ARTICLE 6. ANIMAL FOODS

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Rule 1. General Provisions

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355 IAC 6-1-1 Definitions and terms

355 IAC 6-1-13

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-29</u>

Sec. 1. (a) The names and definitions for commercial feeds shall be the official definitions of feed ingredients adopted by the Association of American Feed Control Officials (AAFCO), except as the director designates otherwise in specific cases.

Indiana commercial feed license

- (b) The terms used in reference to commercial feeds shall be the official feed terms adopted by the AAFCO, except as the director designates otherwise in specific cases.
- (c) The following commodities, when unground and when not mixed or intermixed with other materials, are hereby declared exempt from the definition of commercial feeds under <u>IC 15-5-13-1</u> [<u>IC 15-5</u> was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008.]:
 - (1) Raw meat.
 - (2) Hay.
 - (3) Straw.
 - (4) Stover.
 - (5) Silages.
 - (6) Cobs.
 - (7) Husks.
 - (8) Hulls.

Provided that these commodities are not adulterated within the meaning of IC 15-5-13-9 [IC 15-5] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See IC 15-19-7-29.].

- (d) The individual chemical compounds and substances of loose salt (sodium chloride) are hereby declared exempt from the definition of commercial feed under IC 15-5-13-1 [IC 15-5] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008.].
- (e)Unmanipulated high moisture (greater than ninety percent (90%) moisture) human food processing byproducts are hereby declared exempt from the definition of commercial feed under IC 15-5-13-1 [IC 15-5] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008.] provided they are not adulterated within the meaning of IC 15-5-13-9 [IC 15-5] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See IC 15-19-7-29.].
- (f) "Custom-mixed feed" includes feed to which the manufacturer retains title and which is fed to animals to which the manufacturer retains title. (State Chemist of the State of Indiana; 355 IAC 6-1-1; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2444; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-2 Label format

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

Sec. 2. (a) Commercial feed, other than custom-mixed feed, shall be labeled with the information prescribed in this rule on the principal display panel of the product and in the following format:

- (1) Product name and brand name, if any, as stipulated in section 3(a)(1) of this rule.
- (2) If a drug is used, label as stipulated in section 3(a)(2) of this rule.
- (3) Purpose statement as stipulated in section 3(a)(3) of this rule.
- (4) Guaranteed analysis as stipulated in section 3(a)(4) of this rule.
- (5) Feed ingredients as stipulated in section 3(a)(5) of this rule.
- (6) Directions for use and precautionary statements as stipulated in section 3(a)(6) of this rule.
- (7) Name and principal mailing address of the manufacturer or person responsible for distributing the feed as stipulated in section 3(a)(7) of this rule.
- (8) Quantity statement.
- (b) The following requirements apply to labeling:
- (1) The information required in subsection (a)(1) through (a)(5), (a)(7), and (a)(8) must appear in its entirety on one (1) side of the label or on one (1) side of the container.
- (2) The information required by subsection (a)(6) shall be displayed in a prominent place on the label or container but not necessarily on the same side as the information in subdivision (1). When the information required by subsection (a)(6) is placed on a different side of the label or container, it shall 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 this section shall be subordinated or obscured by other statements or designs.
- (c) Custom mixed feed shall be accompanied with the information prescribed in this rule using labels, invoice, delivery ticket, or another distribution document bearing the following information:
 - (1) The name and address of the manufacturer.
 - (2) The name and address of the purchaser.
 - (3) The date of sale or delivery.
 - (4) The custom mixed feed name and brand name if any.
 - (5) The product name and net quantity of each commercial feed and each other ingredient used in the mixture.
 - (6) The direction for use and precautionary statements as required by sections 7 and 8 of this rule.
 - (7) If a drug containing product is used, the:
 - (A) purpose of the medication (claim statement); and
 - (B) established name of each active drug ingredient and the level of each drug used in the final mixture expressed in accordance with section 4(d) of this rule.

(State Chemist of the State of Indiana; 355 IAC 6-1-2; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2444; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-3 Label information

Authority: IC 15-19-7-34

Affected: IC 15-19-7-26; IC 15-19-7-28

Sec. 3. (a) Commercial feed, other than custom-mixed feed, shall be labeled with the information prescribed as follows:

- (1) Product name and brand name, if any, as follows:
 - (A) 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 conformtherewith. A commercial feed for a particular animal class must be suitable for that purpose.
 - (B) Commercial, registered brand or trade names are not permitted in guarantees or ingredient listings and only in the product name of feeds produced by or for the firm holding the rights to such a name.

- (C) The name of a commercial feed shall not be derived from one (1) 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 ingredient or combination of ingredients is quantitatively guaranteed in the guaranteed analysis, and the brand or product name is not otherwise false or misleading.
- (D) The word "protein" shall not be permitted in the product name of a feed that contains added nonprotein nitrogen.
- (E) When the name carries a percentage value, it shall be understood to signify protein and/or equivalent protein from nonprotein nitrogen 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 practices. Digital numbers shall not be used in a product name in such a manner as to be misleading or confusing to the customer.
- (F) 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 unless the director designates otherwise.
- (G) The word "vitamin", or a contraction thereof, or any word suggesting vitamin can be used only in the name of a feed which is represented to be a vitamin supplement, and which is labeled with the minimum content of each vitamin declared, as specified in section 4(c) of this rule.
- (H) 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.
- (I) The term "meat" and "meat byproducts" shall be qualified to designate the animal from which the meat and meat byproducts is derived unless the meat and meat byproducts are made from cattle, swine, sheep, and goats.
- (2) If a drug is used, the following requirements apply:
 - (A) The word "medicated" shall appear directly following and below the product name in type size, no smaller than half the type size of the product name.
 - (B) Purpose statement as required in subdivision (3).
 - (C) The purpose of medication (claim statement).
 - (D) An active ingredient statement listing the active drug ingredients by their established name and the amounts in accordance with section 4(d) of this rule.
- (3) Requirements for purpose statement are as follows:
 - (A) The statement of purpose shall contain the specific species and animal class or classes for which the feed is intended as defined in subdivision (4).
 - (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 defined in subdivision (4), which may include, but is not limited to, weight range, sex, or age of the animal 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 or classes 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 of the premix. This section is applicable to commercial feeds regulated under subdivision (4)(J)(ii)(JJ).
 - (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. This section is applicable to commercial feeds regulated under subdivision (4)(J)(ii)(JJ).
 - (F) The purpose statement of a product shall include a statement of enzyme functionality if enzymatic activity is represented in any manner.
- (4) Guarantees for crude protein, equivalent crude protein from nonprotein nitrogen, amino acids, crude fat, crude fiber,

acid detergent fiber, calcium, phosphorus, salt, and sodium shall be the sequence of nutritional guarantees when such guarantee is stated. Other required and voluntary guarantees should follow in a general format such that the units of measure used to express guarantees (percentage, parts per million, International Units, etc.) are listed in a sequence that provides a consistent grouping of the units of measure as follows:

- (A) Required guarantees for swine formula feeds are as follows:
 - (i) Animal classes as follows:
 - (AA) Prestarter, two (2) to eleven (11) pounds.
 - (BB) Starter, eleven (11) to forty-four (44) pounds.
 - (CC) Grower, forty-four (44) to one hundred ten (110) pounds.
 - (DD) Finisher, one hundred ten (110) to two hundred forty-two (242) pounds (market).
 - (EE) Gilts, sows, and adult boars.
 - (FF) Lactating gilts and sows.
 - (ii) Guaranteed analysis for swine complete feeds and supplements (all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Minimum percentage of lysine.
 - (CC) Minimum percentage of crude fat.
 - (DD) Maximum percentage of crude fiber.
 - (EE) Minimum and maximum percentage of calcium.
 - (FF) Minimum percentage of phosphorus.
 - (GG) Minimum and maximum percentage of salt (if added).
 - (HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (II) Minimum selenium in parts per million.
 - (JJ) Minimum zinc in parts per million.
- (B) Required guarantees for formula poultry feeds (broilers, layers, and turkeys) as follows:
 - (i) Animal classes as follows:
 - (AA) Layer, chickens that are grown to produce eggs for food, for example, table eggs:
 - (aa) starting/growing, from day of hatch to approximately ten (10) weeks of age;
 - (bb) finisher, from approximately ten (10) weeks of age to the time first egg is produced (approximately twenty (20) weeks of age);
 - (cc) laying, from the time the first egg is laid throughout the time of egg production; and
 - (dd) breeders, chickens that produce fertile eggs for hatch replacement layers to produce eggs for food, table eggs, from the time the first egg is laid throughout their productive cycle.
 - (BB) Broilers, chickens that are grown for human food:
 - (aa) starting/growing, from the day of hatch to approximately five (5) weeks of age;
 - (bb) finisher, from approximately five (5) weeks of age to market, (forty-two (42) to fifty-two (52) days); and
 - (cc) breeders, hybrid strains of chickens whose offspring are grown for human food (broilers) any age and either sex.
 - (CC) Broilers, breeders, chickens whose offspring are grown for human food (broilers):
 - (aa) starting/growing, from the day of hatch until approximately ten (10) weeks of age;
 - (bb) finishing, from approximately ten (10) weeks of age to the time the first egg is produced, approximately twenty (20) weeks of age; and
 - (cc) laying, fertile egg producing chickens (broilers/roasters) from the day of the first egg throughout the time fertile eggs are produced.
 - (DD) Turkeys:
 - (aa) starting/growing, turkeys that are grown for human food from the day of the hatch to approximately thirteen (13) weeks of age (females) and sixteen (16) weeks of age (males);
 - (bb) finisher, turkeys that are grown for human food, females from approximately thirteen (13) weeks of age to approximately seventeen (17) weeks of age; males from sixteen (16) weeks

- of age to twenty (20) weeks of age (or desired market weight);
- (cc) laying, female turkeys that are producing eggs; from the time the first egg is produced, throughout the time they are producing eggs; and
- (dd) breeder, turkeys that are grown to produce fertile eggs, from the day of hatch to the time the first eggs produced (approximately thirty (30) weeks of age), both sexes.
- (ii) Guaranteed analysis for poultry complete feeds and supplements (all animal classes):
 - (AA) minimum percentage of crude protein;
 - (BB) minimum percentage of lysine;
 - (CC) minimum percentage of methionine;
 - (DD) minimum percentage of crude fat;
 - (EE) maximum percentage of crude fiber;
 - (FF) minimum and maximum percentage of calcium;
 - (GG) minimum percentage of phosphorus;
 - (HH) minimum and maximum percentage of salt (if added); and
 - (II) minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
- (C) Required guaranteed for beef cattle formula feeds as follows:
 - (i) Animal classes as follows:
 - (AA) Calves (birth to weaning).
 - (BB) Cattle on pasture may be specific as to production stage, for example:
 - (aa) shocker;
 - (bb) feeder;
 - (cc) replacement heifers;
 - (dd) brood cows; or
 - (ee) bulls.
 - (CC) Feedlot cattle.
 - (ii) Guaranteed analysis for beef complete feeds and supplements (all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.
 - (CC) Minimum percentage of crude fat.
 - (DD) Maximum percentage of crude fiber.
 - (EE) Minimum and maximum percentage of calcium.
 - (FF) Minimum percentage of phosphorus.
 - (GG) Minimum and maximum percentage of salt (if added).
 - (HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (II) Minimum percentage of potassium.
 - (JJ) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
 - (iii) Guaranteed analysis for beef mineral feeds (if added) as follows:
 - (AA) Minimum and maximum percentage calcium.
 - (BB) Minimum percentage of phosphorus.
 - (CC) Minimum and maximum percentage of salt.
 - (DD) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (EE) Minimum percentage of magnesium.
 - (FF) Minimum percentage of potassium.
 - (GG) Minimum copper in parts per million.
 - (HH) Minimum selenium in parts per million.
 - (II) Minimum zinc in parts per million.

- (JJ) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound.
- (D) Required guarantees for dairy formula feeds as follows:
 - (i) Animal classes as follows:
 - (AA) Veal milk replacer, milk replacer to be fed for veal production.
 - (BB) Herd milk replacer, milk replacer to be fed for herd replacement calves.
 - (CC) Starter, approximately three (3) days to three (3) months.
 - (DD) Growing heifers, bulls, and dairy beef as follows:
 - (aa) Grower 1, three (3) months to twelve (12) months of age.
 - (bb) Grower 2, more than twelve (12) months of age.
 - (EE) Lactating dairy cattle.
 - (FF) Nonlactating dairy cattle.
 - (ii) Guaranteed analysis for veal and herd replacement milk replacer as follows:
 - (AA) Minimum percentage crude protein.
 - (BB) Minimum percentage crude fat.
 - (CC) Maximum percentage of crude fiber.
 - (DD) Minimum and maximum percentage calcium.
 - (EE) Minimum percentage of phosphorus.
 - (FF) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
 - (iii) Guaranteed analysis for dairy cattle complete feeds and supplements as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.
 - (CC) Minimum percentage of crude fat.
 - (DD) Maximum percentage of crude fiber.
 - (EE) Maximum percentage of acid detergent fiber.
 - (FF) Minimum and maximum percentage of calcium.
 - (GG) Minimum percentage of phosphorus.
 - (HH) Minimum selenium in parts per million.
 - (II) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
 - (iv) Required guaranteed analysis for dairy mixing and pasture mineral as follows:
 - (AA) Minimum and maximum percentage of calcium.
 - (BB) Minimum percentage of phosphorus.
 - (CC) Minimum and maximum percentage of salt.
 - (DD) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (EE) Minimum percentage of magnesium.
 - (FF) Minimum percentage of potassium.
 - (GG) Minimum selenium in parts per million.
 - (HH) Minimum vitamin A, other than the precursors of vitamin A, in International Units per pound.
- (E) Required guarantees for equine formula feeds as follows:
 - (i) Animal classes as follows:
 - (AA) Foal.
 - (BB) Mare.
 - (CC) Breeding.
 - (DD) Maintenance.
 - (ii) Guaranteed analysis for equine complete feeds and supplements (all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Minimum percentage of crude fat.
 - (CC) Maximum percentage of crude fiber.

- (DD) Minimum and maximum percentage of calcium.
- (EE) Minimum percentage of phosphorus.
- (FF) Minimum copper in parts per million.
- (GG) Minimum selenium in parts per million.
- (HH) Minimum zinc in parts per million.
- (II) Minimum vitamin A, other than the precursors of vitamin A, in International Units per pound (if added).
- (iii) Guaranteed analysis for equine mineral feeds (all animal classes) as follows:
 - (AA) Minimum and maximum percentage of calcium.
 - (BB) Minimum percentage of phosphorus.
 - (CC) Minimum and maximum percentage of salt (if added).
 - (DD) Minimum and maximum percentage of sodium shall be guaranteed only when the total sodium exceeds that furnished by the maximum salt guarantee.
 - (EE) Minimum copper in parts per million.
 - (FF) Minimum selenium in parts per million.
 - (GG) Minimum zinc in parts per million.
 - (HH) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
- (F) Required guaranteed for goat and sheep formula feeds as follows:
 - (i) Animal classes as follows:
 - (AA) Starter.
 - (BB) Grower.
 - (CC) Finisher.
 - (DD) Breeder.
 - (EE) Lactating.
 - (ii) Guaranteed analysis for goat and sheep complete feeds and supplements (all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Maximum percentage of equivalent crude protein from nonprotein nitrogen when added.
 - (CC) Minimum percentage of crude fat.
 - (DD) Maximum percentage of crude fiber.
 - (EE) Minimum and maximum percentage of calcium.
 - (FF) Minimum percentage of phosphorus.
 - (GG) Minimum and maximum percentage of salt (if added).
 - (HH) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (II) Minimum and maximum copper in parts per million (if added, or if total copper exceeds twenty (20) parts per million).
 - (JJ) Minimum selenium in parts per million.
 - (KK) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
- (G) Required guarantees for duck and geese formula feeds as follows:
 - (i) Animal classes as follows:
 - (AA) Ducks as follows:
 - (aa) Starter, zero (0) to three (3) weeks of age.
 - (bb) Grower, three (3) to six (6) weeks of age.
 - (cc) Finisher, six (6) weeks to market.
 - (dd) Breeder developer, eight (8) to nineteen (19) weeks of age.
 - (ee) Breeder, twenty-two (22) weeks to end of lay.
 - (BB) Geese as follows:
 - (aa) Starter, zero (0) to four (4) weeks of age.

- (bb) Grower, four (4) to eight (8) weeks of age.
- (cc) Finisher, eight (8) weeks to market.
- (dd) Breeder developer, ten (10) to twenty-two (22) weeks of age.
- (ee) Breeder, twenty-two (22) weeks to end of lay.
- (ii) Guaranteed analysis for duck and geese complete feeds and supplements (for all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Minimum percentage of crude fat.
 - (CC) Maximum percentage of crude fiber.
 - (DD) Minimum and maximum percentage of calcium.
 - (EE) Minimum percentage of phosphorus.
 - (FF) Minimum and maximum percentage of salt (if added).
 - (GG) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
- (H) Required guarantees for fish complete feeds and supplements as follows:
 - (i) Animal species shall be declared in lieu of animal class as follows:
 - (AA) Trout.
 - (BB) Catfish.
 - (CC) Species other than trout or catfish.
 - (ii) Guaranteed analysis for all fish complete feeds and supplements as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Minimum percentage of crude fat.
 - (CC) Maximum percentage of crude fiber.
 - (DD) Minimum percentage of phosphorus.
- (I) Required guarantees for rabbit complete feeds and supplements as follows:
 - (i) Animal classes as follows:
 - (AA) Grower, four (4) to twelve (12) weeks of age.
 - (BB) Breeder, twelve (12) weeks of age and over.
 - (ii) Guaranteed analysis for rabbit complete feeds and supplements (all animal classes) as follows:
 - (AA) Minimum percentage of crude protein.
 - (BB) Minimum percentage of crude fat.
 - (CC) Minimum and maximum percentage of crude fiber (the maximum crude fiber shall not exceed the minimum by more than five (5.0) units).
 - (DD) Minimum and maximum percentage of calcium.
 - (EE) Minimum percentage of phosphorus.
 - (FF) Minimum and maximum percentage of salt (if added).
 - (GG) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
 - (HH) Minimum vitamin A, other than precursors of vitamin A, in International Units per pound (if added).
- (J) The required guarantees of grain mixtures withorwithout molasses and feeds other than those described in clauses (A) through (I) shall include the following items, unless exempted in clause (K), in the order listed as follows:
 - (i) Animal classes and species for which the product is intended.
 - (ii) Guaranteed analysis as follows:
 - (AA) Minimum percentage crude protein.
 - (BB) Maximum or minimum percentage of equivalent crude protein from nonprotein nitrogen as required in section 4(e) of this rule.
 - (CC) Minimum percentage of crude fat.
 - (DD) Maximum percentage of crude fiber.
 - (EE) Minerals in formula feeds, to include in the following order:
 - (aa) Minimum and maximum percentages of calcium.

- (bb) Minimum percentage of phosphorus.
- (cc) Minimum and maximum percentage of salt (if added).
- (dd) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee.
- (ee) Other minerals.
- (FF) Minerals in feeds ingredients as specified by the official definitions of the Association of American Feed Control Officials.
- (GG) Vitamins in such terms as specified in section 4(c) of this rule.
- (HH) Total sugars as invert on dried molasses products or products being sold primarily for their sugar content.
- (II) Viable lactic acid producing micro-organisms for use in silages in terms specified in section 4(g) of this rule.
- (JJ) A commercial feed, for example, vitamin/mineral premix or base mix, intended to provide a specialized nutritional source for use in the manufacture of other feeds, must state its intended purpose and guarantee those nutrients relevant to such stated purpose.

(K) Exemptions as follows:

- (i) A mineral guarantee for feed, excluding those feeds manufactured as complete feeds and for feed supplements intended to be mixed with grain to produce a complete feed for swine, poultry, fish, and veal and herd milk replacers is not required when the feed or feed ingredient:
 - (AA) is not intended or represented or does not serve as a principal source of that mineral to the animal; or
 - (BB) is intended for nonfood producing animals and contains less than six and five-tenths percent (6.5%) total mineral.
- (ii) Guarantees for vitamins are not required when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.
- (iii) 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.
- (iv) Guarantees for micro-organisms 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 no specific label claims are made.
- (v) The indication for animal classes and species is not required on single ingredient products if the ingredient is not intended, represented, or defined for a specific animal class or species.
- (vi) Mixtures of whole seeds intended to be fed to wild birds may be labeled showing, by weight percentage, the amount of seed by kind, and a weight designated as "other" that includes weed seed, other crop seed, and inert matter contained in the mixture to total one hundred percent (100%), in lieu of supplying guarantees for minimum crude protein, minimum crude fat, and maximum crude fiber. If the feed contains greater than two and five-tenths percent (2.5%) weed seed by weight, the labeling must include the statement, "Note: This feed contains more than two and five-tenths percent (2.5%) weed seed by weight, printed on the label."
- (5) Feed ingredients, collective terms for the grouping of feed ingredients, or appropriate statements as provided under the provisions of Section 6(4) of <u>IC 15-5-13</u> [<u>IC 15-5</u> was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See <u>IC 15-19-7-26.7</u> as follows:
 - (A) The name of each ingredient as defined in the Official Publication of the Association of American Feed Control Officials, common or usual name, or one approved by the director.
 - (B) Collective terms for the grouping of feed ingredients as defined in the Official Definitions of Feed Ingredients published in the Official Publication of the Association of American Feed Control Officials in lieu of the individual ingredients, provided that:
 - (i) 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
 - (ii) the manufacturer shall provide the feed control official, upon request, with a list of individual ingredients,

within a defined group, that are or have been used at manufacturing facilities distributing in or into the state.

- (6) Directions for use and precautionary statements or reference to their location if the detailed feeding directions and precautionary statements required by sections 7 and 8 of this rule appear elsewhere on the label.
- (7) Name and principal mailing address of the manufacturer or person responsible for distributing the feed. The principal mailing address shall include the street address, city, state, and zip code; however, the street address may be omitted if it is shown in the current city directory or telephone directory.
- (8) Net weight or quantity statement.
- (b) The director or the director's agent may request labels or labeling under the following conditions:
- (1) When the license applicant is a new firm and the labeling practices of the applicant have not been observed.
- (2) When labels or labeling of a licensee have been found to be in violation.
- (3) When analytical problems are noted.
- (4) When a consumer complaint has been received.

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355 IAC 6-1-4 Expression of guarantees

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 4. (a) The guarantees for crude protein, equivalent crude protein from nonprotein nitrogen, lysine, methionine, other amino acids, crude fat, crude fiber, and acid detergent fiber shall be in terms of percentage.
 - (b) Mineral guarantees as follows:
 - (1) When the calcium, salt, and sodium guarantees are given in the guaranteed analysis, such shall be stated and conform to the following:
 - (A) When the minimum is below two and five-tenths percent (2.5%), the maximum shall not exceed the minimum by more than five-tenths (0.5) percentage point.
 - (B) When the minimum is two and five-tenths percent (2.5%) but less than five percent (5.0%), the maximum shall not exceed the minimum by more than one (1) percentage point.
 - (C) When the minimum is above five percent (5.0%) or greater the maximum shall not exceed the minimum by more than twenty percent (20%) of the minimum and in no case shall the maximum exceed the minimum by more than five (5) percentage points.
 - (2) 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 ten thousand (10,000) ppm and in percentage when the concentration is ten thousand (10,000) ppm (one percent (1%)) or greater.
 - (3) Products labeled with a quantity statement, for example, tablets, capsules, granules, or liquid, may state mineral guarantees in milligrams per unit, for example, tablets, capsules, granules, or liquids, consistent with the quantity statement and directions for use.
- (c) Guarantees for minimum vitamin content of commercial feeds shall be listed in the order specified and stated in milligrams per pound or in units consistent with those employed for the quantity statement unless otherwise specified as follows:
 - (1) Vitamin A, other than precursors of vitamin A, in International Units per pound.
 - (2) Vitamin D3, in products offered for poultry feeding, in International Chick Units per pound.
 - (3) Vitamin D for other uses, International Units per pound.
 - (4) Vitamin E, in International Units.
 - (5) 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.
 - (6) Vitamin B12, in milligrams or micrograms per pound.
 - (7) All other vitamin guarantees shall express the vitamin activity in milligrams per pound in terms of the following:

- (B) Riboflavin.
- (C) D pantothenic acid.
- (D) Thiamine.
- (E) Niacin.
- (F) Vitamin B6.
- (G) Folic acid.
- (H) Choline.
- (I) Biotin.
- (J) Inositol.
- (K) P-amino benzoic acid.
- (L) Ascorbic acid.
- (M) Carotene.
- (d) Guarantees for drugs shall be stated in terms of percent by weight, except as follows:
- (1) Antibiotics, present as less than two thousand (2,000) grams per ton (total) of commercial feed shall be stated in grams per ton of commercial feed.
- (2) Antibiotics present at or more than two thousand (2,000) grams per ton (total) of commercial feed, shall be stated in grams per pound of commercial feed.
- (3) 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, wherein, quantitative guarantees are required regardless of the level or purpose of the antibiotic.
- (4) 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 direction.
- (e) Commercial feeds containing any added nonprotein nitrogen shall be labeled as follows:
- (1) The following for ruminants:
 - (A) Complete feeds, supplements, and concentrates containing added nonprotein nitrogen and containing more than five percent (5%) protein from natural sources shall be guaranteed as crude protein, minimum, _____%. [sic.] (This includes not more than _____% [sic.] equivalent protein from nonprotein nitrogen.)
 - (B) Mixed feed concentrates and supplements containing less than five percent (5%) protein from natural sources shall be guaranteed as follows:
 - (i) Equivalent crude protein from nonprotein.
 - (ii) Nitrogen, minimum, % [sic.].
 - (C) Ingredient sources of nonprotein nitrogen such as urea, diammonium phosphate, ammonium polyphosphate solution, ammoniated rice hulls, or other basic nonprotein nitrogen ingredients defined by the Association of American Feed Control Officials shall be guaranteed as follows:
 - (i) Nitrogen, minimum, _____% [sic.] equivalent crude.
 - (ii) Protein from nonprotein nitrogen, minimum, % [sic.].
 - (2) The following for nonruminants:
 - (A) Complete feeds, supplements, and concentrates containing crude protein from all forms of nonprotein nitrogen, added as such, shall be labeled as crude protein, minimum _______% [sic.]. (This includes not more than ______% [sic.] equivalent crude protein that is not nutritionally available to (species of animal for which feed is intended).)
 - (B) Premixes, concentrates, or supplements intended for nonruminants containing more than one and twenty-five hundredths percent (1.25%) equivalent crude protein from all forms of nonprotein 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.".
- (f) 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.
- (g) Guarantees for microorganisms shall be stated 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.

(h) 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 protease (bacillus subtilis) five and five-tenths (5.5) milligrams amino acids liberated/min./milligram. If two (2) 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. (State Chemist of the State of Indiana; 355 IAC 6-1-4; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2450; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-5 Suitability

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 5. (a) The nutritional content of a commercial feed, other than a customer-formula feed, shall be as purported or is represented to possess by its labeling. Such animal feed, its labeling, and intended use must be suitable for the intended purpose of the product.
- (b) If the director has reasonable cause to believe a feed is not nutritionally suitable, then the director may request the feed manufacturer to either submit an "Affidavit of Suitability" certifying, or by an alternate procedure certify, the nutritional adequacy of the feed. The Affidavit of Suitability or alternate procedure shall be based on valid scientific evidence. The submission of a completed Affidavit of Suitability shall serve as substantiation of the suitability of the feed.
- (c) If an Affidavit of Suitability, or alternative procedure acceptable to the director is not submitted by the feed manufacturer or labeler within thirty (30) days of written notification, the director may deem the feed adulterated under section 7(c) of this rule and order the feed removed from the marketplace.
 - (d) The Affidavit of Suitability shall contain the following information:
 - (1) The feed company's name.
 - (2) The feed's product name.
 - (3) The name and title of the affiant submitting the document.
 - (4) A statement that the affiant has knowledge of the nutritional content of the feed and based on valid scientific evidence the feed is nutritionally adequate for its intended purpose.
 - (5) Date of submission.
 - (6) The signature of the affiant notarized by a certified notary public.

 $(State\ Chemist\ of the\ State\ of\ Indiana;\ 355\ IAC\ 6-1-5; filed\ Apr\ 4,2002,9:26\ a.m.:\ 25\ IR\ 2452; readopted\ filed\ Nov\ 12,2008,11:24\ a.m.:\ 2008\ 1203-IR-355080677RFA; readopted\ filed\ Oct\ 17,2014,9:27\ a.m.:\ 2014\ 112-IR-355140344RFA; readopted\ filed\ Oct\ 26,2020,10:26\ a.m.:\ 2020\ 1125-IR-355200460RFA)$

355 IAC 6-1-6 Ingredients

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 6. (a) 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 Association of American Feed Control Officials, the common or usual name, or one approved by the director.
 - (b) The name of each ingredient must be shown in letters or type of the same size.
 - (c) No reference to quality or grade of an ingredient shall appear in the ingredient statement of a feed.
 - (d) The term "dehydrated" may precede the name of any product that has been artificially dried.
- (e) A single ingredient product defined by the Association of American Feed Control Officials is not required to have an ingredient statement.
- (f) Tentative definitions for ingredients shall not be used until adopted as official, unless no official definition exists or the ingredient has a common accepted name that requires no definition, that is, sugar.
 - (g) When the word "iodized" is used in connection with a feed ingredient, the feed ingredient shall contain not less than

seven-thousandths percent (0.007%) iodine, uniformly distributed. (State Chemist of the State of Indiana; 355 IAC 6-1-6; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2452; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-7 Directions for use and precautionary statements

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 7. (a) Directions for use and precautionary statements on the labeling of all commercial feeds and custom-mixed feeds containing additives (including drugs, special purpose additives, or nonnutritive additives) shall:
 - (1) 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
 - (2) include, but not limited to, all information prescribed by all applicable regulations under the federal Food, Drug, and Cosmetic Act.
- (b) Adequate directions for use and precautionary statements are required for feeds containing nonprotein nitrogen as specified in section 8 of this rule.
- (c) 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. (State Chemist of the State of Indiana; 355 IAC 6-1-7; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2452; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-8 Nonprotein nitrogen

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 8. (a) Urea and other nonprotein nitrogen products defined in the official publication of the Association of American Feed Control Officials are acceptable ingredients only in commercial feeds for ruminant animals as a source of equivalent crude protein. If the commercial feed contains more than eight and seventy-five hundredths percent (8.75%) of the equivalent crude protein from all forms of nonprotein nitrogen, added as such, or the equivalent crude protein from all forms of nonprotein nitrogen, added as such, exceeds one-third (1/3) of the total crude protein, the label shall bear adequate directions for 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.
- (b) Nonprotein nitrogen defined in the official publication of the Association of American Feed Control Officials, when so indicated, are acceptable ingredients in commercial feeds distributed as feed for nonruminant animals as a source of nutrients other than equivalent crude protein. The maximum equivalent crude protein from nonprotein nitrogen sources when used in nonruminant rations shall not exceed one and twenty-five hundredths percent (1.25%) of the total daily ration.
- (c) On labels such as those for medicated feeds which bear adequate feeding directions and/or warning statements, the presence of added nonprotein 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 nonprotein nitrogen. (State Chemist of the State of Indiana; 355 IAC 6-1-8; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2453; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-9 Drug and feed additives

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

Sec. 9. (a) A labeler of a commercial feed that contains additives (including drugs, other special purpose additives, or

nonnutritive additives) 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.

- (b) Satisfactory evidence of safety and efficacy of a commercial feed may be any of the following:
- (1) When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in 21 CFR, or are prior sanctioned, informal review sanctioned, or generally recognized as safe for such use.
- (2) When the commercial feed is itself a drug as defined in Section 1(7) 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 21 U.S.C. 360(b).
- (3) When one (1) 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 that purpose through the federal Virus, Serum, and Toxins Act of 1913, as amended.
- (4) When the commercial feed is a direct fed microbial product, including the following:
 - (A) The product meets the particular fermentation product definition.
 - (B) The microbial content statement, as expressed in the labeling, is limited to the statement, "Contains a source of live (viable) naturally occurring micro-organisms.". This statement shall appear on the label.
 - (C) The source is stated with a corresponding guarantee expressed in accordance with section 4 of this rule.
- (5) When the commercial feed is an enzyme product, including the following:
 - (A) The product meets the particular enzyme definition defined by the Association of American Feed Control Officials.
 - (B) The enzyme is stated with a corresponding guarantee expressed in accordance with section 4 of this rule.

(State Chemist of the State of Indiana; 355 IAC 6-1-9; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2453; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-10 Adulterants

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-29</u>

Sec. 10. (a) For the purpose of Section 9 of the Act, "poisonous or deleterious substances" includes, but is not limited to, the following:

- (1) Fluorine and any mineral or mineral mixture that is to be used directly for the feeding of domestic animals and in which the fluorine exceeds the following:
 - (A) Twenty-hundredths percent (0.20%) for breeding and dairy cattle.
 - (B) Thirty-hundredths percent (0.30%) for slaughter cattle.
 - (C) Thirty-hundredths percent (0.30%) for sheep.
 - (D) Forty-five hundredths percent (0.45%) for swine.
 - (E) Sixty-hundredths percent (0.60%) for poultry.
- (2) 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:
 - (A) Four-thousandths percent (0.004%) for breeding and dairy cattle.
 - (B) Nine-thousandths percent (0.009%) for slaughter cattle.
 - (C) Six-thousandths percent (0.006%) for sheep.
 - (D) One-hundredth percent (0.01%) for lambs.
 - (E) Fifteen-thousandths percent (0.015%) for swine.
 - (F) Three-hundredths percent (0.03%) for poultry.
- (3) 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 fifty (50) milligrams of fluorine per one hundred (100) pounds of body weight.
- (4) Soybean meal, flakes, or pellets or other vegetable meals, flakes, or pellets that have been extracted with trichlorethylene or other chlorinated solvents.

- (5) Sulfur dioxide, sulfurous acid, and salts of sulfurous acid when used in or on feeds or feed ingredients that are considered or reported to be a significant source of vitamin B1 (thiamine).
- (b) All screenings or byproducts 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 viable prohibited noxious weed seeds, not more than fifty (50) viable restricted noxious weed seeds per pound, and not more than one hundred (100) per pound of other viable weed seeds. (State Chemist of the State of Indiana; 355 IAC 6-1-10; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-11 Good manufacturing practices

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-29</u>

Sec. 11. For the purpose of enforcement of <u>IC 15-5-13-9(9)</u> [<u>IC 15-5</u>] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See <u>IC 15-19-7-29.7</u>, the director adopts the following as current good manufacturing practices:

- (1) The regulations prescribing good manufacturing practices for Type B and Type C medicated feeds as published in 21 CFR 225.
- (2) The regulations prescribing good manufacturing practices for Type A medicated articles as published in 21 CFR 226. (State Chemist of the State of Indiana; 355 IAC 6-1-11; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-12 Payment of inspection fee; interstate exclusion

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-30</u>

Sec. 12. Manufacturers and distributors located in Indiana who furnish substantial quantities of commercial feeds to customers in other states may apply to the director for interstate exclusion status. When so designated, the following conditions apply:

- (1) Those distributors shall not be charged the inspection fee by the supplier on commercial feeds purchased from any supplier.
- (2) Those distributors shall report and pay the inspection fee on all commercial feeds they distribute in Indiana each quarter including feeds they distribute under another distributor's label.
- (3) No credit may be claimed on the quarterly report for payment of the inspection fee to another distributor.
- (4) A list of parties designated with interstate exclusion status will be maintained and provided by the director.

(State Chemist of the State of Indiana; 355 IAC 6-1-12; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-1-13 Indiana commercial feed license

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-24</u>

Sec. 13. The application for Indiana commercial feed license shall be on forms provided by the director or forms reproduced locally by the applicant that has all the following information and in the following general order:

- (1) Name, complete mailing address, and physical location of the applicant.
- (2) Telephone number, FAX number, and e-mail addresses, if applicable.
- (3) A list of subsidiaries located in Indiana or any out-of-state subsidiaries who distribute directly into Indiana.
- (4) A designation whether the applicant manufactures or distributes commercial feeds under their label in or into Indiana.
- (5) A designation whether the applicant manufactures or distributes pet foods or specialty pet foods in containers of ten (10)

pounds or less or containers exceeding ten (10) pounds or bulk.

- (6) A designation if the manufacturer is located in Indiana and manufactures only custom-mixed feeds.
- (7) The printed name and title of the person who is the contact person for the applicant.
- (8) The signature of the applicant.

(State Chemist of the State of Indiana; 355 IAC 6-1-13; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2454; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

Rule 2. Pet Food

355 IAC 6-2-1	Definitions and terms
<u>355 IAC 6-2-2</u>	Label format and labeling
355 IAC 6-2-3	Brand and product names
355 IAC 6-2-4	Expression of guarantees
<u>355 IAC 6-2-5</u>	Ingredients
355 IAC 6-2-6	Drugs and pet food additives
355 IAC 6-2-7	Nutritional adequacy
355 IAC 6-2-8	Feeding directions
355 IAC 6-2-9	Statements of calorie content
355 IAC 6-2-10	Descriptive terms
355 IAC 6-2-11	Manufacturer or distributor; name and address

355 IAC 6-2-1 Definitions and terms

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

Sec. 1. The definitions in IC 15-5-13 [IC 15-5] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See IC 15-19-7.] shall apply throughout this rule in addition to the following:

- (1) "All life stages" means gestation/lactation, growth, and adult maintenance life stages.
- (2) "Family" means a group of products, which are nutritionally adequate for any or all life stages based on their nutritional similarity to a lead product, that has been successfully test-fed according to an AAFCO feeding protocol.
- (3) "Immediate container" means the unit, can, box, tin, bag, or other receptacle or covering in which a pet food or specialty pet food is displayed for sale to retail purchasers, but does not include containers used as shipping containers.
- (4) "Ingredient statement" means a collective and contiguous listing on the label of the ingredients of which the pet food or specialty pet food is composed.
- (5) "Principal display panel" means the part of a label that is most likely to be displayed, presented, shown, or examined under normal and customary conditions of display for retail sale.

(State Chemist of the State of Indiana; 355 IAC 6-2-1; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-2 Label format and labeling

Authority: IC 15-19-7-34

Affected: IC 15-19-7-26; IC 15-19-7-28

Sec. 2. (a) Pet food and specialty pet food shall be labeled with the following information prescribed in this section:

- (1) Product name and brand name, if any, on the principal display panel as stipulated in section 3 of this rule.
- (2) The species of pet or specialty pet for which the food is intended conspicuously designated on the principal display panel.
- (3) Quantity statement, as defined in Section 6(1) of <u>IC 15-5-13</u> [<u>IC 15-5</u>] was repealed by P.L.2-2008, SECTION 83, effective July 1, 2008. See IC 15-19-7-26.], on the principal display panel.

- (4) Guaranteed analysis as stipulated in section 4 of this rule.
- (5) Ingredient statement as stipulated in section 5(a) of this rule.
- (6) A statement of nutritional adequacy or purpose if required under section 7 of this rule.
- (7) Feeding directions if required under section 8 of this rule.
- (8) Name and address of the manufacturer or distributor as stipulated in section 11 of this rule.
- (b) When a pet food or specialty pet food enclosed in an outer container or wrapper is intended for retails ale, all required label information shall appear on the outer container or wrapper.
- (c) A vignette, graphic, or pictorial representation on a pet food or specialty pet food labels hall not misrepresent the contents of the package.
- (d) The use of the word "proven" in connection with a label claim for a pet food or specialty pet food is not permitted unless the claim is substantiated by scientific or other empirical evidence.
- (e) No statement shall appear upon the label or labeling of a pet food or specialty pet food which makes false or misleading comparisons between that product and any other product.
- (f) A personal or commercial endorsement is permitted on a pet food or specialty pet food label provided the endorsement is not false or misleading.
- (g) A statement on a pet food or specialty pet food label stating "Improved", "New", or similar designation shall be substantiated and limited to six (6) months production.
- (h) A statement on a pet food or specialty pet food label stating preference or comparative attribute claims shall be substantiated and limited to one (1) year production, after which the claims hall be removed or resubstantiated. (State Chemist of the State of Indiana; 355 IAC 6-2-2; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-3 Brand and product names

Authority: IC 15-19-7-34

Affected: IC 15-19-7-26; IC 15-19-7-28

- Sec. 3. (a) The words "100%", or "All", or words of similar designation shall not be used in the brand or product name of a pet food or specialty pet food if the product contains more than one (1) ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments.
- (b) An ingredient or a combination of ingredients may form a part of the product name of a pet food or specialty pet food as follows:
 - (1) When the ingredients derived from animals, poultry, or fish constitutes at least ninety-five percent (95%) of the total weight of the product. Water sufficient for processing may be excluded when calculating the percentage; however, the ingredient shall constitute at least seventy percent (70%) of the total product weight.
 - (2) When any ingredient constitutes at least twenty-five percent (25%) of the weight of the product, provided the following:
 - (A) Water sufficient for processing may be excluded when calculating the percentage; however, the ingredients shall constitute at least ten percent (10%) of the total product weight.
 - (B) A descriptor is used with the ingredient name. This descriptor shall imply other ingredients are included in the product formula. Examples of descriptors include the following:
 - (i) Dinner.
 - (ii) Platter.
 - (iii) Entree.
 - (iv) Formula.
 - (v) Recipe.
 - (C) The descriptor shall be in the same size, style, and color print as the ingredient name.
 - (3) When a combination of ingredients that are included in the product name in accordance with this subsection meets all of the following:
 - (A) Each ingredient constitutes at least three percent (3%) of the product weight, excluding water sufficient for processing.

- (B) The names of the ingredients appear in the order of their respective predominance by weight in the product.
- (C) All such ingredient names appear on the label in the same size, style, and color print.
- (c) When the name of any ingredient appears in the product name of a pet food or elsewhere on the product label and includes a descriptor, such as "with" or similar designation, the named ingredients must each constitute at least three percent (3%) of the product weight exclusive of water for processing. If the names of more than one (1) ingredient are shown, they shall appear in their respective order of predominance by weight in the product. The three percent (3%) minimum level shall not apply to claims for nutrients, such as, but not limited to, vitamins, minerals, and fatty acids, as well as condiments. The word "with," or similar designation, and named ingredients shall be in the same size, style, color, and case print and be of no greater size than:

Panel Size	Max "with claim" Type Size
< 5 sq. in.	1/8"
5–25 sq. in.	1/4"
25–100 sq. in.	3/8"
100–400 sq. in.	1/2"
400 sq. in. +	1"

- (d) A flavor designation may be included as part of the product name or elsewhere on the label of a pet food or specialty pet food when the flavor designation meets all of the following:
 - (1) The flavor designation:
 - (A) conforms to the name of the ingredient as listed in the ingredient statement; or
 - (B) is identified by the source of the flavor in the ingredient statement.
 - (2) The word "flavor" is printed in the same size type and with an equal degree of conspicuousness as the name of the flavor designation.
 - (3) Substantiation of the flavor designation, the flavor claim, or the ingredient source is provided upon request.
- (e) The product name of the pet food or specialty pet food shall not be derived from one (1) or more ingredients unless all ingredients are included in the name, except as specified by subsection (b) or (c), provided that the name of an ingredient or combination of ingredients may be used as a part of the product name if:
 - (1) the ingredient or combination of ingredients is present in sufficient quantity to impart a distinctive characteristic to the product or is present in amounts that have a material bearing upon the price of the product or upon acceptance of the product by the purchaser thereof; or
 - (2) it does not constitute a representation that the ingredient or combination of ingredients is present to the exclusion of other ingredients.
- (f) Contractions or coined names referring to ingredients shall not be used in the brand name of a pet food or specialty pet food unless it is in compliance with subsection (b), (c), or (d). (State Chemist of the State of Indiana; 355 IAC 6-2-3; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2455; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-4 Expression of guarantees

Authority: IC 15-19-7-34

Affected: <u>IC 15-19-7-26</u>; <u>IC 15-19-7-28</u>

- Sec. 4. (a) The guaranteed analysis shall be listed in the following order and format unless otherwise specified in this rule:
- (1) A pet food or specialty pet food label shall list the following required guarantees:
 - (A) Minimum percentage of crude protein.
 - (B) Minimum percentage of crude fat.
 - (C) Maximum percentage of crude fat, if required by section 10 of this rule.
 - (D) Maximum percentage of crude fiber.
 - (E) Maximum percentage of moisture.
 - (F) Additional guarantees shall follow moisture.
- (2) When ash is listed in the guaranteed analysis on a pet food or specialty pet food label, it shall be guaranteed as a maximum percentage and shall immediately follow moisture.

- (3) A dog or cat food label shall list other required or voluntary guarantees in the same order and units of the nutrients in the AAFCO dog (or cat) food nutrient profiles. Guarantees for substances not listed in the AAFCO dog (or cat) food nutrient profiles, or not otherwise provided for in this rule, shall immediately follow the listing of the recognized nutrients and shall be accompanied by an asterisk referring to the disclaimer "Not recognized as an essential nutrient by the AAFCO dog (or cat) food nutrient profiles.". The disclaimer shall appear immediately after the last such guarantee in the same size type as the guarantees.
- (4) A specialty pet food label shall list other required or voluntary guarantees as required by 355 IAC 6-1-3-4(J) [355 IAC 6-1-3-4(J) [355 IAC 6-1-3-4(J)].
- (b) The sliding scale method of expressing a guaranteed analysis on a pet food or specialty pet food label (for example, "Minimum crude protein 15-18%") is prohibited.
- (c) The label of a pet food or a specialty pet food that is formulated as and represented to be a mineral supplement shall include minimum guarantees for all minerals from sources declared in the ingredient statement:
 - (1) established by an AAFCO-recognized nutrient profile, expressed as the element in units specified in the nutrient profile; or
 - (2) expressed as the element in units specified in 355 IAC 6-1-3-4(b) [355 IAC 6-1-4(b)] when no species-specific nutrient profile has been recognized by AAFCO;
- and provided that mineral guarantees required by subdivisions (1) and (2) may be expressed in milligrams per unit, for example, tablets, capsules, granules, or liquids, consistent with those employed in the quantity statement and directions for use, and a weight equivalent, for example, one (1) fluid ounce equals twenty-eight (28) grams, for liquid products.
- (d) The label of a pet food or a specialty pet food that is formulated as and represented to be a vitamin supplement shall include minimum guarantees for all vitamins from sources declared in the ingredient statement:
 - (1) established by an AAFCO-recognized nutrient profile, expressed in units specified in the nutrient profile; or
 - (2) expressed in units specified in 355 IAC 6-1-3-4(c) [355 IAC 6-1-4(c)] when no species-specific nutrient profile has been recognized by AAFCO;
- and provided that vitamin guarantees required by this subsection may be expressed in approved units, for example, IU, mg, g, per unit, for example, tablets, capsules, granules, or liquids, consistent with those employed in the quantity statement and directions for use, and a weight equivalent, for example, one (1) fluid ounce equals twenty-eight (28) grams, for liquid products.
- (e) When the label of a pet food or specialty pet food includes a comparison of the nutrient content of the food with levels established by an AAFCO-recognized nutrient profile, such as a table of comparison, a percentage, or any other designation referring to an individual nutrient or all of the nutrient levels, the following apply:
 - (1) The product shall meet the AAFCO-recognized nutrient profile.
 - (2) The statement of comparison shall be preceded by a statement that the product meets the AAFCO-recognized profile; however, the statement that the product meets the AAFCO-recognized nutrient profile is not required provided that the nutritional adequacy statement as per section 7(a)(1) or 7(b)(2)(A) of this rule appears elsewhere on the product label.
 - (3) The statement of comparison of the nutrient content shall constitute a guarantee, but need not be repeated in the guaranteed analysis.
 - (4) The statement of comparison may appear on the label separate and apart from the guaranteed analysis.
- (f) The maximum moisture declared on a pet food or specialty pet food label shall not exceed seventy-eight percent (78.00%) or the natural moisture content of the ingredients, whichever is higher. However, pet food and specialty pet food, such as, but not limited to, those consisting principally of stew, gravy, sauce, broth, aspic, juice, or a milk replacer, and that are so labeled, may contain moisture in excess of seventy-eight percent (78.00%).
- (g) Guarantees for crude protein, crude fat, and crude fiber are not required when the pet food or specialty pet food is intended for purposes other than to furnish these substances or they are of minor significance relative to the primary purpose of the product, such as a mineral or vitamin supplement.
- (h) Guarantees for micro-organisms and enzymes shall be stated in the format as stipulated in 355 IAC 6-1-3-4(g) and (h) [355 IAC 6-1-4(g) and 355 IAC 6-1-4(h)]. (State Chemist of the State of Indiana; 355 IAC 6-2-4; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2456; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-5 Ingredients

Authority: <u>IC 15-19-7-34</u>

Affected: IC 15-19-7-26; IC 15-19-7-28

Sec. 5. (a) Each ingredient of a pet food or specialty pet food shall be listed in the ingredient statement as follows:

- (1) The names of all ingredients in the ingredient statement shall be shown in letters or type of the same size.
- (2) The ingredients shall be listed in descending order by their predominance by weight in nonquantitative terms.
- (3) Ingredients shall be listed and identified by the name and definition established by AAFCO.
- (4) Any ingredient for which no name and definition have been so established shall be identified by the common or usual name of the ingredient.
- (b) The ingredients "meat" or "meat byproducts" shall be qualified to designate the animal from which the meat or meat byproducts are derived unless the meat or meat byproducts are derived from cattle, swine, sheep, goats, or any combination thereof. For example, ingredients derived from horses shall be listed as "horsemeat" or "horsemeat byproducts".
 - (c) Brand or trade names shall not be used in the ingredient statement.
- (d) A reference to the quality, nature, form, or other attribute of an ingredient shall be allowed when the reference meets the following:
 - (1) The designation is not false or misleading.
 - (2) The ingredient imparts a distinctive characteristic to the pet food or specialty pet food because it possesses that attribute.
- (e) A reference to quality or grade of the ingredient does not appear in the ingredient statement. (State Chemist of the State of Indiana; 355 IAC 6-2-5; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2457; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-6 Drugs and pet food additives

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7</u>

- Sec. 6. (a) An artificial color may be used in a pet food or specialty pet food only if it has been shown to be harmless to pets or specialty pets. The permanent or provisional listing of an artificial color in the United States Food and Drug regulations as safe for use, together with the conditions, limitations, and tolerances, if any, incorporated therein, shall be deemed to be satisfactory evidence that the color is, when used pursuant to such regulations, harmless to pets or specialty pets.
- (b) Evidence may be required to prove the safety and efficacy or utility of a pet food or specialty pet food which contains additives or drugs, when used according to directions furnished on the label. Satisfactory evidence of the safety and efficacy of a pet food or specialty pet food may be established when the pet food or specialty pet food:
 - (1) contains such additives, the use of which conforms to the requirements of the applicable regulation in 21 CFR, or are "prior sanctioned" or "Generally Recognized as Safe" for such use; or
 - (2) itself is a drug or contains a drug as defined in <u>IC 15-5-13-1-7</u> [sic] 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 21 U.S.C. 360(b).
- (c) When a drug is included in a pet food or specialty pet food, the format required by 355 IAC 6-1-3(a)(2) for labeling medicated feeds shall be used. (State Chemist of the State of Indiana; 355 IAC 6-2-6; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2458; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-7 Nutritional adequacy

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-26</u>

Sec. 7. (a) The label of a pet food or specialty pet food that is intended for all life stages of the pet or specialty pet may

include an unqualified claim, directly or indirectly, such as "complete and balanced", "perfect", "scientific", or "100% nutritious" if at least one (1) of the following apply:

- (1) The product meets the nutrient requirements for all life stages established by an AAFCO-recognized nutrient profile.
- (2) The product meets the criteria for all life stages as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol.
- (3) The product is a member of a product family that is nutritionally similar to a lead product that contains a combination of ingredients that has been fed to a normal animal as the sole source of nourishment in accordance with the testing procedures established by AAFCO for all life stages, provided the following:
 - (A) The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO.
 - (B) The family product meets the criteria for all life stages.
 - (C) Under circumstances of reasonable doubt, the director may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.
- (b) The label of a pet food or specialty pet food that is intended for a limited purpose or a specific life stage, but not for all life stages, may include a qualified claim, such as "complete and balanced", "perfect", "scientific", or "100% nutritious" when the product and claim meets all of the following:
 - (1) The claim is qualified with a statement of the limited purpose or specific life stage for which the product is intended or suitable, for example, "complete and balanced for puppies (or kittens)". The claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style, and color print.
 - (2) The product meets at least one (1) of the following:
 - (A) The nutrient requirements for the limited purpose or specific life stage established by an AAFCO-recognized nutrient profile.
 - (B) The criteria for a limited purpose or a specific life stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol.
 - (C) The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients that, when fed for such limited purpose, will satisfy the nutrient requirements for such limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided the following:
 - (i) The nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO.
 - (ii) The family product meets the criteria for such limited purpose.
 - (iii) Under circumstances of reasonable doubt, the director may require the manufacturer to perform additional testing for the family product to substantiate the claim of nutritional adequacy.
- (c) Dog and cat food labels shall include a statement of nutritional adequacy or purpose of the product, except when the dog or cat food is clearly and conspicuously identified on the principal display panel as a "snack" or "treat". The statement shall consist of one (1) of the following:
 - (1) A claim that the dog or cat food meets the requirements of one (1) or more of the recognized categories of nutritional adequacy, gestation/lactation, growth, maintenance, and all life stages. The claims hall be stated verbatimas one (1) of the following:
 - (A) "(Name of product) is formulated to meet the nutritional levels established by the AAFCO Dog (or Cat) Food Nutrient Profiles for ______." (Blank is to be completed by using the stage or stages of the pet's life, such as gestation/lactation, growth, maintenance, or the words "All Life Stages").
 - (B) "Animal feeding tests using AAFCO procedures substantiate that (Name of Product) provides complete and balanced nutrition for ______." (Blank is to be completed by using the stage or stages of the pet's life tested, such as gestation/lactation, growth, maintenance, or the words "All Life Stages").
 - (C) "(Name of Product) provides complete and balanced nutrition for _____ (Blank is to be completed by using the stage or stages of the pet's life, such as gestation, lactation, growth, maintenance, or the words "All Life Stages") and is comparable in nutritional adequacy to a product which has been substantiated using AAFCO feeding tests.".
 - (2) A nutritional or dietary claim for purposes other than those listed in subsection (a) or (b) if the claim is scientifically substantiated.
 - (3) The statement, "This product is intended for intermittent or supplemental feeding only", if a product does not meet the

requirements of subsection (a) or (b) or any other special nutritional or dietary need and so is suitable only for limited or intermittent or supplementary feeding.

- (d) A product intended for use by, or under the supervision or direction of a veterinarian shall make a statement in accordance with subsection (c)(1) or (c)(3).
- (e) A signed affidavit attesting that the product meets the requirements of subsection (a) or (b)(2) shall be submitted to the director upon request.
- (f) If the nutrient content of a product does not meet those nutrient requirements established by an AAFCO-recognized nutrient profile, or if no requirement has been established by an AAFCO recognized nutritional authority for the life stages of the intended species, the claimed nutritional adequacy or purpose of the product shall be scientifically substantiated.
- (g) The following AAFCO-recognized nutritional authority, nutrient profile, and/or animal feeding protocol shall be acceptable as the basis for a claim of nutritional adequacy as an AAFCO-recognized nutrient profile or nutritional authority for:
 - (1) Dogs, the AAFCO dog food nutrient profiles.
 - (2) Cats, the AAFCO cat food nutrient profiles.
 - (3) Specialty pets, the nutrient recommendations approved by the Committee on Animal Nutrition of the National Research Council of the National Academy of Sciences, provided that this nutrient recommendation is recognized only for the specific specialty pet for which the profile is intended.
- (4) As an AAFCO-recognized animal feeding protocol, the AAFCO Dog and Cat Food Feeding Protocols. (State Chemist of the State of Indiana; 355 IAC 6-2-7; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2458; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-8 Feeding directions

Authority: IC 15-19-7-34

Affected: <u>IC 15-19-7-26</u>; <u>IC 15-19-7-28</u>

- Sec. 8. (a) Dog or cat food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in section 7(c)(1) of this rule, except those pet foods labeled in accordance with section 7(d) of this rule, shall list feeding directions on the product label. These directions shall be consistent with the intended use indicated in the nutritional adequacy statement unless a limited use or more limited life stage designation is declared elsewhere, for example, adult formula. These directions shall be expressed in common terms and shall appear prominently on the label. Feeding directions shall, at a minimum, state, "Feed (weight/unit of product) per (weight only) of dog (or cat).". The frequency of feeding shall also be specified.
- (b) When a dog or cat food is intended for use by or under the supervision or direction of a veterinarian, the statement, "Use only as directed by your veterinarian" may be used in lieu of feeding directions.
- (c) Specialty pet food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in section 7(a) of this rule, shall list feeding directions on the product label. These feeding directions shall be adequate to meet the nutrient requirements of the intended species of specialty pet as recommended by the AAFCO-recognized nutritional authority. These directions shall be expressed in common terms and shall appear prominently on the label. The frequency of feeding shall also be specified. (State Chemist of the State of Indiana; 355 IAC 6-2-8; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2459; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-9 Statements of calorie content

Authority: <u>IC 15-19-7-34</u>

Affected: IC 15-19-7-26; IC 15-19-7-28

Sec. 9. (a) Except as required in section 10 of this rule, the label of a dog or cat food may bear a statement of calorie content when the label meets all of the following:

- (1) The statement shall be separate and distinct from the "Guaranteed Analysis" and shall appear under the heading "Calorie Content"
- (2) The statement shall be measured in terms of metabolizable energy (ME) on an as-fed basis and must be expressed as

kilocalories per kilogram (kcal/kg) of product, and may also be expressed as kilocalories per familiar household measure, for example, cans, cups, and pounds.

(3) The calorie content is determined by one (1) of the following methods:

(A) By calculation using the following modified Atwater formula:

$$ME(kcal/kg) = 10[(3.5 \times CP) + (8.5 \times CF) + (3.5 \times NFE)]$$

Where: ME = Metabolizable energy.

CP = % crude protein as-fed.

CF = % crude fat as-fed.

NFE = % nitrogen-free extract (carbohydrate) as-fed.

The percentages of CP and CF are the arithmetic averages from proximate analyses of at least four (4) production batches of the product, and the NFE is calculated as the difference between one hundred (100) and the sum of CP, CF, and the percentages of crude fiber, moisture, and ash (determined in the same manner as CP and CF).

- (B) In accordance with a testing procedure established by AAFCO.
- (4) An affidavit shall be provided upon request to the director, substantiating that the calorie content was determined by either of the following:
 - (A) Subdivision (3)(A), in which case the results of all the analyses used in the calculation shall accompany the affidavit.
 - (B) Subdivision (3)(B), in which case the summary data used in the determination of calorie content shall accompany the affidavit.
- (5) The calorie content statement shall appear as one (1) of the following:
 - (A) The claim on the label or other labeling shall be followed parenthetically by the word "calculated" when the calorie content is determined in accordance with subdivision (3)(A).
 - (B) The value of calorie content stated on the label that is determined in accordance with subdivision (3)(B) shall not exceed or understate the value determined in accordance with subdivision (3)(A) by more than fifteen percent (15%).
- (b) Comparative claims shall not be false, misleading, or given undue emphasis and shall be based on the same methodology for the products compared. (State Chemist of the State of Indiana; 355 IAC 6-2-9; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2460; errata filed April 8, 2002, 11:15 a.m.: 25 IR 2521; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-10 Descriptive terms

Authority: IC 15-19-7-34

Affected: IC 15-19-7-26; IC 15-19-7-28

Sec. 10. (a) The following are requirements for calorie terms:

- (1) "Light" requirements are as follows:
 - (A) A dog food product that bears on its label the terms "light", "lite", "low calorie", or words of similar designation shall:
 - (i) contain no more than three thousand one hundred (3,100) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand five hundred (2,500) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred (900) kcal ME/kg for products containing sixty-five percent (65%) or more moisture;
 - (ii) include on the label a calorie content statement:
 - (AA) in accordance with the format provided in section 9 of this rule; and
 - (BB) that states no more than three thousand one hundred (3,100) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand fivehundred (2,500) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred (900) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and
 - (iii) include on the label feeding directions that reflect a reduction in calorie intake consistent with the intended

use.

- (B) A cat food product that bears on its label the terms "light", "lite", "low calorie", or words of similar designation shall:
 - (i) contain no more than three thousand two hundred fifty (3,250) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand six hundred fifty (2,650) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred fifty (950) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and
 - (ii) include on the label a calorie content statement:
 - (AA) in accordance with the format provided in section 9 of this rule; and
 - (BB) that states no more than three thousand two hundred fifty (3,250) kcal ME/kg for products containing less than twenty percent (20%) moisture, no more than two thousand six hundred fifty (2,650) kcal ME/kg for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than nine hundred fifty (950) kcal ME/kg for products containing sixty-five percent (65%) or more moisture; and
 - (iii) include on the label feeding directions which reflect a reduction in calorie intake consistent with the intended use.
- (2) "Less" or "reduced calories" requirements are as follows:
 - (A) A dog or cat food product that bears on its label a claim of "less calories", "reduced calories", or words of similar designation, shall include the following on the label:
 - (i) The name of the product of comparison and the percentage of calorie reduction (expressed on an equal weight basis) explicitly stated and juxtaposed with the largest or most prominent use of the claim on each panel of the label where the term appears.
 - (ii) The comparative statement printed in type of the same color and style and at least half the type size used in the claim.
 - (iii) A calorie content statement in accordance with the format provided in section 9 of this rule.
 - (iv) Feeding directions that reflect a reduction in calories compared to feeding directions for the product of comparison.
 - (B) A comparison between products in different categories of moisture content, that is, less than twenty percent (20%), twenty percent (20%) or more but less than sixty-five percent (65%), sixty-five percent (65%) or more, is misleading.
- (b) The following are requirements for fat terms:
- (1) "Lean" requirements are as follows:
 - (A) A dog food product that bears on its label the terms "lean", "low fat", or words of similar designation shall:
 - (i) contain no more than nine percent (9%) crude fat for products containing less than twenty percent (20%) moisture, no more than seven percent (7%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than four percent (4%) crude fat for products containing sixty-five percent (65%) or more moisture; and
 - (ii) include on the product label in the guaranteed analysis a maximum crude fat guarantee:
 - (AA) immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule; and
 - (BB) that is no more than nine percent (9%) crude fat for products containing less than twenty percent (20%) moisture, no more than seven percent (7%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than four percent (4%) crude fat for products containing sixty-five percent (65%) or more moisture.
 - (B) A cat food product that bears on its label the terms "lean", "low fat", or words of similar designation shall:
 - (i) contain a maximum percentage of crude fat which is no more than ten percent (10%) crude fat for products containing less than twenty percent (20%) moisture, no more than eight percent (8%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than five percent (5%) crude fat for products containing sixty-five percent (65%) or more moisture; and
 - (ii) include on the product label in the guaranteed analysis a maximum crude fat guarantee:

- (AA) immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule; and
- (BB) that is no more than ten percent (10%) crude fat for products containing less than twenty percent (20%) moisture, no more than eight percent (8%) crude fat for products containing twenty percent (20%) or more but less than sixty-five percent (65%) moisture, and no more than five percent (5%) crude fat for products containing sixty-five percent (65%) or more moisture.
- (2) "Less" or "reduced fat" requirements for a dog or cat food product that bears on its label a claim of "less fat", "reduced fat", or words of similar designation, shall include the following on the label:
 - (A) The name of the product of comparison and the percentage of fat reduction (expressed on an equal weight basis) explicitly stated and juxtaposed with the largest or most prominent use of the claim on each panel of the label on where the term appears.
 - (B) The comparative statement printed in type of the same color and style and at least half the type size used in the claim.
 - (C) A maximum crude fat guarantee in the guaranteed analysis immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in section 4(a)(1) of this rule.
- (c) A comparison on the label between products in different categories of moisture content, that is, less than twenty percent (20%), twenty percent (20%) or more but less than sixty-five percent (65%), sixty-five percent (65%) or more, is misleading. (State Chemist of the State of Indiana; 355 IAC 6-2-10; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2460; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

355 IAC 6-2-11 Manufacturer or distributor; name and address

Authority: <u>IC 15-19-7-34</u> Affected: <u>IC 15-19-7-26</u>

Sec. 11. (a) The label of a pet food or specialty pet food shall specify the name and address of the manufacturer or distributor. The statement of the place of business shall include the street address, city, state, and zip code; however, the street address may be omitted if such street address is shown in a current city directory or telephone directory for the city listed on the label.

(b) When a person manufactures or distributes a pet food or specialty pet food in a place other than the principal place of business, the label may state the principal place of business in lieu of the actual place where each package of such pet food or specialty pet food was manufactured or package or from where each package is to be distributed. (State Chemist of the State of Indiana; 355 IAC 6-2-11; filed Apr 4, 2002, 9:26 a.m.: 25 IR 2462; readopted filed Nov 12, 2008, 11:24 a.m.: 20081203-IR-355080677RFA; readopted filed Oct 17, 2014, 9:27 a.m.: 20141112-IR-355140344RFA; readopted filed Oct 26, 2020, 10:26 a.m.: 20201125-IR-355200460RFA)

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