

Title 15
DEPARTMENT OF AGRICULTURE

Subtitle 18 STATE CHEMIST

15.18.09 Pet Food and Specialty Pet Food

Authority: Agricultural Article Section 6-101 et seq., Annotated Code of Maryland

Notice of Proposed Action

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The Secretary of Agriculture proposes to establish the requirements for registering pet food and specialty food prior to distribution in Maryland.

Statement of Purpose

The purpose of this action is to establish regulatory requirements for pet food and specialty food. This regulation establishes labeling requirements, dietary requirements, nutrient profiles, and other requirements that are necessary for the consumer to make educated decisions when purchasing pet food or specialty pet food. This regulation also establishes labeling standards for raw milk being sold as pet food, which is a growing market in the state.

Comparison to Federal Standards

There is no corresponding federal standard to this proposed action.

Estimate of Economic Impact

The proposed action has no economic impact.

Economic Impact on Small Businesses

The proposed action has minimal or no economic impact on small businesses.

Impact on Individuals with Disabilities

The proposed action has no impact on individuals with disabilities.

Opportunity for Public Comment

Comments may be sent to Tom Phillips, State Chemist, Maryland Department of Agriculture, 50 Harry S. Truman Parkway, Annapolis, Maryland 21401, or call [\(410\) 841-2721](tel:(410)841-2721), or email to tom.phillips@maryland.gov, or fax to [\(410\) 841-2740](tel:(410)841-2740). Comments will be accepted through February 15, 2017. A public hearing is scheduled for February 13, 2017, at 1 p.m. at the Maryland Department of Agriculture, 50 Harry S. Truman Parkway, Annapolis, Maryland 21401.

Economic Impact Statement Part C

A. Fiscal Year in which regulations will become effective: FY 2017

B. Does the budget for the fiscal year in which regulations become effective contain funds to implement the regulations?

Yes

C. If 'yes', state whether general, special (exact name), or federal funds will be used:

Special funds (State Chemist Funds)

D. If 'no', identify the source(s) of funds necessary for implementation of these regulations:

E. If these regulations have no economic impact under Part A, indicate reason briefly:

These regulations will have no economic impact because they conform to the current AAFCO industry standards as adopted in other states.

F. If these regulations have minimal or no economic impact on small businesses under Part B, indicate the reason and attach small business worksheet.

See E above.

G. Small Business Worksheet:

TITLE 15 DEPARTMENT OF AGRICULTURE

Subtitle 18 STATE CHEMIST 15.18.09 Pet Food and Specialty Pet Food

.01 Scope and Purpose.

This chapter establishes the requirements for registering pet food and specialty pet food prior to distribution in Maryland.

.02 Incorporation by Reference

The technical standards provided in this chapter are found in the official publication of the Association of American Feed Control Officials (AAFCO), Dog and Cat Nutrient Profiles, pp. 150 – 175 (2016); AAFCO Official Publication, Pet Food Product Families, pp. 176-190 (2016) which are incorporated by reference.

.03 Definitions.

A. *In this chapter, the following terms have the meanings indicated.*

B. *Terms Defined.*

(1) *“AAFCO” means the Association of American Feed Control Officials.*

(2) *“All Life Stages” means gestation/lactation, growth and adult maintenance life stages.*

(3) *“Family” means a group of products that are nutritionally adequate for any or all life stages based on nutritional similarity to a lead product, which has been successfully test-fed according to an AAFCO feeding protocol(s).*

(4) “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.

(5) “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.

(6) “Principal Display Panel” means the part of a label on the pet food or specialty pet food that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.

(7) “Pet” means dog or cat.

(8) “Pet Food” means any commercial feed prepared and distributed for consumption by dogs or cats.

(9) “Secretary” means the Secretary of the Maryland Department of Agriculture, or designee.

(10) “Specialty Pet” means any domesticated pet normally maintained in a cage or tank, such as, but not limited to, gerbils, hamsters, canaries, psittacine birds, mynahs, finches, tropical fish, goldfish, snakes and turtles.

(11) “Specialty Pet Food” means any commercial feed prepared and distributed for consumption by specialty pets.

(12) “Raw Milk” means any milk or milk product, exclusive of any USDA licensed biologics, from any species other than humans, that has not been pasteurized in accordance with processes recognized by the U.S. Food and Drug Administration.

.04 Label Format for Pet Food and Specialty Pet Food.

A. *General Requirements.* In addition to other requirements for commercial feed provided by law, the requirements of this regulation shall apply also to pet food and specialty pet food:

B. *Pet Food Labeling.* A pet food and specialty pet food shall be labeled with the following information:

(1) The product name and brand name if any, on the principal display panel as specified § 6-109 (a) (2), Subtitle 1, Title 6, of the Agricultural Article, Annotated Code of Maryland;

(2) A statement specifying the species name of the pet or specialty pet for which the food is intended, conspicuously designated on the principal display panel;

(3) A quantity statement as defined in § 11-308, Subtitle 3, Title 11, of the Agricultural Article, Annotated Code of Maryland., on the principal display panel, by weight (pounds and ounces, and metric), liquid measure (quarts, pints, and fluid ounces and metric) or by count;

(4) Guaranteed analysis as specified in § 6-109 (a) (5), Subtitle 1, Title 6, of the Agricultural Article, Annotated Code of Maryland;

(5) An ingredient statement as specified § 6-109 (a) (3), Subtitle 1, Title 6, of the Agricultural Article, Annotated Code of Maryland;

(6) A statement of nutritional adequacy or purpose if required under this regulation;

(7) Feeding directions if required under this regulation;

(8) Name and address of the manufacturer or distributor as stipulated in § 6-109 (a) (4), Subtitle 1, Title 6, of the Agricultural Article, Annotated Code of Maryland.

(9) The label shall bear a unique and traceable lot number or production date.

C. *Requirements for Outer Container or Wrapper.* When a pet food or specialty pet food is enclosed in an outer container or wrapper and is intended for retail sale, the following requirements apply to the outer container or wrapper:

(1) A vignette, graphic, or pictorial representation of any product on any pet food or specialty pet food label shall not misrepresent the contents of the package;

(2) The use of the term “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;

(3) No statement shall appear upon the label of any pet food or specialty pet food which makes false or misleading comparisons between that food and any other pet or specialty pet food;

(4) Personal or commercial endorsement(s) are permitted on pet food or specialty pet food labels if it is not false or misleading;

(5) A statement on a pet food or specialty pet food label stating “improved”, “new” or a similar designation shall be substantiated and limited to six months’ production;

(6) A statement on a pet food or specialty pet food label stating preference or a comparative attribute/attributes claim shall be substantiated and is limited to one year of production, after which the claim shall be removed or re-substantiated; and

D. *Requirement for Raw Milk.* Raw milk distributed as pet food or specialty pet food shall bear the following statement:

(a) **“WARNING; NOT FOR HUMAN CONSUMPTION – THIS PRODUCT HAS NOT BEEN PASTEURIZED, MAY CONTAIN HARMFUL BACTERIA AND MAY CAUSE FOODBORNE ILLNESS.”**

(b) This warning statement shall be displayed in a conspicuous manner and shall not be smaller than the height of the minimum font for the quantity statement as shown in the following table:

<i>Panel Size</i>	<i>Warning Statement Minimum Type Size</i>
$< 5 \text{ in.}^2$	$1/16 \text{ in.}$
$> 5 - \leq 25 \text{ in.}^2$	$1/8 \text{ in.}$
$> 25 - \leq 100 \text{ in.}^2$	$3/16 \text{ in.}$
$> 100 - \leq 400 \text{ in.}^2$	$1/4 \text{ in.}$
$> 400 \text{ in.}^2$	$1/2 \text{ in.}$

(c) The label shall bear a unique and traceable lot number or production date.

.05 Brand and product names

A. *General Requirements.* In addition to the requirements for commercial feed provided by law, the following requirements of the regulation apply also to pet food and specialty pet food.

B. *Designation of “100%” or “All”.* The designation “100%” or “All” or words of similar connotation shall not be used in the brand name or product name of a pet food or specialty pet food if the product contains more than one ingredient, provided, for the purpose of this subdivision only, not including water sufficient for processing, required decharacterizing agents and trace amounts of preservatives and condiments.

C. *Designation of Ingredients.* An ingredient or a combination of ingredients may form a part of the product name of a pet food or specialty pet food if:

(1) The ingredient(s) constitutes at least 95 percent of the total weight of the product. Water sufficient for processing may be excluded when calculating the percentage, however, the ingredients shall constitute at least 70 percent of the total product weight;

(2) Any ingredient constitutes at least 25 percent of the weight of the product, provided that:

(a) Water sufficient for processing may be excluded when calculating the percentage, as long as the ingredients constitute at least ten percent of the total product weight;

(b) A descriptor is used with the ingredient name(s). This descriptor shall imply that other ingredients are included in the product formula. Examples of descriptors include “dinner,” “platter,” “entrée,” “formula” and “recipe; and

(c) The descriptor is in the same size, style, and color print as the ingredient name(s); or

(3) The combination of ingredients which are included in the product name complies with the following:

(a) Each ingredient constitutes at least three percent of the product weight, excluding water sufficient for processing;

(b) The name of the ingredients appear in the order of respective predominance by weight in the product; and

(c) All the ingredient names appear on the label in the same size, style and color print.

D. *Use of Ingredient Name.* When the name of an ingredient appears in the product name of a pet food or specialty pet food or elsewhere on the product label and includes a descriptor such as “with” or similar designation, the named ingredient(s) shall each constitute at least three percent of the product weight exclusive of water for processing. If the names of more than one ingredient are shown, they shall appear in respective order of predominance by weight in the product. The three percent minimum level does not apply to claims for condiments or nutrients, such as, but not limited to, vitamins, minerals and fatty acids. The word “with,” or similar designation, and named ingredient(s) shall be in the same size, style, color and case print and be of no greater size than:

<i>Panel Sizes</i>	<i>Maximum “With Claim” Type Size</i>
$< 5 \text{ square inches}$	$1/8 \text{ inch}$
$5 - \leq 25 \text{ Square inches}$	$1/4 \text{ inch}$

25 – ≤ 100 square inches	3/8 inch
100 – ≤ 400 square inches	1/2 inch
> 400 square inches	1 inch

E. Designation of Flavor. 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 if the flavor designation meets the following requirements:

- (1) The flavor designation:
 - (a) Conforms to the name of the ingredient 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; and
- (3) Substantiation of the flavor designation, the flavor claim or the ingredient source is provided upon request.

F. Ingredients as Product Name. The product name of the pet food or specialty pet food shall not be derived from one or more ingredients unless all ingredients are included in the name, except as specified by (Section .04 B, C, or D), 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.

G. Contractions or Coined Names. Contractions or coined names referring to ingredients shall not be used in the brand name of any pet food or specialty food unless they are in compliance with (Section .04 B, C, or D).

H. Designation of Raw Milk. When pet food or specialty pet food consists of raw milk, the words, “Raw (blank) Milk” shall appear conspicuously on the principal display panel. (Blank is to be completed by using the species of animal from which the raw milk is collected.)

.06 Expressions of Guarantees.

A. General Requirements. In addition to the requirements for commercial feed provided by law, the following requirements of these regulations shall also apply to pet food and specialty pet food.

B. Guaranteed Analysis Requirement. The “Guaranteed Analysis” shall be listed in the following order and format unless otherwise specified in these Regulations:

- (1) A pet food or specialty pet food label shall list the following guarantees in the following order:
 - (a) minimum percentage of crude protein;
 - (b) minimum percentage of crude fat;
 - (c) maximum percentage of crude fat, if required by (Section .12);
 - (d) maximum percentage of crude fiber;
 - (e) maximum percentage of moisture; and
 - (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 the moisture guarantee.
- (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 (current printed AAFCO OP). Guarantees for substances not listed in the AAFCO Dog or Cat Food Nutrient Profiles, or not otherwise provided for in these Regulations, shall immediately follow the listing of the recognized nutrients and be accompanied by an asterisk referring to the disclaimer “not recognized as an essential nutrient by the AAFCO Dog or Cat Nutrient Profiles.” The disclaimer shall appear immediately after the last guarantee under this item in the same size type as the guarantees.
- (4) A specialty pet food label shall list other required or voluntary guarantees in the same order and units of the nutrients in an AAFCO-recognized nutrient profile for the specific species; however, if no species-specific AAFCO-recognized nutrient profile is available, the order and units shall follow the same order and units of nutrients in the AAFCO Cat Food Nutrient Profile. Guarantees for substances not listed in an AAFCO recognized nutrient profile for the specific species of animal shall immediately follow the listing of recognized nutrients and shall be accompanied by an asterisk referring to the disclaimer “not recognized as an essential nutrient by the _____.” (Blank is to be completed by listing the specific AAFCO nutrient profile.) This disclaimer shall appear immediately after the last such guarantee in the same size type as the guarantees. No such disclaimer shall be required unless an AAFCO-recognized nutrient profile is available for the specific species of specialty pet.

C. *Sliding scale method prohibited.* The sliding scale method of expressing any guaranteed analysis (for example, "protein 15-18 %") is prohibited.

D. *Mineral Supplement Representation.* The Label of a pet food or a specialty pet food that is formulated as and represented to be a mineral supplement shall include:

(1) minimum, guarantees for all minerals from sources declared in the ingredient statement and established by an AAFCO-recognized nutrient profile, expressed as the element in units specified in the nutrient profile; or

(2) minimum guarantees for all minerals from sources declared in the ingredient statement as the element in units specified in the AAFCO Cat Food Nutrient Profiles, if no species-specific nutrient profile has been recognized by AAFCO; and provided that

(a) mineral guarantees required by Section .06 D (1) and (2) may be expressed in milligrams (mg) per unit, such as tablets, capsules, granules, or liquids, consistent with those employed in the quantity statement and directions for use; and

(b) a weight equivalent, such as 1 fluid ounce = 28 grams, for liquid products.

E. *Representation of Vitamin Supplement.* The label of any pet food or specialty pet food, which is formulated as and represented to be a vitamin supplement, shall include:

(1) Minimum guarantees for all vitamins from sources declared in the ingredient statement and established by an AAFCO-recognized nutrient profile, expressed in units specified in the nutrient profile; or

(2) minimum guarantees for all vitamins from sources declared in the ingredient statement expressed in units specified in AAFCO Cat Food Nutrient Profiles when no species-specific nutrient profile has been recognized by AAFCO; and provided that

(a) vitamin guarantees required by Section .06 E (1) and (2) may be expressed in approved units, such as IU, mg, or g, per unit, such as tablets, capsules, granules or liquids, consistent with those employed in the quantity statement and directions for use; and

(b) a weight equivalent such, as 1 fluid ounce = 28 grams, for liquid products.

F. *Comparison of Nutrient Content.* When the label of any 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 .09 B (1) or Section .09 C(1) 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; and

(4) The statement of comparison may appear on the label separate and apart from the guaranteed analysis.

G. *Moisture Declaration.* The maximum moisture declared on a pet food or specialty pet food label shall not exceed 78 percent or the natural moisture content of the ingredients, whichever is higher. However, pet food or specialty pet food such as those consisting principally of stew, gravy, sauce, broth, aspic, juice or a milk replacer, which are so labeled, may contain moisture in excess of 78 percent.

H. *Guarantees for Crude Ingredient.* Guarantees for crude protein, crude fat and crude fiber are not required if the pet food or specialty pet food is intended for purposes other than to furnish the substances or the substances are of minor significance relative to the primary purpose of the product, such as a mineral or vitamins supplement.

I. *Guarantees for Microorganisms.* Guarantees for microorganisms and enzymes shall be stated in the following format:

(1) Guarantees for microorganisms shall be stated in colony forming units per gram (CFU/gm) when directions are for using the product in grams, or in colony 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.

(2) 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*) 5.5 mg amino acids liberated/min./mg. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.

.07 Ingredients.

A. *General Requirements.* In addition to the requirements for commercial feed provided by law, the following requirements of these regulations shall also apply to pet food and specialty pet food.

B. *Ingredient Statement Requirement.* 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 predominance by weight in nonquantitative terms;

(3) ingredients shall be listed and identified by the name and definition established by AAFCO; and

(4) any ingredient with no established name and definition shall be identified by the common or usual name of the ingredient.

C. *Meat and By-products Ingredients.* The ingredients “meat” and “meat by-products” shall be qualified to designate the animal from which the meat or meat by-products are derived unless the meat or meat by-products are derived from cattle, swine, sheep goats or any combination of those animals. For example, ingredients derived from horses shall be listed as “horsemeat” or “horsemeat by-products.”

D. *Prohibition.* Brand or trade names shall not be used in an ingredient statement.

E. *Ingredient Attributes.* A reference to the quality, nature, form, or other attribute of an ingredient shall be allowed when the reference meets all of 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; and
- (3) A reference to quality or grade of the ingredient does not appear in the ingredient statement.

.08 Pet food additives.

A. *General Requirements.* In addition to the requirements for commercial feed provided by law, the following requirements of these regulations shall also apply to pet food and specialty pet food.

B. *Artificial Color.* An artificial color may be used in a pet food or specialty pet food if it has been shown to be harmless to pets or specialty pets. The permanent or provisional listing of an artificial color listed in Code of Federal Regulations (CFR), Title 21, 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.

C. *Safety and Efficiency of Additives.* 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 contains such additives, the use of which conforms to the requirements of the applicable regulation in CFR, Title 21 or which are “prior sanctioned” or “informal review sanctioned” or “Generally Recognized as Safe” for such use.

.09 Nutritional Adequacy

A. *General Requirements.* In addition to the requirements for commercial feed provided by law, the following requirements of these regulations shall also apply to pet food and specialty pet food.

B. *Nutritional Claim.* 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 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(s); or
- (3) the product is a member of a product family that is nutritionally similar to a lead product containing 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 that:
 - (a) the nutritional similarity of the family product can be substantiated according to the Procedures for Establishing Pet Food Product Families developed by AAFCO (AAFCO Official Publication, pp 191, 2016);
 - (b) the family product meets the criteria for all life stages; and
 - (c) the Secretary may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.

C. *Limited Purpose Nutritional Claim.* The label of a pet food or specialty pet food that is intended for a limited purpose (such as size of dog) 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” if 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, such as, “complete and balanced for puppies (or kittens),” and the claim and the required qualification shall be juxtaposed on the same label panel and in the same size, style and color print; and
- (2) The product meets at least one 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 feeding protocol(s); or
 - (c) The requirements of a product family which is nutritionally similar to a lead product that contains a combination of ingredients which, when fed for the limited purpose, will satisfy the nutrient requirements for the limited purpose and has had its capabilities in this regard demonstrated by adequate testing, and provided that:

- (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 the limited purpose; and*
- (iii) *the Secretary may require the manufacturer to perform additional testing of the family product in order to substantiate the claim of nutritional adequacy.*

D. Dog and Cat Food Labels. 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”, “treat” or “supplement.” The statement shall consist of one of the following:

(1) A claim that the dog or cat food meets the requirements of one or more of the recognized categories of nutritional adequacy: gestation/lactation, growth, maintenance, and all life stages. The claim shall be stated verbatim as one 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”). For a dog food, when the blank includes the words “growth” or “All Life Stages”, one of the following phrases shall also be added verbatim to the end of the claim:

(b) “including growth of large size dogs (70 lbs. or more as an adult)” if the product has been formulated to meet the levels of nutrients specifically referenced in the Dog Food Nutrient Profiles as being applicable to large size growing dogs.

(c) “except for growth of large size dogs (70lbs/ or more as an adult)” if the product has not been formulated to meet the levels of nutrients specifically referenced in the Dog Food Nutrient Profiles as being applicable to large size growing dogs; or

(i) “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”); or

(ii) “(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.”

(iii) A nutritional or dietary claim for purposes other than those listed in .09 B or C of this regulation, if the claim is scientifically substantiated; or

(iv) The statement “This product is intended for intermittent or supplemental feeding only,” if a product does not meet the requirements of this part or any other special nutritional or dietary need and so is suitable only for limited or intermittent or supplementary feeding.

E. Products Intended for Veterinarians. A product intended for use by a veterinarian or direction of a veterinarian shall contain a statement in accordance with .09 D of this Regulation.

F. Affidavit for Product. A signed affidavit attesting that the product meets the requirements of .09 B or C of this Regulation shall be submitted to the Secretary upon request.

G. Products That Do Not Meet AAFCO Nutrient Requirements. 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 stage(s) of the intended species, the claimed nutritional adequacy or purpose of the product shall be scientifically substantiated by the applicant for registration.

H. AAFCO Recognized Nutrient Requirements. The following AAFCO-recognized nutritional authority, nutrient profile, and animal feeding protocol are acceptable as the basis for a claim of nutritional adequacy:

(1) As an AAFCO-recognized nutrient profile or:

(a) For dogs, the AAFCO Dog Food Nutrient Profiles;

(b) For cats, the AAFCO Cat Food Nutrient Profiles;

(c) For 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; and

(d) As an AAFCO –recognized animal feeding protocol(s), the AAFCO Dog and Cat Food Feeding Protocols (AAFCO Official Publication, pp 176 – 190, 2016).

.10 Feeding Directions

A. Dog or Cat Food Snacks or Treats. Dog or cat food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in .08.C.(a) except those pet foods labeled in accordance with .08.D shall list feeding directions on the product label. These directions shall be consistent with the intended use(s) indicated in the nutritional adequacy statement, unless a limited use or more limited life stage designation is declared elsewhere (e.g., “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. Products Intended for Veterinarians. 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 Snacks or Treats. Specialty pet food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in Section .09 B 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.

.11 Statements of Calorie Content

A. Dog and Cat Labels. The label of a dog or cat food shall bear a statement of calorie content and meet all of the following:

(1) The statement shall be separate and distinct from the "Guaranteed Analysis" and appear under the heading "Calorie Content";

(2) The statement shall be measured in terms of metabolizable energy (ME) on an "as fed" basis and shall be expressed as "kilocalories per kilogram" (kcal/kg) of product, and may also be expressed as kilocalories per familiar household measure, (e.g., cans or cups) or unit of product (e.g., treats or pieces); and

(3) The calorie content shall be determined by one of the following methods:

(a) By calculation using the "modified Atwater" formula:

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

Where: ME = Metabolizable Energy

CP = % crude protein "as fed"

CF = % crude fat "as fed"

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

And the percentages of CP and CF are the average values of these components in the product as determined by sound scientific methods, such as, but not limited to scientifically accurate calculations made from the formula of the product or upon chemical analysis of the product. The NFE is calculated as the difference between 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); or

(b) In accordance with a testing procedure established by AAFCO.

(i) An affidavit shall be provided upon request to the Secretary, substantiating that the calorie content was determined by:

(ii) Section .11 A (3) (a) in which case the summary data used in the calculation shall accompany the affidavit; or

(iii) Section .11 A (3) (b) in which case the summary data used in the determination of calorie content shall accompany the affidavit.

(c) The calorie content statement shall appear as one of the following:

(i) The heading "Calorie Content" on the label or other labeling shall be followed parenthetically by the word "calculated" when the calorie content is determined in accordance with .11 A (3) (a); or

(ii) The heading "Calorie Content" on the label or other labeling shall be followed parenthetically by the word "fed" when the caloric content is determined in accordance with Section .11 A (3) (b).

B. Comparative Claim. Comparative claims shall not be false, misleading or given undue emphasis and shall be based on the same methodology for the products compared.

.12 Descriptive Terms

A. Calorie Terms.

(1) a dog food product that bears on its label the terms "light", "lite", "low calorie", or words of similar designation shall:

(a) contain no more than 3,100 kcal ME/kg for products containing less than 20 percent moisture, no more than 2,500 kcal ME/kg for products containing 20 percent or more but less than 65 percent moisture, and no more than 900 kcal ME/kg for products containing 65 percent or more moisture;

(b) include on the label a calorie content statement:

(i) in accordance with the format provided in Section .11; and

(ii) which states not more than 3,100 kcal ME/KG for products containing less than 20 percent moisture, no more than 2,500 kcal ME/kg for products containing 20 percent or more but less than 65 percent moisture, and no more than 900 kcal ME/kg for products containing 65 percent or more moisture; and
(iii) Include on the label feeding directions which reflect a reduction in calorie intake consistent with the intended use.

(2) A cat food product that bears on its label the terms "light," "lite," "low calorie," or words of similar designation shall:

(a) contain no more than 3,250 kcal ME/kg for products containing less than 20 percent moisture, no more than 2,650 kcal ME/kg for products containing 20 percent or more but less than 65 percent moisture, and no more than 950 kcal ME/kg for products containing 65 percent or more moisture;

(b) include on the label a calorie content statement:

(i) in accordance with the format provided in Section .11;

(ii) which states not more than 3,250 kcal ME/KG for products containing less than 20 percent moisture, no more than 2,650 kcal ME/kg for products containing 20 percent or more but less than 65 percent moisture, and no more than 950 kcal ME/kg for products containing 65 percent or more moisture; and

(c) include on the label feeding directions which reflect a reduction in calorie intake consistent with the intended use.

B. "Less" or "Reduced Calories"

(1) A dog or cat food product that has on its label a claim of "fewer calories," "reduced calories," or words of similar designation, shall comply with requirements of this section.

(2) The dog or cat food product shall have a label that includes the following:

(a) 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 on which the term appears;

(b) The comparative statement printed in type of the same color and style and at least one-half the type size used in the claim;

(c) A calorie content statement in accordance with the format provided in Section .11

(d) Feeding directions that reflect a reduction in calories compared to feeding directions for the product of comparison; and

(e) A comparison between products in different categories of moisture content (i.e., less than 20 percent, 20 percent or more but less than 65 percent, 65 percent or more) is misleading.

C. Fat Terms.

(1) A dog food product that bears on its label the terms "lean," "low fat," or words of similar designation shall:

(a) Contain no more than 9 percent crude fat for products containing less than 20 percent moisture, no more than seven percent crude fat for products containing 20 percent or more but less than 65 percent moisture, and no more than four percent crude fat for products containing 65 percent or more moisture;

(b) Include on the product label in the guaranteed analysis:

(i) A maximum crude fat guarantee immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in Section .06 B (1) (c) and

(ii) A maximum crude fat guarantee that is no more than 9 percent crude fat for products containing less than 20 percent moisture, no more than seven percent crude fat for products containing 20 percent or more but less than 65 percent moisture, and no more than four percent crude fat for products containing 65 percent or more moisture.

(2) A cat food product that bears on its label the terms "lean," "low fat," or words of similar designation shall:

(a) Contain no more than 10 percent crude fat for products containing less than 20 percent moisture, no more than eight percent crude fat for products containing 20 percent or more but less than 65 percent moisture, and no more than five percent crude fat for products containing 65 percent or more moisture;

(b) Include on the product label in the guaranteed analysis:

(i) A maximum crude fat guarantee immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in Section .06 B (1) (c); and

(ii) A maximum crude fat guarantee that is no more than ten percent crude fat for products containing less than 20 percent moisture, no more than eight percent crude fat for products containing 20 percent or more but less than 65 percent moisture, and no more than five percent crude fat for products containing 65 percent or more moisture.

(3) 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 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 which the term appears;

(b) 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 .06 B (1) (c);

(i) The comparative statement printed in type of the same color and style and at least one-half the type size used in the claim; and

(ii) A comparison between products in different categories of moisture content, for example, less than 20 percent, 20 percent or more but less than 65 percent, 65 percent or more, is misleading.

.13 Raw Milk

Raw milk may not be registered for the use as pet food for any species when it is packaged in containers that resemble containers intended for milk for human consumption, or it is stored at retail with, or in the vicinity of, milk or milk products intended for human consumption.

.14 Manufacturer or Distributor; Name and Address.

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 should include the street address, city, state and zip code. If 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 the pet food or specialty pet food was manufactured or packaged or from which each package is to be distributed.

.15 Records and Reports.

Any manufacturer of any commercial feed and any distributor of any commercial feed, including pet food and specialty pet food, shall maintain and furnish upon request by the Secretary or his authorized representative, such records and reports as the Secretary deems necessary to indicate the accuracy of any registration of a commercial feed manufacturing facility, any registration of a pet food or specialty pet food, and any other records and reports required by the commercial feed law.

JOSEPH BARTENFELDER
Secretary of Agriculture