330 CMR 14.00: MANUFACTURE, SALE AND DISTRIBUTION OF COMMERCIAL FEED - OTHER THAN PET FOOD

Section

14.01: Definitions and Terms

The definitions of terms used in 330 CMR 14.00 shall be the same as those adopted by the Association of American Feed Control Officials ("AAFCO"), as amended, except as otherwise provided.

14.02: Registration

No person shall distribute commercial feed in the commonwealth unless the feed is registered with the Department, except that the following feeds are exempt from this requirement:

(1) customer formula feeds, raw meat, hay, straw, stover, silages, cobs, husk, hulls when underground and not intermixed with other materials and not adulterated;

(2) individual chemical compounds which meet all of the following criteria:
(a) The Association of American Feed Control Officials has adopted a definition of the product;
(b) The product is either GRAS or is not covered by a specific Food and Drug Administration regulation;
(c) The product is either a natural occurring product of relatively uniform chemical composition or is manufactured to meet the AAFCO definition of the product;
(d) The use of the product in the feed industry constitutes a minor portion of its total industrial use; and

(3) Small quantities of additives, which are intended to impart special desirable characteristics shall be permitted.

14.03: Labeling

(1) Commercial feeds, other than customer-formula feed, distributed in the Commonwealth shall be labeled, at a minimum, with the following information on the principal display panel of the product and in the following general format:
(a) Net weight, net volume or net count;
(b) Product name and brand name if any;
(c) Guaranteed analysis of:
1. minimum percentage of crude protein;
2. minimum percentage of crude fat; and
3. maximum percentage of crude fiber;
(d) For mineral feeds formulated entirely or mainly from mineral ingredients the label shall include the following, if added:
1. minimum and maximum percentage of calcium;
2. minimum and maximum percentage of salt; and
(e) Name and principal mailing address of the manufacturer and distributor, including the street address, city, state, zip code.

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(2) The following substances may be guaranteed:
(a) Maximum or minimum percentage of equivalent protein from non-protein nitrogen as required;
(b) minimum and maximum percentage of calcium;
(c) minimum and maximum percentage of salt;
(d) minimum percentage of phosphorus ;
(e) vitamins;
(f) total sugars as invert on dried molasses or products being sold primarily for their sugar content.
(g) minerals, when there are no specific label claims and when commercial feed contains less than 6.5% of mineral elements;
(h) vitamins, when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement;
(i) crude protein, crude fat, and crude fiber, 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;
(j) microorganisms, 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 no specific label claims are made; or
(k) the indication for animal class(es) and species is not required on single ingredient products if the ingredient is not intended, represented, or defined for a specific animal Class(es) or species.

(3) Products sold solely as mineral or vitamin supplements need not show guarantees for protein, fat and fiber.

(4) The common or usual name of each ingredient must be listed on the label, except:
(a) a collective term may be used for a group of ingredients all of which perform a similar function so long as the manufacturer provides the Department, upon request, with a list of the individual ingredients within the defined group. When a collective term for a group of ingredients is used on the label, individual ingredients within that group shall not be listed on the label; and
(b) the registrant may affix the statement, "Ingredients as registered with the State" in lieu of an ingredient list on the label where the list of ingredients has been filed with the Department and the registrant makes this list available to the feed purchaser upon request.

(5) If drugs are used the following must appear on the label:
(a) The word "medicated", directly following and below the product name in type size no smaller than ½ the type size of the product name;
(b) The purpose of the medication;
(c) The required directions for use and precautionary statements, or reference to their location if the detailed feeding directions and precautionary statements appear elsewhere on the label; and
(d) An active drug ingredient statement listing the active drug ingredients by their established name and the amounts.

(6) A statement of the purpose as follows:
(a) A list of the specific species and animal class(es) for which the feed is intended;
(b) The manufacturer shall have flexibility in describing in more specific and common language the defined animal class, species and purpose while being consistent with the category of animal class which may include, but is not limited to weight range(s), sex, or ages of the animal(s) for which the feed is manufactured;
(c) The purpose statement may be excluded from the label if the product name includes a description of the species and animal class(es) for which the product is intended;
(d) The purpose statement of a premix for the manufacture of feed may exclude the animal class and species and state “For Further Manufacture of Feed” if the nutrients contained in the premix are guaranteed and sufficient for formulation into various animal species feeds and premix specifications are provided by the end user; and

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(e) The purpose statement of a single purpose ingredient blend, such as a blend of animal protein products, milk products, fat products, roughage products or molasses products may exclude the animal class and species and state "For Further Manufacture of Feed" if the label guarantees of the nutrients contained in the single purpose nutrient blend are sufficient to provide for formulation into various animal species feeds.

(7) All information required to be on the label must appear in its entirety on one side of the label or container. Adequate directions for use and precautionary statements required 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 is placed on a different side with a statement such as "see back of label for directions of use," none of the information required shall be subordinated or obscured by other statements or designs.

14.04: Brand and Product Names

(1) The brand or product name must be appropriate for the intended use of the feed and not be misleading. If the name indicates the feed is made for a specific use, the character of the feed must be appropriate to that use.

(2) Commercial, registered brand or trade names are not permitted in guarantees or ingredient listings.

(3) The name of a commercial feed shall not be derived from one or more ingredients of a mixture to the exclusion of the other ingredients and shall not be one representing any components of a mixture unless all components are included in the name, except that, if any ingredient(s) is intended to impart a distinctive characteristic to the product which is of significance to the purchaser, the name of that ingredient(s) may be used as a part of the brand name if the ingredient or brand or product name is not otherwise false or misleading.

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

(5) When the name carries a percentage value, it shall signify protein and/or equivalent protein content only, even though it may not explicitly modify the percentage with the word "protein", except that other percentage values may be permitted if they are followed by the proper description and conform to good labeling practices. Digital numbers shall not be used in such a manner as to be misleading or confusing to the customer.

(6) Single ingredient feeds shall have a product name in accordance with the designated definition of feed ingredients as recognized by the Association of American Feed Control Officials.

(7) The word "vitamin", or a contraction thereof, or any word suggesting vitamin may be used only in the name of a feed which is labeled with the minimum content of each vitamin declared.

(8) The word "mineralized" shall not be used in the name of a feed, except for "TRACE MINERALIZED SALT" and the product must contain significant amounts of trace minerals which are recognized as essential for animal nutrition.

(9) The term "meat" and "meat by-products" shall be qualified to designate the animal from which the meat and meat by-product are derived unless the meat and meat by-products are from cattle, swine, sheep or goats.

14.05: Expression of Guarantees

(1) The guarantees for crude protein, equivalent crude protein from non-protein nitrogen, lysine, methionine, crude fat, crude fiber and acid detergent fiber shall be in terms of percentage.

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(2) Where calcium, salt, and sodium guarantees are given in the guaranteed analysis, they must conform to the following:

(a) When the minimum is below 2.5%, the maximum shall not exceed the minimum by more than 0.5 percentage point;

(b) When the minimum is 2.5% but less than 5.0%, the maximum shall not exceed the minimum by more than one percentage point;

(c) When the minimum is above 5.0% or greater the maximum shall not exceed the minimum by more than 20% of the minimum and in no case shall the maximum exceed the minimum by more than five percentage points;

(d) When stated, guarantees for minimum and maximum total sodium, and salt; minimum potassium, magnesium, sulfur, phosphorus and maximum fluoride shall be 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; and

(e) Products labeled with a quantity statement shall state mineral guarantees in milligram (mg) per unit consistent with the quantity statement and direction for use.

(3) Guarantees for minimum vitamin content of commercial feeds shall be listed in the order specified below and stated in mg/lb or in units consistent with those employed for the quantity statement unless otherwise specified:

(a) Vitamin A, other than precursors of vitamin A, in International Units per pound;

(b) Vitamin D-3 in products offered for poultry feeding, in International Chick Units per pound;

(c) Vitamin D for other uses, International Units per pound;

(d) Vitamin E, in International Units per pound;

(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;

(f) All other vitamin guarantees shall express the vitamin activity in milligrams per pound for the following: menadione; riboflavin; dpantothenie acid; thiamine; niacin; vitamin B-6; Folic acid, choline, biotin, inositol; p-amino benzoic acid; ascorbic acid; and carotene.

(4) Guarantees for drugs shall be stated in terms of percent by weight, except:

(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;

(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;

(c) Labels for commercial feeds containing growth promotion and/or feed efficiency levels of antibiotics, which are to be fed continuously as the sole ration, are not required to make quantitative guarantees except as specifically noted in the Federal Food Additive Regulations for certain antibiotics, where, quantitative guarantees are required regardless of the level or purpose of the antibiotic;

(d) 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.

(5) Commercial feeds containing any added non-protein nitrogen shall be labeled as follows:

FOR RUMINANTS:

(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 crude protein from non-protein nitrogen)

(b) Mixed feed concentrates and supplements containing less than 5% protein from natural sources may be guaranteed as follows:

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

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(c) Ingredients 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,_____%

FOR NON-RUMINANTS:

(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);

(b) Premixes, concentrates or supplements intended for non-ruminants containing more than 1.25% equivalent crude protein from all forms of non-protein, 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.

(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) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/g) when directions are for using the products 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.

(8) Guarantees for enzymes shall be stated in units of enzymatic activity per unit weight or volume, consistent with label directions. The source organism for each type of enzymatic activity shall be specified, such as: Proteus (Bacillus subtilis) 5.5 mg amino acids liberated\min.\milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.

14.06: Ingredients

(1) The name of each ingredient or collective term for the grouping of ingredients, when required to be listed, shall be the name as defined in the Official Definitions of Feed Ingredients as published in the Official Publication of the AAFCO, as amended the common or usual name.

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

(3) No reference to quality or grade of an ingredient shall appear in the ingredient statement.

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

(5) A single ingredient product defined by the Association of American Feed Control Officials is not required to have an ingredient statement.

(6) Tentative definitions for ingredients shall not be used until adopted as official, unless there is no official definition or the ingredient has a common accepted name that requires no definition. (*i.e.* sugar).

(7) 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.

14.07: Directions for Use and Precautionary Statements

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

(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

(b) Include, but not be limited to, all information described by all applicable regulations under the Federal Food, Drug and Cosmetic Act, as amended.

(2) Adequate directions for use and precautionary statements are required for feeds containing non-protein nitrogen.

(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.

14.08: Non-Protein Nitrogen

(1) Urea and other non-protein nitrogen products are acceptable ingredients only in commercial feeds for ruminant animals as a source of equivalent crude protein. 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 nitrogen, added as such, exceeds ⅓ 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.

(2) Non-protein nitrogen when so indicated, are acceptable ingredients in commercial feeds distributed to non-ruminant animals as a source of nutrient 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.

(3) 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 due to the presence of non-protein nitrogen.

14.09: Drug and Feed Additives

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

(2) Satisfactory evidence of safety and efficacy of a commercial feed may be:

(a) When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in the Code of Federal Regulations, Title 21, or other applicable regulation adopted by the United States Food and Drug Administration, or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use, or

(b) When the commercial feed is itself a drug as defined in Section 3(g) of the Food, Drug and Cosmetic Act and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under Title 21 U.S.C.360(b), or

(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, as amended, or

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(d) When the commercial feed is a direct fed microbial product and:
1. The product meets the particular fermentation product definition; and
2. 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
3. The source is stated with a corresponding guarantee.

(e) When the commercial feed is an enzyme product and:
1. The product meets the particular enzyme definition by the Association of American Feed Control Officials; and
2. The enzyme is stated with a corresponding guarantee.

14.10: Adulterants

(1) For the purposes of M.G.L. c. 128, § 54, the term "poisonous or deleterious substances" shall include but is not limited to the following:

(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;

(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;

(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;

(d) Soybean meal, flakes or pellets or other vegetable meals, flakes or pellets which have been extracted with trichlorethylene or other chlorinated solvents;

(e) 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).

(2) All screenings or by-products of grains and seeds containing weed seeds, when used in commercial feed or sold as such to the ultimate consumer, shall be ground fine enough or otherwise treated to destroy the viability of such weed seeds so that the finished product contains no more than four viable prohibited weed seeds per pound and not more than 100 viable restricted weed seeds per pound as defined by the M.G.L. c. 128 and the regulations promulgated thereunder.

14.11: Good Manufacturing Practices

(1) For the purposes of enforcing 330 CMR 14.00, the Department adopts the following as current good manufacturing practices:

(a) The Regulations prescribing good manufacturing practices for Type B/C medicated Feeds adopted under the Federal Food, Drug and Cosmetic Act, as published in 21 CFR, 225, §§ 225.1-225.202 as amended; and

(b) The Regulations prescribing good manufacturing practices for Type A medicated articles adopted under the Federal Food, Drug and Cosmetic Act, as published in 21 CFR 226, §§ 226.1-226.115 as amended.

REGULATORY AUTHORITY

330 CMR 14.00: M.G.L. c. 128, §§ 51 through 58.

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