial feed is in compliance with WV Code 19-14-1 et seq. and these rules, then all previous notices of violations for that commercial feed will be

canceled.

15.5. The commissioner may take other action as considered necessary in order to carry out the provisions of WV Code §19-14-1 et seq. and these rules.

§61-5-16. Good Manufacturing Practices.

16.1. For the purposes of enforcement of WV Code §19-14-10 and of section 12 of these rules, 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 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 WV Code §19-14-10 or of section 12 of these rules.

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

APPENDIX

TABLE 61-5-A

Charges for tests on non-official samples

Aflatoxin (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 - Kjeldahl	$7.30 per sample
Total Digestible Nutrients	$46.60 per sample

WEST VIRGINIA LEGISLATURE
LEGISLATIVE RULE-MAKING REVIEW COMMITTEE
Room M-152, State Capitol
Charleston, West Virginia 25305
(304) 340-3286

NOTICE OF ACTION TAKEN BY LEGISLATIVE RULE-MAKING REVIEW COMMITTEE

September 10, 1991

TO: Ken Hechler, Secretary of State, State Register

TO: The Honorable Cleve Benedict
Department of Agriculture
State Capitol
Charleston, WV 25305

FROM: Legislative Rule-Making Review Committee

PROPOSED RULE: Commercial Feed

The Legislative Rule-Making Review Committee recommends that the West Virginia Legislature:

1. Authorize the agency to promulgate the Legislative Rule
   (a) as originally filed ____
   (b) as modified by the agency X

2. Authorize the agency to promulgate part of the Legislative rule; a statement of reasons for such recommendation is attached. ____

3. Authorize the agency to promulgate the Legislative rule with certain amendments; amendments and a statement of reasons for such recommendation is attached. ____

4. Authorize the agency to promulgate the Legislative rule as modified with certain amendments; amendments and a statement of reasons for such recommendation is attached. ____

5. Recommends that the rule be withdrawn; a statement of reasons for such recommendation is attached. ____

Pursuant to Code 29A-3-11(c), this notice has been filed in the State Register and with the agency proposing the rule.

cc: Barbara Smith
Compliance Division