Chapter Four
Model Bill and Regulations

Editor—Doug Lueders, MN

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Officially Adopted by Association of American Feed Control Officials and Endorsed by American Feed Industry Association, National Grain and Feed Association, and Pet Food Institute

Although this Bill and the Regulations have not been passed into law in all the states, the subject matter covered herein does represent the official policy of this Association.

AN ACT

To regulate the manufacture and distribution of commercial feeds in the State of _____, BE IT ENACTED by the Legislature of the State of _____.

Section 1. Title
This Act shall be known as the "_____ Commercial Feed Law of 20____."

Section 2. Enforcing Official
This Act shall be administered by the _____ of the State of _____, hereinafter referred to as the "_____."

Section 3. Definitions of Words and Terms
When used in this Act:

(a) The term "brand name" means any word, name, symbol, or device, or any combination thereof, identifying the commercial feed of a distributor or registrant/licensee and distinguishing it from that of others.

(b) The term "commercial feed" means all materials or combination of materials which are distributed or intended for distribution for use as feed or for mixing in feed, unless such materials are specifically exempted. Unmixed whole seeds and physically altered entire unmixed seeds, when such whole or physically altered seeds are not chemically changed or are not adulterated within the meaning of Section 7(a) of this Act, are exempt. The _____ by rule may exempt from this definition, or from specific provisions of this Act, commodities such as hay, straw, stover, silage, cobs, husks, hulls, and individual chemical compounds or substances when such commodities, compounds or substances are not inter-mixed with other materials, and are not adulterated within the meaning of Section 7(a) of this Act.

(c) The term "contract feeder" means a person who is an independent contractor, feeds commercial feed to animals pursuant to a contract whereby such commercial feed is supplied, furnished, or otherwise provided to such person and whereby such person's remuneration is determined all or in part by feed consumption, mortality, profits, or amount or quality of product.

(d) The term "customer-formula feed" means commercial feed which consists of a mixture of commercial feeds and/or feed ingredients each batch of which is manufactured according to the specific instructions of the final purchaser.

(e) The term "distribute" means to offer for sale, sell, exchange, or barter, commercial feed; or to supply, furnish, or otherwise provide commercial feed to a contract feeder.

(f) The term "distributor" means any person who distributes.
(g) The term "drug" means any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man and articles other than commercial feed intended to affect the structure or any function of the animal body.
(h) The term "feed ingredient" means each of the constituent materials making up a commercial feed.
(i) The term "label" means a display of written, printed, or graphic matter upon or affixed to the container in which a commercial feed is distributed, or on the invoice or delivery slip with which a commercial feed is distributed.
(j) The term "labeling" means all labels and other written, printed, or graphic matter (1) upon a commercial feed or any of its containers or wrapper or (2) accompanying such commercial feed.
(k) The term "manufacture" means to grind, mix or blend, or further process a commercial feed for distribution.
(l) The term "mineral feed" means a commercial feed intended to supply primarily mineral elements or inorganic nutrients.
(m) The term "official sample" means a sample of commercial feed taken by the _____ or their agent in accordance with the provisions of Section 11(c), (e), or (f) of this Act.
(n) The term "percent" or "percentages" means percentages by weights.
(o) The term "person" includes individual, partnership, corporation, and association.
(p) The term "pet food" means any commercial feed prepared and distributed for consumption by dogs or cats.
(q) The term "pet" means dog or cat.
(r) The term "product name" means the name of the commercial feed which identifies it as to kind, class, or specific use and distinguishes it from all other products bearing the same brand name.
(s) The term "quantity statement" means the net weight (mass), liquid measure or count.
(t) The term, "raw milk" means any milk or milk product, exclusive of USDA licensed veterinary biologics, from any species other than humans, that has not been pasteurized in accordance with processes recognized by the US Food and Drug Administration.
(u) The term "specialty pet" means any domesticated animal 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.
(v) The term "specialty pet food" means any commercial feed prepared and distributed for consumption by specialty pets.
(w) The term "ton" means a net weight of two thousand pounds avoirdupois.

Section 4. Registration and Licensing

Option A. Registration

(a) No person shall manufacture a commercial feed in this State, unless they have filed with the _____ on forms provided by the _____, their name, place of business and location of each manufacturing facility in this State.
(b) No person shall distribute in this State a commercial feed, except a customer-formula feed, which has not been registered pursuant to the provisions of this section. The application for registration shall be submitted in the manner prescribed by the _____. Upon approval by the _____ the registration shall be

issued to the applicant. All registrations expire on the 31st day of December of each year. (Option: A registration shall continue in effect unless it is cancelled by the registrant or unless it is cancelled by the _ pursuant to Subsection (c) of this section.

(c) The _ is empowered to refuse registration of any commercial feed not in compliance with the provisions of this Act and to cancel any registration subsequently found not to be in compliance with any provision of this Act: Provided, That no registration shall be refused or canceled unless the registrant shall have been given an opportunity to be heard before the _ and to amend their application in order to comply with the requirements of this Act.

Option B. Licensing

(a) Any person:
  (1) Who manufactures a commercial feed within the state; or
  (2) Who distributes a commercial feed in or into the state; or
  (3) Whose name appears on the label of a commercial feed as guarantor, shall obtain a license for each facility which distributes in or into the state authorizing them to manufacture or distribute commercial feed before they engage in such activity. Any person who makes only retail sales of commercial feed which bears labeling or other approved indication that the commercial feed is from a licensed manufacturer, guarantor, or distributor who has assumed full responsibility for the tonnage inspection fee due under this Act is not required to obtain a license.

(b) Any person who is required to obtain a license shall submit an application on a form provided or approved by the _ accompanied by a license fee of _ paid to the _ for each facility. The license year shall be . Each license shall expire on _ (day) _ (month) of the year for which it is issued; provided that any license shall be valid through of the next ensuing year or until the issuance of the renewal license, whichever event first occurs, if the holder thereof has filed a renewal application with the on or before _ of the year for which the current license was issued. Any new applicant who fails to obtain a license within fifteen working days of notification of the requirement to obtain a license, or any licensee who fails to comply with license renewal requirements, shall pay a _ dollar late fee in addition to the license fee.

(c) The form and content of the commercial feed license application shall be established by rules adopted by the .

(d) The _ may request from, at any time, a license applicant or licensee copies of labels and labeling in order to determine compliance with the provisions of this Act.

(e) The _ is empowered to refuse to issue a license to any person not in compliance with the provisions of this Act. The _ may suspend or revoke

any license issued to any person found not in compliance with any provision of this Act. The _ may place conditions that limit production or distribution

of a particular commercial feed on the license of any person found not to be in compliance with this Act. No license shall be conditionalized, suspended, refused or revoked unless the applicant or licensee shall first be given an opportunity to be heard before the _ in order to comply with the requirements of this Act.

Option C. Registration and Licensing

(a)Any person:

(1) Who manufactures a commercial feed within the state; or

(2) Who distributes a commercial feed in or into the state; or
(3) Whose name appears on the label of a commercial feed as guarantor,
shall obtain a license for each facility which distributes in or into the state authorizing them to manufacture or distribute commercial feed before they engage in such activity. Any person who makes only retail sales of commercial feed which bears labeling or other approved indication that the commercial feed is from a licensed manufacturer, guarantor, or distributor who has assumed full responsibility for the tonnage inspection fee due under this Act is not required to obtain a license.

(b) Any person who is required to obtain a license shall submit an application on a form provided or approved by the _ accompanied by a license fee of _ paid to the _ for each facility. The license year shall be . Each license shall expire on _ (day) _ (month) of the year for which it is issued; provided that any license shall be valid through of the next ensuing year or until the issuance of the renewal license, whichever event first occurs, if the holder thereof has filed a renewal application with the on or before _ of the year for which the current license was issued. Any new applicant who fails to obtain a license within fifteen working days of notification of the requirement to obtain a license, or any licensee who fails to comply with license renewal requirements, shall pay a _ dollar late fee in addition to the license fee.

(c) The form and content of the commercial feed license application shall be established by rules adopted by the .

(d) The _ may request from, at any time, a license applicant or licensee copies of labels and labeling in order to determine compliance with the provisions of this Act.

(e) No person shall distribute in this state commercial feed, such as but not limited to; canned animal food, pet food, specialty pet food, supplements or medicated feed, until it is registered with the _ by the licensee whose name appears on the label. An application for each brand and/or product name shall be made on a form furnished by the _ and shall be accompanied by a fee of $ per product. Upon the approval of an application by the , a copy of the registration shall be furnished to the applicant. All registrations expire on the _ day of _ (month) each year. (Option: A registration shall continue in effect unless it is canceled by the registrant or unless it is canceled by the _ pursuant to subsection (f) of this section.)

(f) The _ is empowered to refuse to issue a license or registration to any manufacturer or distributor not in compliance with the provisions of this Act. The may suspend or revoke any license or cancel any registration issued to any person found not to be in compliance with any provision of this

Act. The _ may place conditions that limit production or distribution of a particular commercial feed on the license of any person found not to be in compliance with this Act. No license shall be conditionalized, suspended, refused or revoked and no registration shall be refused or canceled unless the licensee shall first be given an opportunity to be heard before the in order to comply with the requirements of this Act.

Section 5. Labeling

A commercial feed shall be labeled as follows:

(a) In case of a commercial feed, except a customer-formula feed, it shall be accompanied by a label bearing the following information.

(1) The quantity statement.
(2) The product name and the brand name, if any, under which the commercial feed is distributed.
(3) The guaranteed analysis, expressed on an "as-is" basis, stated in such terms as the _ by regulation determines is required to advise the user of the composition of the commercial feed or to support claims made in the labeling. In all cases the substances or elements must be determinable by laboratory methods such as the methods published by the AOAC International.
(4) The common or usual name of each ingredient used in the manufacture of the commercial feed: Provided, that the _ by regulation may permit the use of a collective term for a group of ingredients which perform a similar function, or the _ may exempt such commercial feeds, or any group thereof, from this requirement of an ingredient statement if the _ finds that such statement is not required in the interest of consumers.
(5) The name and principal mailing address of the manufacturer or the person responsible for distributing the commercial feed.
(6) Adequate directions for use for all commercial feeds containing drugs and for such other commercial feeds as the _ may require by regulation as necessary for their safe and effective use.
(7) Such precautionary statements as the _ by regulation determines are necessary for the safe and effective use of the commercial feed.

(b) In the case of a customer-formula feed, it shall be accompanied by a label, invoice, delivery slip, or other shipping document, bearing the following information:
(1) Name and address of the manufacturer.
(2) Name and address of the purchaser.
(3) Date of delivery.
(4) The product name and quantity statement of each commercial feed and each other ingredient used in the mixture.
(5) Adequate directions for use for all customer-formula feeds containing drugs and for such other feeds as the _ may require by regulation as necessary for their safe and effective use.
(6) The directions for use and precautionary statements as required by Regulation 7 and 8.
(7) If a drug containing product is used:
I. The purpose of the medication (claim statement)
II. The established name of each active drug ingredient and the level of each drug used in the final mixture expressed in accordance with Regulation 4 (d).

Section 6. Misbranding

A commercial feed shall be deemed to be misbranded:
(a) If its labeling is false or misleading in any particular.
(b) If it is distributed under the name of another commercial feed.
(c) If it is not labeled as required in Section 5 of this Act.
(d) If it purports to be or is represented as a commercial feed, or if it purports to contain or is represented as containing a commercial feed ingredient, unless

such commercial feed or feed ingredient conforms to the definition, if any, prescribed by regulation by the .

(e) If any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs, or devices in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.

Section 7. Adulteration

A commercial feed shall be deemed to be adulterated:

(a)

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

(2) If it bears or contains any added poisonous, added deleterious, or added non-nutritive substance which is unsafe within the meaning of Section 406 of the Federal Food, Drug, and Cosmetic Act (other than one which is (i) a pesticide chemical in or on a raw agricultural commodity: or (ii) a food additive); or

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

(4) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a) of the Federal Food, Drug, and Cosmetic Act; provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 408 of the Federal Food, Drug, and Cosmetic Act and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed feed shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed feed is not greater than the tolerance prescribed for the raw agricultural commodity unless the feeding of such processed feed will result or is likely to result in a pesticide residue in the edible product of the animal, which is unsafe within the meaning of Section 408 (a) of the Federal Food, Drug, and Cosmetic Act; or

(5) If it is, or it bears or contains any color additive which is unsafe within the meaning of Section 721 of the Federal Food, Drug, and Cosmetic Act; or

(6) If it is, or it bears or contains any new animal drug which is unsafe within the meaning of Section 512 of the Federal Food, Drug, and Cosmetic Act; or

(7) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for feed; or

(8) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(9) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter which is unsafe within the meaning of Section 402 (a)(1) or (2) of the Federal Food, Drug, and Cosmetic Act; or

(10) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(11) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with the regulation or exemption in effect pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act.

(b) If any valuable constituent has been in whole or in part omitted or abstracted there from or any less valuable substance substituted therefore.

(c) If its composition or quality falls below or differs from that which it is purported or is represented to possess by its labeling.

(d) If it contains a drug and the methods used in or the facilities or controls used for its manufacture, processing, or packaging do not conform to current good manufacturing practice regulations promulgated by the _ to assure that the drug meets the requirement of this Act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess. In promulgating such regulations, the _ shall adopt the current good manufacturing practice regulations for Type A medicated Articles and Type B and Type C Medicated Feeds established under authority of the Federal Food, Drug, and Cosmetic Act, unless the _ determines that they are not appropriate to the conditions which exist in this State.

(e) If it contains viable weed seeds in amounts exceeding the limits which the _ shall establish by rule or regulation.

Section 8. Prohibited Acts

The following acts and the causing thereof within the State of _ are hereby prohibited.

(a) The manufacture or distribution of any commercial feed that is adulterated or misbranded.

(b) The adulteration or misbranding of any commercial feed.

(c) The distribution of agricultural commodities such as whole seed, hay, straw, stover, silage, cobs, husks, and hulls, which are adulterated within the meaning of Section 7(a), of this Act.

(d) The removal or disposal of a commercial feed in violation of an order under Section 13 of this Act.

(e) The failure or refusal to register and/or obtain a license in accordance with Section 4 of this Act.

(f) The violation of Section 14(f) of this Act.

(g) The failure to pay inspection fees or file reports as required by Sections 9 and 12 of this Act.

(h) Bags or totes used for commercial feeds (including customer-formula feed) shall not be re-used unless appropriately cleaned. A firm that intends to re-use bags or totes must document its cleanout procedures.

(i) The distribution of raw milk for use as commercial feed for any species:

(1) If it has not been decharacterized using a sufficient quantity of food coloring as designated by _ (director, commissioner, etc.);

(2) If it has been decharacterized using food coloring unless the food coloring has been approved by the US Food and Drug Administration, or in the case of raw milk labeled as organic, approved by the US Department of Agriculture;

(3) If it has been decharacterized and the nutritive value of the milk has been adversely affected by the decharacterization;

(4) That is packaged in containers that are or resemble those used for the

packaging of milk for human consumption;

(5) That is stored at retail with, or in the vicinity of, milk or milk products intended for human consumption;

(6) If it does not comply with Section 8 (a) through (h) of this Act.

Section 9. Inspection Fees and Reports

(a) An inspection fee at the rate of _ cents per ton shall be paid on commercial feeds distributed in this State by the person whose name appears on the label as the manufacturer, guarantor or distributor, except that a person other than the manufacturer, guarantor or distributor may assume liability for the inspection fee, subject to the following:

(1) No fee shall be paid on a commercial feed if the payment has been made by a previous distributor.

(2) No fee shall be paid on customer-formula feeds if the inspection fee is paid on the commercial feeds which are used as ingredients therein.

(3) No fee shall be paid on commercial feeds which are used as ingredients for the manufacture of commercial feeds which are registered. If the fee has already been paid, credit shall be given for such payment.

(4) In the case of a commercial feed which is distributed in the State only in packages of ten pounds or less, an annual fee of _ shall be paid in lieu of the inspection fee specified above.

(5) The minimum inspection fee shall be _ per _ (reporting period).

(6) In the case of specialty pet food which is distributed in the state only in packages of one pound or less, an annual fee of _ per product shall be paid up to a maximum annual fee of _ per manufacturer in lieu of an inspection fee.

(b) Each person who is liable for the payment of such fee shall:

(1) File, on or before the last day of the month following the inspection fee reporting period, setting forth the number of net tons of commercial feeds distributed in this State during the preceding reporting period; and upon filing such statement shall pay the inspection fee at the rate stated in paragraph (a) of this Section. Inspection fees which are due and owing and have not been remitted to the _ within 15 days following the date due shall have a penalty fee of _ per cent (minimum _) added to the amount due when payment is finally made. The assessment of this penalty fee shall not prevent the _ from taking other actions as provided in this chapter.

(2) Keep such records as may be necessary or required by the _ to indicate accurately the tonnage of commercial feed distributed in this State, and the _ shall have the right to examine such records to verify statements of tonnage. Failure to make an accurate statement of tonnage or to pay the inspection fee or comply as provided herein shall constitute sufficient cause for the cancellation of all registrations on file for the distributor.

(c) Fees collected shall constitute a fund for the payment of the costs of inspection, sampling, and analysis, and other expenses necessary for administration of this Act.

(d) Records or reports maintained or filed under Section 9, Inspection Fees and Reports, are confidential and not subject to disclosure under applicable public records acts.

Section 10. Rules and Regulations

(a) The _ is authorized to promulgate such rules and regulations for commercial feeds (which includes pet and specialty pet foods) as are specifically authorized in this Act and such other reasonable rules and regulations as may be necessary for the efficient enforcement of this Act. In the interest of uniformity the _ shall by regulation adopt, unless the _ determines that they are inconsistent with the provisions of this Act or are not appropriate to conditions which exist in this state, the following:

(1) The Official Definitions of Feed Ingredients and Official Feed Terms adopted by the Association of American Feed Control Officials and published in the Official Publication of that organization, and
(2) Any regulation promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act: Provided, that the _ would have the authority under this Act to promulgate such regulations.

(b) Before the issuance, amendment, or repeal of any rule or regulation authorized by this Act, the _ shall publish the proposed regulation, amendment, or notice to repeal an existing regulation in a manner reasonably calculated to give interested parties, including all current registrants, adequate notice and shall afford all interested persons an opportunity to present their views thereon, orally or in writing, within a reasonable period of time. After consideration of all views presented by interested persons, the _ shall take appropriate action to issue the proposed rule or regulation or to amend or repeal an existing rule or regulation. The provisions of this paragraph notwithstanding, if the _ pursuant to the authority of this Act, adopts the Official Definitions of Feed Ingredients and Official Feed Terms as adopted by the Association of American Feed Control Officials, or regulations promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act, any amendment or modification adopted by said Association or by the US Secretary of Health and Human Services, in the case of regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, shall be adopted automatically under this Act without regard to the publication of the notice required by this paragraph (b), unless the _ by order specifically determines that said amendment of modification shall not be adopted.

(c) **Food and Drug Rules.** Federal regulations contained in Title 21, Code of Federal Regulations, part 507, not otherwise adopted herein, also are adopted as feed rules of this state.

Section 11. Inspection, Sampling, and Analysis

(a) For the purpose of enforcement of this Act, and in order to determine whether its provisions have been complied with, including whether or not any operations may be subject to such provisions, officers or employees duly designated by the _ , upon presenting appropriate credentials, and a written notice to the owner, operator, or agent in charge, are authorized (1) to enter, during normal business hours, any factory, warehouse, or establishment within the State in which commercial feeds are manufactured, processed, packed, or held for distribution, or to enter any vehicle being used to transport or hold such feeds; and (2) to inspect at reasonable times and within reasonable limits and in a reasonable manner, such factory, warehouse, establishment or vehicle and all pertinent equipment, finished and unfinished materials, containers, and labeling therein. The inspection may include the verification of records, and production and control procedures related to the manufacture, distribution, storage, handling, use or disposal of commercial feed as may be necessary to determine compliance with this Act.

(b) A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable

promptness. Upon completion of the inspection, the person in charge of the facility or vehicle shall be so notified.

(c) If the officer or employee making such inspection of a factory, warehouse, or other establishment has obtained a sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises the inspector/ sampler shall give to the owner, operator, or agent in charge a receipt describing the samples obtained.

(d) If the owner of any factory, warehouse, or establishment described in paragraph (a), or their agent, refuses to admit the or their agent to inspect in accordance with paragraphs (a) and (b), the is authorized to obtain from any State Court a warrant directing such owner or his agent to submit the premises described in such warrant to inspection.

(e) For the enforcement of this Act, the or their duly designated agent is authorized to enter upon any public or private premises including any vehicle of transport during regular business hours to have access to, and to obtain samples, and to examine records relating to distribution of commercial feeds.

(f) Sampling and analysis shall be conducted in accordance with methods published by the AOAC International, or in accordance with other generally recognized methods.

(g) The results of all analyses of official samples shall be forwarded by the to the person named on the label and to the purchaser. When the inspection and analysis of an official sample indicates a commercial feed has been adulterated or misbranded and upon request within 30 days following the receipt of the analysis the shall furnish to the registrant a portion of the sample concerned.

(h) The , in determining for administrative purposes whether a commercial feed is deficient in any component, shall be guided by the official sample as defined in paragraph (n) of Section 3 and obtained and analyzed as provided for in paragraphs (c), (e), and (f) of Section 11 of this Act.

Section 12. Certificates

To facilitate continued access to markets for commercial feed and feed ingredients, the may:

(a) Inspect, audit or certify commercial feed manufacturer or distributor facilities at the request of the manufacturer or distributor to the extent authorized by this Act, or on the basis of other records voluntarily supplied by the manufacturer or distributor;

(b) Issue certificates pursuant to subsection (a), such as, but not limited to, certificates of export from the state;

(c) Promulgate, amend or adopt rules to inspect, audit or certify and issue certificates pursuant to this Section; and

(d) Include a schedule of fees that addresses all activities required under this section. Such fees shall not duplicate those set forth in other sections of this Act.

Section 13. Detained Commercial Feeds

(a) "Withdrawal from distribution" orders: When the or their authorized agent has reasonable cause to believe any lot of commercial feed is being distributed in violation of any of the provisions of this Act or any of the prescribed regulations under This Act, the may issue and enforce a written or printed "withdrawal from distribution" order, warning the distributor not to dispose of the lot of commercial feed in any manner until written permission is given by the or

the Court. The _ shall release the lot of commercial feed so withdrawn when said provisions and regulations have been complied with. If compliance is not obtained within 30 days, the _ may begin, or upon request of the distributor or registrant shall begin, proceedings for condemnation.

(b) "Condemnation and Confiscation": Any lot of commercial feed not in compliance with said provisions and regulations shall be subject to seizure on complaint of _ to a court of competent jurisdiction in the area in

which said commercial feed is located. In the event the court finds the said commercial feed to be in violation of this Act and orders the condemnation of said commercial feed, it shall be disposed of in any manner consistent with the quality of the commercial feed and the laws of the State: provided, that in no instance shall the disposition of said commercial feed be ordered by the court without first giving the claimant an opportunity to apply to the court for release of said commercial feed or for permission to process or re-label said commercial feed to bring it into compliance with this Act.

Section 14. Penalties

(a) Any person convicted of violating any of the provisions of this Act or who shall impede, hinder, or otherwise prevent, or attempt to prevent, said or their duly authorized agent in performance of their duty in connection with the provisions of this Act, shall be adjudged guilty of a misdemeanor and shall be fined not less than _ or more than _ for the first violation, and not less

than or more than _ for a subsequent violation.

(b) Nothing in this Act shall be construed as requiring the _ or their

representative to: (1) report for prosecution, or (2) institute seizure proceedings, or (3) issue a withdrawal from distribution order, as a result of minor violations of the Act, or when the _ believes the public interest will best be served by

suitable notice of warning in writing.

(c) It shall be the duty of each _ attorney to whom any violation is reported

to cause appropriate proceedings to be instituted and prosecuted in a court of competent jurisdiction without delay. Before the _ reports a violation for

such prosecution, an opportunity shall be given the distributor to present their view to the .

(d) The _ is hereby authorized to apply for and the court to grant a temporary

or permanent injunction restraining any person from violating or continuing to violate any of the provisions of this Act or any rule or regulation promulgated under the Act notwithstanding the existence of other remedies at law. Said injunction to be issued without bond.

(e) Any person adversely affected by an act, order, or ruling made pursuant to the provisions of this Act may within 45 days thereafter bring action in the (here name the particular Court in the county where the enforcement official has his office) for judicial review of such actions. The form of the proceeding shall be any which may be provided by statutes of this state to review decisions of administrative agencies, or in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunctions.

(f) Any person who uses to their own advantage, or reveals to other than the _ , or officers of the _ (appropriate departments of this State),

or to the courts when relevant in any judicial proceeding, any information acquired under the authority of this Act, concerning any method, records, formulations, or processes which as a trade secret is entitled to protection, is guilty of a misdemeanor and shall on conviction thereof be fined not less than $ or imprisoned for not less than _ year(s) or both: Provided, That this prohibition shall not be deemed as prohibiting the _ , or their duly authorized agent, from exchanging information of a regulatory nature with duly

appointed officials of the United States Government, or of other States, who are similarly prohibited by law from revealing this information.

(g) Any person who violates any of the provisions of this Act or an order, standard, stipulation, agreement, citation, or schedule of compliance of the or impedes, hinders, or otherwise prevents or attempts to prevent performance of a duty by the in connection with this Act may be subject to a civil penalty of up to $ per violation, per day as determined by the .

(h) In any action to compel performance of an order of the to enforce this Act, the court must require a defendant adjudged responsible to perform the acts within the person's power that are reasonably necessary to accomplish the purposes of the order.

(i) The civil penalties and payments provided for in this section may be recovered by a civil action brought by the in the name of the state.

Section 15. Cooperation with Other Entities

The may cooperate with and enter into agreements with governmental agencies of this State, other States, agencies of the Federal Government, and private associations in order to carry out the purpose and provisions of this Act.

Section 16. Publication

The shall publish at least annually, in such forms as the may deem proper, information concerning the sales of commercial feeds, together with such data on their production and use as the may consider advisable, and a report of the results of the analyses of official samples of commercial feeds sold within the State as compared with the analyses guaranteed in the registration and on the label; Provided, That the information concerning production and use of commercial feed shall not disclose the operations of any person.

Section 17. Constitutionality

If any clause, sentence, paragraph, or part of this Act shall for any reason be judged invalid by any court of competent jurisdiction, such judgment shall not affect, impair, or invalidate the remainder thereof but shall be confined in its operation to the clause, sentence, paragraph, or part thereof directly involved in the controversy in which such judgment shall have been rendered.

Section 18. Repeal

All laws and parts of laws in conflict with or inconsistent with the provisions of this Act are hereby repealed. (The specific statute and specific code sections to be repealed may have to be stated.)

Section 19. Effective Date

This Act shall take effect and be in force from and after the first day of .

Model Regulations Under the Model Bill

Editor—Doug Lueders, MN

Pursuant to due publication and public hearing required by the provisions of Chapter _ of the Laws of this State, the _ has adopted the following Rules and Regulations.

Regulation 1. Definition and Terms

(a) The names and definitions for commercial feeds shall be the Official Definition of Feed Ingredients adopted by the Association of American Feed Control Officials (AAFCO), except as the _ designates otherwise in specific cases.

(b) The terms used in reference to commercial feeds shall be the Official Feed Terms adopted by AAFCO, except as the _ designates otherwise in specific cases.

(c) The following commodities are hereby declared exempt from the definition of commercial feed, under the provisions of Section 3(b) of the Act: Raw meat, hay, loose salt, straw, stover, silages, cobs, husks, and hulls when unground and when not mixed or intermixed with other materials: Provided that these commodities are not adulterated within the meaning of Section 7(a), of the Act.

(d) Principal Display Panel means the out-facing side of the feed tag, or if no tag, the part of the label that is most likely to be displayed, presented, shown or examined under normal and customary conditions of display for retail sale.

Regulation 2. Label Format

(a) Commercial feed, other than custom formula feed, shall bear the information prescribed in this regulation on the label of the product and in the following format.
  (1) Product name and brand name, if any, as stipulated in Regulation 3(a)(1).
  (2) If a drug is used, label as stipulated in Regulation 3(a)(2).
  (3) Purpose statement as stipulated in Regulation 3(a)(3).
  (4) Guaranteed analysis as stipulated in Regulation 3(a)(4).
  (5) Feed ingredients as stipulated in Regulation 3(a)(5).
  (6) Directions for use and precautionary statements as stipulated in Regulation 3(a)(6).
  (7) Name and principal mailing address of manufacturer or persons responsible for distributing the feed as stipulated in Regulation 3(a)(7).
  (8) Quantity statement.

(b)
  (1) The information as required in Regulation 2(a)(1), (2), (3) and (8) must appear in its entirety on the principal display panel.
  (2) The information as required in Regulation 2(a)(4), (5), (6) and (7) shall be displayed in a prominent place on the feed tag or label, but not necessarily on the principal display panel. When a precautionary statement required by Regulation 2(a)(6) does not appear on the principal display panel, it must be referenced on the principal display panel with a statement such as "See back of label for precautions."

(c) None of the information required by Regulation 2 shall be subordinated or obscured by other statements or designs.

(d) Customer-formula feed shall be accompanied with the information prescribed in this regulation using labels, invoice, delivery ticket, or other shipping 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 customer-formula feed name and brand name if any.
  (5) The product name and net quantity of each registered commercial feed and each other ingredient used in the mixture.
  (6) The direction for use and precautionary statements as required by Regulations 7 and 8.
  (7) If a drug containing product is used:
    I. The purpose of the medication (claim statement)
    II. The established name of each active drug ingredient and the level of each drug used in the fi mixture expressed in accordance with Regulation 4 (d).

Regulation 3. Label Information

(a) Commercial feed, other than customer-formula feed, shall be labeled with the information prescribed in this regulation.
  (1) Product name and brand name if any.
    I. The brand or product name must be appropriate for the intended use of the feed and must not be misleading. If the name indicates the feed is made for a specific use, the character of the feed must conform therewith. A commercial feed for a particular animal class, must be suitable for that purpose.
    II. 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.
    III. The name of a commercial feed shall not be derived from one or more ingredients of a mixture to the exclusion of other ingredients and shall not be one representing any components of a mixture unless all components are included in the name: Provided, that if any ingredient or combination of ingredients is intended to impart a distinctive characteristic to the product which is of signifi to the purchaser, the name of that ingredient or combination of ingredients may be used as a part of the brand name or product name if the ingredients or combination of ingredients is quantitatively guaranteed in the guaranteed analysis, and the brand or product name is not otherwise false or misleading.
    IV. The word "protein" shall not be permitted in the product name of a feed that contains added non-protein nitrogen.
    V. When the name carries a percentage value, it shall be understood to signify protein and/or equivalent protein content only, even though it may not explicitly modify the percentage with the word "protein": Provided, that other percentage values may be permitted if they are followed by the proper description and conform to good labeling practice. Digital numbers shall not be used in such a manner as to be misleading or confusing to the customer.
    VI. 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 _ designates otherwise.

VII. 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 Regulation 4(c).

VIII. 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.

IX. The term "meat" and "meat by-products" shall be qualified to designate the animal from which the meat and meat by-products is derived unless the meat and meat by-products are made from cattle, swine, sheep and goats.

X. If the commercial feed 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.)

(2) If a drug is used:

I. The word "medicated" shall appear directly following and below the product name in type size, no smaller than one-half the type size of the product name.

II. Purpose statement as required in Regulation 3(a)(3).

III. The purpose of medication (claim statement).

IV. An active ingredient statement listing the active drug ingredients by their established name and the amounts in accordance with Regulation 4 (d).

(3) Purpose Statement

I. The statement of purpose shall contain the specific species and animal class(es) for which the feed is intended as defi in Regulation 3(a)(4).

II. The manufacturer shall have fl in describing in more specifi and common language the defi animal class, species and purpose while being consistent with the category of animal class defi in Regulation 3(a)(4) which may include, but is not limited to weight range(s), sex, or ages of the animal(s) for which the feed is manufactured.

III. The purpose statement may be excluded from the label if the product name includes a description of the species and animal class(es) for which the product is intended.

IV. 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 applicable to commercial feeds regulated under Regulation 3(a)(4)(XI)(b)(10).]

V. 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 applicable to commercial feeds regulated under Regulation 3(a)(4)(XI)(b)(10).]

VI. The purpose statement of a product shall include a statement of enzyme functionality if enzymatic activity is represented in any manner.

VII. The statement of purpose for single ingredient feeds shall be stated as "Single Ingredient Feed" or "Feed Ingredient." The manufacturer of a single ingredient feed or feed ingredient shall have flexibility in describing in more specific and common language the intended use of the feed ingredient dependent on species and class.

(4) Guarantees—Crude Protein, Equivalent Crude Protein from Non Protein Nitrogen, Amino Acids, Crude Fat, Crude Fiber, Acid Detergent Fiber, Neutral 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. Individual nutrient guarantees are not required if listed as exempt in section XII.

I. Required guarantees for swine formula feeds
   a. Animal classes
      (1) Prestarter—2 to 11 pounds
      (2) Starter—11 to 44 pounds
      (3) Grower—44 to 110 pounds
      (4) Finisher—110 pounds to market weight
      (5) Gilts, sows, and adult boars
      (6) Lactating gilts and sows
   b. Guaranteed analysis for swine complete feeds and supplements (all animal classes)
      (1) Minimum percentage of crude protein
      (2) Minimum percentage of lysine
      (3) Minimum percentage of crude fat
      (4) Maximum percentage of crude fiber
      (5) Minimum and maximum percentage of calcium
      (6) Minimum percentage of phosphorus
      (7) Minimum and maximum percentage of salt (if added)
      (8) Minimum and maximum percentage of total sodium shall be guaranteed only when total sodium exceeds that furnished by the maximum salt guarantee
      (9) Minimum selenium in parts per million (ppm)

II. Required guarantees for Formula Poultry Feeds (Broilers, Layers and Turkeys)
   a. Animal Classes
      (1) Layer - Chickens that are grown to Produce eggs for food, e.g., table eggs
         (a) Starting/Growing - From day of hatch to approximately 10 weeks of age.
         (b) Finisher - From approximately 10 weeks of age to time fi egg is produced. (Approximately 20 weeks of age).
         (c) Laying - From time first egg is laid throughout the time of egg production.
         (d) Breeders - Chickens that produce fertile eggs for hatch replacement layers to produce eggs for food, table eggs, from time first egg is laid throughout their productive cycle.
      (2) Broilers - Chickens that are grown for human food.

(a) Starting/growing - From day of hatch to approximately 5 weeks of age.
(b) Finisher - From approximately 5 weeks of age to market, (42 to 52 days).
(c) Breeders - Hybrid strains of chickens whose offspring are grown for human food, (broilers), any age and either sex.

(3) Broilers, Breeders - Chickens whose offspring are grown for human food (broilers).
(a) Starting/Growing - From day of hatch until approximately 10 weeks of age.
(b) Finishing - From approximately 10 weeks of age to time fi egg is produced, approximately 20 weeks of age.
(c) Laying - Fertile egg producing chickens (broilers/ roasters) from day of first egg throughout the time fertile eggs are produced.

(4) Turkeys
(a) Starting/Growing - Turkeys that are grown for human food from day of hatch to approximately 13 weeks of age (females) and 16 weeks of age (males).
(b) Finisher - Turkeys that are grown for human food, females from approximately 13 weeks of age to approximately 17 weeks of age; males from 16 weeks of age to 20 weeks of age, (or desired market weight).
(c) Laying - Female turkeys that are producing eggs; from time first egg is produced, throughout the time they are producing eggs.
(d) Breeder - Turkeys that are grown to produce fertile eggs, from day of hatch to time first egg is produced (approximately 30 weeks of age), both sexes.

b. Guaranteed Analysis for Poultry Complete feeds and Supplements (all animal classes)
(1) Minimum percentage of Crude Protein
(2) Minimum percentage of Lysine
(3) Minimum percentage of Methionine
(4) Minimum percentage of Crude Fat
(5) Maximum percentage of Crude Fiber
(6) Minimum and maximum percentage of Calcium
(7) Minimum percentage of Phosphorus
(8) Minimum and maximum percentage of Salt (if added)
(9) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee

III. Required Guarantees for Beef Cattle Formula Feeds.
a. Animal Classes
(1) Calves (birth to weaning)
(2) Cattle on Pasture (may be specifi as to production stage; e.g. stocker, feeder, replacement heifers, brood cows, bulls, etc.)
(3) Feedlot Cattle
b. Guaranteed analysis for Beef Complete Feeds and Supplements (all animal classes)
(1) Minimum percentage of Crude Protein

(2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
(3) Minimum percentage of Crude Fat
(4) Maximum percentage of Crude Fiber
(5) Minimum and maximum percentage of Calcium
(6) Minimum percentage of Phosphorus
(7) Minimum and maximum percentage of Salt (if added)
(8) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
(9) Minimum percentage of Potassium
(10) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

c. Guaranteed analysis for Beef Mineral Feeds (if added)
(1) Minimum and maximum percentage Calcium
(2) Minimum percentage of Phosphorus
(3) Minimum and maximum percentage of Salt
(4) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
(5) Minimum percentage of Magnesium
(6) Minimum percentage of Potassium
(7) Minimum Copper in parts per million (ppm)
(8) Minimum Selenium in parts per million (ppm)
(9) Minimum Zinc in parts per million (ppm)
(10) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound

IV. Required Guarantees for Dairy Formula Feeds
a. Animal Classes
(1) Veal Milk Replacer
(2) Herd Milk Replacer
(3) Starter
(4) Non-Lactating Dairy Cattle: Replacement Dairy Heifers, Dairy Bulls and Dairy Calves
(5) Lactating Dairy Cows
(6) Dry Dairy Cows

b. Guaranteed Analysis for Veal and Herd Replacement Milk Replacer
(1) Minimum percentage Crude Protein
(2) Minimum percentage Crude Fat
(3) Maximum percentage of Crude Fiber
(4) Minimum and maximum percentage Calcium
(5) Minimum percentage of Phosphorus
(6) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

c. Guaranteed Analysis for Dairy Cattle Complete Feeds and Supplements
(1) Minimum percentage of Crude Protein
(2) Maximum percentage of Equivalent Crude Protein from Non-Protein Nitrogen (NPN) when added
(3) Minimum percentage of Crude Fat
(4) Maximum percentage of Crude Fiber
(5) Maximum percentage of Acid Detergent Fiber (ADF)

(6) Minimum and maximum percentage of Calcium
(7) Minimum percentage of Phosphorus
(8) Minimum Selenium in parts per million (ppm)
(9) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

d. Required Guaranteed Analysis for Dairy Mixing and Pasture Mineral (if added)
(1) Minimum and maximum percentage of Calcium
(2) Minimum percentage of Phosphorus
(3) Minimum and maximum percentage of Salt
(4) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
(5) Minimum percentage of Magnesium
(6) Minimum percentage of Potassium
(7) Minimum Selenium in parts per million (ppm)
(8) Minimum Vitamin A, other than the precursors of Vitamin A, in international Units per pound

V. Required Guarantees for Equine Formula Feeds
a. Animal Classes
(1) Growing
(2) Broodmare
(3) Maintenance
(4) Performance (Including Stallions)

b. Guaranteed Analysis for Equine Complete Feeds and Supplements (all animal classes)
(1) Minimum percentage of Crude Protein
(2) Minimum percentage of Crude Fat
(3) Maximum percentage of Crude Fiber
(4) Maximum percentage of Acid Detergent Fiber (ADF)
(5) Maximum percentage of Neutral Detergent Fiber (NDF)
(6) Minimum and maximum percentage of Calcium
(7) Minimum percentage of Phosphorus
(8) Minimum Copper in parts per million (ppm) (if added)
(9) Minimum Selenium in parts per million (ppm)
(10) Minimum Zinc in parts per million (ppm)
(11) Minimum Vitamin A, other than the precursors of Vitamin A, in International Units per pound (if added)

c. Guaranteed Analysis for Equine Mineral Feeds (all animal classes)
(1) Minimum and maximum percentage of Calcium
(2) Minimum percentage of Phosphorus
(3) Minimum and maximum percentage of Salt (if added)
(4) Minimum and maximum percentage of Sodium
(5) Minimum Copper in parts per million (ppm) (if added)
(6) Minimum Selenium in parts per million (ppm)
(7) Minimum Zinc in parts per million (ppm)
(8) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

VI. Required Guarantees for Goat Formula Feeds
a. Animal Classes
(1) Starter
(2) Grower

(3) Finisher
(4) Breeder
(5) Lactating

b. Guaranteed Analysis For Goat Complete Feeds And Supplements (all animal classes)
(1) Minimum percentage of Crude Protein
(2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
(3) Minimum percentage of Crude Fat
(4) Maximum percentage of Crude Fiber
(5) Maximum percentage of Acid Detergent Fiber
(6) Minimum and maximum percentage of Calcium
(7) Minimum percentage of Phosphorus
(8) Minimum and maximum percentage of Salt (if added)
(9) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee.
(10) Minimum and maximum Copper in parts per million (ppm) (if added).
(11) Minimum Selenium in parts per million (ppm).
(12) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added).

VII. Required Guarantees for Sheep Formula Feeds
a. Animal Classes
(1) Starter
(2) Grower
(3) Finisher
(4) Breeder
(5) Lactating

b. Guaranteed Analysis for Sheep Complete Feeds and Supplements (all animal classes)
(1) Minimum percentage of Crude Protein
(2) Maximum percentage of equivalent crude protein from Non-Protein Nitrogen (NPN) when added
(3) Minimum percentage of Crude Fat
(4) Maximum percentage of Crude Fiber
(5) Minimum and maximum percentage of Calcium
(6) Minimum percentage of Phosphorus
(7) Minimum and maximum percentage of Salt (if added)
(8) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee.
(9) Minimum and maximum Copper in parts per million (ppm) (if added, or if total copper exceeds 20 ppm)
(10) Minimum Selenium in parts per million (ppm)
(11) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

VIII. Required Guarantees for Duck and Geese Formula Feeds.
a. Animal Classes
(1) Ducks
(a) Starter - 0 to 3 weeks of age
(b) Grower - 3 to 6 weeks of age

(c) Finisher - 6 weeks to market
(d) Breeder Developer - 8 to 19 weeks of age
(e) Breeder - 22 weeks to end of lay

(2) Geese
(a) Starter - 0 to 4 weeks of age
(b) Grower - 4 to 8 weeks of age
(c) Finisher - 8 weeks to market
(d) Breeder Developer - 10 to 22 weeks of age
(e) Breeder - 22 weeks to end of lay

b. Guaranteed Analysis for Duck and Geese Complete Feeds and Supplements (for all animal classes)
(1) Minimum percentage of Crude Protein
(2) Minimum percentage of Crude Fat
(3) Maximum percentage of Crude Fiber
(4) Minimum and maximum percentage of Calcium
(5) Minimum percentage of Phosphorus
(6) Minimum and maximum percentage of Salt (if added)
(7) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee

IX. Required Guarantees for Fish Complete Feeds and Supplements
a. Animal Species shall be declared in lieu of animal class
(1) Trout
(2) Catfish
(3) Species other than trout or catfish
(1) Minimum percentage of Crude Protein
(2) Minimum percentage of Crude Fat
(3) Maximum percentage of Crude Fiber
(4) Minimum percentage of Phosphorus

X. Required Guarantees for Rabbit Complete Feeds and Supplements
a. Animal Classes
(1) Grower - 4 to 12 weeks of age
(2) Breeder - 12 weeks of age and over
b. Guaranteed analysis for Rabbit Complete Feeds and Supplements (all animal classes)
(1) Minimum percentage of Crude Protein
(2) Minimum percentage of Crude Fat
(3) Minimum and maximum percentage of Crude Fiber (the maximum crude fiber shall not exceed the minimum by more than 5.0 units)
(4) Minimum and maximum percentage of Calcium
(5) Minimum percentage of Phosphorus
(6) Minimum and maximum percentage of Salt (if added)
(7) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
(8) Minimum Vitamin A, other than precursors of Vitamin A, in International Units per pound (if added)

XI. The required guarantees of grain mixtures with or without molasses and feeds other than those described in regulation 3(a)(4) (I thru X) shall include the following items, unless exempted in section XII, in the order listed:

a. Animal class(es) and species for which the product is intended.
b. Guaranteed analysis
   (1) Minimum percentage Crude Protein
   (2) Maximum or minimum percentage of equivalent Crude Protein from Non-Protein Nitrogen as required in Regulation 4(e)
   (3) Minimum percentage of Crude Fat
   (4) Maximum percentage of Crude Fiber
   (5) Minerals in formula feeds, to include in the following order:
      (a) Minimum and maximum percentages of Calcium
      (b) Minimum percentage of Phosphorus
      (c) Minimum and maximum percentage of Salt (if added)
      (d) Minimum and maximum percentage of total Sodium shall be guaranteed only when total Sodium exceeds that furnished by the maximum salt guarantee
      (e) Other Minerals
   (6) Minerals in feed ingredients - as specified by the official definitions of the Association of American Feed Control Officials
   (7) Vitamins in such terms as specified in Regulation 4(c)
   (8) Total sugars as invert on dried molasses products or products being sold primarily for their sugar content
   (9) Viable lactic acid producing microorganisms for use in silages in terms specified in Regulation 4(g)
   (10) A commercial feed (e.g. vitamin/mineral premix, base mix, etc.) 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. Article II of AAFCO's "Criteria for Labeling Nutritional Indicators" is not applicable to the label guarantees for these specialized commercial feeds

XII. Exemptions.
a. 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:
   (1) The feed or feed ingredient is not intended or represented or does not serve as a principal source of that mineral to the animal; or
   (2) The feed or feed ingredient is intended for non-food producing animals and contains less than 6.5% total mineral.
b. Guarantees for vitamins are not required when the commercial feed is neither formulated for nor represented in any manner as a vitamin supplement.
c. Guarantees for crude protein, crude fat, and crude fiber are not required when the commercial feed is intended for purposes other than to furnish these substances or they are of minor significance relating to the primary purpose of the product, such as drug premixes, mineral or vitamin supplements, and molasses.
d. Guarantees for microorganisms are not required when the commercial feed is intended for a purpose other than to furnish these substances or they are of minor significance relating to the

primary purpose of the product, and no specific label claims are made.

e. The indication for animal class(es) and species is not required on single ingredient products if the ingredient is not intended, represented, or defined for a specific animal class(es) or species.

(5) Feed ingredients, collective terms for the grouping of feed ingredients, or appropriate statements as provided under the provisions of Section 5(a)(4) of the Act.

I. 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 .

II. 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; Provide that:

a. 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.

b. 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.

III. The registrant may affix the statement, "Ingredients as registered with the State" in lieu of ingredient list on the label. The list of ingredients must be on file with the . This list shall be made available to the feed purchaser upon request.

(6) Directions for use and precautionary statements or reference to their location if the detailed feeding directions and precautionary statements required by Regulations 7 and 8 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, zip code; However, the street address may be omitted if it is shown in the current city directory or telephone directory.

(8) Quantity Statement

I. Net quantity shall be declared in terms of weight, liquid measure or count, based on applicable requirements under Section 4 of the Fair Packaging and Labeling Act.

II. Net quantity labeled in terms of weight shall be expressed both in pounds, with any remainder in terms of ounces or common or decimal fractions of the pound and in appropriate SI metric system units; or in the case of liquid measure, both in the largest whole unit (quarts, quarts and pints, or pints, as appropriate) with any remainder in terms of fluid ounces or common or decimal fractions of the pint or quart and in appropriate Si metric system units.

III. When the declaration of quantity of contents by count does not give adequate information as to the quantity of feed in the container, it shall be combined with such statement of weight, liquid measure, or size of the individual units as will provide such information.

Regulation 4. Expression of Guarantees

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

(b) Mineral Guarantees

(1) When the calcium, salt, and sodium guarantees are given in the guaranteed analysis such shall be stated and conform to the following:

I. When the minimum is below 2.5%, the maximum shall not exceed the minimum by more than 0.5 percentage point.

II. When the minimum is 2.5% but less than 5.0%, the maximum shall not exceed the minimum by more than one percentage point.

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

(2) When stated, guarantees for minimum and maximum total sodium, and salt: minimum potassium, magnesium, sulfur, phosphorus and maximum fluorine shall be in terms of percentage. Other minimum mineral guarantees shall be stated in parts per million (ppm) when the concentration is less than 10,000 ppm and in percentage when the concentration is 10,000 ppm (1%) or greater.

(3) Products labeled with a quantity statement (e.g., tablets, capsules, granules, or liquid) may state mineral guarantees in milligrams (mg) per unit (e.g., 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 are stated in mg/lb. or in units consistent with those employed for the quantity statement unless otherwise specified:

(1) Vitamin A, other than precursors of vitamin A, in International Units per pound.

(2) Vitamin D-3 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 per pound.

(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 B-12, 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: menadione; riboflavin; d-pantothenic acid; thiamine; niacin; vitamin B-6; folic acid; choline; biotin; inositol; p-amino benzoic acid; ascorbic acid; and carotene.

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

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

(2) Antibiotics present at 2,000 or more 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 directions.

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

(1) For ruminants

a. Complete feeds, supplements, and concentrates containing added non-protein nitrogen and containing more than 5% protein from natural sources shall be guaranteed as follows:
Crude Protein, minimum, _ %
(This includes not more than _ % equivalent crude protein from non-protein nitrogen).

b. Mixed feed concentrates and supplements containing less than 5% protein from natural sources may be guaranteed as follows:
Equivalent Crude Protein from Non-Protein Nitrogen, minimum, %

c. Ingredient sources of non-protein nitrogen such as Urea, Diammonium Phosphate, Ammonium Polyphosphate Solution, Ammoniated Rice Hulls, or other basic non-protein nitrogen ingredients defined by the Association of American Feed Control Officials shall be guaranteed as follows:
Nitrogen, minimum, %
Equivalent Crude Protein from Non-Protein Nitrogen, minimum, %

(2) For non-ruminants

a. Complete feeds, supplements and concentrates containing crude protein from all forms of non-protein nitrogen, added as such, shall be labeled as follows:
Crude protein, minimum _ %
(This includes not more than _ % equivalent crude protein

which is not nutritionally available to (species of animal for which feed is intended).

b. Premixes, concentrates or supplements intended for non-ruminants containing more than 1.25% equivalent crude protein from all forms of non-protein 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) 5.5 mg amino acids liberated/min./milligram. If two or more sources have the same type of activity, they shall be listed in order of predominance based on the amount of enzymatic activity provided.

(i) Guarantees for dietary starch, sugars, and fructans for Commercial Feeds, other than customer-formula feed, Pet Food and Specialty Pet Food Products:
  (1) A commercial feed which bears on its labeling a claim in any manner for levels of "dietary starch," "sugars," "fructans," or words of similar designation, shall include on the label:
    (a) Guarantees for maximum percentage of dietary starch and maximum percentage sugars, in the Guaranteed Analysis section immediately following the last fiber guarantee.
    (b) A maximum percentage guarantee for fructans immediately following sugars, if the feed contains forage products.
  (2) When such guarantees for dietary starch, sugars or fructans for commercial feeds appear on the label, feeding directions shall indicate the proper use of the feed product and a recommendation to consult with a veterinarian or nutritionist for a recommended diet.

Regulation 5. Substantiation of Nutritional Suitability

(a) A commercial feed, other than a customer-formula feed, shall be nutritionally suitable for its intended purpose as represented by its labeling.

(b) If the has reasonable cause to believe a commercial feed is not nutritionally suitable, the may request the feed manufacturer to either submit an "Affidavit of Suitability" or an alternative procedure acceptable to the , certifying the nutritional adequacy of the feed. The Affidavit of Suitability or alternate procedure of suitability shall serve as substantiation of the suitability of the feed.

(c) If an Affidavit of Suitability, or alternative procedure acceptable to the is not submitted by the feed manufacturer within 30 days of written notification the may deem the feed adulterated under section 7(c) of this Act 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) The date of submission; and
  (6) The signature of the affiant notarized by a certified Notary Public.

Regulation 6. Ingredients

(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 .

(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, (i.e. sugar).
(g) When the word "iodized" is used in connection with a feed ingredient, the feed ingredient shall contain not less than 0.007% iodine, uniformly distributed.

Regulation 7. Directions for Use and Precautionary Statements

(a) Directions for use and precautionary statements on the labeling of all commercial feeds and customer-formula feeds containing additives (including drugs, special purpose additives, or non-nutritive additives) shall:
  (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 be limited to, all information described 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 non-protein nitrogen as specified in Regulation 8.
(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.
(d) Raw milk distributed as commercial feed shall bear the following statement: **"WARNING: NOT FOR HUMAN CONSUMPTION - THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA."** This statement shall be displayed in a conspicuous manner and shall not be smaller than the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

Panel Size	Minimum Warning Statement Type Size
≤5 in.^{2}	1/16 in.
>5–≤25 in.^{2}	1/8 in.
>25–≤100 in.^{2}	3/16 in.
>100–≤400 in.^{2}	1/4 in.
>400 in.^{2}	1/2 in.

Regulation 8. Non-Protein Nitrogen

(a) Urea and other non-protein 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 8.75% of equivalent crude protein from all forms of non-protein nitrogen, added as such, or the equivalent crude protein from all forms of non-protein nitrogen, added as such, exceeds one-third of the total crude protein, the label shall bear adequate

directions for the safe use of feeds and a precautionary statement: **"CAUTION: USE AS DIRECTED."** The directions for use and the caution statement shall be in type of such size so placed on the label that they will be read and understood by ordinary persons under customary conditions of purchase and use.

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

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

Regulation 9. Drug and Feed Additives

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

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

(1) When the commercial feed contains such additives, the use of which conforms to the requirements of the applicable regulation in Title 21, Code of Federal Regulations, or which are "prior sanctioned" or "informal review sanctioned" or "generally recognized as safe" for such use, or

(2) When the commercial feed is itself a drug as defined in Section 3(g) of the Act and is generally recognized as safe and effective for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under Section 512 of the Federal Food, Drug, and Cosmetic Act, or

(3) When one of the purposes for feeding a commercial feed is to impart immunity (that is to act through some immunological process) the constituents imparting immunity have been approved for the purpose through the Federal Virus, Serum and Toxins Act of 1913, as amended, or

(4) When the commercial feed is a direct fed microbial product and:

I. The product meets the particular fermentation product definition; and

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

III. The source is stated with a corresponding guarantee expressed in accordance with Regulation 4.(g).

(5) When the commercial feed is an enzyme product and:

I. The product meets the particular enzyme definition defined by the Association of American Feed Control Officials; and

II. The enzyme is stated with a corresponding guarantee expressed in accordance with Regulation 4.(h).

Regulation 10. Adulterants

(a) For the purpose of Section 7(a)(1) of the Act, the terms "poisonous or deleterious substances" include but are not limited to the following:
  (1) Fluorine and any mineral or mineral mixture which is to be used directly for the feeding of domestic animals and in which the fluorine exceeds 0.20% for breeding and dairy cattle; 0.30% for slaughter cattle; 0.30% for sheep; 0.35% for lambs; 0.45% for swine; and 0.60% for poultry.
  (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: 0.004% for breeding and dairy cattle; 0.009% for slaughter cattle; 0.006% for sheep; 0.01% for lambs; 0.015% for swine and 0.03% for poultry.
  (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 50 milligrams of Fluorine per 100 pounds of body weight.
  (4) Soybean meal, flakes or pellets or other vegetable meals, flakes or pellets which 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 which are considered or reported to be a significant source of vitamin B1 (Thiamine).

(b) All screenings or by-products of grains and seeds containing weed seeds, when used in commercial feed or sold as such to the ultimate consumer, shall be ground fine enough or otherwise treated to destroy the viability of such weed seeds so that the finished product contains no more than _ viable prohibited weed seeds per pound and not more than _ viable restricted weed seeds per pound.

Regulation 11. Current Good Manufacturing Practices and Hazard Analysis and Risk-Based Preventive Controls

(a) For the purposes of enforcement of Section 7(d) of the Act the _ 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 Title 21, Code of Federal Regulations, 225.1–225.202.
  (2) The regulations prescribing good manufacturing practices for Type A Medicated Articles as published in the Title 21, Code of Federal Regulations, 226.1–226.115.

(b) Pursuant to Section 10 of the Act, the _ adopts the requirements of Title 21, Code of Federal Regulations, part 507.

Regulation 12. Certain Mammalian Proteins Prohibited in Ruminant Feed

(a) Pursuant to Section 7(a)(1) or 7(a)(3) of the Act, the _ adopts the requirements of Title 21, Code of Federal Regulations, 589.2000.

(b) Pursuant to Section 7(a)(1) or 7(a)(3) of the Act, the _ adopts the requirements of Title 21, Code of Federal Regulations, 589.2001.

AFFIDAVIT

Affidavit of Suitability

_____ _____
(Company Name) (Product Name and Code Number)

1. Affiant is the _____ of _____
(Title) (Name of Company)
and is duly authorized to make and execute this Affidavit for and on behalf of said company.
2. Affiant has knowledge of the nutritional content of the above listed feed product and is familiar with the nutritional requirements for the animal species and animal class(es) for which the feed product is intended.
3. Affiant has knowledge of valid scientific evidence that supports the suitability of the product for the intended animal species and animal class for which this feed is intended. A copy of the product label is attached to this affidavit.

_____ By _____
(Name of Company) (Name)

_____
(Title)

Subscribed and sworn to before me

this _____ day of _____ , 20_____

_____
(Notary Public)

Criteria for Labeling Nutritional Indicators

Section Editor—Chair, Feed Labeling Committee

I. Nutritional Considerations

(a) Nutritional indicators identified as important by 50% of a panel of 10 recognized experts chosen by the joint AAFCO/Industry Label Task Force will be required as a guarantee provided that the other requirements of these criteria are met. **Five of the experts shall be from Land Grant Universities and 5 from the regulated industry.**

(b) The nutritional indicator must be compatible with the feed product's intended purpose to be permitted as a guarantee.

(c) There must be a general recognition and understanding of the nutritional indicator by the feeder, to be permitted as a guarantee.

(d) If feeding safety or efficacy is dependent upon the knowledge of presence and level of a nutritional indicator, it may be required as a guarantee even though it was not identified in I (a) above.

II. Enforceability

To be permitted as a guarantee, a nutrient indicator must be: verifiable by an established AOAC method; or other recognized method.

III. Economics

(a) It will be assumed that there will be a commensurate benefit to the feeder from the guarantee of the nutrient, unless evidence is provided to show that the cost of the state monitoring and/or industry implementation of the guarantee would not provide commensurate value to the feeder.

IV. Historically Required

If the nutritional indicator has a historical significance and is required by current state law and/or regulation, then only this criterion applies and the nutritional indicator should be guaranteed.

Exception

A nutritional indicator may be removed if agreed upon by two-thirds of the members of the expert panel established in I(a).

V. Voluntary Guarantees

(a) May be included on a feed label provided that criteria established by II and III above are met.

Model Regulations for Pet Food and Specialty Pet Food Under the Model Bill

Section Editor—Stan Cook, MO

These Model Regulations are approved by the Association of American Feed Control Officials (AAFCO) under the Model Bill and in conjunction with the Model Regulations. States proposing to adopt these Model Regulations for Pet Food and Specialty Pet Food under their own state feed law are encouraged to adopt AAFCO's Model Regulations for feed, which also apply to pet food and specialty pet food, unless otherwise noted within these regulations.

Pursuant to due publication and public hearing required by the provisions of Chapter of the Laws of this State, the has adopted the following Rules and Regulations.

Regulation PF1. Definitions and Terms

The definitions in the Model Bill and Model Regulations shall apply in addition to the following:

(a) "All Life Stages" means gestation/lactation, growth, and adult maintenance life stages.

(b) "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, which has been successfully test-fed according to an AAFCO feeding protocol(s).

(c) "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.

(d) "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.

(e) "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.

Regulation PF2. Label Format and Labeling

(a) Pet food and specialty pet food shall be labeled with the following information prescribed in this Regulation:
  (1) Product name and brand name, if any, on the principal display panel as stipulated in Regulation PF3;
  (2) A Statement specifying the species name 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 3(s) of this Act and Regulation 3(a)(8) of the Model Regulations, by weight (pounds and ounces, and metric), liquid measure (quarts, pints and fluid ounces, and metric) or by count, on the principal display panel;
  (4) Guaranteed analysis as stipulated in Regulation PF4;
  (5) Ingredient statement as stipulated in Regulation PF5(a);
  (6) A statement of nutritional adequacy or purpose if required under Regulation PF7;
  (7) Feeding directions if required under Regulation PF8; and
  (8) Name and address of the manufacturer or distributor as stipulated in Regulation PF11.

(b) When a pet food or specialty pet food enclosed in an outer container or wrapper is intended for retail sale, 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 label shall 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 claim shall be removed or re-substantiated.
(i) Raw milk distributed as pet food or specialty pet food shall bear the following statement **"WARNING: NOT FOR HUMAN CONSUMPTION - THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA."** This statement shall be displayed in a conspicuous manner and shall not be smaller than the height of the minimum font required by the Federal Fair Packaging and Labeling Act for the quantity statement as shown in the following table:

Panel Size	Minimum Warning Statement Type Size
≤5 in.^{2}	1/16 in.
>5–≤25 in.^{2}	1/8 in.
>25–≤100 in.^{2}	3/16 in.
>100–≤400 in.^{2}	1/4 in.
>400 in.^{2}	1/2 in.

Regulation PF3. Brand and Product Names

(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 ingredient, not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments.
(b) An ingredient or combination of ingredients may form part of a product name of a pet food or specialty pet food:
  (1) When the ingredient(s) constitutes at least 95% 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% of the total product weight.
  (2) When any ingredient(s) constitutes at least 25% of the weight of the product, provided that:
    A. Water sufficient for processing may be excluded when calculating the percentage, however, the ingredients(s) shall constitute at least 10% of the total product weight; and
    B. A descriptor is used with the ingredient name(s). This descriptor shall imply other ingredients are included in the product formula.

Examples of descriptors include “dinner,” “platter,” “entree,” “formula,” and “recipe”; and

C. The descriptor shall be in the same size, style, and color print as the ingredient name(s).

(3) When a combination of ingredients which are included in the product name in accordance with Regulation PF3(b) meets all of the following:

A. Each ingredient constitutes at least 3% of the product weight, excluding water sufficient for processing; and

B. The names of the ingredients appear in the order of their respective predominance by weight in the product; and

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 specialty pet food or elsewhere on the product label and includes a descriptor such as “with” or similar designation, the named ingredient(s) must each constitute at least 3% of the product weight exclusive of water for processing. If the names of more than one ingredient are shown, they shall appear in their respective order of predominance by weight in the product. The 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 in.^{2}	1/8 in.
>5–≤25 in.^{2}	1/4 in.
>25–≤100 in.^{2}	3/8 in.
>100–≤400 in.^{2}	1/2 in.
>400 in.^{2}	1 in.

(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; and

(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.

(e) 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 Regulation PF3 (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 which 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 Regulation PF3 (b), (c), or (d).

(g) 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.)

Regulation PF4. Expression of Guarantees

(a) 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 required guarantees;

A. Minimum percentage of crude protein;
B. Minimum percentage of crude fat;
C. Maximum percentage of crude fat, if required by Regulation PF10;
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 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 these Regulations, 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 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 recognized 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.

(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 which 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 expressed as the element in units specified in the AAFCO Cat Food Nutrient Profiles when no species-specific nutrient profile has been recognized by AAFCO; and provided that
  (3) Mineral guarantees required by Regulation PF4 (c)(1) and (2) may be expressed in milligrams (mg) per unit (e.g., tablets, capsules, granules, or liquids) consistent with those employed in the quantity statement and directions for use; and
  (4) A weight equivalent (e.g., 1 fl. oz. = 28 grams) for liquid products.

(d) The label of a pet food or a 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 the AAFCO Cat Food Nutrient Profiles when no species-specific nutrient profile has been recognized by AAFCO; and provided that
  (3) Vitamin guarantees required by Regulation PF4(d)(1) and (2), may be expressed in approved units (e.g., IU, mg, g) per unit (e.g., tablets, capsules, granules, or liquids) consistent with those employed in the quantity statement and directions for use; and
  (4) A weight equivalent (e.g., 1 fl. oz. = 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 profi 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; and
  (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 Regulation PF7(a)(1) or PF7(b)(2)(A) appears elsewhere on the product label; and
  (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.

(f) The maximum moisture declared on a pet food or specialty pet food label shall not exceed 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 which are so labeled, may contain moisture in excess of 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 microorganisms and enzymes shall be stated in the format as stipulated in Model Regulations 4(g) and (h).

Regulation PF5. Ingredients

(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, style and color;
  (2) The ingredients shall be listed in descending order by their predominance by weight in non-quantitative terms;
  (3) Ingredients shall be listed and identified by the name and definition established by AAFCO; and
  (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 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 thereof. For example, ingredients derived from horses shall be listed as "horsemeat" or "horsemeat by-products."

(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 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.

Regulation PF6. Drugs and Pet Food Additives

(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:
  (1) When the pet food or specialty pet food contains such additives, the use of which conforms to the requirements of the applicable regulation in the Code of Federal Regulations, Title 21, or which are "prior sanctioned" or "informal review sanctioned" or "Generally Recognized as Safe" for such use; or
  (2) When the pet food or specialty pet food itself is a drug or contains a drug as defi in Section 3 (g) of this Act and is "generally recognized as safe and effective" for the labeled use or is marketed subject to an application approved by the Food and Drug Administration under Title 21, U.S.C. 360(b).

(c) When a drug is included in a pet food or specialty pet food, the format required by Model Regulation 3(a)(2) for labeling medicated feeds shall be used.

Regulation PF7. Nutritional Adequacy

(a) The label of a pet food or specialty pet food which is intended for all life stages and sizes 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 and sizes established by an AAFCO-recognized nutrient profile; or
  (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 which is nutritionally similar to a lead product which 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 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; and
    B. The family product meets the criteria for all life stages; and
    C. Under circumstances of reasonable doubt, the (State Control Official) 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 which is intended for a limited purpose (such as size of dog) or a specific life stage, but not for all life stages and sizes, may include a qualified claim such as "complete and balanced," "perfect," "scientific," or "100% nutritious" when the product and claim meet 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; 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; or
    B. The criteria for a limited purpose or a specific life stage as substantiated by completion of the appropriate AAFCO-recognized animal feeding protocol(s); or
    C. The requirements of a product family which is nutritionally similar to a lead product which contains a combination of ingredients which, 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 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; and
      ii. The family product meets the criteria for such limited purpose; and
      iii. Under circumstances of reasonable doubt, the (State Control Official) 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," "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 must also be added verbatim to the end of the claim:

i. "including growth of large size dogs (70 lb. 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.

ii. "except for growth of large size dogs (70 lb. 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

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"); or

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 Regulation PF7(a) or (b) if the claim is scientifically substantiated; or

(3) The statement: "This product is intended for intermittent or supplemental feeding only," if a product does not meet the requirements of Regulation PF7(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 Regulation PF7(c)(1) or (3).

(e) A signed affidavit attesting that the product meets the requirements of Regulation PF7(a) or PF7(b)(2) shall be submitted to the _____ 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 stage(s) 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:

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

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.

(2) As an AAFCO-recognized animal feeding protocol(s), the AAFCO Dog and Cat Food Feeding Protocols.

Regulation PF8. Feeding Directions

(a) Dog or cat food, including snacks or treats, labeled as complete and balanced for any or all life stages, as provided in Regulation PF7(c)(1), except those pet foods labeled in accordance with Regulation PF7(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) 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 Regulation PF7(a), 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.

Regulation PF9. Statements of Calorie Content

(a) The label of a dog or cat food, including snacks, treats, and supplements, 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 must be expressed both as "kilocalories per kilogram" ("kcal/kg") of product, and 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 is determined by one of the following methods:

A. By calculation using the following "Modified Atwater" formula:
ME (kcal/kg) = 10[(3.5 × CP) + (8.5 × CF) + (3.5 × 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.

(4) An affidavit shall be provided upon the request of _ , substantiating that the calorie content was determined by:

A. Regulation PF9(a)(3)A in which case the summary data used in the calculation shall be included in the affidavit; or

B. Regulation PF9(a)(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 of the following:

A. 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 Regulation PF9(a)(3)A; or

B. The heading "Calorie Content" on the label or other labeling shall be followed parenthetically by the word "fed" when the calorie content is determined in accordance with Regulation PF9(a)(3)B.

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

Regulation PF10. Descriptive Terms

(a) Calorie Terms

(1) "Light"

A. A dog food product which bears on its label the terms "light," "lite," "low calorie," or words of similar designation shall:

i. Contain no more than 3100 kcal ME/kg for products containing less than 20% moisture, no more than 2500 kcal ME/kg for products containing 20% or more but less than 65% moisture, and no more than 900 kcal ME/kg for products containing 65% or more moisture; and

ii. Include on the label a calorie content statement:

aa. In accordance with the format provided in Regulation PF9; and

bb. Which states no more than 3100 kcal ME/kg for products containing less than 20% moisture, no more than 2500 kcal ME/kg for products containing 20% or more but less than 65% moisture, and no more than 900 kcal ME/kg for products containing 65% or more moisture; and

iii. Include on the label feeding directions which reflect a reduction in calorie intake consistent with the intended use.

B. A cat food product which bears on its label the terms "light," "lite," "low calorie," or words of similar designation shall:

i. Contain no more than 3250 kcal ME/kg for products containing less than 20% moisture, no more than 2650 kcal ME/kg for products containing 20% or more but less than 65% moisture, and no more than 950 kcal ME/kg for products containing 65% or more moisture; and

ii. Include on the label a calorie content statement:

aa. In accordance with the format provided in Regulation PF9; and

bb. Which states no more than 3250 kcal ME/kg for products containing less than 20% moisture, no more than 2650 kcal ME/kg for products containing 20% or more but less

than 65% moisture, and no more than 950 kcal ME/kg for products containing 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"

A. A dog or cat food product which bears on its label a claim of "less calories," "reduced calories," or words of similar designation, shall include 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 on which the term appears; and

ii. 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

iii. A calorie content statement in accordance with the format provided in Regulation PF9; and

iv. Feeding directions which 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 (i.e., less than 20%, 20% or more but less than 65%, 65% or more) is misleading.

(b) Fat Terms

(1) "Lean"

A. A dog food product which bears on its label the terms "lean," "low fat," or words of similar designation shall:

i. Contain no more than 9% crude fat for products containing less than 20% moisture, no more than 7% crude fat for products containing 20% or more but less than 65% moisture, and no more than 4% crude fat for products containing 65% or more moisture;

ii. Include on the product label in the Guaranteed Analysis:

aa. A maximum crude fat guarantee immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in Regulation PF4(a)(1); and

bb. A maximum crude fat guarantee which is no more than 9% crude fat for products containing less than 20% moisture, no more than 7% crude fat for products containing 20% or more but less than 65% moisture, and no more than 4% crude fat for products containing 65% or more moisture.

B. A cat food product which 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 10% crude fat for products containing less than 20% moisture, no more than 8% crude fat for products containing 20% or more but less than 65% moisture, and no more than 5% crude fat for products containing 65% or more moisture; and

ii. Include on the product label in the Guaranteed Analysis:

aa. A maximum crude fat guarantee immediately following the minimum crude fat guarantee in addition to the mandatory guaranteed analysis information as specified in Regulation PF4(a)(1); and

bb. A maximum crude fat guarantee which is no more than 10% crude fat for products containing less than 20% moisture, no more than 8% crude fat for products containing 20% or more but less than 65% moisture, and no more than 5% crude fat for products containing 65% or more moisture.

(2) "Less" or "Reduced Fat"

A. A dog or cat food product which bears on its label a claim of "less fat," "reduced fat," or words of similar designation, shall include on the label:

i. 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; and

ii. 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

iii. 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 Regulation PF4(a)(1).

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

Regulation PF11. Manufacturer or Distributor; Name and Address

(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 packaged or from where each package is to be distributed.

Guidelines for Tartar Control Claims

The AAFCO Pet Food Committee supports and recommends the following guidelines as developed by the Center for Veterinary Medicine of the US Food and Drug Administration for dental health claims with respect to rawhides, biscuits, and other pet food products:

(1) Foods bearing claims to cleanse, freshen, or whiten teeth by virtue of their abrasive or mechanical action are not objectionable.

(2) Foods bearing claims for plaque or tartar reduction or prevention, or control of breath odor may be misbranded. However, if these claims are made only with respect to the products' abrasive action, enforcement would be a low priority. Thus, CVM is exercising discretion by not objecting to these types of claims at this time.

(3) Foods bearing expressed or implied drug claims to prevent or treat dental diseases (e.g., gingivitis, gum problems, tooth loss) are not permissible unless they are the subject of approved New Animal Drug Applications.

(4) Food ingredients that are not GRAS (generally recognized as safe) for the intended purpose of affecting the teeth or gums may be unapproved food additives or unapproved drugs, depending on the nature of the claim.

(5) Foods bearing claims for plaque or tartar reduction, prevention, or control of breath odor that achieve their effect, in part or in total, by means other than mechanical action must have an approved New Animal Drug Application or a letter of no objection from the FDA prior to being marketed.

Guidelines for "Natural" Claims

AAFCO recommends and supports the following guidelines for use of the term "natural" in the labeling of commercial feeds, pet foods, and specialty pet foods.

(1) In the AAFCO-defined feed term "natural," the use of the term "natural" is only acceptable in reference to the product as a whole when all of the ingredients and components of ingredients meet the definition.

(2) In the definition, the use of the term "natural" is false and misleading if any chemically synthesized ingredients are present in the product; however, AAFCO recommends that exceptions be made in the cases when chemically synthesized vitamins, minerals, or other trace nutrients are present as ingredients in the product, provided that the product is not a dietary supplement and that a disclaimer is used to inform the consumer that the vitamins, minerals or other trace nutrients are not natural.

AAFCO recommends that an acceptable use of the disclaimer would be stated as follows on the product labeling:

A. The disclaimer, such as "Natural with added vitamins, minerals, and other trace nutrients [include the items as appropriate to match the chemically synthesized ingredient(s)]," is juxtaposed with the term "natural"; and

B. The disclaimer appears with the largest or most prominent use of the term "natural" on each panel of the label on which the term appears, in the same style and color print and at least one-half the size of the term "natural"; and

C. All other ingredients and components of ingredients in the product meet the definition of the AAFCO-approved feed term "natural."

(3) If the disclaimer that is juxtaposed with the term "natural" is used only to identify in generic terms those vitamins, minerals and other trace nutrients which are not natural, AAFCO recommends that the disclaimer should not be construed as a nutrient claim which would warrant vitamin and mineral guarantees. However, if the disclaimer makes reference to a specific nutrient (e.g., "with added calcium"), a guarantee would be warranted.

(4) AAFCO also recommends that exceptions be made when the term "natural" is used only in reference to a specific ingredient (e.g., "natural cheese flavor"), even though the product as a whole may not meet the definition of the AAFCO-defined feed term "natural," and that the reference does not imply that the product as a whole is "natural."

Guidelines for "Human Grade" Claims

AAFCO recommends and supports the following guidelines for the use of the term "human grade" in the labeling of pet foods and specialty pet foods.

(1) In the AAFCO-defined feed term "human grade," the use of the term "human grade" is only acceptable in reference to the product as a whole. The feed term specifies that every ingredient and the resulting product must be stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for current good manufacturing practices (cGMPs) for human edible foods as specified in 21 CFR part 117.

(2) In the definition, the term "human grade" is false and misleading if the product

as a whole is not human edible. "Human grade" claims may not be made for individual ingredients in a finished product that does not fully adhere to the manufacturing and ingredient specifications identified above.

(3) In order to substantiate that a "human grade" claim is truthful and not misleading, a manufacturer making one or more "human grade" claims must have documentation that:
   A. Each of the individual ingredient suppliers has verified that the individual ingredients supplied to the manufacturer are fit for human consumption.
   B. Every ingredient and the resulting product are stored, handled, processed, and transported in a manner that is consistent and compliant with regulations for cGMPs for human edible foods as specified in 21 CFR part 117.
   C. The manufacturing facility is licensed to produce human food by the appropriate authority (which varies by jurisdiction). Such evidence may include, but is not limited to, facility licenses or permits for operation of edible food manufacturing facilities or results of most recent inspections issued by local, county, or state public health authorities.

(4) A pet food or specialty pet food product with "human grade" claims must be clearly labeled for its intended use as animal food, such as "dog food" or "cat treats," and follow all other pet food or specialty pet food labeling requirements. The following also applies to labeling:
   A. Statements of quality or grade may not appear in the ingredient statement [PF5(d)(3)].
   B. All uses of the words "human grade" on the label can be no larger than the statement of intended use required by PF2(a)(2).
   C. A claim of "human grade ingredients" is only acceptable if the product complies with all parts of this guideline.
   D. In order to use the term "human grade" on labeling (brochures, point of sale materials, websites, etc.), the statement of intended use must also be included. All uses of the words "human grade" on labeling can be no larger than the statement of intended use.

AAFCO Methods for Substantiating Nutritional Adequacy of Dog and Cat Foods

This section contains the minimum testing methods for the substantiation of nutritional adequacy claims, calorie content claims, and procedures for establishing pet food product families referenced in AAFCO Model Pet Food and Specialty Pet Food Regulations PF2, 4, 7, 8, 9 and/or 10. These methods represent minimum requirements. Companies may choose, or may need, to perform additional testing to substantiate their claims.

AAFCO Dog and Cat Food Nutrient Profiles—Introduction

The Pet Food committee recommends that the revisions to the AAFCO Dog and Cat Food Nutrient Profiles not be enforced until 12 months (1/1/2017) for new products in development and 24 months (1/1/2018) for existing products after publication of the revised AAFCO Dog and Cat Food Nutrient Profiles in the print version of the AAFCO OP.

The Pet Food committee also recommends that the revisions to PF7 of the Pet Food Model Regulations for Pet and Specialty Pet Food Under the Model Bill not be enforced

until enforcement commences for the revised AAFCO Dog and Cat Food Nutrient Profiles.

Delayed enforcement and implementation of the revised PF7 language for nutritional adequacy statements would allow nutritional adequacy statements on products in the market place to be either: verbatim as shown in 2014 OP hard copy, or verbatim as shown in the OP hard copy containing the revised nutrient profiles, until 24 months after publication of the revised nutrient profiles at which time the statement must be as verbatim in the revised PF7.

The original Canine and Feline Nutrition Expert Subcommittees convened in 1990 were charged by the chair of the AAFCO Pet Food Committee to establish practical nutrient profiles for both dog and cat foods based on commonly used ingredients. These subcommittees established the "AAFCO Dog Food Nutrient Profiles" and the "AAFCO Cat Food Nutrient Profiles" that appeared in the Official Publication of the AAFCO in 1992 and 1993, respectively. The profiles were reviewed in 1994/95 and updates to the maximum concentrations for vitamin A in dog foods were implemented in 1996.

The National Research Council (NRC) in 2006 updated its published *Nutrient Requirements of Dogs* and *Nutrient Requirements of Cats* in a single publication that combined recommendations for both species.[1] In 2007 the AAFCO Pet Food Committee again formed Canine and Feline Nutrition Expert Subcommittees and charged these subcommittees with the task of revising the AAFCO Nutrient Profiles in consideration of the information in the 2006 NRC *Nutrient Requirements of Dogs and Cats* (2006 NRC). In addition, the subcommittees considered information in the NRC *Mineral Tolerance of Animals Second Revised Edition, 2005* (2005 *Mineral Tolerance of Animals*).[2] Finally, the subcommittees also reviewed and considered the recommended nutrient concentrations for dog and cat food products as published in February 2008 by the European Pet Food Industry Federation (Federation Europeenne de l'Industrie des Alimentis pour Animaux Familiers (FEDIAF)), titled *F.E.D.I.A.F. Nutritional Guidelines for Complete and Complementary Pet Food for Cats and Dogs*, (FEDIAF Guidelines) that are roughly the European equivalent to the AAFCO Dog and Cat Food Nutrient Profiles.[3]

The AAFCO Dog and Cat Food Nutrient Profiles were designed to establish practical minimum and some maximum nutrient concentrations for dog and cat foods, formulated from commonly used, non-purified, complex ingredients. The concentrations differ from minimum nutrient requirements traditionally developed by the NRC Committee on Animal Nutrition. Many of the NRC minimum nutrient requirements are based on research with purified diets and/or highly bioavailable nutrient sources that are not practical to use in commercial dog and cat foods. Therefore, unlike the previous NRC publications *Nutrient Requirements of Dogs* in 1985[4] and *Nutrient Requirements of Cats* in 1986,[5] the *Nutrient Requirements of Dogs and Cats* in 2006 contained two additional listings of nutrient concentrations for adequate intake and recommended allowance (RA) in addition to minimum requirements. The concentrations for RA's of nutrients in the 2006 NRC are at least equal to, or greater than, concentrations for adequate intakes and minimum requirements, respectively, and are defined as "the concentration or amount of a nutrient in a diet formulated to support a given physiological state." When appropriate, the RA takes into consideration the bioavailability of the nutrient. Thus, the Canine and Feline Nutrition Expert Subcommittees of 2007 primarily used the RA in the 2006 *Nutrient Requirements of Dogs and Cats* in evaluating whether revision was needed to one or more of the minimum recommended concentrations in the profiles. Values for specific nutrient concentrations were added or modified where indicated and supported by recent scientific publications, practical experience, or unpublished data.

The AAFCO Dog and Cat Food Nutrient Profiles have been criticized and faulted for not explicitly indicating the apparent nutrient digestibility, sometimes called nutrient

availability or bioavailability, required to make the listed concentrations adequate for meeting the animal's daily requirements. When a minimum requirement has been established for a particular nutrient, the expected apparent digestibility to meet the minimum requirement for that nutrient at the recommended concentration listed in an AAFCO Nutrient Profile can be calculated using the formula:

[(minimum requirement) × (its apparent digestibility in the diet(s) used to establish the minimum requirement)/(recommended concentration in the AAFCO Profile)] × 100.

In the above formula, the minimum requirement is expressed in the same units as in the AAFCO Nutrient Profile and digestibility is expressed in decimal equivalents. As an example, the NRC lists the minimum crude protein requirement for puppies to be met by formulas containing 18% crude protein on a dry matter basis with the digestibility of the protein sources estimated to be near 100%. The 2016 AAFCO Dog Food Nutrient Profile for Growth and Reproduction recommends the minimum crude protein concentration of dry matter to be 22.5%. Therefore, the expected apparent digestibility for crude protein in a diet formulated to meet the AAFCO Dog Food Nutrient Profile for Growth and Reproduction is at least 80% [(18 × (1.00)/22.5) × 100].

For nutrients known to be essential, but that lack sufficient data to establish a minimum requirement, the typical digestibility for the nutrient in ingredients and food matrices similar to those used to establish the apparent amount to fulfill the animal's need for the nutrient should be ensured. The 2006 *Nutrient Requirements of Dogs and Cats* discusses average or typical apparent digestibility for such nutrients when explaining how a RA was set. As an example, for adult dogs there is no established minimum requirement for iron, although iron is considered essential for adult dogs. In setting the RA of 30 mg/kg in dietary dry matter for adult maintenance, the NRC subcommittee considered the apparent digestibility of iron to be 20%. However, the explanatory text in the publication notes that measured apparent digestibility of iron in the scientific literature has ranged from close to 100% to less than 10%, and is affected by numerous factors such as the specific source of iron, the concentration of other specific minerals or other ingredients in the diet, as well as the iron status of the animal.

The specific example for iron can be generalized to most essential minerals, and demonstrates the impossibility that any list of concentrations can invariably ensure that all nutrient requirements are fulfilled in all diet formulas without additional considerations. As stated for the previous editions of the AAFCO Dog and Cat Food Nutrient Profiles, formulating a product according to the Profiles is only one part of a nutritionally sound, scientific development that must consider all other aspects of the product. The fact that a dog or cat food is formulated to meet a specific AAFCO Profile should not deter or discourage the manufacturer from conducting appropriate feeding trials to further confirm and ensure the diet is nutritionally adequate for its intended use.

Indications regarding expected nutrient availability from some ingredient sources are given in footnotes. It is important to read the footnotes to the tables as they contain information critical to many of the recommended concentrations. Additionally, manufacturers must make allowances to nutrient concentrations prior to processing to account for losses during processing and subsequent storage. The recommended concentrations in the Profiles are those expected to be present at the time the formula is consumed by the animal.

The established profiles are the "AAFCO Dog Food Nutrient Profiles" and "AAFCO Cat Food Nutrient Profiles" as the terms are applied in AAFCO model pet food regulations referring to nutritional adequacy. Under these model regulations, dog and cat foods substantiated for nutritional adequacy by reference to the AAFCO Dog and Cat Food Nutrient Profiles for a designated life stage(s) must be formulated to contain

at least the minimum concentrations of nutrients specified in the Profiles, and, for some nutrients, not more than any maximum concentration listed for that specific nutrient in the Profiles as shown in this section. Products with their nutritional adequacy substantiated by AAFCO Feeding Protocols are not mandated to meet the minimum or maximum concentrations listed in the Profiles. Additionally, snacks, treats or products intended for intermittent or supplemental feeding only are not mandated to meet the concentrations in the Profiles unless their labeling references the Profiles.

The AAFCO Dog and Cat Food Nutrient Profiles and the AAFCO Feeding Protocols are the only methods recognized by AAFCO for substantiating the nutritional adequacy of "complete and balanced" dog or cat foods. If a product is substantiated by a feeding trial and does not meet the AAFCO Dog or Cat Food Nutrient Profiles, the label cannot reference the Profiles. An unqualified reference to an AAFCO Dog or Cat Food Nutrient Profile is an implied guarantee that the product contains the minimum concentrations for all nutrients in the profile and no more than any maximum concentration listed for a specific nutrient in the profile.

Minimum and some maximum nutrient concentrations were established in the Profiles for two categories; growth and reproduction (gestation/lactation), and adult maintenance. Maximum nutrient concentrations were established for nutrients where the potential for overuse or toxicity is of concern and likely to occur if attention is not paid to the concentrations of those nutrients. The absence of a maximum concentration should not be interpreted to mean that nutrients without a specific maximum content are safe at any concentration. Rather, it reflects the lack of information in dogs and cats on toxic concentrations of that nutrient. Establishing a maximum concentration implies safety below that concentration for long term consumption and to set a maximum arbitrarily might prove worse than no maximum at all.

The nutrient concentrations are expressed on a dry matter (DM) basis and at a specified caloric density. Diets should be corrected for caloric density as indicated below. Reference to the concentrations of nutrients on a product label in the guaranteed analysis must be expressed in the same units and order as given in the AAFCO Dog or Cat Food Nutrient Profiles. For the purposes of determining metabolizable energy (ME), use the methods specified in Model Regulation PF9.

AAFCO Dog Food Nutrient Profiles Based on Dry Matter[a]

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum[b]	Maximum
Crude protein	%	22.5	18.0	
Arginine	%	1.0	0.51	
Histidine	%	0.44	0.19	
Isoleucine	%	0.71	0.38	
Leucine	%	1.29	0.68	
Lysine	%	0.90	0.63	
Methionine	%	0.35	0.33	
Methionine-cystine	%	0.70	0.65	
Phenylalanine	%	0.83	0.45	
Phenylalanine-tyrosine	%	1.30	0.74	

(continued)

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum[b]	Maximum
Threonine	%	1.04	0.48	
Tryptophan	%	0.20	0.16	
Valine	%	0.68	0.49	
Crude fat[c]	%	8.5	5.5	
Linoleic acid	%	1.3	1.1	
alpha-Linolenic acid	%	0.08	ND[d]	
Eicosapentaenoic + Docosahexaenoic acid	%	0.05	ND[d]	
(Linoleic + Arachidonic):(alpha-Linolenic + Eicosapentaenoic + Docosahexaenoic) acid ratio				30:1
Minerals				
Calcium	%	1.2	0.5	2.5 (1.8)[e]
Phosphorus	%	1.0	0.4	1.6
Ca:P ratio		1:1	1:1	2:1
Potassium	%	0.6	0.6	
Sodium	%	0.3	0.08	
Chloride	%	0.45	0.12	
Magnesium	%	0.06	0.06	
Iron[f]	mg/kg	88	40	
Copper[g]	mg/kg	12.4	7.3	
Manganese	mg/kg	7.2	5.0	
Zinc	mg/kg	100	80	
Iodine	mg/kg	1.0	1.0	11
Selenium	mg/kg	0.35	0.35	2
Vitamins and others				
Vitamin A	IU/kg	5000	5000	250,000
Vitamin D	IU/kg	500	500	3000
Vitamin E[h]	IU/kg	50	50	
Thiamine[i]	mg/kg	2.25	2.25	
Riboflavin	mg/kg	5.2	5.2	
Pantothenic acid	mg/kg	12	12	
Niacin	mg/kg	13.6	13.6	
Pyridoxine	mg/kg	1.5	1.5	

(continued)

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum[b]	Maximum
Folic acid	mg/kg	0.216	0.216	
Vitamin B_{12}	mg/kg	0.028	0.028	
Choline	mg/kg	1360	1360	

[a]Presumes a caloric density of 4000 kcal ME/kg, as determined in accordance with Regulation PF9. Formulations greater than 4000 kcal ME/kg should be corrected for energy density; formulations less than 4000 kcal ME/kg should not be corrected for energy. Formulations of low-energy density should not be considered adequate for reproductive needs based on comparison to the Profiles alone.
[b]Recommended concentrations for maintenance of body weight at an average caloric intake for dogs of a given optimum weight.
[c]Although a true requirement for crude fat per se has not been established, the minimum concentration was based on recognition of crude fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.
[d]ND = not determined. Although a minimum requirement has not been determined, sufficient amounts of omega-3 fatty acids are necessary to meet the maximum omega-6:omega-3 fatty acid ratio.
[e]The maximum of 1.8% is applicable to formulas that may be fed to large size puppies (those weighing 70 lb. or greater as mature lean adults). For other life stages, including non-large-size growth formulas, the maximum calcium is 2.5% DM.
[f]Average apparent digestibility for iron associated with recommended minimums is 20% of that consumed. Because of very poor apparent digestibility, iron from carbonate or oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration for iron.
[g]Because of very poor apparent digestibility, copper from oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration for copper.
[h]It is recommended that the ratio of IU of vitamin E to grams of polyunsaturated fatty acids (PUFA) be ≥0.6:1. A diet containing 50 IU of vitamin E will have a ratio ≥0.6:1 when the PUFA content is 83 grams or less. Diets containing more than 83 grams of PUFA should contain an additional 0.6 IU of vitamin E for every gram of PUFA.
[i]Because processing may destroy up to 90% of the thiamine in the diet, allowances in formulation should be made to ensure the minimum nutrient concentration for thiamine is met after processing.

AAFCO Dog Food Nutrient Profiles Based on Calorie Content

Nutrient	Units per 1000 kcal ME	Growth and Reproduction Minimum	Adult Maintenance Minimum[a]	Maximum
Crude protein	g	56.3	45.0	
Arginine	g	2.50	1.28	
Histidine	g	1.10	0.48	
Isoleucine	g	1.78	0.95	
Leucine	g	3.23	1.70	

(continued)

Nutrient	Units per 1000 kcal ME	Growth and Reproduction Minimum	Adult Maintenance Minimum[a]	Maximum
Lysine	g	2.25	1.58	
Methionine	g	0.88	0.83	
Methionine-cystine	g	1.75	1.63	
Phenylalanine	g	2.08	1.13	
Phenylalanine-tyrosine	g	3.25	1.85	
Threonine	g	2.60	1.20	
Tryptophan	g	0.50	0.40	
Valine	g	1.70	1.23	
Crude fat[b]	g	21.3	13.8	
Linoleic acid	g	3.3	2.8	
alpha-Linolenic acid	g	0.2	ND[c]	
Eicosapentaenoic + Docosahexaenoic acid	g	0.1	ND[c]	
(Linoleic + Arachidonic):(alpha-Linolenic + Eicosapentaenoic + Docosahexaenoic) acid ratio				30:1
Minerals				
Calcium	g	3.0	1.25	6.25 (4.5)[d]
Phosphorus	g	2.5	1.00	4.0
Ca:P ratio		1:1	1:1	2:1
Potassium	g	1.5	1.5	
Sodium	g	0.80	0.20	
Chloride	g	1.10	0.30	
Magnesium	g	0.15	0.15	
Iron[e]	mg	22	10	
Copper[f]	mg	3.1	1.83	
Manganese	mg	1.8	1.25	
Zinc	mg	25	20	
Iodine	mg	0.25	0.25	2.75
Selenium	mg	0.09	0.08	0.5
Vitamins and others				
Vitamin A	IU	1250	1250	62,500
Vitamin D	IU	125	125	750
Vitamin E[g]	IU	12.5	12.5	

(continued)

Nutrient	Units per 1000 kcal ME	Growth and Reproduction Minimum	Adult Maintenance Minimum[a]	Maximum
Thiamine[h]	mg	0.56	0.56	
Riboflavin	mg	1.3	1.3	
Pantothenic acid	mg	3.0	3.0	
Niacin	mg	3.4	3.4	
Pyridoxine	mg	0.38	0.38	
Folic acid	mg	0.054	0.054	
Vitamin B_{12}	mg	0.007	0.007	
Choline	mg	340	340	

[a]Recommended concentrations for maintenance of body weight at an average caloric intake for dogs of a given optimum weight.
[b]Although a true requirement for crude fat per se has not been established, the minimum concentration was based on recognition of crude fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.
[c]ND = not determined. Although a minimum requirement has not been determined, sufficient amounts of omega-3 fatty acids are necessary to meet the maximum omega-6:omega-3 fatty acid ratio.
[d]Maximum of 4.5 g Ca/1000 kcal ME is applicable to formulas; that may be fed to large size puppies (those weighing 70 lb. or greater as mature lean adults). For other life stages, including non-large-breed growth formulas, the maximum calcium is 6.25 g Ca/1000 kcal ME.
[e]Average apparent digestibility for iron associated with recommended minimums is 20% of that consumed. Because of very poor apparent digestibility, iron from carbonate or oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration for iron.
[f]Because of very poor apparent digestibility, copper from oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration for copper.
[g]It is recommended that the ratio of IU of vitamin E to grams of polyunsaturated fatty acids (PUFA) be ≥0.6:1. A diet containing 50 IU of vitamin E will have a ratio ≥0.6:1 when the PUFA content is 83 grams or less. Diets containing more than 83 grams of PUFA should contain an additional 0.6 IU of vitamin E for every gram of PUFA.
[h]Because processing may destroy up to 90% of the thiamine in the diet, allowances in formulation should be made to ensure the minimum nutrient concentration for thiamine is met after processing.

Changes to and Rationale for Nutrient Concentrations—Dog Foods

Caloric Density

The 2007 AAFCO Canine Nutrition Expert Subcommittee (CNES) chose to set the presumed caloric density for dog food products at 4000 kcal metabolizable energy (ME) per kilogram (kg) dry matter (DM) for both the nutrient concentrations per kg DM and the nutrient amounts per 1000 kcal ME in order to be consistent with the presumed caloric density used in the 2006 *Nutrient Requirements of Dogs and Cats*[1] and in the current AAFCO Cat Food Nutrient Profiles. Prior to the 2016 revisions to the Profiles,

the presumed caloric density for dog foods was set at 3500 kcal ME/kg DM for nutrient concentrations per kg DM and at 4500 kcal ME/kg DM for nutrient amounts per 1000 kcal ME, although mathematical conversion between the two tables was accomplished using 3500 kcal/kg DM as the caloric density. The presumed caloric density is not a minimum or a maximum content that a product must meet to reference the profile, but it does dictate the factor used to convert between expressions of nutrient content per kg DM versus per 1000 kcal ME and the minimum concentrations of required nutrients in complete and balanced products. Because the denominator for converting from concentrations per kg DM to amounts per 1000 kcal ME has increased from 3.5 to 4.0, values in the per 1000 kcal ME table in some instances may appear less than corresponding values listed prior to 2016 even though DM concentrations may not have changed or even increased slightly. Corrections to amounts of nutrients in formulations differing in caloric density from the presumed value of 4000 kcal ME/kg DM are discussed below.

Protein

The minimum concentration of protein for growth and reproduction was increased slightly from 22% to 22.5% DM consistent with the RA for growth established by the 2006 NRC.[1] The minimum concentration in the AAFCO Dog Food Nutrient Profile for Adult Maintenance was not changed from the previous value of 18%.

The CNES established minimum recommended amounts for the essential amino acids methionine and phenylalanine consistent with the RA proposed by the NRC in addition to the previous minimum recommended amounts of methionine plus cystine and phenylalanine plus tyrosine. The CNES felt it prudent to include specific minimums for methionine and phenylalanine because although some, or all, of the requirement for cystine and tyrosine can be met from excess methionine and phenylalanine, respectively, the reverse is not true. Some of the previous recommendations for dietary concentrations of essential amino acids in the Dog Food Nutrient Profile for Adult Maintenance (i.e., histidine, lysine, threonine and tryptophan) were greater than the corresponding RA in the 2006 NRC and the CNES elected to retain the previously recommended amounts for these amino acids in the current Dog Food Nutrient Profile for Adult Maintenance.

Minimum concentrations of some essential amino acids in the Dog Food Nutrient Profile for Growth and Reproduction were increased, usually to match the NRC RA for growth (i.e., arginine, leucine, methionine, methionine-cystine, phenylalanine-tyrosine and valine). Although the NRC RA for total crude protein during lactation is essentially identical to the RA for growth (22.0% versus 22.5%), several of the RA for essential amino acids during lactation are greater than the RA for growth. In some cases (i.e., histidine, isoleucine, lysine, phenylalanine, and threonine) the difference was small and the CNES elected to set the recommended amount in the Growth and Reproduction Profile at the larger NRC RA for lactation. For other essential amino acids (i.e., leucine and valine) the RA proposed by the NRC for lactation is substantially more than the RA for growth, and in the case of leucine and valine the concentrations are equal to, or greater than, the corresponding RA for the cat during lactation, an obligate carnivore with protein requirements generally greater than those for the dog. The NRC ad hoc committee indicated that it set the RA based on, "lowest concentrations of each of the essential amino acids from digestible protein in commercial dry expanded diets that have been shown to sustain normal gestation and lactation for bitches."[1] The CNES chose not to increase the recommended concentrations for leucine and valine to those of the NRC RA for lactation based on lack of documented problems with the previous concentrations in the AAFCO Dog Food Nutrient Profile for Growth and Reproduction and the relative disparity in the RA between canine versus feline protein requirements. The CNES did

not elect to change the tryptophan concentration in the Dog Food Nutrient Profile for Growth and Reproduction for two reasons. The CNES had access to feeding studies and a publication showing that the minimum requirement for tryptophan in Labrador retriever puppies was less than the current concentration in AAFCO Dog Food Nutrient Profile for Growth and Reproduction and that the tryptophan concentration of 0.2% DM already provided approximately a 25% safety margin.[6] The CNES was also aware that it was nearly impossible to formulate a product at the minimum protein concentration to contain more than 0.2% tryptophan on a DM basis from typical ingredients without including crystalline tryptophan in the formula.

Insufficient data were available to demonstrate detrimental effects of high protein intake in the normal dog to allow for any definitive maximum concentrations for protein or amino acids to be established. The CNES is aware of the findings regarding excess lysine at some concentration between 2.0% and 4.0% lysine/kg DM to produce depression in growth of puppies and clinical signs associated with arginine deficiency when arginine is present at 0.4% DM, and that FEDIAF has established a concentration of 2.8% lysine in DM as a maximum.[3,7] However, this information was available prior to the establishment of the original AAFCO Nutrient Profiles and did not result in a maximum lysine content being established by the 1990 Expert Subcommittee. Furthermore, the 2007 CNES notes that the minimum recommended arginine content for growth and reproduction is 2.5 times the concentration of 0.4% arginine/kg DM required to produce the noted adverse effects in combination with lysine at more than 2.0%/kg DM.

Fat/Fatty Acids

The CNES increased the minimum recommended amount for total fat in the AAFCO Dog Food Nutrient Profiles by 0.5% to 8.5% for Growth and Reproduction and 5.5% for Adult Maintenance. These concentrations are consistent with the RA for total fat in the 2006 NRC and the FEDIAF Guidelines. The CNES also increased the minimum recommended linoleic acid concentration in the Growth and Reproduction Profile from 1.0% to 1.3% and in the Adult Maintenance Profile from 1.0% to 1.1%, again consistent with the RA in the 2006 NRC. The CNES did not set a minimum recommended concentration for arachidonic acid in either profile, but did establish minimum recommended concentrations for some fatty acids in the n-3 (omega-3) series in the Growth and Reproduction Profile, specifically, alpha-linolenic acid at 0.08%, and the combination of eicosapentaenoic plus docosahexaenoic acids at 0.05%, of DM. Because the scientific evidence to date indicates that these n-3 fatty acids are needed for the development of the nervous and visual systems during fetal and neonatal life stages, the CNES did not feel there was scientific justification for setting minimum recommended concentrations for n-3 fatty acids for adult maintenance. A recommendation in a comment to list quantities of alpha-linolenic acid and eicosapentaenoic plus docosahexaenoic acids for adult maintenance as being not determined (ND) was accepted by the AAFCO Pet Food Committee.

The CNES did not establish maximum concentrations for fat or fatty acids despite the NRC listing a safe upper limit (SUL) for total crude fat, linoleic acid, and the combination of eicosapentaenoic plus docosahexaenoic acids. The CNES felt it likely that insufficiencies in other nutrients will occur in a conventional formula before an inclusion of 33% crude fat in DM is reached. Also, although some differences in delayed hypersensitivity reactions were noted in studies cited by the NRC as the basis for setting the SUL for eicosapentaenoic plus docosahexaenoic acids, the 2007 CNES noted that those differences are not unequivocally undesirable or detrimental.[8,9] The CNES did elect to set a maximum for the ratio of the sum of linoleic plus arachidonic acids to the

sum of alpha-linolenic, eicosapentaenoic, and docosahexaenoic acids at 30:1 given the modulating effects of n-3 fatty acids on n-6 metabolism and the predominant contribution of these fatty acids to the n-6 and n-3 fatty acid contents, respectively, in conventional dog food formulas.

Calcium and Phosphorus

The CNES decreased the recommended minimum concentration of calcium and phosphorus in the Adult Maintenance Profile by 0.1% to 0.5% and 0.4%, respectively. The current recommended minimum concentrations are 0.1% more than the RA for calcium and phosphorus on a DM basis for adult maintenance in the 2006 NRC but consistent with the concentrations in the FEDIAF Guidelines. The CNES recommended that the calcium and phosphorus in growth formulas for the large breed or large size dogs (those breeds typically attaining lean adult body weights of 70 pounds or more) be allowed to decrease to 0.9% and 0.75%, respectively, while still being judged to meet the Growth and Reproduction Nutrient Profile. However, based on comments and a publication[10] demonstrating that some diets containing 0.88% to 1.04% Ca on a DM basis (2.2 to 2.6 g Ca/1000 kcal ME) when fed to medium or large breed puppies produced inhibited growth in 10-week growth studies compared to diets containing between 1.3 to 1.8% Ca, the AAFCO Pet Food Committee elected to keep the minimum recommended calcium and phosphorus concentrations in the Growth and Reproduction Nutrient Profile at 1.2% and 1.0%, respectively, for all dog food products that substantiate nutritional adequacy based on being formulated to meet the nutrient content of the Dog Food Nutrient Profile for Growth and Reproduction.

Because of concerns for excess calcium to produce detrimental effects in growing dogs of large and giant breeds,[11–13] the 2007 CNES deemed that additional restriction to the maximum limit for calcium was warranted for large size growth formulations and lowered the maximum calcium concentration to 1.8% DM for these products. The CNES did not believe it necessary to decrease the previous maximum calcium concentration of 2.5% for adult dogs or growing dogs of small or moderate size breeds, and retained the maximum of 2.5% for the adult maintenance products as well as gestation/lactation products and growth products for small and moderate size breeds of dogs. The AAFCO Pet Food Committee discussed and considered the proposal at length for having two maximum calcium concentrations applicable to different products. The Pet Food Committee notes that unless a product's labeling restricts the product to specific breeds, products bearing an All Life Stages claim based on the product being formulated to meet the AAFCO Dog Food Nutrient Profile for Growth and Reproduction should not contain more than 1.8% calcium on a DM basis. The CNES retained the maximum phosphorus concentration of 1.6% DM for both profiles, as well as the minimum and maximum values of 1:1 and 2:1, respectively, for the calcium to phosphorus ratio.

Other Macrominerals

Potassium

The 2007 CNES elected to retain the recommended minimum potassium concentration at 0.6% DM for both Profiles. Although the RA in the 2006 NRC and some concentrations in the FEDIAF Guidelines are less than 0.6% DM for potassium, the CNES felt that the potassium concentration did not warrant changing especially given that potential toxicosis of potassium was not a practical concern. Thus, a maximum concentration for potassium was not established.

Sodium and Chloride

The 2007 CNES did not change the minimum recommendation for sodium or chloride in the Growth and Reproduction Nutrient Profile as the values are slightly above

the 2006 NRC RA. The 2007 CNES made an editorial increase in the recommended minimum concentrations for sodium and chloride in the Adult Maintenance Nutrient Profile to match the 2006 NRC RA. For sodium the increase was from 0.06% to 0.08% DM and for chloride from 0.09 to 0.12% DM. The recommended minimum concentrations for sodium and chloride in both dog food nutrient profiles continue to reflect the 1:1.5 sodium to chloride ratio of salt previously used by the 1990 CNES to justify recommended chloride concentrations. As noted by the 1990 CNES, because palatability and food consumption would decline due to excess sodium before adverse health effects were observed, setting a maximum concentration for sodium was not of practical concern.

Magnesium

The 2007 CNES increased the minimum recommended concentration for magnesium from 0.04 to 0.06% in Adult Maintenance and Growth and Reproduction Nutrient Profiles to match the 2006 NRC RA for adult maintenance and peak lactation, respectively. The 2007 CNES deleted the maximum recommended concentration for magnesium due to lack of data specific to dogs in both the 2006 NRC and the 2005 *Mineral Tolerances of Animals*. The only comment regarding maximum magnesium content in the 2006 NRC was that a SUL for magnesium in the diets of dogs was greater than 1.7% DM.

Microminerals

Iron

The 2007 CNES made an editorial change to the minimum concentration for iron in the Growth and Reproduction Nutrient Profile to make the concentration consistent with a presumed caloric density of 4000 kcal ME/kg DM which makes the recommended concentration consistent with the RA from the 2006 NRC and the FEDIAF Guidelines for same life stages. The 2007 CNES decreased the recommendation for adult maintenance from 80 to 40 mg/kg DM based on considerations that the RA of the 2006 NRC was 30 mg/kg DM and the FEDIAF Guidelines concentration was 36 mg/kg DM. The 2007 CNES deleted the maximum concentration for iron based on one scientific and one practical regulatory consideration. First, the 2006 NRC indicated that appropriate data for setting a SUL for iron in dog foods are not available. The previous maximum concentration was stated to be based on tolerance data in swine. The 2005 *Mineral Tolerance of Animals* indicated that the listed tolerance of 3000 mg/kg DM for swine needed to be confirmed by long-term studies and all other tolerances for iron listed in that publication are 6 times less than 3000 mg/kg DM. Second, the implied safety of a maximum concentration presumes some amount of apparent digestibility and, as noted above, the apparent digestibility of iron in any given diet or combination of ingredients can vary from less than 10% to near 100%. Some sources of iron are considered unavailable and used for their technical effects (i.e., color) on the product and not for their nutrient contribution of iron to the animal. Such unavailable sources will still contribute iron to an analytical result for determining product content, and thus a maximum concentration set for available sources of iron might prohibit use of unavailable sources for coloring, whereas a maximum concentration set for unavailable colorants might permit use of unsafe amounts of available sources on the basis of analytical content. Thus, the 2007 CNES elected to delete the previous maximum of 3000 mg/kg DM and not list any other value as a maximum for iron. Manufacturers should note that iron is toxic at some amount greater than the recommended quantities, but the exact amount is unknown for dogs.

Copper

The minimum concentration for copper in the Adult Maintenance Nutrient Profile was not changed from the previous amount of 7.3 mg/kg DM, the concentration being

consistent with that of the FEDIAF Guidelines and slightly more than the 2006 NRC RA of 6.0 mg/kg. The 2007 CNES increased the minimum recommended concentration in the Growth and Reproduction Nutrient Profile to 12.4 mg/kg DM, consistent with the 2006 NRC RA for peak lactation and slightly more than FEDIAF Guidelines and the NRC RA for growth. Because of poor bioavailability, the use of copper oxide as a nutritional source is excluded.[14] The 2007 CNES deleted the copper maximum concentration for many of the same science-based reasons cited above for deleting the maximum for iron content.

Manganese

The minimum concentration for manganese in the Adult Maintenance Nutrient Profile was not changed from the previous amount of 5.0 mg/kg DM, the amount being slightly more than the 2006 NRC RA of 4.8 and slightly less than the FEDIAF Guidelines of 5.6 mg/kg DM. The 2007 CNES increased the minimum recommended concentration in the Growth and Reproduction Nutrient Profile to 7.2 mg/kg DM, consistent with the 2006 NRC RA for peak lactation and slightly more than FEDIAF Guidelines concentrations and NRC RA for growth.

Zinc

The 2006 NRC RA for zinc in growth, reproduction, and adult maintenance formulations was less than the previous concentration in the Dog Food Nutrient Profiles of 120 mg/kg DM and the 2007 CNES decreased the recommended minimum concentration to 100 mg/kg DM in the Growth and Reproduction Nutrient Profile and to 80 mg/kg DM in the Adult Maintenance Nutrient Profile consistent with the 2006 NRC RA and FEDIAF Guidelines concentrations. Both the 2005 *Mineral Tolerance of Animals* and the 2006 *Nutrient Requirements of Dogs and Cats* state there is not enough data available to set a tolerance or SUL for zinc in dog foods. The 2007 CNES elected to delete the previous maximum concentration of 1000 mg/kg DM that was based on the maximum tolerance concentration recommended for swine rations. The CNES noted that the swine tolerance of 1000 mg/kg DM was the greatest concentration for any tolerance for zinc listed in the 2005 *Mineral Tolerance of Animals*.

Iodine

The 2006 NRC RA for iodine in dog foods is 0.88 mg/kg DM. The FEDIAF Guideline concentrations range from 0.9 to 1.5 mg/kg DM. In considering the basis for these various recommended concentrations the 2007 CNES felt a recommended minimum concentration of 1.0 mg/kg to be prudent and adequate to support adult maintenance as well as growth and reproduction.

The 2007 CNES revised the maximum concentration for iodine based on the following considerations. Although neither the 2005 *Mineral Tolerances for Animals* nor the 2006 *Nutrient Requirements of Dogs and Cats* established a tolerance or SUL for iodine in diets for dogs, both publications cite data that indicate a commercial formulation containing 5.6 mg iodine/kg diet had adverse effects on thyroid function.[15,16] FEDIAF also notes these studies, but faulted the studies for using a diet deficient in calcium, phosphorus and potassium, and fed in excessive quantities. The 2008 FEDIAF Guidelines indicate a maximum concentration for iodine of 11 mg/kg DM when other minerals are within acceptable concentrations and the products are fed in appropriate quantities. The tolerances for iodine in the 2005 *Mineral Tolerances of Animals* that have been established for various species range from 5 mg/kg DM in diets for horses to 400 mg/kg DM in diets for swine. Given that the NRC tolerance for horses is 10 times less than the general maximum concentration of 50 mg iodine/kg DM recommended by AAFCO, the 2007 CNES felt the value of 50 mg/kg DM to no longer be appropriate for setting a maximum concentration for iodine in dog foods. The 2007 CNES acknowledges that additional studies may allow further refinement of a maximum amount of iodine in

foods for dogs, but until such data are available the CNES felt it prudent to adopt the FEDIAF position and set 11 mg iodine per kg DM as the maximum concentration of iodine in dog foods.

Selenium

The recommended minimum concentration of selenium was increased to 0.35 mg/kg DM in Adult Maintenance and Growth and Reproduction Nutrient Profiles consistent with the 2006 NRC RA for selenium. The 2007 CNES notes there is a difference between added selenium and total selenium content. The approval of food additives for addition of selenium to animal feeds limits the total amount of selenium that may be added to feed to 0.3 mg/kg from all approved sources on an as-fed basis (90% DM feeds), roughly equivalent to 0.333 mg/kg on a DM basis. The recommended minimum concentration of 0.35 mg selenium/kg DM in dog foods is the sum of selenium from all ingredients in the product, both approved food additives used specifically to add selenium to the product, as well as selenium contained as a constituent of other ingredients. As there is generally more than 0.05 mg selenium/kg DM in ingredients used to supply protein and fat to typical pet food formulations, the 2007 CNES believes the limitation of 0.3 mg selenium/kg DM from approved selenium additives will not hinder a manufacturer's ability to meet the minimum recommended concentration of 0.35 mg selenium/kg DM.

Both the 2006 NRC and the 2005 *Mineral Tolerance of Animals* state no data are available upon which to establish a SUL or tolerance for selenium in diets for dogs. Both NRC publications cite the fifth edition of *Trace Elements in Human and Animal Nutrition* published in 1986 for information indicating a dietary concentration of 5 mg/kg DM resulted in toxicity in dogs.[17] The 2007 CNES acknowledges the NRC has indicated in the years since the publication of the first edition of *Mineral Tolerance of Domestic Animals* set a tolerance of 2.0 mg of selenium per kg DM for all species in 1980 that the value has been challenged as an underestimate of the true tolerance for several species, and that during 1980 to 2005 greater tolerances for selenium have been established for some species. Although the true tolerance for dogs may be greater than 2, but less than 5, mg selenium/kg DM, the 2007 CNES believes it to be prudent to retain the maximum concentration for selenium at 2.0 mg/kg DM until such time as empirical data permit a greater and more definitive maximum to be established.

Vitamins

The 2007 CNES did not believe there were data sufficient to change any of the recommended minimum concentrations for the fat soluble vitamins or the maximum concentration for vitamin A. The 2007 CNES decreased the maximum vitamin D concentration in consideration of the SUL and maximums set by the 2006 NRC and FEDIAF Guidelines based on the studies conducted by Tryfondidou et al.[18,19] The maximum vitamin D concentration was reduced to 3000 IU/kg DM (750 IU/1000 kcal ME) which is 6 times the recommended minimum concentration and 1000 IU/kg less than the amount shown to produce disruption of endochondrial ossification in growing Great Dane puppies. The 2007 CNES noted that the 2006 *Nutrient Requirements of Dogs and Cats* had not established a SUL for vitamin E based on there being no information on vitamin E toxicity in dogs, and so deleted the maximum concentration for vitamin E in the Dog Food Nutrient Profiles. The 2007 CNES increased the minimum concentrations of thiamine, riboflavin and pyridoxine consistent with the RA of the 2006 NRC. For pantothenic acid, niacin, folic acid, vitamin B_{12} and choline, the 2007 CNES elected to set the recommended concentrations in the AAFCO Dog Food Nutrient Profiles equal to the 2006 NRC adequate intake (AI) recommendation based on indications that the AI already provided a margin of safety above the minimum requirements for these compounds.

AAFCO Cat Food Nutrient Profiles Based on Dry Matter[a]

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum[b]	Maximum
Crude protein	%	30.0	26.0	
Arginine	%	1.24	1.04	
Histidine	%	0.33	0.31	
Isoleucine	%	0.56	0.52	
Leucine	%	1.28	1.24	
Lysine	%	1.20	0.83	
Methionine	%	0.62	0.20	1.5
Methionine-cystine	%	1.10	0.40	
Phenylalanine	%	0.52	0.42	
Phenylalanine-tyrosine	%	1.92	1.53	
Threonine	%	0.73	0.73	
Tryptophan	%	0.25	0.16	1.7
Valine	%	0.64	0.62	
Crude fat[c]	%	9.0	9.0	
Linoleic acid	%	0.6	0.6	
alpha-Linolenic acid	%	0.02	ND[d]	
Arachidonic acid	%	0.02	0.02	
Eicosapentaenoic + Docosahexaenoic acid	%	0.012	ND	
Minerals				
Calcium	%	1.0	0.6	
Phosphorus	%	0.8	0.5	
Potassium	%	0.6	0.6	
Sodium	%	0.2	0.2	
Chloride	%	0.3	0.3	
Magnesium[e]	%	0.08	0.04	
Iron[f]	mg/kg	80	80	
Copper (extruded)[g]	mg/kg	15	5	
Copper (canned)[g]	mg/kg	8.4	5	
Manganese	mg/kg	7.6	7.6	
Zinc	mg/kg	75	75	
Iodine	mg/kg	1.8	0.6	9.0
Selenium	mg/kg	0.3	0.3	
Vitamins and others				
Vitamin A	IU/kg	6668	3332	333,300

(continued)

Nutrient	Units DM Basis	Growth and Reproduction Minimum	Adult Maintenance Minimum[b]	Maximum
Vitamin D	IU/kg	280	280	30,080
Vitamin E[h]	IU/kg	40	40	
Vitamin K[i]	mg/kg	0.1	0.1	
Thiamine[j]	mg/kg	5.6	5.6	
Riboflavin	mg/kg	4.0	4.0	
Pantothenic acid	mg/kg	5.75	5.75	
Niacin	mg/kg	60	60	
Pyridoxine	mg/kg	4.0	4.0	
Folic acid	mg/kg	0.8	0.8	
Biotin[k]	mg/kg	0.07	0.07	
Vitamin B_{12}	mg/kg	0.020	0.020	
Choline	mg/kg	2400	2400	
Taurine (extruded)	%	0.10	0.10	
Taurine (canned)	%	0.20	0.20	

[a]Presumes an energy density of 4000 kcal ME/kg as determined in accordance with Regulation PF9. Formulations greater than 4000 kcal ME/kg should be corrected for energy density; formulations less than 4000 kcal ME/kg should not be corrected for energy. Formulations of low-energy density should not be considered adequate for growth or reproductive needs based on comparison to the Profiles alone.
[b]Recommended concentrations for maintenance of body weight at an average caloric intake for cats of a given optimal weight.
[c]Although a true requirement for crude fat per se has not been established, the minimum concentration was based on recognition of crude fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.
[d]ND = not determined.
[e]If the mean urine pH of cats fed *ad libitum* is not below 6.4, the risk of struvite urolithiasis increases as the magnesium content of the diet increases.
[f]Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration.
[g]Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration.
[h]Add 10 IU vitamin E above the minimum concentration for each gram of fish oil per kilogram of diet.
[i]Vitamin K does not need to be added unless the diet contains more than 25% fish on a dry matter basis.
[j]Because processing and specific ingredients may destroy up to 90% of the thiamine in the diet, allowances in formulation should be made to ensure the minimum nutrient concentration is met after processing.
[k]Biotin does not need to be added unless the diet contains antimicrobial or antivitamin compounds.

AAFCO Cat Food Nutrient Profiles Based on Calorie Content

Nutrient	Units per 1000 kcal ME	Growth and Reproduction Minimum	Adult Maintenance Minimum[a]	Maximum
Crude protein	g	75	65	
Arginine	g	3.10	2.60	
Histidine	g	0.83	0.78	
Isoleucine	g	1.40	1.30	
Leucine	g	3.20	3.10	
Lysine	g	3.00	2.08	
Methionine	g	1.55	0.5	3.75
Methionine-cystine	g	2.75	1.00	
Phenylalanine	g	1.30	1.05	
Phenylalanine-tyrosine	g	4.80	3.83	
Threonine	g	1.83	1.83	
Tryptophan	g	0.63	0.40	4.25
Valine	g	1.55	1.55	
Crude fat[b]	g	22.5	22.5	
Linoleic acid	g	1.40	1.40	
alpha-Linolenic acid	g	0.05	ND[c]	
Arachidonic acid	g	0.05	0.05	
Eicosapentaenoic + Docosahexaenoic acid	g	0.03	ND	
Minerals				
Calcium	g	2.5	1.5	
Phosphorus	g	2.0	1.25	
Potassium	g	1.5	1.5	
Sodium	g	0.5	0.5	
Chloride	g	0.75	0.75	
Magnesium[d]	g	0.20	0.10	
Iron[e]	mg	20.0	20.0	
Copper (extruded)[f]	mg	3.75	1.25	
Copper (canned)[f]	mg	2.10	1.25	
Manganese	mg	1.90	1.90	
Zinc	mg	18.8	18.8	
Iodine	mg	0.45	0.15	2.25
Selenium	mg	0.075	0.075	
Vitamins and others				
Vitamin A	IU	1667	833	83,325

(continued)

Nutrient	Units per 1000 kcal ME	Growth and Reproduction Minimum	Adult Maintenance Minimum[a]	Maximum
Vitamin D	IU	70	70	7520
Vitamin E[g]	IU	10	10	
Vitamin K[h]	mg	0.025	0.025	
Thiamine[i]	mg	1.40	1.40	
Riboflavin	mg	1.00	1.00	
Pantothenic acid	mg	1.44	1.44	
Niacin	mg	15	15	
Pyridoxine	mg	1.0	1.0	
Folic acid	mg	0.20	0.20	
Biotin[j]	mg	0.018	0.018	
Vitamin B_{12}	mg	0.005	0.005	
Choline	mg	600	600	
Taurine (extruded)	g	0.25	0.25	
Taurine (canned)	g	0.50	0.50	

[a]Recommended concentrations for maintenance of body weight at an average caloric intake for cats of a given optimal weight.
[b]Although a true requirement for crude fat per se has not been established, the minimum concentration was based on recognition of crude fat as a source of essential fatty acids, as a carrier of fat-soluble vitamins, to enhance palatability, and to supply an adequate caloric density.
[c]ND = not determined.
[d]If the mean urine pH of cats fed *ad libitum* is not below 6.4, the risk of struvite urolithiasis increases as the magnesium content of the diet increases.
[e]Because of very poor bioavailability, iron from carbonate or oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration.
[f]Because of very poor bioavailability, copper from oxide sources that are added to the diet should not be considered in determining the minimum nutrient concentration.
[g]Add 10 IU vitamin E above the minimum concentration for each gram of fish oil per kilogram of diet.
[h]Vitamin K does not need to be added unless the diet contains more than 25% fish on a dry matter basis.
[i]Because processing and specific ingredients may destroy up to 90% of the thiamine in the diet, allowances in formulation should be made to ensure the minimum nutrient concentration is met after processing.
[j]Biotin does not need to be added unless the diet contains antimicrobial or antivitamin compounds.

Changes to and Rationale for Nutrient Concentrations—Cat Foods

Caloric Density

The 2007 AAFCO Feline Nutrition Expert Subcommittee (FNES) retained the presumed caloric density for cat food products at 4000 kcal ME/kg DM for both the nutrient concentrations per kg DM and the nutrient amounts per 1000 kcal ME. As discussed below and in the footnotes to the Tables of the AAFCO Cat Food Nutrient Profiles, products with a caloric density greater than 4000 kcal ME/kg should have nutrient concentrations corrected for energy density. Nutrient concentrations in products with energy densities less than 4000 kcal ME/kg should not be corrected.

Protein

The 2007 FNES did not change the minimum concentrations of crude protein in the Cat Food Nutrient Profiles, the current values being equal to or greater than the corresponding 2006 NRC RA and FEDIAF Guidelines.[1,3] The FNES made modifications to concentrations for some essential amino acids to bring the recommended concentrations in line with the RA in the 2006 NRC and the FEDIAF Guidelines. Minor increases between 0.02 to 0.04% in amounts of histidine, isoleucine and leucine were made in the Growth and Reproduction Profile. The amount for methionine and methionine plus cystine was decreased for adult maintenance. Significant increases were made to the recommended phenylalanine and phenylalanine plus tyrosine concentrations to bring the recommendations in line with the RA in the 2006 NRC which are based on studies establishing the requirements for maximum nitrogen retention and black hair color.[20,21]

Because of work showing an adverse effect of high concentrations of methionine, the maximum concentration of 1.5% was retained.[22] The FNES also set a maximum of 1.7% for tryptophan based on the work of Herwill and the recommendations in the 2006 NRC and FEDIAF Guidelines.[1,3,23]

Fat/Fatty Acids

The 2007 FNES retained the minimum recommended concentrations of crude fat at 9% DM and at 0.02% for arachidonic acid. The minimum concentration for linoleic acid was increased to 0.6% in both Cat Food Nutrient Profiles consistent with the corresponding 2006 NRC RA and FEDIAF Guidelines. Similar to the CNES, the FNES established minimum recommended concentrations for some fatty acids in the n-3 (omega-3) series in the Growth and Reproduction Profile, specifically, alpha-linolenic acid at 0.02%, and the combination of eicosapentaenoic plus docosahexaenoic acids at 0.012%, of DM. The FNES notes that the NRC[1] stated no requirement for alpha-linolenic acid in adult cats had been demonstrated and that although a theoretical argument could be made for the adult cat to require eicosapentaenoic plus docosahexaenoic acids on a similar order of magnitude as arachidonic acid given the low delta-6 desaturase activity in the species, no objective data were available to support the establishment of any required concentrations. Although the FNES did not feel there was scientific justification for setting minimum recommended concentrations for n-3 fatty acids for adult cats, a recommendation in a comment to list quantities of alpha-linolenic acid and eicosapentaenoic plus docosahexaenoic acids for adult maintenance as being not determined (ND) was accepted by the AAFCO Pet Food Committee.

Minerals

The 2007 FNES increased the recommended concentrations for copper in canned formulas in the Growth and Reproduction Nutrient Profile and for iodine and selenium

in both Cat Food Nutrient Profiles. The recommended copper concentration in canned products for growth and reproduction was increased from 5.0 to 8.4 mg/kg DM to match the 2006 NRC RA for gestation and lactation.

For iodine the 2007 FNES increased the recommended concentration in the Growth and Reproduction Nutrient Profile to match the 2006 NRC RA and the FEDIAF Guidelines. The recommended concentration of iodine for adult maintenance was increased to match the amount recommended in the FDIAF Guidelines rather than the 2006 NRC RA in consideration of the findings of Wedekind *et al.*[24] The 2007 FNES also set a maximum for iodine content in cat foods based on the findings of Wedekind *et al.*[24]

The 2007 FNES increased the recommended concentrations for selenium in the Cat Food Nutrient Profiles from 0.1 to 0.3 mg/kg to match the recommendations of the 2006 NRC RA and the FEDIAF Guidelines. The 2007 FNES elected to delete the maximum recommended amount of zinc from the Cat Food Nutrient Profiles noting that the 2006 NRC indicated the safe upper limit of zinc for cats was > 600 mg/kg DM for at least short periods of time and that the swine tolerance of 1000 mg/kg DM was the greatest concentration for any tolerance for zinc listed in the 2005 *Mineral Tolerance of Animals*. The FNES retained the recommended concentrations set by the 1990 FNES for all other minerals in the Cat Food Nutrient Profiles.

Vitamins and Others

The 2007 FNES decreased the recommended minimum concentrations for vitamins A and D in the Cat Food Nutrient Profiles based on the 2006 NRC RA. The 2007 FNES increased the maximum concentration for vitamin D in the Cat Food Nutrient Profiles based on the work of Sih *et al.* and the SUL in the 2006 NRC.[25]

The 2007 FNES increased the recommended concentration of vitamin E to more closely coincide with the recommendations of the 2006 NRC and the FEDIAF Guidelines. The recommended concentration of vitamin K in diets containing 25% or more DM derived from fish was unchanged from previous values consistent with the FEDIAF Guidelines.

Recommended concentrations of thiamine and pantothenic acid in the Cat Food Nutrient Profiles were increased to match the 2006 NRC RA. The recommended concentrations of the remaining water soluble vitamins and for taurine were unchanged from the previous values, several being equal or greater than the 2006 NRC RA (riboflavin, niacin, pyridoxine, folic acid and taurine) with previous recommended concentrations for biotin, vitamin B_{12} and choline being between the 2006 NRC AI and RA.

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Correcting for Moisture Content

The values given in the Profiles are listed in terms of dry matter (DM). However, the values listed in the guaranteed analysis on dog and cat food labels are given on an "as is" or "as fed" (AF) basis, and values reported from laboratories may be given on either an AF or DM basis. The difference between a value reported on a DM basis versus an AF basis is proportional to the moisture (water) content of the food. The greater the moisture content of a food, the greater the food's DM values for nutrients would be compared to the corresponding AF values. This discrepancy makes direct comparison between the guaranteed analysis values on a food label and the Profile table values impossible without first correcting one or the other set of values so that both are on an equal-moisture basis.

One method of correcting for moisture is the adjustment of the values listed in the guaranteed analysis or reported from a laboratory on an AF basis to a DM basis before comparing with the Profile values. This is done by dividing each AF value by the proportion of DM in the food [(100 − % moisture)/100]. The examples shown below use the guaranteed analysis values, but these adjustments are equally valid for actual laboratory results reported on an AF basis.

Example A1: A Dry Dog Food Making a Growth Claim: Moisture-Adjusted Guaranteed Analysis Values

Nutrient	Guaranteed Analysis Values	Dog Food Nutrient Profile Minimum Values for Growth	Moisture-Adjusted Guaranteed Analysis Values	Moisture-Adjusted Guaranteed Analysis vs. Profile Values
Crude protein	min. 21%	22.5%	23.3%	OK
Crude fat	min. 8%	8.5%	8.9%	OK
Crude fiber	max. 4%		4.4%	
Moisture	max. 10%	0%	0%	
Calcium	min. 1.1%	1.2%	1.2%	OK
Phosphorus	min. 0.9%	1.0%	1.0%	OK

Directly comparing the guaranteed values in Example A1 for crude protein, crude fat, calcium, and phosphorus to the minimum values for growth given in the Dog Food Nutrient Profile indicates this food would appear to be deficient. However, this comparison is not valid, because the values for the food are listed on a 10% moisture (90% DM) basis, but the Profile values are given on a 0% moisture (100% DM) basis. To put both sets of values on an equal-moisture basis, the guaranteed values were adjusted to 100% DM by dividing each value by the proportion of DM in the food (0.90). With this correction, it becomes apparent that the moisture-adjusted guaranteed analysis values of the reported nutrients do, in fact, meet the minimum recommended concentrations of the Dog Food Nutrient Profile for Growth and Reproduction.

As an alternative method to converting the guaranteed values to a DM basis, the Profile values can be adjusted to match the moisture content of the food. This can be achieved by simply multiplying each Profile value by the proportion of DM in the food (0.9 in example A1). Such calculations yield the following:

Example A2: A Dry Dog Food Making a Growth Claim: Moisture-Adjusted Guaranteed Analysis Values

Nutrient	Guaranteed Analysis Values	Dog Food Nutrient Profile Minimum Values for Growth	Moisture-Adjusted Profile Values for Growth	Guaranteed Analysis vs. Moisture-Adjusted Profile Values
Crude protein	min. 21%	22.5%	20.25%	OK
Crude fat	min. 8%	8.5%	7.65%	OK
Crude fiber	max. 4%			
Moisture	max. 10%	0%	10%	
Calcium	min. 1.1%	1.2%	1.08%	OK
Phosphorus	min. 0.9%	1.0%	0.9%	OK

Correcting for Energy Density

The values given in the Profiles presume an energy density of 4000 kcal ME/kg DM. Some dog and cat foods will have energy densities close to this amount. However, many products may have DM energy densities considerably greater than the presumed values. When these more energy-dense products are fed, the dog or cat will require less of the food to meet its caloric requirements. Under these circumstances, the concentrations of the other nutrients in the food should be increased proportionately, so that the dog or cat will receive the needed amount of each nutrient in the smaller amount of food. Therefore, when the energy density of the dog or cat food exceeds 4000 kcal ME/kg DM the nutrient concentrations should be corrected for caloric content before valid comparisons to the appropriate AAFCO Nutrient Profile are made.

Conversely, products could be much lower in energy density than 4000 kcal ME/kg DM. Theoretically, a lower concentration of the other nutrients should be required, assuming that the dog or cat is allowed, and able, to consume enough of the product to meet its caloric needs and that those caloric needs are typical for the average dog or cat of the specific life stage. Because this assumption does not always hold true, the nutrient content should not be decreased in less energy-dense products, that is, the nutrient concentrations in such products should not be corrected for energy density. In fact, if the food is intended to supply significantly fewer calories in somewhat smaller amounts of food than typically consumed by the average weight and specific life stage of the animal, the concentrations of some nutrients per 1000 kcal ME may need to be increased compared to amounts listed in the tables to ensure the animal is provided adequate amounts of those essential nutrients in the quantity of food containing the targeted consumption of daily calories. Furthermore, unless a product meeting the definition for a “lite” or “low calorie” product as specified in Model Regulation PF10 has successfully passed the appropriate AAFCO Feeding Protocols, the product should not be considered adequate for growth or reproduction, regardless of the concentrations of the other nutrients.

The first step in correcting for energy density is to determine the actual energy density of the food. The determination should be done in accordance with Model Regulation PF9. After determining the energy density of the food, the nutrient values can be converted to a per 4000 kcal ME/kg DM or a per 1000 kcal ME basis and compared to the values in the appropriate AAFCO Nutrient Profile.

Example B1: A Canned Cat Food Making a Growth Claim: Moisture- and Energy-Adjusted Guaranteed Analysis Values

Nutrient	Guaranteed Analysis Values	Moisture-Adjusted Guaranteed Analysis Values	Moisture- and Energy-Adjusted Guaranteed Analysis Values	Growth and Reproduction Cat Food Profi Values per kg DM	Status of Energy-Adjusted Guaranteed Analysis vs. Profi Values
Crude protein	min. 9%	36%	32.1%	30.0	OK
Crude fat	min. 7%	28%	25%	9.0	OK
Crude fiber	max. 1%				
Moisture	max. 75%	0%	0%		
Ash	max. 2%				
Calcium	min. 0.25%	1.0%	0.89%	1.0	Low
Phosphorus	min. 0.2%	0.8%	0.71%	0.8	Low
Energy[a]	1120 kcal ME/kg AF	4480 kcal ME/kg DM	4000 kcal ME/kg DM	4000 kcal ME/kg DM	

[a]Energy = (3.5 × g crude protein) + (8.5 × g crude fat) + [3.5 × g nitrogen-free extract (CHO)] = (3.5 × 90) + (8.5 × 70) + (3.5 × 60) = 1120; % nitrogen-free extract = 100 − (% crude protein + % crude fat + % crude fiber + % moisture + % ash)

A cursory examination of the values listed in the guaranteed analysis compared to the minimum values given in the Cat Food Nutrient Profiles expressed as per kg DM containing 4000 kcal ME revealed that a direct comparison would not be valid. Because the food in Example B1 was 75% moisture (25% DM), the major reason for the discrepancy was likely due to water content. By first dividing the guaranteed values by the proportion of DM (0.25), the moisture-adjusted guaranteed values were derived. Comparing these corrected values with the Profile values, this food appeared to meet the minimums for a growth claim.

However, in this example, direct comparison of the moisture-adjusted guaranteed values with the Profile values was premature. The high DM crude fat content of the food compared to the Profile value (25% vs. 9.0%) was an indication that the food was probably more energy-dense than the Profile value of 4000 kcal ME/kg DM. When calculated, in fact, it was found to be 4480 kcal ME/kg DM (1120 kcal ME/kg AF). Therefore a second adjustment to account for the differences in energy density was warranted. This was achieved by dividing each moisture-adjusted guaranteed value by 4480 (the DM energy density of the food) and then multiplying the result by 4000 (the standard energy density). This second manipulation revealed that the energy-adjusted guaranteed analysis values for the calcium and phosphorus were, in fact, below minimum concentrations for growth.

As demonstrated with the moisture correction methods above, an alternative to correcting the values of the food to meet the Profile energy density is correcting the Profile values to meet the food's energy density. Below, each Profile value was divided by 4000, and the result was multiplied by the appropriate value for energy density (1120 in this example).

Example B2: A Canned Cat Food Making a Growth Claim: Energy-Adjusted Profile DM Values

Nutrient	Guaranteed Analysis Values	Cat Food Nutrient Profile Minimum Values for Growth	Energy-Adjusted Profile Values	Guaranteed vs. Energy-Adjusted Profile Values (Column 2 vs. 4)
Crude protein	min. 9%	30.0%	8.4%	OK
Crude fat	min. 7%	9.0%	2.5%	OK
Crude fiber	max. 1%			
Moisture	max. 75%			
Ash	max. 2%			
Calcium	min. 0.25%	1.0%	0.28%	Low
Phosphorus	min. 0.2%	0.8%	0.22%	Low
Energy	1120 kcal ME/kg AF	4000 kcal ME/kg DM	1120 kcal ME/kg AF	

Note that although the energy-adjusted minimum for crude fat calculated out to be 2.5%, a much higher concentration of crude fat (in this case 7%) predefined the higher energy density and dictated the need for energy adjustment in the first place. Because for the most part a higher concentration of crude fat predetermines what the higher energy density will be, the energy-adjusted Profile minimum value for crude fat should always be met and will often be grossly exceeded.

The last method for correcting for energy density is to convert the guaranteed values for the food to a per 1000 kcal basis, and to compare these values with those listed in the appropriate Profile based on Calorie Content. This is accomplished by dividing the AF values in the guaranteed analysis by the AF energy density (1120 kcal ME/kg in this example) and then multiplying the result by 1000 kcal ME/kg. The result is the values appearing in the fourth column of Example B3 below with the conclusion being identical to that reached in Examples B1 and B2 above.

Example B3: A Canned Cat Food Making a Growth Claim: Energy-Adjusted Guaranteed Analysis Values

Nutrient	Guaranteed Analysis Values	Amount per kg (1000 g) As Fed	Product Amount per 1000 kcal ME	Profile Amount per 1000 kcal ME	Status
Crude protein	9%	90 g	80.4 g	75	OK
Crude fat	7%	70 g	62.5 g	22.5	OK
Crude fiber	1%	10 g			
Moisture	75%	750 g			
Ash	2%	20 g			
Calcium	0.25%	2.5 g	2.2 g	2.5	Low

(continued)

Nutrient	Guaranteed Analysis Values	Amount per kg (1000 g) As Fed	Product Amount per 1000 kcal ME	Profile Amount per 1000 kcal ME	Status
Phosphorus	0.20%	2.0 g	1.9 g	2.0	Low
Nitrogen-free extract (CHO)[a]	(8%)	60 g			
Energy[b]		1120 kcal			

[a]% nitrogen-free extract = 100 − (% crude protein + % crude fat + % crude fiber + % moisture + % ash)
[b]Energy = (3.5 × 90) + (8.5 × 70) + (3.5 × 60) = 1120

AAFCO Dog and Cat Food Feeding Protocols

A successfully completed, feeding protocol validates the nutritional adequacy of the product's ingredient formula and resulting nutrient profile for the species and life stage(s) to which the product was fed. For the nutritional adequacy claim to be valid, it is expected that the nutrient delivery of the product will not be significantly degraded over the shelf life of the product.

Minimum Feeding Protocol for Proving an Unqualified Representation of Nutritional Adequacy for a Dog or Cat Food

The minimum testing necessary to prove an unqualified claim for nutritional adequacy may be obtained by using the gestation/lactation and the growth protocols. These protocols must be used sequentially. Thus, a manufacturer desiring to prove an unqualified claim for nutritional adequacy must use the litters obtained from performing the gestation/lactation protocol for the growth period. Test puppies or kittens shall receive the test diet as their sole source of nourishment, other than dam's or queen's milk, during lactation, weaning, and growth.

Selection of puppies or kittens shall be on a statistically sound basis from each of the litters qualifying for the gestation/lactation protocol with equal sex distribution preferred.

Minimum Feeding Protocol for Proving an Adult Maintenance Claim for a Dog Food

Dogs

A minimum of eight healthy adult dogs at least one year of age and of optimal body weight shall be required to start the test. Bitches in gestation or lactation shall be excluded. All animals starting the test must pass an initial physical examination by a veterinarian. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. A minimum of 30 dogs shall be required for developing a historical colony average, with data used to establish averages for all parameters coming from the same individual dogs. A minimum of eight dogs shall be required for the concurrent control group. Breed distribution shall be similar in all groups.

Diet

The same formulation shall be fed throughout the test although different production

batches may be used. Diets fed to a concurrent control group or to dogs in the

determination of historical colony averages must have successfully passed the minimum feeding protocol for an adult maintenance claim for a dog food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall run for a minimum of 26 weeks and shall begin when dogs are placed on the test diet.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Dogs shall be fed *ad libitum* or based on energy needs. Fresh water shall be provided *ad libitum*. Any interruption in the feeding protocol must be disclosed and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption shall be measured and recorded for all animals if any animal is removed for poor food intake.
(2) Individual body weights shall be measured and recorded at the beginning, weekly, and at the end of the test.
(3) Hemoglobin, packed cell volume, serum alkaline phosphatase and serum albumin shall be measured and recorded at the end of the test.
(4) All dogs shall be given a complete physical examination by a veterinarian at the beginning and at the end of the test. Each dog shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.
(5) Any medication and the reason for its use must be recorded.
(6) A number of dogs, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Dogs may be removed for poor food intake only during the first two weeks of the test. Data already collected from dogs removed from the test shall be retained although it does not have to be included in the final results.
(7) A necropsy shall be conducted on any dog which dies during the test and the findings recorded.

Interpretation

A. The diet shall fail if any dog shows clinical or pathological signs of nutritional deficiency or excess.
B. All dogs not removed for non-nutritional reasons or poor food intake must successfully finish the test.
C. No individual dog shall lose more than 15% of its initial body weight. The average percent body weight change (fi compared to initial) shall not be less than either:
    1. −10%; or
    2. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).
D. The average final hemoglobin, packed cell volume and serum albumin values shall not be less than either:
    1. a. Hemoglobin - 14.0 g/dL (no individual <12.0 g/dL),
        b. PCV - 42% (no individual <36%),
        c. Albumin - 2.8 g/dL (no individual <2.4 g/dL); or

2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

E. The average fi serum alkaline phosphatase value shall not be greater than either:
1. 150 IU/L (no individual >300 IU/L); or
2. The historical colony average plus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
3. The average for the concurrent control group, plus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Optional Procedures

The testing requirements for a maintenance dog food may be met by successfully performing either the growth or gestation/lactation protocols in lieu of performing the maintenance protocol.

Minimum Feeding Protocol for Proving an Adult Maintenance Claim for a Cat Food

Cats

A minimum of eight healthy adult cats at least one year of age and of optimal body weight shall be required to start the test. Queens in gestation or lactation shall be excluded. All animals starting the test must pass an initial physical examination by a veterinarian. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. A minimum of 30 cats shall be required for developing a historical colony average, with data used to establish averages for all parameters coming from the same individual cats. A minimum of eight cats shall be required for the concurrent control group.

Diet

The same formulation shall be fed throughout the test although different production batches may be used. Diets fed to a concurrent control group or to cats in the determination of historical colony averages must have successfully passed a minimum feeding protocol for an adult maintenance claim for a cat food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall run for a minimum of 26 weeks and shall begin when cats are placed on the test diet.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Cats shall be fed *ad libitum* or based on energy needs. Fresh water shall be provided *ad libitum*. Any interruption in the feeding protocol must be disclosed and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption shall be measured and recorded for all animals if any animal is removed for poor food intake.
(2) Individual body weights shall be measured and recorded at the beginning, weekly, and at the end of the test.
(3) Hemoglobin, packed cell volume, serum alkaline phosphatase, serum albumin and whole blood taurine shall be measured and recorded at the end of the test.
(4) All cats shall be given a complete physical examination by a veterinarian at the beginning and at the end of the test. Each cat shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.
(5) Any medication and the reason for its use must be recorded.
(6) A number of cats, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Cats may be removed for poor food intake only during the first two weeks of the test. Data already collected from cats removed from the test shall be retained although it does not have to be included in the final results.
(7) A necropsy shall be conducted on any cat which dies during the test and the findings recorded.

Interpretation

A. The diet shall fail if any cat shows clinical or pathological signs of nutritional deficiency or excess.
B. All cats not removed for non-nutritional reasons or poor food intake must successfully finish the test.
C. No individual cat shall lose more than 15% of its initial body weight. The average percent body weight change (final compared to initial) shall not be less than either:
    1. −10%; or
    2. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).
D. The average final hemoglobin, packed cell volume, whole blood taurine and serum albumin values shall not be less than either:
    1. a. Hemoglobin - 10.0 g/dL (no individual <8.0 g/dL)
        b. PCV - 30% (no individual <24%)
        c. Taurine - 300 nmole/mL (no individual <200 nmole/mL)
        d. Albumin - 2.8 g/dL (no individual <2.4 g/dL); or
    2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
    3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the

two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

E. The average final serum alkaline phosphatase value shall not be greater than:
   1. 100 IU/L (no individual >200 IU/L); or
   2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
   3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Optional Procedures

The testing requirements for a maintenance cat food may be met by successfully performing either the growth or gestation/lactation protocols in lieu of performing the maintenance protocol.

Minimum Feeding Protocol for Proving a Growth Claim for a Dog Food

Puppies

A minimum of eight puppies from three different bitches shall be required to start the test. The puppies shall be no older than eight weeks of age and weaned. All puppies starting the test must pass an initial physical examination by a veterinarian. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. Historical colony averages for weight gain of puppies must be developed for each sex. Colony statistics shall be calculated with at least 30 males to determine the colony male average weight gain ($\mu_{MaleColony}$) ± standard deviation ($\sigma_{MaleColony}$). In addition, at least 30 females shall be used to determine the colony female average weight gain ($\mu_{FemaleColony}$) ± standard deviation ($\sigma_{FemaleColony}$). A minimum of 30 puppies shall be required for developing the historical colony averages for parameters other than weight gain with all data coming from the same individual puppies. When using a concurrent control group, a minimum of eight puppies for the control group and eight puppies for the test group derived from at least three different bitches shall be required to form the test and concurrent control groups. The test group shall have the same gender distribution as the concurrent control group.

Diet

The same formulation shall be fed throughout the test, although different production batches may be used. Diets fed to a concurrent control group or to puppies in the determination of historical colony averages must have successfully passed a minimum feeding protocol for a growth claim for a dog food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall run for a minimum of 10 weeks.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Puppies shall be fed *ad libitum* or based on energy needs. Fresh water shall be provided *ad libitum.*

Puppies may be fed individually or in groups. The historical or concurrent control groups shall be fed in a manner similar to that of the treatment group. Any interruption in the feeding protocol must be disclosed and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption shall be measured and recorded for all animals if any animal is removed for poor food intake.
(2) Individual body weights shall be measured and recorded at the beginning, weekly, and at the end of the test.
(3) Hemoglobin, packed cell volume, and serum albumin shall be measured and recorded at the end of the test.
(4) All puppies shall be given a complete physical examination by a veterinarian at the beginning and at the end of the test. Each puppy shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.
(5) Any medication and the reason for its use must be recorded.
(6) A number of puppies, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Puppies may be removed for poor food intake only during the fi two weeks of the test. Data already collected from puppies removed from the test shall be retained although it does not have to be included in the fi results.
(7) A necropsy shall be conducted on any puppy which dies during the test and the findings recorded.

Interpretation

A. The diet shall fail if any puppy shows clinical or pathological signs of nutritional deficiency or excess.
B. All puppies not removed for non-nutritional reasons or poor food intake must successfully finish the test.
C. The average body weight gain shall not be less than either:
    1. 80% of the historical colony average, with averages for males and females determined separately for both the test and colony groups; or
    2. The average body weight gain for n puppies ($n \geq 8$) shall not be less than either the adjusted historical colony average minus 1.64 times the standard error. (See Appendix 1 for mathematical formulas required to calculate adjusted historical colony average and standard error regarding weight gain); or
    3. The average body weight gain shall not be less than the average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group). (See Appendix 2 for mathematical formulas required to calculate the standard error of the difference of the two group averages for weight gain).
D. The average final hemoglobin, packed cell volume and serum albumin values shall not be less than either:
    1. Hemoglobin - 11.0 g/dL (no individual <9.0 g/dL)
    PCV - 33% (no individual <27%)
    Albumin - 2.6 g/dL (no individual <2.2 g/dL); or
    2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or

3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Minimum Feeding Protocols for Proving a Growth Claim for a Cat Food

Kittens

A minimum of eight kittens from three different queens shall be required to start the test. The kittens shall be no older than nine weeks of age and weaned. All kittens starting the test must pass an initial physical examination by a veterinarian. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. Historical colony averages for weight gain of kittens must be developed for each sex. Colony statistics shall be calculated with at least 30 males to determine the colony male average weight gain ($\mu_{MaleColony}$) ± standard deviation ($\sigma_{MaleColony}$). In addition, at least 30 females shall be used to determine the colony female average weight gain ($\mu_{FemaleColony}$) ± standard deviation ($\sigma_{FemaleColony}$).

A minimum of 30 kittens shall be required for developing the historical colony averages for parameters other than weight gain with all data coming from the same individual kittens. When using a concurrent control group, a minimum of eight kittens for the control group and eight kittens for the test group derived from at least three different queens shall be required to form the test and concurrent control groups. The test group shall have the same gender distribution as the concurrent control group.

Diet

The same formulation shall be fed throughout the test, although different production batches may be used. Diets fed to a concurrent control group or to kittens in the determination of historical colony averages must have successfully passed a minimum feeding protocol for a growth claim for a cat food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall run for a minimum of 10 weeks.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Kittens shall be fed *ad libitum* or according to energy needs. Fresh water shall be provided *ad libitum*. Kittens may be fed individually or in groups. The historical or concurrent control groups shall be fed in a manner similar to that of the treatment group. Any interruption in the feeding protocol must be disclosed and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption shall be measured and recorded for all animals if any animal is removed for poor food intake.
(2) Individual body weights shall be measured and recorded at the beginning, weekly, and at the end of the test.
(3) Hemoglobin, packed cell volume, whole blood taurine, and serum albumin shall be measured and recorded at the end of the test.

(4) All kittens shall be given a complete physical examination by a veterinarian at the beginning and at the end of the test. Each kitten shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.
(5) Any medication and the reason for its use must be recorded.
(6) A number of kittens, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Kittens may be removed for poor food intake only during the first two weeks of the test. Data already collected from kittens removed from the test shall be retained although it does not have to be included in the final results.
(7) A necropsy shall be conducted on any kitten which dies during the test and the findings recorded.

Interpretation

A. The diet shall fail if any kitten shows clinical or pathological signs of nutritional deficiency or excess.
B. All kittens not removed for non-nutritional reasons or poor food intake must successfully finish the test.
C. The average body weight gain shall not be less than either:
    1. 80% of the historical colony average, with averages for males and females determined separately for both the test and colony groups; or
    2. The average body weight gain for n kittens ($n \geq 8$) shall not be less than either the adjusted historical colony average minus 1.64 times the standard error. (See Appendix 1 for mathematical formulas required to calculate adjusted historical colony average and standard error regarding weight gain); or
    3. The average body weight gain shall not be less than the average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group). (See Appendix 2 for mathematical formulas required to calculate the standard error of the difference of the two group averages for weight gain).
D. The average final hemoglobin, packed cell volume, whole blood taurine and serum albumin values shall not be less than either:
    1. a. Hemoglobin - 10.0 g/dL (no individual <8.0 g/dL)
        b. PCV - 29% (no individual <26%)
        c. Taurine - 300 nmole/mL (no individual <200 nmole/mL)
        d. Albumin - 2.7 g/dL (no individual <2.4 g/dL); or
    2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
    3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Minimum Feeding Protocol for Proving a Gestation/ Lactation Claim for a Dog Food

Dogs

Enough bitches shall be used to ensure that a minimum of eight pregnant bitches start the test. The bitches must be in at least their second heat period and at least one year of age. All bitches starting the test must pass an initial physical examination by a veterinarian. There is no specific size or breed requirement, but the bitches and studs must be of the same breed. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. A minimum of 30 bitches shall be required for developing a historical colony average, with data used to establish averages for all parameters coming from the same individual bitches. A minimum of eight bitches shall be required for the concurrent control group. Breed distribution must be similar in all groups.

Diet

The same formulation shall be fed throughout the test, although different production batches may be used. Diets fed to a concurrent control group or to bitches in the determination of historical colony averages must have successfully passed the minimum feeding protocol for a gestation/lactation claim for a dog food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall begin at or before estrus, and shall end when the puppies are 4 weeks of age, independent of age at weaning.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Animals shall be fed *ad libitum* or based on energy needs which are affected by the size of litter being nursed. Fresh water shall be provided *ad libitum*. Any interruption in the feeding protocol must be disclosed, and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption for the bitch during gestation and for the bitch and her puppies during lactation shall be measured and recorded for all animals if any animal is removed for poor food intake.

(2) For each bitch, body weights shall be measured and recorded at breeding, weekly during gestation, within 24 hours after whelping, weekly during lactation, and at the end of the test. For the puppies, body weights shall be measured and recorded within 24 hours after birth, weekly, and at the end of the test.

(3) The litter size at birth, at one day of age, and at the end of the test shall be recorded. Stillbirths and congenital abnormalities shall be recorded.

(4) Hemoglobin, packed cell volume, and serum albumin shall be measured and recorded for the bitch at the end of the test.

(5) All bitches shall be given a complete physical examination by a veterinarian at the beginning of the test, and at the end of the test. Each bitch shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded. All puppies shall be given a complete physical examination by a veterinarian within 72 hours after birth, and at the end of the test. Each puppy shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.

(6) Any medication and the reason for its use must be recorded.

(7) A number of bitches, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Bitches may be removed for poor food intake only during the fi two weeks of the test. Data already collected from bitches or puppies removed from the test shall be retained although it does not have to be included in the fi results.

(8) A necropsy shall be conducted on any bitch or puppy which dies during the test and the findings recorded.

Interpretation

A. The diet shall fail if any bitch or puppy shows clinical or pathological signs of nutritional deficiency or excess.

B. All bitches not removed for non-nutritional reasons or poor food intake must successfully finish the test. Eighty percent of all one-day-old puppies must survive and successfully finish the test.

C. The pregnant bitches on the test shall show weight gain during gestation. The average percent body weight change (breeding through the end of the test) of the bitches shall not be less than either:
   1. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
   2. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).

D. The average weight of the puppies at the end of the test shall not be less than either:
   1. 80% of the historical colony average; or
   2. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals. (See Appendix 1 for mathematical formulas required to calculate adjusted historical colony average and standard error regarding weight gain); or
   3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defi as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group). (See Appendix 2 for mathematical formulas required to calculate the standard error of the difference of the two group averages for weight gain).

E. At the end of the test, the average litter size of the bitches completing the test shall not be less than either:
   1. 80% of the historical colony average; or
   2. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
   3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defi as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).

F. The average final hemoglobin, packed cell volume, and serum albumin values shall not be less than either:
   1. a. Hemoglobin - 10.0 g/dL (no individual <8.0 g/dL),
      b. PCV - 30% (no individual <24%),
      c. Albumin - 2.4 g/dL (no individual <2.2 g/dL); or

2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Minimum Feeding Protocol For Proving a Gestation/ Lactation Claim for a Cat Food

Cats

Enough queens shall be used to ensure that a minimum of eight pregnant queens start the test. The queens must be in at least their second heat period and at least one year of age. All queens starting the test must pass an initial physical examination by a veterinarian. Historical colony averages shall be acquired from a similar population of animals within the same testing facility that accurately represents the size and breed of the test group. A minimum of 30 queens shall be required for developing a historical colony average, with data used to establish averages for all parameters coming from the same individual queens. A minimum of eight queens shall be required for the concurrent control group.

Diet

The same formulation shall be fed throughout the test, although different production batches may be used. Diets fed to a concurrent control group or to queens in the determination of historical colony averages must have successfully passed the minimum feeding protocol for a gestation/lactation claim for a cat food. It may be helpful to consider diet type (i.e., dry vs. semi-moist vs. canned) in establishing colony averages.

Duration of Test

The test shall begin at or before estrus, and shall end when the kittens are 6 weeks of age, independent of age at weaning.

Feeding Parameters

The test diet shall be the sole source of nutrients except for water. Animals shall be fed *ad libitum* or based on energy needs which are affected by the size of litter being nursed. Fresh water shall be provided *ad libitum*. Any interruption in the feeding protocol must be disclosed, and may invalidate the test.

Clinical Observations and Measurements

(1) Individual daily food consumption for the queen during gestation and for the queen and her kittens during lactation shall be measured and recorded for all animals if any animal is removed for poor food intake.

(2) For each queen, body weights shall be measured and recorded at breeding, weekly during gestation, within 24 hours after queening, weekly during lactation, and at the end of the test. For the kittens, body weights shall be measured and recorded within 24 hours after birth, weekly, and at the end of the test.

(3) The litter size at birth, at one day of age, and at the end of the test shall be recorded. Stillbirths and congenital abnormalities shall be recorded.
(4) Hemoglobin, packed cell volume, whole blood taurine, and serum albumin shall be measured for the queen at the end of the test.
(5) All queens shall be given a complete physical examination by a veterinarian at the beginning of the test and at the end of the test. Each queen shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded. All kittens shall be given a complete physical examination by a veterinarian within 72 hours after birth, and at the end of the test. Each kitten shall be evaluated as to general health, body and hair coat condition, and comments shall be recorded.
(6) Any medication and the reason for its use must be recorded.
(7) A number of queens, not to exceed 25% of those starting the test, may be removed for non-nutritional reasons or poor food intake. The reason for their removal must be recorded. Queens may be removed for poor food intake only during the first two weeks of the test. Data already collected from queens or kittens removed from the test shall be retained although it does not have to be included in the final results.
(8) A necropsy shall be conducted on any queen or kitten which dies during the test and findings recorded.

Interpretation

A. The diet shall fail if any queen or kitten shows clinical or pathological signs of nutritional deficiency or excess.
B. All queens not removed for non-nutritional reasons or poor food intake must successfully finish the test. Eighty percent of all one-day-old kittens must survive and successfully finish the test.
C. The pregnant queens on the test shall show weight gain during gestation. The average percent body weight change (breeding through the end of the test) of the queens shall not be less than either:
    1. −10% (no individual < −15%); or
    2. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals: or
    3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).
D. The average weight of the kittens at the end of the test shall not be less than either:
    1. 80% of the historical colony average; or
    2. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root number of test animals. (See Appendix 1 for mathematical formulas required to calculate adjusted historical colony average and standard error regarding weight gain); or
    3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group). (See Appendix 2 for mathematical formulas required to calculate

the standard error of the difference of the two group averages for weight gain).

E. At the end of the test, the average litter size of the queens completing the test shall not be less than either:
   1. 80% of the historical colony average; or
   2. The historical colony average minus 1.64 times the standard error. The standard error is defined as the colony standard deviation divided by the square root number of test animals; or
   3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 1.76 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.05$, if $n = 8$ per group).

F. The average final hemoglobin, packed cell volume, whole blood taurine and serum albumin values shall not be less than either:
   1. a. Hemoglobin - 9.5 g/dL (no individual <8.0 g/dL)
      b. PCV - 29% (no individual <26%)
      c. Taurine - 300 nmole/mL (no individual <200 nmole/mL)
      d. Albumin - 2.7 g/dL (no individual <2.4 g/dL); or
   2. The historical colony average minus 2.33 times the standard error. The standard error is defined as the colony standard deviation divided by the square root of the number of test animals; or
   3. The average for the concurrent control group, minus the allowance for normal variation. The allowance for normal variation is defined as 2.62 times the pooled estimate of the standard error of the difference of the two group averages (one-tailed, two sample *t*-test at $p \leq 0.01$, if $n = 8$ per group).

Criteria for Substantiation of Continued Validity of Nutritional Adequacy Based on Feeding Protocol Results

Definition

A protocol substantiated formula is a dog or cat food, whether marketed or not, that has passed one or more AAFCO dog or cat food feeding protocols for substantiation of nutritional adequacy of one or more life stages. These are products that comply with Model Regulation (MR) PF7(a)(2) or PF7(b)(2)(B). A protocol substantiated formula may be a Product Family lead product. A protocol substantiated formula may carry a claim of nutritional adequacy substantiated via animal feeding protocol in compliance with PF7(c)(1)(B). A Product Family Member can be established according to the Procedures For Establishing Product Families. These Product Family Members may also carry a claim of nutritional adequacy substantiated via animal feeding protocol in compliance with PF7(c)(1)(B), provided they have been tested in a feeding protocol for determining metabolizable energy.

Formula Changes

Substitution of one or more different ingredients for ingredients used in a protocol substantiated formula necessitates redoing the previously passed protocol(s) in order to retain a nutritional adequacy claim permitted by MR PF7(c)(1)(B), unless the manufacturer has data on file that are sufficient to establish that the protocol substantiated formula is the lead member of a Pet Food Product Family and the new formula meets the criteria for being a member of the product family for bearing the claim specified in MR PF7(c)(1)(B). Substitution of one or more different ingredients for ingredients used in a

Product Family Member formula necessitates re-establishing that the new formula meets the criteria for being a member of the product family.

A change in ingredient proportions in a protocol substantiated formula that mandates a reordering of the listed ingredients according to their predominance of weight necessitates redoing the previously passed protocol(s) in order to retain a nutritional adequacy claim permitted by MR PF7(c)(1)(B), unless the manufacturer has data on file that are sufficient to establish that the protocol substantiated formula is the lead member of a Pet Food Product Family and the new formula meets the criteria for being a member of the product family.

Marketed Formulas

Every 5 years a manufacturer shall demonstrate continued validity of its marketed protocol substantiated formula products that bear a nutritional adequacy statement permitted in MR PF7(c)(1)(B) by producing data sufficient to show that the mean of six analyses from six independent, randomly selected batches of the currently marketed formula contains at least 95% of each of the key nutrients (dog and cat foods: crude protein, calcium, phosphorus, zinc, lysine, thiamine; plus for cat foods: potassium and taurine) used for establishment of a family member product using data from analyses of the original formula used in the feeding protocol(s) as the original nutrient values. The absence of data necessary to establish the original protocol substantiated formula as a lead product in a Pet Food Product Family for formulas marketed for 5 or more years necessitates redoing the previously passed protocol(s) in order to retain a nutritional adequacy claim permitted by MR PF7(c)(1)(B),

Every 5 years, a manufacturer shall demonstrate continued validity of its Product Family Members that bear a nutritional adequacy statement permitted in MR PF7(c)(1)(B) by producing data sufficient to show that the currently marketed formula meets the criteria for being a member of a Pet Food Product Family using data from the original feeding protocol(s) as the lead product criteria for establishment of a Pet Food Product Family.

Appendix 1: Calculation Formulas for Adjusted Colony Average and Standard Error for Weight Gain of Puppies or Kittens.

These mathematical formulas are to be used when evaluating weight gain produced by a test diet against the historical colony average.

$$\text{Adjusted Colony Average} = \frac{\left(\text{No. of TestMales} \times \mu_{\text{MaleColony}}\right) + \left(\text{No. of TestFemales} \times \mu_{\text{FemaleColony}}\right)}{N}$$

The Colony standard error is defined as:

$$\text{SE} = \sqrt{\frac{\sigma^2_{\text{MaleColony}} + \sigma^2_{\text{FemaleColony}}}{2 \times N}}.$$

Appendix 2: Calculation Formulas for Standard Error of the Difference Between Test and Concurrent Control Group for Weight Gain of Puppies or Kittens

These mathematical formulas are to be used when evaluating weight gain produced by a test diet against weight gain produced by a concurrent control group fed a diet having successfully passed the same feeding protocol.

Calculate the following test statistics:

Puppies or Kittens	Standard Deviation	*n*
Male Test (MT)	SD_{MT}	n_{MT}
Female Test (FT)	SD_{FT}	n_{FT}
Male Control (MC)	SD_{MC}	n_{MC}
Female Control (FC)	SD_{FC}	n_{FC}

$$SE_{diff} = \sqrt{\frac{(n_{MT}-1)\times SD_{MT}^2+(n_{MC}-1)\times SD_{MC}^2+(n_{FT}-1)\times SD_{FT}^2+(n_{FC}-1)\times SD_{FC}^2}{n_{MT}+n_{MC}+n_{FT}+n_{FC}-4}\times\left[\frac{2}{N}\right]}$$

Note: The test and control groups of N each ($N \geq 8$) must contain at least 2 male pairs or at least 2 female pairs.

If the test (T) and control (C) are composed of all male or all female offspring then the standard error of the difference of the two group averages simplifies to:

$$SE_{diff} = \sqrt{\frac{SD_T^2+SD_C^2}{N}},$$

Procedures For Establishing Pet Food Product Families

When pet food manufacturers substantiate nutritional adequacy by animal feeding tests performed in accordance with the AAFCO feeding protocols for dog and cat foods, and wish to establish product families, the following procedures shall be followed:

A. *Each company may establish families of products which are nutritionally similar to a lead product produced by that company which has been successfully test-fed by the appropriate AAFCO feeding protocol(s). The other products within the established family must meet the following criteria:*
   1. All products within a family must be of the same processing type;
   2. All products within a family must also be in the same moisture content category (less than 20%, 20% or more but less than 65%, 65% or more) as determined by the same analytical method; and
   3. The label for the family members must bear a statement of nutritional adequacy for the same or less demanding life stage for which the lead product was successfully tested. Life stages in descending order are "all life stages," gestation/lactation or growth, and maintenance; and
   4. The dry matter metabolizable energy (ME) content of the product family member (same Method for both lead and family member) must be within ±7.5% of the lead product's dry matter ME content as determined by either an animal feeding study using the AAFCO "Minimum Protocol for Use in the Determination of Metabolizable Energy of Dog and Cat Foods" which has been corrected for moisture content, or the "Modified Atwater" formula as found in AAFCO Official Pet Food Regulation PF9(a)(3)(A) which has been corrected for moisture content; and
   5. The product family member must:
      a. Meet, as determined by laboratory analysis, the dry matter nutrient levels and ratios of the lead family product for crude protein, calcium, phosphorus, zinc, lysine, thiamine, and additionally potassium and taurine for cat foods; and
      b. All other nutrients in the AAFCO Nutrient Profile shall be formulated to meet or exceed the nutrient levels and ratios of the lead family product or the AAFCO Nutrient Profiles, whichever is lower and shall not exceed the maximums established by the AAFCO Nutrient Profiles; and
   6. Nutritional adequacy statement:
      a. The lead product, whose nutritional adequacy is substantiated by an AAFCO Animal Feeding Protocol shall bear a label statement consistent with AAFCO Official Pet Food Regulation PF7(c)(1)B. Family members whose ME is substantiated by an ME feeding study shall bear the same label statement.
      b. Family members whose ME is substantiated by using the "Modified Atwater" formula shall bear a label statement consistent with the AAFCO Official Pet Food Regulation PF7(c)(1)C.

B. *When formula changes are made to family members, life stage feeding tests need not be conducted unless the product does not meet the requirements established for the family.*

C. *Affidavits shall be made available upon request to the state control official for the lead product and for each product within the established family.*

AAFCO Dog and Cat Food Metabolizable Energy Protocols

Method 1: Quantitative Collection

I. Animals

A minimum of six (6) fully grown animals at least one (1) year of age shall complete the test. The animals shall be in good health and of known weight. Animals shall be individually housed in metabolism cages. If urine is not collected and metabolizable energy is calculated based on correction factors for urine energy loss as specified in the protocol, protected covered runs may be used in lieu of metabolism cages.

II. Feeding Procedures

Feeding procedures shall be standardized. The feeding shall consist of two phases. The first phase shall be the pre-collection period of at least five (5) days with the objective of acclimating the test animals to the diet and adjusting food intake, as necessary, to maintain body weight. The second phase shall be the total collection period of at least five (5) days (120 hours). The amount of food offered during the second phase shall remain constant. Food intake shall be recorded throughout both phases.

III. Food

Food type, flavor, and production codes representing the composite feed shall be recorded. The food source shall remain constant throughout the test period.

IV. Food Allowances

The amount of food presented to each animal may be based upon existing data on the quantity of food required to maintain body weight, or the estimated daily energy needs required for maintenance of various weights of dogs (Table 5, 1985 Nutrient Requirements of Dogs, NRC, or 132 kcal ME times body weight in kilograms to the 0.75 power) or cats (Table 4, 1986 Nutrient Requirements of Cats, NRC, or 70 kcal ME per kilogram body weight). *Ad libitum* feeding also may be used.

V. Times of Feeding

Animals shall be fed at least once daily and at the same time each day. Water shall be available at all times. Food shall be fed as is, or per normal feeding instructions for the product. The excess food shall be weighed back after the feeding.

VI. Pre-Trial Termination

If, during the pre-collection phase, the food is continually rejected or results in minimal consumption by a majority of the animals, the trial shall not proceed into the collection phase.

VII. Feces Collection

It is imperative that all collection containers be clearly marked using double labels. The labels shall include the animal number, diet number, and dates of collection. Feces shall be collected daily over 120 hours. Every effort should be made to collect all of the feces and avoid collecting hair. The methodology is as follows:

1. Weigh collection container and record weight.
2. Place feces in the respective animal's container for that day of collection. Collect feces as quantitatively as possible.
3. Place collections in freezer for storage.

4. Feces may be dried each day.
    a. Weigh and record the weight of the feces and container each day, and determine net weight of feces. If the volume of feces is large, an aliquot may be retained for drying.
    b. Dry daily feces collection (or aliquot). Feces should be thin enough to dry quickly. Otherwise, nitrogen and carbon losses may occur due to fermentation products.
    c. Composite the entire 120-hour collection or proportional aliquots.

VIII. Sample Preparation

A. Food

The food shall be blended to ensure a uniform consistency and an adequate quantity used for appropriate assays. Ample quantities of the remaining sample should be frozen and retained until assay results have been reviewed and found acceptable.

B. Feces

Feces shall be analyzed using composite samples. The samples shall be blended to ensure a uniform consistency and an adequate quantity used for appropriate assays. Ample quantities of the remaining sample should be frozen and retained until assay results have been reviewed and found acceptable.

C. Urine

If urine collections are made, they shall be for the same period as the feces collections. Urine shall be collected, with a minimum of contamination, in a urine receptacle containing sulfuric acid to stabilize the urine and prevent nitrogen loss. After the total urine volume is determined, aliquot samples shall be freeze-dried in an appropriate container.

IX. Analytical Determinations

Prepared samples shall be used for analysis. AOAC International approved analytical methodology shall be used when available. Food, feces, and urine (if collected) shall be assayed for gross energy (bomb calorimetry). If urine is not collected, food and feces also shall be assayed for crude protein.

X. Calculation of Metabolizable Energy

The determination is based on assays of the gross energy consumed, minus the energy in the feces and correction for energy lost in the urine (or energy lost in urine as determined by calorimetry).

A. Without urine collection

Data may be entered into the supporting data worksheet entitled Quantitative Collection Method Without Urine Collection which follows the Affidavit of Dog or Cat Food Caloric Content. Data for food must be entered on an "as fed" (AF) basis. Data for feces may be entered on a dry matter (DM) or wet (as collected) basis. However, all data for feces must be recorded on the same basis.

ME = {gross energy of food consumed − gross energy of feces collected − [(grams protein consumed − grams protein in feces) × correction factor for energy lost in urine]}/amount of food consumed

Correction factor for energy lost in urine = 1.25 kcal/g for dogs, 0.86 kcal/g for cats.

Example:

$$\text{ME (kcal/kg)} = \frac{(a \times b) - (c \times d) - [(b \times e/100) - (d \times f/100)] \times g}{b} \times 1000$$

a = gross energy of food = 4.35 kcal/g
b = amount of food consumed = 1250 g
c = gross energy of feces = 1.65 kcal/g
d = amount of feces collected = 600 g
e = protein in food = 24%
f = protein in feces = 9%
g = correction factor (dog) = 1.25 kcal/g

$a \times b = 4.35 \times 1250 = 5437.5$ kcal gross energy of food consumed
$c \times d = 1.65 \times 600 = 990$ kcal gross energy of feces collected
$b \times e/100 = 1250 \times 24/100 = 300$ g protein of food consumed
$d \times f/100 = 600 \times 9/100 = 54$ g protein in feces
$(300 - 54) \times 1.25 = 307.5$ kcal energy lost in urine

$$\text{ME} = \frac{(5437.5 - 990 - 307.5)}{1250} \times 1000$$

$$= 3310 \text{ kcal ME/kg food}$$

B. With urine collection
Data may be entered into the supporting data worksheet entitled Quantitative Collection Method with Urine Collection which follows the Affidavit of Dog or Cat Food Caloric Content. Data for food must be entered on an "as fed" (AF) basis. Data for feces may be entered on a dry matter (DM) or wet (as collected) basis. However, all data for feces must be recorded on the same basis.

ME = (gross energy of food consumed − gross energy of feces collected − gross energy of urine collected)/amount of food consumed

$$\text{ME (kcal/kg)} = \frac{(a \times b) - (c \times d) - (e \times f)}{b} \times 1000$$

Example:
a = gross energy of food = 4.35 kcal/g
b = amount of food consumed = 1250 g
c = gross energy of feces = 1.65 kcal/g
d = amount of feces collected = 600 g
e = gross energy of urine = 0.25 kcal/mL
f = volume of urine = 1230 mL

$a \times b = 4.35 \times 1250 = 5437.5$ kcal gross energy of food consumed
$c \times d = 1.65 \times 600 = 990$ kcal gross energy of feces collected
$e \times f = 307.5$ kcal gross energy of urine collected

$$\text{ME} = \frac{(5437.5 - 990 - 307.5)}{1250}$$

×1000

= 3310 kcal ME/kg food

Method 2: Indicator Method

I. Animals

A minimum of six (6) fully grown animals at least one (1) year of age shall complete the test. The animals shall be in good health and of known weight. Animals shall be individually housed.

II. Feeding Procedures

Feeding procedures shall be standardized. The feeding shall consist of two phases. The first phase shall be the pre-collection period of at least five (5) days with the objective of acclimating the test animals to the diet and adjusting food intake, as necessary, to maintain body weight. The second phase shall be the collection period, during which aliquots of feces shall be collected from at least three separate days.

III. Food

Food type, flavor, and production codes representing the composite feed shall be recorded. The food source shall remain constant throughout the test period.

Approximately 0.25% chromic oxide shall be uniformly mixed in a quantity of food sufficient to feed all animals for the duration of the pre-collection and collection periods. The chromic oxide should be of high quality and free of soluble chromium. Fisher Certified powder or equivalent is suitable.

For dry diets, the chromic oxide powder should be premixed with a feed ingredient before incorporation into the diet. Although it possibly could be sprayed onto an extruded product, the uniformity of dispersion is questionable.

For canned diets, the chromic oxide powder should be added as an aqueous slurry. To aid in dispersion, a small amount of liquid detergent should be added to the slurry. This should help overcome the hydrophobic nature of chromic oxide and its tendency to form balls in solution.

IV. Food Allowances

The amount of food presented to each animal may be based upon existing data on the quantity of food required to maintain body weight, or the estimated daily energy needs required for maintenance of various weights of dogs (Table 5, 1985 Nutrient Requirements of Dogs, NRC, or 132 kcal ME times body weight in kilograms to the 0.75 power) or cats (Table 4, 1986 Nutrient Requirements of Cats, NRC, or 70 kcal ME per kilogram body weight). *Ad libitum* feeding also may be used.

V. Times of Feeding

Animals shall be fed at least once daily and at the same time each day. Water should be available at all times. Food shall be fed as is, or per normal feeding instructions for the product. The excess food shall be weighed back after the feeding.

VI. Pre-Trial Termination

If, during the pre-collection phase, the food is continually rejected or results in minimal consumption by a majority of the animals, the trial shall not proceed into the collection phase.

VII. Feces Collection

It is imperative that all collection containers be clearly marked using double labels. The labels shall include the animal number, diet number, and dates of collection.

Aliquots of feces from three separate days shall be collected. Every effort should be made to avoid collecting hair. The aliquots shall be dried and composited.

VIII. Sample Preparation

A. Food

The food shall be blended to ensure a uniform consistency and an adequate quantity used for appropriate assays. Ample quantities of the remaining sample should be frozen and retained until assay results have been reviewed and found acceptable.

B. Feces

The feces shall be analyzed using composite samples. The samples shall be blended to ensure a uniform consistency and an adequate quantity used for appropriate assays. Ample quantities of the remaining sample should be frozen and retained until assay results have been reviewed and found acceptable.

IX. Analytical Determinations

Prepared samples shall be used for analysis. AOAC International approved analytical methodology shall be used when available. Food and feces shall be assayed for gross energy (bomb calorimetry), crude protein, and chromium.

Food and feces should be analyzed for chromium by the same method. The preferred method of analysis is atomic absorption spectrophotometry.[1] Controlled sample digestion and oxidation of the chromic oxide to chromates is critical for reproducible results. Colorimetric analysis of chromium is less reproducible than atomic absorption spectrophotometry.

X. Calculation of Metabolizable Energy

The determination is based on assays of the gross energy consumed, minus the energy in the feces and correction for energy lost in the urine. Data may be entered into the supporting data worksheet entitled Indicator Method which follow the Affidavit of Dog or Cat Food Caloric Content. Data for food must be entered on an "as fed" (AF) basis. Data for feces may be entered on a dry matter (DM) or wet (as collected) basis. However all data for feces must be recorded on the same basis.

ME = digestible energy − (digestible protein × correction factor for energy lost in urine)
Correction factor = 1.25 kcal/g for dogs, 0.86 kcal/g for cats

$$\text{DE} = 1 - \frac{\text{gross energy of feces} \times \%\ \text{Cr}_2\text{O}_3\ \text{in food}}{\text{energy of food} \times \%\ \text{Cr}_2\text{O}_3\ \text{in feces}} \times \text{gross energy of food}^{\ \text{gross}}$$

$$\text{DP} = 1 - \frac{\%\ \text{protein in feces} \times \%\ \text{Cr}_2\text{O}_3\ \text{in food}}{\%\ \text{protein in food} \times \%\ \text{Cr}_2\text{O}_3\ \text{in feces}} \times \%\ \text{protein in food}$$

DE (kcal/g food) = $\{1 - [(b \times c)/(a \times d)]\} \times a$

$$\text{DP}\ (\text{g digestible protein/g food}) = \frac{\left\{1 - \left[(f \times c)/(e \times d)\right]\right\}}{100} \times e$$

ME (kcal/kg food) = $[\text{DE} - (\text{DP} \times g)] \times 1000$

Example:

a = gross energy of food = 4.35 kcal/g
b = gross energy of feces = 1.65 kcal/g
c = percent chromic oxide in food = 0.25%
d = percent chromic oxide in feces = 0.52%
e = protein in food = 24%
f = protein in feces = 9%
g = correction factor (dog) = 1.25 kcal/g protein digested

$$DE = \{1 - [(1.65 \times 0.25)/(4.35 \times 0.52)]\} \times 4.35$$
$$= 3.56 \text{ kcal/g food}$$

$$DP = \frac{\left\{1 - \left[(9 \times 0.25) / (24 \times 0.52)\right]\right\} \times 24}{100}$$
$$= 0.197 \text{ g digestible protein/g food}$$

$$ME = 3.56 - (0.197 \times 1.25) \times 1000$$
$$= 3310 \text{ kcal ME/kg food}$$

XI. Reference

[1] Arthur D. The determination of chromium in animal feed and excreta by atomic absorption spectrophotometry. Can Spect 1970; 15:134.

AFFIDAVITS

(a) Affidavit of Pet Food Testing Protocol Completion

[For products labeled with the nutritional adequacy claim referenced in PF7(c)(1)(B)]

Affidavit for Animal Testing

(Company Name)

_____

(Product Name)

1. Affiant is the _____ of _____ and
   (Title) (Company Name)

   is duly authorized to make and execute this Affidavit for and on behalf of said company.
2. Affiant is familiar with the requirements of the Association of American Feed Control Officials (AAFCO) Official Pet Food Regulations 7 (a), (b), (c), and (d). that pertain to the label representations of nutritional adequacy of dog and cat food products.
3. The nutritional representation which appears on the product label that is attached to this Affidavit, has been substantiated by adequate testing. This product has successfully completed the AAFCO _____ Food Feeding Protocol
   (Dog or Cat)
   for _____ .
   (Life Stage(s))

4. The test results substantiating the representation of nutritional adequacy appearing on the attached label have been completed and recorded and such results are on file at _____ .
   (Location of Records)

Name: _____

Title: _____

Signature: _____

Company Name: _____

Address: _____

Subscribed and sworn before me this

_____ Day of _____, 20 .

_____

(Notary Signature)

Pet Food Product Family

Nutritional Similarity Substantiation

I. _
(Company Name)
for _
(Product Name)
for Comparison to _
(Lead Product Name)

II. Moisture Category as determined by the same analytical method for the lead and for this product):

Dry (Less than 20%)

Semi-moist (20% or more but less than 65%)

Canned (65% or more)

III. Processing Type:
This Product: _ Lead Product: _

IV. Life Stage (All Life Stages, Gestation/Lactation or Growth, and Maintenance):
This Product: _ Lead Product: _

V. Metabolizable Energy (ME) Content (dry matter basis):
ME determined by: ☐ AAFCO Animal Feeding Study*
☐ Modified Atwater Formula**
This Product: _ Kcal/kg Lead Product: _ Kcal/kg

VI. Nutrient Levels (determined by laboratory analysis on a dry matter basis):

Key Nutrients	Units	This Product	Lead Product
Crude protein	%		
Calcium	%		
Phosphorus	%		
Zinc	mg/kg		
Lysine	%		
Thiamine	mg/kg		
Potassium (cat only)	%		
Taurine (cat only)	%		

Other nutrients are formulated to meet or exceed the minimum levels and ratios of the lead product or AAFCO Nutrient Profiles, whichever is lower, and shall not exceed the maximums established by the AAFCO Nutrient Profiles. Substantiation for individual nutrients shall be furnished upon request.

*Substantiation of animal feeding study results shall be furnished upon request.

**Data and calculation of ME results shall be furnished upon request.

(b) Affidavit of Pet Food Nutritional Similarity

[For pet food product family members labeled with the nutritional adequacy claim referenced in PF7(c)B and C]

Affidavit

(Company Name)

for

(Product Name)

for Product Comparison to Animal Testing Affidavit

for

(Lead Product Name)

1. Affiant is the (Title) of (Company Name) and is duly authorized to make and execute this Affidavit for and on behalf of said company.
2. Affiant is familiar with the requirements of the (AAFCO) Official Pet Food Regulations PF7(a), (b), (c), and (d) that pertain to the label representation of nutritional adequacy of dog and cat food products.
3. The product to which this Affidavit pertains (listed above and on the product label that is attached) meets the criteria to be considered a member of a family of products whose lead product (listed above and a copy of the label and Affidavit attached) has been substantiated by adequate testing that was performed in accordance with the requirements established by AAFCO for such testing. The information and date verifying such criteria are attached.
4. The nutritional representations made in this Affidavit are based upon scientifically accurate calculations made from the formula for this product and upon a chemical laboratory analysis of the product which are recorded and such results are on file at (Location of Records), and will be furnished to the state feed control official upon request.

Name:

Title:

Signature:

Company Name:

Address:

Subscribed and sworn before me this

Day of , 20 .

(Notary Signature)

(c) Affidavit of Pet Food Formulation – AAFCO Nutrient Profile(s)

[For products labeled with the nutritional adequacy claim referenced in PF7(c)(1)(A)]

Affidavit for

(Company Name) (Product Name)

1. Affiant is the (Title) of (Company Name) and is duly authorized to make and execute this Affidavit for and on behalf of said company.
2. Affiant is familiar with the requirements of the Association of American Feed Control Officials (AAFCO) Official Pet Food Regulations 7(a), (b), (c), and (d) that pertain to the label representation of nutritional adequacy of dog and cat food products.
3. The product to which this Affidavit pertains (listed above and on the product label that is attached) contains ingredients in quantities to meet the nutrient levels for (Life Stage(s)) of the (Dog or Cat).

   This product meets the nutrient levels established in the AAFCO (Dog or Cat) Food Nutrient Profiles for (Growth/Reproduction, Maintenance or All Life Stages).
4. The nutritional representations made in this Affidavit are based upon (scientifically accurate calculations made from the formula for this product) or (upon a chemical laboratory analysis of the product) which are recorded and such results are on file at (Location of Records) and will be furnished to the State Feed Official upon request.

Name:

Title:

Signature:

Company Name:

Address:

Subscribed and sworn before me this

Day of , 20 .

_____

(Notary Signature)

(d) Affidavit of Dog or Cat Food Calorie Content

_____ Affidavit _____ Calorie Content
(Company Name) (Number)

Statement for _____
(Product Name)

1. Affiant is the _____ of _____
(Title) (Company Name)
and is duly authorized to make and execute this Affidavit for and on behalf of said company.

2. Affiant is familiar with the requirements of AAFCO Regulation PF9 concerning label representations as to calorie content statements on dog and cat food products.

3. The product to which this Affidavit pertains contains _____ kcal/kg
metabolizable energy and _____ kcal per _____ (e.g., can, cup, biscuit).

4. The representations made in this Affidavit are based (check one that applies)
   a. upon calculations as per Regulation PF9(a)(3)A, using the following summary data:

   Average crude protein %
   Average crude fat %
   Average crude fiber %
   Average moisture %
   Average ash %
   Calculated NFE %

   b. upon adequate testing of digestibility in accordance with AAFCO procedures as per Regulation PF9(a)(3)B. Supportive summary data are attached.

5. The data substantiating this representation of calorie content are recorded and on file at _____ and will be furnished to the feed control official upon request.

By
(Name)

_____
(Title)

_____
(Signature)

_____
(Company Name)

Subscribed and sworn before me this

_____ Day of , 20 .

_____
(Notary Signature)

Data to Support a Calorie Content Claim

Calculated Method

Batch No.	CP Crude Protein AF[a] (%)	CF Crude Fat AF (%)	CFb Crude Fiber AF (%)	Mo Moisture AF (%)	Ash Ash AF (%)	NFE AF (%)	ME (kcal/kg)
1							
2							
3							
4							
Average							

[a]AF = as fed.

$$\text{NFE (\%)} = 100 - (\text{CP} + \text{CF} + \text{CFb} + \text{Mo} + \text{Ash})$$

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

Quantitative Collection Method Without Urine Collection

Data to Support a Calorie Content Claim

Dog ID No.	*a* Gross Energy of Food AF[a] (kcal/g)	*b* Food Consumed AF (g)	*c* Gross Energy Feces AF (g)	*d* Feces Collected DM[b] (g)	*e* Protein Food AF (%)	*f* Protein Feces DM (%)	*g* Correction Factor (kcal/g)	ME (kcal/g)
1								
2								
3								
4								
5								
6								
							Average ME	

[a]AF = as fed.
[b]DM = dry matter.

$$\text{ME (kcal/kg)} = \frac{(a \times b) - (c \times d) - \left[(b \times e/100) - (d \times f/100)\right] \times g}{b} \times 1000$$

Correction factor = 1.25 kcal/g for dogs, 0.86 kcal/g for cats

Data to Support a Calorie Content Claim

Batch No.	CP Crude Protein AF[a] (%)	CF Crude Fat AF (%)	CFb Crude Fiber AF (%)	Mo Moisture AF (%)	Ash Ash AF (%)	NFE AF(%)	ME (kcal/g)
1							
2							
3							
4							
5							
6							

[a]AF = as fed.

$$\text{NFE (\%)} = 100 - (\text{CP} + \text{CF} + \text{CFb} + \text{Mo} + \text{Ash})$$

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

Quantitative Collection Method with Urine Collection

Data to Support a Calorie Content Claim

Dog ID No.	*a* Gross Energy of Food AF[a] (kcal/g)	*b* Food Consumed AF (g)	*c* Gross Energy Feces AF (g)	*d* Feces Collected DM[b] (g)	*e* Gross Energy Urine (kcal/mL)	*f* Urine Collected (mL)	ME (kcal/g)
1							
2							
3							
4							
5							
6							
						Average ME	

[a]AF = as fed.
[b]DM = dry matter.

$$\text{ME (kcal/kg)} = \frac{[(a \times b) - (c \times d) - (e \times f)]}{b} \times 1000$$

Data to Support a Calorie Content Claim

Batch No.	CP Crude Protein AF[a] (%)	CF Crude Fat AF (%)	CFb Crude Fiber AF (%)	Mo Moisture AF (%)	Ash Ash AF (%)	NFE AF (%)	ME (kcal/kg)
1							
2							
3							
4							
Average							

[a]AF = as fed.

$$\text{NFE (\%)} = (\text{CP} + \text{CF} + \text{CFb} + \text{Mo} + \text{Ash})$$

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

Indicator Method

Data to Support a Calorie Content Claim

Dog ID No.	*a* Gross Energy of Food AF[a] (kcal/g)	*b* Gross Energy Feces DM[b] (kcal/g)	*c* $C_{12}0_3$ in Food AF (%)	*d* $C_{12}0_3$ in Feces DM (%)	*e* Protein Food AF (%)	*f* Protein Feces DM (%)	*g* Correction Factor (kcal/g)	ME (kcal/g)
1								
2								
3								
4								
5								
6								
							Average ME	

[a]AF = as fed.
[b]DM = dry matter.

DE (kcal/g food) = $\{1 - [(b \times c)/(a \times d)]\} \times a$

DP (g digestible protein/g food) = $[1 - (f \times c)/(e \times d)] \times e$

ME (kcal/g food) = $[DE - (DP \times g)] \times 1000$

Correction factor = 1.25 kcal/g for dogs, 0.86 kcal/g for cats

Batch No.	CP Crude Protein AF[a] (%)	CF Crude Fat AF (%)	CFb Crude Fiber AF (%)	Mo Moisture AF (%)	Ash Ash AF (%)	NFE AF (%)	ME (kcal/g)
1							
2							
3							
4							
Average							

[a]AF = as fed.

$$\text{NFE (\%)} = 100 - (\text{CP} + \text{CF} + \text{CFb} + \text{Mo} + \text{Ash})$$

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

AAFCO Pet Food Regulations Label Review Checklist

Company Name: _

Data to Support a Calorie Content Claim

Product Name: _

Calculated Method

Reviewer: _

This Label Review Checklist is intended as a guide in determining whether this pet food or specialty pet food label is in compliance with the AAFCO Model Regulations for Pet Food and Specialty Pet Food.

*Note: There are also federal regulations that apply to the labeling and manufacture of animal food. It is recommended that pet food manufacturers and distributors check with FDA for additional information on federal labeling requirements. The AAFCO Business of Pet Food Website has a page with links to additional information on federal labeling requirements as well. The website address is http://petfood.aafco.org

A "Yes" response to the questions below indicates compliance for that item.

A "No" response indicates a violation of the regulation mentioned.

I. Animal Species – Model Pet Food Regulation PF2(a)(2)

(1) Do the words "Dog Food," "Cat Food," "Canine Formula," "Feline Diet," "Hamster Food" or similar designation appear conspicuously on the principal display panel? Yes _ No _

II. Quantity Statement – Model Pet Food Regulation PF2(a)(3)

(1) Is there a quantity statement on the principal display panel in either net weight or net volume (avoirdupois and metric) or by count?
Yes No _

(2) If volume is listed on a liquid vitamin or mineral supplement, i
equivalent listed elsewhere on label? PF4(c)(4) and PF4(d)(4)
Yes No _

CHAPTER FOUR

III. Location of Required Label Information – Model Pet Food Regulation PF2(b)

(1) Does all required label information appear on the outer container or wrapper?
Yes No _

IV. Product Claims – Model Pet Food Regulation PF2(c)(d)(e)(f)(g)

If product claims and/or graphic representations are made:

(1) Does adequate substantiation exist for each claim? Yes _ No _

(2) Are the claims truthful and not misleading? Yes _ No _

(3) If a claim of "new" or "improved" is made, is it limited to six (6) months of production? Yes _ No _

V. Product Comparison Claims – Model Pet Food Regulation PF2(h)

(1) If the label includes any claims of comparison to another product, is the name of the product of comparison included on the label?

Yes No

(a) If "yes," is documentation, data, etc., available to support the claim?
Yes No _

(b) Is the claim limited to one (1) year production? Yes _ No _

VI. Product Name – Model Pet Food Regulation PF3

The following AAFCO Official Pet Food or Specialty Pet Food Regulations refer to ingredient(s) that form part of the product name:

(1) If the pet food or specialty pet food claims "100%" or "All" within the product name (PF3(a)):

(a) Does the pet food or specialty pet food contain only one ingredient other than water for processing, decharacterizing agents, or trace amounts of preservatives and condiments? Yes _ No _

(2) If the product name is formed by using an ingredient or combination of ingredients without further qualification ("95% Rule"- PF3(b)(1) Example: My Favorite Beef Dog Food):

(a) Is the formulation comprised of at least 95% of the named ingredient(s), exclusive of water sufficient for processing, [but not less than 70% of the total product weight] in the formulation?
Yes No _

(b) Is the named ingredient listed in the ingredient statement?
Yes No _

(c) If multiple ingredients are listed, are they in the same order in both the product name and ingredient statement and is each ingredient at least 3% of formula? Yes _ No _

(d) Are all ingredients that are included in the product name printed in the same size, style and color print? Yes _ No _

(3) If a product name is formed using an ingredient or a combination of ingredients and is listed with a primary descriptor term such as "dinner," "entrée," "formula," etc. ("25% Rule"- PF3(b(2), Example: My Favorite Salmon Entrée Cat Food):

(a) Is the formulation comprised of at least 25% of the named ingredient(s), exclusive of water sufficient for processing, [but not less than 10% of the total product weight] in the formulation? Yes _ No _

(b) Is the named ingredient listed in the ingredient statement?
Yes No _

(c) If multiple ingredients are listed, are they in the same order in both the product name and ingredient statement and is each ingredient at least 3% of the formula? (Example: My Favorite Beef, Chicken and Lamb Dinner Dog Food)? Yes _ No _

(d) Are all ingredients and primary descriptor that are included in the product name printed in same size, style and color print? Yes _ No _

(4) If there is an ingredient name in the product name or elsewhere on the label that

includes a descriptor term such as "with" ("With Rule"- PF3(c)Example: My Favorite Dog Food With Beef):

(a) Does each ingredient named constitute at least 3% of the formulation, exclusive of water sufficient for processing (except for nutrients or condiments)? Yes _ No _

(b) If multiple ingredients are listed, are they in the same order in both the product name and ingredient statement and is each ingredient at least 3% of formula? Yes _ No _

(c) Is the word "with" in the same size, style, color and case print as the ingredients that are included in the product name? Yes _ No _

(d) Does the product name meet the print size specifications listed in the following table? Yes _ No_

Panel Size	Maximum "With Claim" Type Size
≤5 in.^{2}	1/8 in.
>5–≤25 in.^{2}	1/4 in.
>25–≤100 in.^{2}	3/8 in.
>100–≤400 in.^{2}	1/2 in.
>400 in.^{2}	1 in.

(5) If a flavor designation is used in the product name or elsewhere on the label:

(a) Does the name correspond to the source of the flavor in the ingredient statement or has it been identified by a source of flavor in the ingredient statement; and is substantiation available to validate the flavor designation? Yes _ No _

(b) If a flavor designation is made, is the word "flavor" printed in the same size type and with an equal degree of conspicuousness as the name of the flavor designation? Yes _ No _

Table Summarizing Product Name Requirements

Claim Rule	Product Name Example With Ingredient	Percentage of Ingredient to Make Claim	Minimum Percent of Ingredient in Formula Weight[a]
"100%"; "All"	"100% Beef"; "All Sweet Potato"	100%[b]	
95%	"Cherry"; "Trout"	95%[c]	70%
25% Descriptor	"Chicken Platter"; "Turkey Recipe"	25%[c]	10%
"with"	"with blueberries, carrots, and cranberries"	3% each[c]	N/A
"Flavor"	Peanut Butter Flavor	Sufficient to impart flavor	N/A

[a]Minimum percentage of ingredient allowed in total product weight, regardless of water content.
[b]not including water sufficient for processing, decharacterizing agents, or trace amounts of preservatives and condiments
[c]not including water sufficient for processing

VII. Expression of Guarantees – Model Pet Food Regulation PF4

(1) Are all required nutrients guaranteed? PF4(a)(1); PF4(g) Yes _ No _

(a) Are mandatory guarantees in the proper order as found in PF4(a)(1)? Yes No _

(b) If label claims have been made that indicate that the product is a source of specific nutrients, are those nutrients guaranteed? Model Bill Section 5(a)(3) Yes No _

(2) Do the guarantees follow the applicable AAFCO nutrient profile order? PF(4)(a)(3) Yes _ No _

(a) For Specialty Pets without an AAFCO-recognized nutrient profile, do the guarantees follow the order of the AAFCO Cat Food Nutrient Profile? PF(4)(a)(4) Yes _ No _

(3) If a guarantee is made for a nutrient not listed as essential by the AAFCO Dog or Cat Food Nutrient Profiles (or in the case of a specialty pet food, the cited AAFCO-recognized nutritional authority for the intended species), is it asterisked to the disclaimer statement? PF4(a)(3) or PF4(a)(4) Yes No _

(4) Are the correct units used? Units must follow those used in AAFCO Dog or Cat Food Nutrient Profiles (or in the case of specialty pet food, in the cited AAFCO-recognized nutrient profile*). PF4(a)(3) or PF4(a)(4) Yes No _

**Note: If no AAFCO-recognized nutrient profile exists for the species, units should follow the AAFCO Cat Food Nutrient Profile for specialty pet food labels.*

(5) Has it been verified that the label does not have sliding scale guarantees? (e.g. Minimum Crude Protein is 15-18%) PF4(b) Yes _ No _

(6) If formulated or represented as a mineral supplement, are guarantees listed as required by PF4(c) (1)-(4)? Yes _ No _

(7) If formulated or represented as a vitamin supplement, are guarantees listed as required by PF4(d)(1)-(4)? Yes _ No _

(8) If the label of the pet food or specialty pet food bears a statement of comparison of the nutrient content of food with levels established in the the AAFCO-recognized nutrient profile, do the following apply? PF4(e)

(a) Does the product meet the nutrient requirements of the AAFCO-recognized nutrient profile? Yes _ No _

(b) Is there a statement that the product meets the AAFCO-recognized nutrient profile, unless the nutritional adequacy statement required by PF7(a)(1) or PF7(b)(2)(A) appears elsewhere on the label? Yes _ No _

(c) Does the comparison comply with the additional requirements in PF4(e)(3)-(4)? Yes _ No _

(9) Has it been verified that the moisture content of the pet food or specialty pet food does not exceed 78% or the natural moisture content of the ingredients, unless the product is consisted of and labeled as: “stew,” “gravy,” “sauce,”

"broth," "aspic," "juice," or a "milk replacer"? PF4(f) Yes _ No _

VIII. Ingredient Statement – Model Pet Food Regulation PF5

(1) Are all ingredients listed in the same size, style, and color and in a single, uninterrupted ingredient statement? Yes _ No _

(2) Are ingredients listed in order of descending predominance by weight? PF5(a)(2) Yes _ No _

(3) Are defined ingredients listed by their AAFCO defined names? PF5(a)(3) Yes No _

(4) If an ingredient has no established AAFCO name or definition, is a common or usual name used? Yes _ No _

(5) Collective terms, brand or trade names have not been used in the ingredient statement? PF5(c) Yes _ No _

(6) There are no references to ingredient quality or grade in the ingredient statement? PF5(d)(3) Yes _ No _

IX. Drugs and Pet Food Additives – Model Pet Food Regulation PF6

(1) If an artificial color is used, has sufficient documentation been collected to demonstrate that it has been shown to be harmless to pets or specialty pets based on the intended use of the feed? PF6(a) Yes _ No _

(2) If an additive or drug is being used, can safety and efficacy be established through satisfactory evidence (i.e. does it conform to the requirements of the applicable regulation in the Code of Federal Regulations, Title 21, or is it prior-sanctioned, informal-review sanctioned or GRAS for such use) when the product is fed according to the label directions? PF6(b) Yes _ No _

(3) If a drug is used: PF6(b)(2) and MR3(a)(2)

(a) Does the word "Medicated" appear directly following and below the product name in font that is no less than one half (1/2) the type size of the product name? MR3(a)(2)I Yes _ No _

(b) Does the label bear a purpose statement that clearly indicates the purpose, class of animal, and species? MR3(a)(2)II Yes _ No _

(c) Does the label have a claim statement (purpose of the medication)? MR3(a)(2) Yes _ No _

(d) Does the label have an active ingredient statement which lists the active drug ingredient by the established name and the amount present? MR3(a)(2)IV Yes _ No _

X. Nutritional Adequacy – Model Pet Food Regulation PF7

Dog and Cat and Specialty Pets

(1) If there is an unqualified nutritional adequacy claim of "complete and balanced," "perfect," "scientific," or "100% nutritious" on the label of the pet food or specialty pet food, is the product complete and balanced for <u>all</u> life stages of the intended species by meeting one of the 3 criteria in PF7(a)? Yes No _

(2) If there is a qualified nutritional adequacy claim for only a limited purpose or specific life stage on the label of the pet food or specialty pet food, is the claim and required qualification on same panel in the same size, style and color print? PF7(b)(1) Yes _ No _

(3) If there is a qualified nutritional adequacy claim for only a limited purpose or specific life stage on the label of the pet food or specialty pet food, is the product "complete and balanced," "perfect," "scientific," or "100% nutritious" for the specific life stage of the intended species by meeting one of the 3 criteria in PF7(b)(2)? Yes _ No _

(4) If the pet food or specialty pet food product is labeled for "use by or under the supervision or direction of a veterinarian," (PF7(d)) does it also contain a nutritional adequacy statement in accordance with PF7(c)(1) or PF7(c)(3)? PF7(d)? Yes _ No _

(5) Are signed affidavits available to support that the pet food or specialty pet food product meets the requirements of PF7(a) or PF7(b)(2)? PF7(e)
Yes No _

Pet (Dog and Cat) Only:

(6) If the dog or cat food product is a "snack," "treat," or "supplement," do the words "snack" or "treat" or "supplement" appear clearly and conspicuously on the principal display panel? PF7(c) Yes _ No _

(7) If the dog or cat food product is not labeled as a "snack" or "treat" or "supplement":

(a) Does the label contain the proper (as appropriate to the intended use and substantiation method) nutritional adequacy statement and in the exact wording shown? PF7(c)(1) Yes _ No _

(b) And, if the product does not meet the requirements of Regulation PF7(a) or (b)(2) or any other special nutritional or dietary need, so is suitable only for limited or supplemental feeding, does the statement "This product is intended for intermittent or supplemental feeding only" appear on the label? PF7(c)(3) Yes_ No_

XI. Feeding Directions – Model Pet Food Regulation PF8

Pet (Dog or Cat) Food Directions:

(1) If dog or cat food (including "treats" or "snacks")***** is labeled as complete and balanced for any or all life stages, does the label have feeding directions? PF8(a) Yes_ No_

**If a dog or cat product is labeled as a snack or treat, and is not represented as "complete and balanced," feeding directions are voluntary unless considered necessary for "safe and effective use."*

(2) Are the feeding directions consistent with all of the intended uses of the product? PF8(a) Yes_ No_

(3) Do the feeding directions state, at minimum, a weight or unit of product per weight of dog or cat and frequency of feeding stated? PF8(a) Yes No_

(4) If the dog or cat food product is labeled for "use by or under the supervision or direction of a veterinarian," does it also carry the statement "Use only as directed by your veterinarian."? PF8(b) Yes _ No _

Specialty Pet Food Directions:

(5) Are the feeding directions adequate to meet the nutritional requirements of the intended species as recommended by the AAFCO-recognized nutritional authority? PF8(c) Yes _ No _

(6) Do the feeding directions for specialty pet foods and treats labeled as complete and balanced for any or all life stages meet all three of the following three criteria? PF(8)(c):

(a) List feeding directions that are adequate to provide the nutrient requirements as determined by an AAFCO-recognized nutritional authority of the intended species? Yes_ No_

(b) Use common terms and appear predominantly on the label?

Yes No

(c) Specify the frequency of feeding? Yes No

Nutritional Supplement Feed:

(7) If a pet food or specialty pet food is labeled as a nutritional supplement, are adequate directions for use provided? MR 7(c) Yes No

XII. Calorie Content – Model Pet Food Regulation PF9 – Applies Only to Pet Food (Dog or Cat)

(1) Does the label bear a calorie content statement? PF9(a) Yes No

(2) Is it separate and distinct from the guaranteed analysis? PF9(a)(1)
Yes No _

(3) Does it appear under the heading "Calorie Content"? PF9(a)(1)
Yes No _

(4) Is it stated in terms of metabolizable energy (ME)? PF9(a)(2)
Yes No _

(5) Is it expressed both in terms of kcal/kg and kcal per familiar household measure or unit of product (cups, cans, treats, pieces)? PF9(a)(2)
Yes No _

(6) Has it been determined by calculation or animal testing procedure following methods in PF9(a)(3)? Yes _ No _

(a) If calculated, does the word "calculated" appear in parentheses immediately after "Calorie Content"? PF9(a)(5)A. Yes _ No _

(b) If determined by animal testing procedures, does the word "fed" appear in parentheses immediately after "Calorie Content"? PF9(a)(5)B.
Yes No _

(7) Is an affidavit available to support the calorie content statement? PF9(a)(4)
Yes No _

XIII. Descriptive Terms – Model Pet Food Regulation PF10 – Applies Only to Pet Food (Dog or Cat)

(1) Calorie Terms- Light-If the product label bears a "light," "lite" or "low calorie" claim:

(a) Does it meet the following requirements? Yes _ No _

Light—PF10(a)(1)(A)—Dog Food

≤3100 kcal/kg	<20% moisture
≤2500 kcal/kg	<65% and ≥20% moisture
≤900 kcal/kg	≥65% moisture

Light—PF10(a)(1)(B)—Cat Food

≤3250 kcal/kg	<20% moisture
≤2650 kcal/kg	<65% and ≥20% moisture
≤950 kcal/kg	≥65% moisture

(b) Does the label contain a calorie content statement? PF10(a)(1)(A)(ii) or PF10(a)(1)(B)(ii) Yes _ No _

(c) Is the claim based on an "as fed" basis? Yes _ No _

(d) Does the calorie content statement follow the format specified in PF9? PF10(a)(1)(A)(ii)(aa) or PF10(a)(1)(B)(ii)(aa) Yes _ No _

(e) Are feeding directions consistent with reduced calorie intake? PF10(a)(1)(A)(iii) or PF10(a)(1)(B)(iii). Yes _ No _

(2) Less or Reduced Calories - Regulation PF10(a)(2) --If the label makes a less or reduced calorie claim:

(a) Is there a product of comparison named? PF10(a)(2)(A)(i)
Yes No _

(b) Is there a percentage of calorie reduction stated on the label? PF10(a)(2)(A)(i) Yes _ No _

(c) Is it expressed on an equal weight basis (i.e., kcal/kg on an as fed basis)? PF10(a)(2)(A)(i) Yes _ No _

(d) Is percent calorie reduction and name of the product of comparison juxtaposed with the most prominent use of this claim on each panel? PF10(a)(2)(A)(i) Yes _ No _

(e) Is print of comparative statement in same color and style and at least 1/2 the type size of the claim? PF10(a)(2)(A)(ii) Yes _ No _

(f) Is there a calorie content statement on the label? PF10(a)(2)(A)(iii) Yes No _

(g) Do feeding directions reflect a reduction in calories? PF10(a)(2)(A)(iv) Yes No _

(h) Are compared products in the same moisture category (e.g., both products must be less than 20% moisture)? PF10(a)(2)(B) Yes No _

(3) Fat Terms - Lean - Regulation PF10(b)(1)--If there is a lean or low-fat claim on label:

(a) Does it meet the following requirements? Yes _ No _

Lean—PF10(b)(1)(A)—Dog Food

≤9% fat	<20% moisture
≤7% fat	<65% and ≥20% moisture
≤4% fat	≥65% moisture

Lean—PF10(b)(1)(B)—Cat Food

≤10% fat	<20% moisture
≤8% fat	<65% and ≥20% moisture
≤5% fat	≥65% moisture

(b) Are there minimum and maximum percent crude fat guarantees? PF10(b)(1)(A)(ii)(aa) or PF10(b)(1)(B)(ii)(aa) Yes _ No _

(4) Less or Reduced Fat - PF10(b)(2)(A)--If there is a reduced fat, less fat or similar claim on label:

(a)Is a product of comparison stated? PF10(b)(2)(A)(i) Yes _ No _

(b) Is there a percentage of reduction based on an equal weight basis (as fed and not dry matter basis) stated? PF10(b)(2)(A)(i) Yes _ No _

(c) Can the stated (claimed) percentage of reduction be determined using the method in the following example: Yes _ No _

"Less or Reduced Fat" Example [PF10(b)(2)]:

Assume the following three products

Guarantee	Brand A	Brand B	Brand C
% Fat (min.)	10	5	5
% Fat (max.)	Not declared	9	7

Claims

Calculation used when there is no maximum fat listed for product to which claim is compared	"Brand B has 10% less fat than Brand A."	Brand B (max.) − Brand A (min.)/Brand A (min.) = (9 − 10)/10 = −1/10 = −10%
Calculation used when both products have maximum fat guaranteed	"Brand C has 22% less fat than Brand B."	Brand C (max.) − Brand B (max.)/Brand B (max.) = (7 − 9)/9 = −2/9 = −22%

(d) Is percent fat reduction and name of the product of comparison juxtaposed with the most prominent use of the claim on each panel? PF10(b)(2)(A)(i) Yes No _

(e) Is the statement in the same style, color and at least 1/2 size type as the claim? PF10(b)(2)(A)(ii) Yes _ No _

(f) Is there a minimum and maximum percent crude fat guarantee? PF10(b)(2)(A)(iii) Yes _ No _

(g) Are compared products in same moisture categories (e.g., both products must be less than 20% moisture)? PF10(b)(2)(B) Yes _ No _

XIV. Manufacturer or Distributor – Model Pet Food Regulation PF11

(1) Is there a name and address, including zip code, of the manufacturer or distributor on label? PF11(a) Yes _ No _

XV. Attachments

(1) If brochures, pamphlets, website, advertisements, promotional material, etc., are produced for this product, does all of the information comply with the AAFCO Pet Food Model Regulations? Yes _ No _

XVI. Raw Milk Distributed as Pet or Specialty Pet Food- Model Bill 3(t); Model Bill 8(i)((1)-(6); Model Pet Food Regulations PF2(i); PF(3)(g)

(1) Does the product fit the definition of "Raw Milk"? Model Bill (Section 3)(t) Yes No _

(2) Is the raw milk appropriately "decharacterized" using a sufficient quantity of animal feed appropriate food coloring; or is it certified and labeled as Organic in compliance with the USDA National Organic Program requirements? Model Bill (Section 8)(i)(1-3) Yes _ No _

(3) Is the raw milk appropriately packaged in a packaging that does not resemble packaging used for milk consumed by Humans? Model Bill (Section 8)(i)(4) Yes No _

(4) Is the raw milk offered for sale sufficiently separate from of the vicinity of milk or milk products for human consumption? Model Bill (Section 8)(i)(5) Yes No _

(5) Have no other "Prohibited Acts" found in Model Bill Section 8 "Prohibited Acts" been violated? Yes No _

(6) If this product is raw milk distributed as pet food or specialty pet food, is the statement: "**WARNING: NOT FOR HUMAN CONSUMPTION-THIS PRODUCT HAS NOT BEEN PASTEURIZED AND MAY CONTAIN HARMFUL BACTERIA**." conspicuously placed on the principal display panel and in font size not smaller than required by the following table?

Panel Size	Minimum Warning Statement Type Size
<5 in.^{2}	1/16 in.
≥5–<25 in.^{2}	1/8 in.
≥25–<100 in.^{2}	3/16 in.
≥100–<400 in.^{2}	1/4 in.
≥400 in.^{2}	1/2 in.

Yes _____ No

(7) If the pet food or specialty pet food consists of raw milk, do the words "Raw (Blank) Milk" appear conspicuously on the display panel? *Blank to be completed using the species of animal from which the milk is collected (e.g. "Raw Goat Milk," "Raw Sheep Milk") Yes _ No _

XVII. Direct Fed Microbials and Enzyme labeling (Pet Food and Specialty Pet Food)

Direct Fed Microbials - Model Regulation 9(b)(4)

If the product claims to be a source of, or guarantees, probiotics or direct-fed microbials:

(1) Does the label bear the statement "Contains a source of live (viable) naturally occurring microorganisms"? MR 9(b)(4)(II) Yes _ No _

(2) Is there a guarantee for total microbes with a parenthetical species list or for individual species listed in descending order of predominance by microbial number? MR 4(g) Yes _ No _

(3) Does the guarantee include only organisms from ingredient definition 36.14 or 96.2 or 96.8 (if yeast)? Yes _ No _

(4) Is the guarantee stated in colony forming units per unit fed, based on the feeding directions (either CFU/g or CFU/lb)? MR 4(g) Yes _ No _

(5) On pet food labels (dog and cat): Is there an asterisk with the guarantee, referring to the disclaimer statement "Not recognized as an essential nutrient by the AAFCO Dog (or Cat) Food Nutrient Profiles"? Yes _ No _

(6) On specialty pet food labels: If an AAFCO-recognized profile exists, is there an asterisk with the guarantee, referring to the disclaimer statement "Not recognized as an essential nutrient by the _ "? PF4(a)(4)

Yes No _

(7) Does the product include an ingredient from ingredient definition 36.11 or 36.12 or 96.2 or 96.8 (if yeast)? Yes _ No _

(a) If the direct fed microbial is a source of bacteria, is the ingredient listed in the ingredient statement using the appropriate fermentation product definition, with the organism name input into the blank? (Example: Dried Lactobacillus acidophilus fermentation product; Liquid *Bifidobacterium bifidum* fermentation product) Yes _ No _

(b) If the direct fed microbial is a source of yeast, is the ingredient listed as "active dry yeast" or "yeast culture" in the ingredient statement? Yes No _

Note: Direct fed microbial ingredients that are a source of bacteria are listed in the ingredient statement using two definitions: The Genus species as listed in 36.14 and the type of fermentation product (Dried Genus species fermentation product or Liquid Genus species fermentation product). They are never listed as just "Genus species" in the ingredient statement. Direct fed microbials that are a source of yeast are listed in the ingredient statement using one of two definitions: Active dry yeast or Yeast

culture.

Enzymes-- Model Regulation 9(b)(5)

If the product claims to be a source of- or guarantees- enzyme activity:

(1) Is there a guarantee for enzyme(s)? MR 9(b)(5)(II) Yes _ No _

(a) Is the source of enzyme activity shown in the guarantee (e.g. Protease (Aspergillus niger))? MR 4(h) Yes _ No _

(b) Is the guarantee listed in the units of enzymatic activity per amount of product fed, consistent with label directions (e.g. mg amino acids liberated/min/g)? MR 4(h) Yes _ No _

(2) If multiple sources of enzyme activity are guaranteed, are the sources identified in the guarantee in descending order of predominance of enzyme activity? MR 4(h) Yes _ No _

(3) On pet food labels (Dog and Cat): is there an asterisk with the guarantee referring to the disclaimer statement "Not recognized as essential by the AAFCO Dog (or Cat) Food Nutrient Profile"? Yes _ No _

(4) On specialty pet food labels: If an AAFCO-recognized profile exists, is there an asterisk with the guarantee, referring to the disclaimer statement "Not recognized as essential by the _ "? Yes _ No _

(5) If the enzyme is derived from a microbial source, does the product include an ingredient from ingredient definition 36.6, 36.7, 36.11, or 36.12?
Yes No _

(a) Is the source shown in ingredient definition 30.1? PF(5)(a)(3)
Yes No _

(b) Is the source associated with the guaranteed enzyme?
Yes No _

Note: For example if the label bears a guarantee for lipase, the ingredient statement must include the appropriate source of enzyme activity, such as: Dried Aspergillus niger fermentation extract.

(6) If the enzyme is derived from a plant or animal product, does the product contain an ingredient providing enzyme activity corresponding to the enzyme in ingredient definition 30.1? Yes _ No _

(a) Is the source shown in ingredient definition 30.1? PF(5)(a)(3)
Yes No _

(b) Is the source associated with the guaranteed enzyme?
Yes No _

Note: Example (1) If the label bears a guarantee for lipase, the ingredient statement must include the appropriate source of enzyme activity, such as: Dried lamb pancreas; Example (2) If the label bears a guarantee for bromelain, the ingredient statement must include the appropriate source of enzyme activity, such as: Dried pineapple.

Model Regulations for Processed Animal Waste Products as Animal Feed Ingredients

Section Editor—Doug Lueders

The following Model Regulations have been developed by the Animal Waste Task Force after consideration of a number of state regulations on the same topic and after careful consideration of a number of regulatory options which might be open to a state control official. It represents the best judgment of the Task Force and is recommended, should any member state choose to adopt it for its use.

Any State Control Official proposing to adopt the following Model Regulations, or regulate Processed Animal Waste Products and Animal Feed Ingredients under his own state feed law and regulations, should read carefully all of the Federal Register notice published by FDA on Recycled Animal Wastes (F.R. 45, No. 251, 86272-86276, Dec. 30, 1980), and the 1981 Recycled Animal Waste Committee Report.

Regulation 1. Legal Authority

Legal Authority (designated specifically by each state to meet legal requirements: Section 10, Model Bill).

Regulation 2. Definitions

Definitions (in addition to those listed in the current issue of the Official Publication of AAFCO).

Regulation 3. Registration

Registration Required (Section 4, Model Bill).

(A) No person shall sell, offer or expose for sale, or distribute in this state, any processed animal waste product intended, promoted, represented, advertised or distributed for use as a commercial feed as defined in Section II prior to registering same with _____, as specified in Section 4 Model Bill.

(B) Application for registration shall be made to the _____ on forms provided by the _____ and shall be accompanied by payment of the statutory registration fee as set forth in _____

(C) Applications for registration shall be accompanied by the following:

(1) A copy of the label or tag which the applicant proposes to use for the processed animal waste product.

(2) A detailed description of the facilities, equipment and method of manufacture to be used in processing, manufacturing and testing of the processed animal waste product.

(3) A sampling schedule, a full description of all tests made, and the results, thereby purporting to show the processed animal waste product meets the standards of _____ and these rules and regulations for registration.

Regulation 4. Registration Refused or Cancelled

(Section 4, Model Bill)

(A) General--Registration of a processed animal waste product shall be refused if:

(1) Applicant or the processed animal waste product is determined to be in violation of any state or federal statute or state agency rule or regulation

affecting or relating to the sale of commercial feeds.

(2) The processed animal waste product contains any pathogenic organisms, drug residues, pesticide residues, harmful parasites, or other toxic or

deleterious substances above levels permitted by (State regulations), Federal Food, Drug, and Cosmetic Act, Sections 406, 408, 409 and 706, or which could be harmful to animals, or which could result in residue in the tissue or by-products of animals above levels determined and promulgated in regulations by the _ to be harmful.

(3) The processed animal waste product does not meet the Quality Standards set forth in _ Definitions, of this regulation.

(4) The processed waste product is not labeled in compliance with law and agency rules and regulations, including Regulation 5 of these rules.

(5) Applicant or registrant fails to perform the testing as specified in Regulation 6 of these rules, or to accurately maintain and display to the _ or his designee, upon demand, the records required.

(B) Registration may be refused pursuant to and in compliance with any statutory provisions authorizing the _ to refuse registration.

(C) Registration may be cancelled by the _ if the product or registrant is found to be in violation of any provision of these regulations.

Regulation 5. Labeling Requirements.

(A) The label, tag, or label invoice accompanying shipments of animal waste products shall contain all information as required by Regulation 2, Model Bill and Regulations.

(B) In addition, it shall include the following information, in the list of guarantees, in following order, in percentages:
(1) maximum moisture, following fiber guarantee.
(2) maximum ash, following moisture guarantee.

(C) Special labeling or warnings required, as appropriate:
(1) If the product contains drug residues, then the label shall contain the following statement in boldface type:
"WARNING: THIS PRODUCT CONTAINS DRUG RESIDUES. DO NOT USE WITHIN 15 DAYS OF SLAUGHTER AND DO NOT USE 15 DAYS PRIOR TO OR DURING THE FOOD PRODUCTION PERIOD OF DAIRY ANIMALS AND LAYING HENS."
(2) If the product contains high levels (25 ppm or greater) of copper, a maximum guarantee of copper and the following statement is required:
"WARNING: CONTAINS HIGH LEVELS OF COPPER: DO NOT FEED TO SHEEP."
(3) If the product derives one-third (1/3) or more of the guaranteed total crude protein from non-protein nitrogen sources, the label shall provide adequate directions for safe use of the product and the precautionary statement:
"CAUTION: USE ONLY AS DIRECTED."

Regulation 6. Testing Required

(A) The purpose of the sampling and testing requirements of this section shall be to determine the presence of harmful materials or biological contaminants specified in (State regulation) and to assure compliance with the quality standards in _ of these regulations.

(B) Any person seeking or receiving registration of any processed animal waste

product shall test, by representative sampling and assaying of such samples, and keep accurate records thereof, the processed animal waste product for which the registration is sought or received. The sample shall be of sufficient size so as to provide meaningful data, statistically reliable in carrying out the

purpose of such sampling and analysis. For example, 10 one-pound samples taken randomly from one day's production run or other identifiable lot, should be packaged in sealed airtight bags for prompt shipment to the analytical laboratory.

(C) The registrant, manufacturer, or producer of any such processed animal waste product ingredient shall conform to the following sample and analyses requirements:

(1) Analyses specifi by the _ to meet the requirements of the quality standards of _ of these regulations shall be conducted on three sequential production runs to establish that the feed ingredient is consistently within the limitations specified prior to registration and/or sale of the processed animal waste product.

Optional

In addition to quality standards, testing on the same production runs or lots should include potential hazardous substances such as the following:

(a) Drugs suspected or known to be used in the feed or as a therapeutic treatment of the animals.
(b) Pesticides used on the animal, facilities, and wastes for pest control.
(c) Pathogenic organisms, at least to include Salmonella and E. coli.
(d) Heavy metals: arsenic, cadmium, copper, lead, mercury and selenium, at least.
(e) Parasitic larva or ova.
(f) Mycotoxins, such as aflatoxins.

(2) Following the initial sequential testing, periodic analyses shall be conducted on production runs no less than one (1) each calendar quarter. Less frequent testing may be allowed where the analytical results show continued uniformity and a consistent margin of compliance. More frequent tests shall be required where the analytical results show a wide range, or show levels close to the established quality standards. Any processed animal waste product that does not meet the quality standards for the product shall be further processed until standards are met, shall be diverted to non-feed uses, or destroyed.

(3) Sequential testing shall again be required when the periodic analyses required by paragraph (C)(2) of this section or other information available to the manufacturer of the ingredient indicates that:

(a) The ingredients are not within the limitations established in these regulations.
(b) Changes are made in the manufacturing process.
(c) New or expanded sources of the raw ingredients are used.
(d) Changes occur in the drugs or pesticides used by the supplier(s) of the raw ingredient(s).

Regulation 7. Records Required

Any person seeking or receiving registration of any processed animal waste product shall keep for a period of two (2) years, accurate records of:

(A) All sources of raw materials and date acquired, including information on drugs and pesticide usage.
(B) All production output, including a code or other method to identify the date of production.
(C) All sales and distribution, including the name and address of the purchaser or to whom distributed, date, quantity and production code.
(D) Sampling and assay records of the testing required by Regulation 6 of this

regulation.

AAFCO Non-Commercial Feed Model Bill

Section Editor—Doug Lueders

Preamble

A bill to provide authority to the _ to regulate the manufacture of non-commercial feed, allow for inspection, sampling and testing of non-commercial feed, and authorize the _ to take enforcement action pursuant to adulterated non-commercial feed to protect the health and safety of animals and food from animals.

Extra Bill Explanation

This Non-Commercial Feed Model Bill was developed to provide express authority for States to regulate the manufacture of feed not in commerce or not intended for distribution into commerce. Its intent is to provide States that adopt it legislatively with the authority to regulate the manufacture of such feed that could present a danger to human or animal health. It does not provide authority to regulate the feeding of animals. Although this Bill has not been passed into law in all the States, the subject matter covered herein represents the official position of this Association.

AN ACT

To regulate non-commercial feed in the State of BE IT ENACTED by the Legislature of the State of .

Section 1. Title

This Act shall be known as the "_ Non-Commercial Feed Law of 20 ."

Section 2. Enforcing Official

This Act shall be administered by the _ of the State of , hereinafter referred to as the " ."

Section 3. Definitions of Words and Terms

When used in this Act:

(a) The term "commercial feed" means all materials or combination of materials which are distributed or intended for distribution for use as feed or for mixing in feed, unless such materials are specifically exempted. Unmixed whole seeds and physically altered entire unmixed seeds, when such whole or physically altered seeds are not chemically changed or are not adulterated within the meaning of Section 7(a) of the Model Bill, are exempt. The _ by rule may exempt from this definition, or from specific provisions of this Act, commodities such as hay, straw, stover, silage, cobs, husks, hulls, and individual chemical compounds or substances when such commodities, compounds or substances are not inter-mixed with other materials, and are not adulterated within the meaning of Section 7(a) of the Model Bill.

(b) The term "distribute" means to offer for sale, sell, exchange, or barter

commercial feed; or to supply, furnish or otherwise provide commercial feed to a contract feeder.

(c) The term "drug" means any article intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in animals other than man and

articles other than feed intended to affect the structure or any function of the animal body.

(d) The term "establishment" includes any of the following, but is not limited to, facilities, equipment and conveyances used for, or in connection with, the receiving, processing, manufacturing, storing, packaging, transportation or use of feed.

(e) The term "feed" means edible material(s) which are consumed by animals and contribute energy and/or nutrients to the animal's diet.

(f) The term "feed ingredient" means a component, part or constituent of any combination or mixture making up a non-commercial feed.

(g) The term "manufacture" means to grind, mix, blend, package, store, transport or further process a non-commercial feed.

(h) The term "non-commercial feed" means all materials or combination of materials, not distributed or intended for distribution, that are for manufacturing and use as feed, or for mixing in feed. A person manufacturing non-commercial feed shall not be subject to licensing, product registration or tonnage fees imposed by the State of .

(i) The term "official sample" means a sample of non-commercial feed taken by the or their agent in accordance with the provisions of Section 7(c), (e), or (f) of this Act.

(j) The term "person" includes individual, partnership, corporation, and association.

Section 4. Adulteration

A non-commercial feed shall be deemed to be adulterated:

(a)

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

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

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

(4) If it is a raw agricultural commodity and it bears or contains a pesticide chemical which is unsafe within the meaning of Section 408 (a) of the Federal Food, Drug, and Cosmetic Act; provided, that where a pesticide chemical has been used in or on a raw agricultural commodity in conformity with an exemption granted or a tolerance prescribed under Section 408 of the Federal Food, Drug, and Cosmetic Act and such raw agricultural commodity has been subjected to processing such as canning, cooking, freezing, dehydrating, or milling, the residue of such pesticide chemical remaining in or on such processed non-commercial feed shall not be deemed unsafe if such residue in or on the raw agricultural commodity has been removed to the extent possible in good manufacturing practice and the concentration of such residue in the processed non-commercial feed is not greater than the tolerance prescribed for the raw agricultural commodity unless the feeding of such processed non-commercial feed will result or is likely to result in a pesticide residue in the edible product of

the animal, which is unsafe within the meaning of Section 408 (a) of the Federal Food, Drug, and Cosmetic Act; or

(5) If it is, or it bears or contains any color additive which is unsafe within the meaning of Section 721 of the Federal Food, Drug, and Cosmetic Act; or

(6) If it is, or it bears or contains any new animal drug which is unsafe within the meaning of Section 512 of the Federal Food, Drug, and Cosmetic Act; or

(7) If it consists in whole or in part of any filthy, putrid, or decomposed substance, or if it is otherwise unfit for non-commercial feed; or

(8) If it has been prepared, packed, or held under unsanitary conditions whereby it may have become contaminated with filth, or whereby it may have been rendered injurious to health; or

(9) If it is, in whole or in part, the product of a diseased animal or of an animal which has died otherwise than by slaughter which is unsafe within the meaning of Section 402 (a)(1) or (2) of the Federal Food, Drug, and Cosmetic Act; or

(10) If its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

(11) If it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with the regulation or exemption in effect pursuant to Section 409 of the Federal Food, Drug, and Cosmetic Act.

(b) If it contains a drug and the methods used in or the facilities or controls used for its manufacture, processing, or packaging do not conform to current good manufacturing practice regulations promulgated by the _ to assure that the drug meets the requirement of this Act as to safety and has the identity and strength and meets the quality and purity characteristics which it purports or is represented to possess. In promulgating such regulations, the _ shall adopt the current good manufacturing practice regulations for Type A medicated Articles and Type B and Type C Medicated Feeds established under authority of the Federal Food, Drug, and Cosmetic Act, unless the _ determines that they are not appropriate to the conditions which exist in this State.

(c) If it is manufactured, processed, packaged, stored, transported or used in a manner that does not conform to the feed safety regulations promulgated by the .

(d) If it contains viable weed seeds in amounts exceeding the limits which the _ shall establish by rule or regulation.

Section 5. Prohibited Acts

The following acts and the causing thereof within the State of _ are hereby prohibited.

(a) The manufacture of any non-commercial feed that is adulterated.

(b) The adulteration of any feed.

(c) The disposal or use of a non-commercial feed in violation of an order under Section 8 of this Act.

(d) The violation of Section 9(f) of this Act.

Section 6. Rules and Regulations

(a) The _ is authorized to promulgate such rules and regulations for non-commercial feed as are specifically authorized in this Act and such other reasonable rules and regulations as may be necessary for the efficient

enforcement of this Act. In the interest of uniformity the _____ shall by regulation adopt, unless the _____ determines that they are inconsistent with the provisions of this Act or are not appropriate to conditions which exist in this state, the following:

(1) The Official Definitions of Feed Ingredients and Official Feed Terms adopted by the Association of American Feed Control Officials and published in the Official Publication of that organization, and
(2) Any regulation promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act (U.S.C. Sec. 301, et seq.): Provided, that the _ would have the authority under this Act to promulgate such regulations.

(b) Before the issuance, amendment, or repeal of any rule or regulation authorized by this Act, the _ shall publish the proposed regulation, amendment, or notice to repeal an existing regulation in a manner reasonably calculated to give interested persons adequate notice and shall afford all interested persons an opportunity to present their views thereon, orally or in writing, within a reasonable period of time. After consideration of all views presented by interested persons, the _ shall take appropriate action to issue the proposed rule or regulation or to amend or repeal an existing rule or regulation. The provisions of this paragraph notwithstanding, if the _ pursuant to the authority of this Act, adopts the Official Definitions of Feed Ingredients or Official Feed Terms as adopted by the Association of American Feed Control Officials, or regulations promulgated pursuant to the authority of the Federal Food, Drug, and Cosmetic Act, any amendment or modification adopted by said Association or by the US Secretary of Health and Human Services, in the case of regulations promulgated pursuant to the Federal Food, Drug, and Cosmetic Act, shall be adopted automatically under this Act without regard to the publication of the notice required by this paragraph (b), unless the _ by order specifically determines that said amendment of modification shall not be adopted.

Section 7. Inspection, Sampling, and Analysis

(a) For the purpose of enforcement of this Act, and in order to determine whether its provisions have been complied with, including whether or not any operations may be subject to the provisions, agents of the _ , upon presenting appropriate credentials, and a written notice to the owner, operator, or agent in charge of the non-commercial feed establishment, are authorized (1) to enter, during normal business hours, any public or private premises, including any establishment within the State in which feed ingredients or non-commercial feeds are stored, manufactured, processed, packed or used, or to enter any vehicle being used to transport or hold such feed ingredients or non-commercial feeds; and (2) to inspect at reasonable times, within reasonable limits and in a reasonable manner, any establishment, vehicle, pertinent equipment, finished and unfinished non-commercial feed or feed ingredients, containers, and labeling therein. The inspection may include: sampling of feed ingredients and mixed feed; verification of storage, production, handling and use control procedures; and verification of records as may be necessary to determine compliance with this Act.

(b) A separate notice shall be given for each such inspection, but a notice shall not be required for each entry made during the period covered by the inspection. Each such inspection shall be commenced and completed with reasonable promptness. Upon completion of the inspection, the owner, operator or agent in charge of the facility or vehicle shall be so notified.

(c) If the _ or their agent making such inspection has obtained an official

sample in the course of the inspection, upon completion of the inspection and prior to leaving the premises a receipt describing the official samples obtained shall be given to the owner, operator, or agent in charge.

(d) If the owner, operator or agent in charge of any non-commercial feed establishment described in paragraph (a), refuses to admit the _ or their agent to inspect in accordance with paragraphs (a) and (b), the _ is authorized to obtain from any State Court a warrant directing such owner, operator or agent in charge to submit the premises described in such warrant to inspection.

(e) Sampling and analysis shall be conducted in accordance with methods published by the AOAC International, or in accordance with other generally recognized methods.

(f) The results of all analyses of official samples shall be forwarded by the _ to the non-commercial feed manufacturer. When the inspection and analysis of an official sample indicates a non-commercial feed has been adulterated, and upon request within 30 days following the receipt of the analysis, the _ shall furnish to the non-commercial feed manufacturer a portion of the official sample concerned.

(g) The _ , in determining for administrative purposes whether a non-commercial feed is adulterated, shall be guided by the official sample as defined in paragraph (g) of Section 3 and obtained and analyzed as provided for in paragraphs (c) and (e) of Section 7 of this Act.

Section 8. Detained Non-Commercial Feed

(a) "Stop-Use" orders: When the _ or their agent has reasonable cause to believe any non-commercial feed is in violation of any of the provisions of this Act or any of the prescribed regulations under this Act, the _ may issue and enforce a written or printed "stop-use" order, warning the owner not to dispose of or use the lot of non-commercial feed in any manner until written permission is given by the _ or the Court. The _ shall release the lot of non-commercial feed upon which such stop-use orders are issued when said provisions and regulations have been complied with. If compliance is not obtained within 30 days, the _ may begin, or upon request of the non-commercial feed manufacturer shall begin, proceedings for condemnation.

(b) "Condemnation and Confiscation": Any non-commercial feed not in compliance with said provisions and regulations shall be subject to seizure on complaint of _ to a court of competent jurisdiction in the area in which said non-commercial feed is located. In the event the court finds the said non-commercial feed to be in violation of this Act and orders the condemnation of said non-commercial feed, it shall be disposed of in any manner consistent with the quality of the non-commercial feed and the laws of the State; provided, that in no instance shall the disposition of said non-commercial feed be ordered by the court without first giving the claimant an opportunity to apply to the court for release of said non-commercial feed or for permission to process said non-commercial feed to bring it into compliance with this Act.

Section 9. Penalties

(a) Any person convicted of violating any of the provisions of this Act or who shall

impede, hinder, or otherwise prevent, or attempt to prevent, said _ or their agent in performance of their duty in connection with the provisions of this Act, shall be adjudged guilty of a misdemeanor and shall be fined not less than _ or more than _ for the first violation, and not less than or more than _ for a subsequent violation.

(b) Nothing in this Act shall be construed as requiring the _ or their agent to:

(1) report for prosecution, or (2) institute seizure proceedings, or (3) issue a withdrawal order, as a result of minor violations of the Act, or when the _ believes the public interest will best be served by suitable notice of warning in writing.

(c) It shall be the duty of each _ attorney to whom any violation is reported

to cause appropriate proceedings to be instituted and prosecuted in a court of competent jurisdiction without delay. Before the _ reports a violation

for such prosecution, an opportunity shall be given the non-commercial feed manufacturer to present their views to the .

(d) The _ is hereby authorized to apply for and the court to grant a temporary

or permanent injunction restraining any person from violating or continuing to violate any of the provisions of this Act or any rule or regulation promulgated under the Act notwithstanding the existence of other remedies at law. Said injunction to be issued without bond.

(e) Any person adversely affected by an act, order, or ruling made pursuant to the provisions of this Act may within 45 days thereafter bring action in the (here name the particular Court in the county where the enforcement official has their office) for judicial review of such actions. The form of the proceeding shall be any which may be provided by statutes of this state to review decisions of administrative agencies, or in the absence or inadequacy thereof, any applicable form of legal action, including actions for declaratory judgments or writs of prohibitory or mandatory injunctions.

(f) Any person who uses to his own advantage, or reveals to other than the , or officers of the _ (appropriate departments of this State), or to the

courts when relevant in any judicial proceeding, any information acquired under the authority of this Act, concerning any method, records, formulations, or processes which as a trade secret is entitled to protection, is guilty of a misdemeanor and shall upon conviction thereof be fined not less than $ _ or imprisoned for not less than _ year(s) or both: Provided, That this

prohibition shall not be deemed as prohibiting the _ , or their agent, from

exchanging information of a regulatory nature with duly appointed officials of the United States Government, or of other States, who are similarly prohibited by law from revealing this information.

Section 10. Cooperation with other entities

The _ may cooperate with and enter into agreements with governmental

agencies of this State, other States, agencies of the Federal Government, and private associations in order to carry out the purpose and provisions of this Act.

Section 11. Constitutionality

If any clause, sentence, paragraph, or part of this Act shall for any reason be judged invalid by any court of competent jurisdiction, such judgment shall not affect, impair, or invalidate the remainder thereof but shall be confined in its operation to the clause, sentence, paragraph, or part thereof directly involved in the controversy in which such judgment shall have been rendered.

Section 12. Effective Date

This Act shall take effect and be in force from and after the first day of .

AAFCO Model Good Manufacturing Practice Regulations for Feed and Feed Ingredients

Section Editor—Doug Lueders

Please see the Current Good Manufacturing Practice regulations, Title 21, CFR parts 507.14–507.28 and the associated checklist, available online at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfCFR/CFRSearch.cfm?CFRPart=507.

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