US Pet Food Regulation: Hot Topics

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Abstract: The US Food and Drug Administration (FDA) Amendments Act of 2007 mandates promulgation of new federal regulations regarding processing, ingredient, and labeling standards for pet foods. Veterinary organizations have submitted comments to assist FDA in this matter. The Association of American Feed Control Officials (AAFCO) is also considering changes that will affect state regulation of pet foods, including revision of the AAFCO Dog and Cat Food Nutrient Profiles and feeding trial protocols, an American College of Veterinary Nutrition proposal to mandate calorie content statements on all dog and cat food labels, and new Good Manufacturing Practices regulations for all animal feeds.

Several changes to the means by which pet foods are regulated are forthcoming. Some of these changes are in reaction to the widely reported recall of dog and cat foods in 2007, while others were under way well before the recall. In both cases, veterinary organizations are involved in the process. Because pet owners often consult with veterinarians on matters relating to pet food, it behooves practitioners to be familiar with these developments.

US Food and Drug Administration

The Center for Veterinary Medicine within the US Food and Drug Administration (FDA) has authority over all animal feeds in interstate commerce. While this authority includes pet foods (complete and balanced foods, treats, supplements, and edible chews), there are no federal regulations stipulating requirements for pet foods specifically (with minor exceptions, such as specifying the conditions of use for iron oxide as a coloring agent in dog and cat foods). For example, while FDA regulations set forth the basic labeling requirements for all animal feeds (e.g., statement of identity, net weight declaration, ingredient declaration, manufacturer's or distributor's name and address), they do not specify rules for declaration of nutrient content, substantiation of nutritional adequacy, or other important aspects of pet food labeling. These issues are instead addressed in the regulations of states that have adopted the Association of American Feed Control Officials (AAFCO) Model Bill and Regulations.

FDA Amendments Act of 2007

Subsequent to a hearing regarding the 2007 recall, the US Congress passed the FDA Amendments Act of 2007 (FDAAA). Most of the FDAAA does not pertain to pet foods, but what it does include with respect to pet foods is far-reaching. The responsibility is placed on FDA to improve its abilities to detect and respond to future incidents involving pet food–borne illness, including better communication with both the public and industry on the status of recalls. Establishment of a reportable food registry, wherein pet food companies must promptly report incidents that may lead to unsafe products, is also a component of the FDAAA. This mandatory reporting system went into effect in September 2009.

While the words themselves are few (BOX 1), the FDAAA requirement for FDA to establish specific pet food regulations, especially with

At a Glance

- US Food and Drug Administration  
- Association of American Feed Control Officials

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regard to nutrition and labeling, may have the biggest impact on commercial pet foods. FDA has invited public comments on this matter, and the American College of Veterinary Nutrition (ACVN), American Academy of Veterinary Nutrition (AAVN), and AVMA have all submitted recommendations. Among the many issues raised by these organizations are the need for calorie content statements, replacement of the crude fiber label guarantee with a more nutritionally relevant measure, and wording on therapeutic diet labels to advise veterinarians and the public that efficacy claims for such products may not have been subject to regulatory scrutiny. The complete comments of these groups, as well as those of other organizations and individuals, may be viewed by visiting regulations.gov (search on “FDA-2007-N-0442” in the “Keyword” box). While the FDAAA mandates that these regulations be promulgated by September 2009, the proposed rules had not been made available for public review and comment at the time this article went to press.

Other Actions
For years before the 2007 recall, FDA had been developing its Animal Feed Safety System (AFSS), a “comprehensive” and “risk-based” program designed to “identify and address gaps” in the management of risk to human and animal health from exposure to animal feeds (including pet foods). Components of the system include the ingredient approval process, contaminant limits, process control (i.e., Good Manufacturing Practices; GMPs), and regulatory oversight.

FDA has been intimately involved in the AAFCO process for many years. In August 2007, FDA and AAFCO signed a Memorandum of Understanding with respect to the latter’s Feed Ingredient Definition procedure. While not the same as a formal Food Additive Petition under FDA regulations, this memorandum increases FDA oversight of the AAFCO procedures for new, amended, or deleted ingredients. FDA has also commissioned a report from the National Research Council (NRC) to help in its safety assessment of novel ingredients.
of commercial pet food production, an expert panel comprising members from academia and the industry was convened by AAFCO to address these issues. The result of the panel's deliberation was the AAFCO Dog and Cat Food Nutrient Profiles, which are still in use. At the same time, the panel instituted changes to improve the scientific rigor of the AAFCO feeding trial protocols (an alternative means of substantiating nutritional adequacy).

Neither the profiles nor the protocols have been revised since 1995. In 2006, NRC published a mandatory reporting system for incidents that may lead to unsafe pet food products went into effect in September 2009.

QuickNotes

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| BOX 2 |

**ACVN PROPOSAL TO AAFCO REGARDING CALORIE CONTENT STATEMENTS ON DOG AND CAT FOOD LABELS**

**Regulation PF9. Statements of Calorie Content**

(a) Except as required in PF1(10), the label of a dog or cat food may shall bear a statement of calorie content when the label meets all of the following:

1. The statement shall be separate and distinct from the “Guaranteed Analysis” and 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 may also be expressed as kilocalories per familiar household measure (e.g., cans, cups, pounds, biscuits); and

3. The calorie content is determined by one of the following methods:

   A. By calculation using the following “Modified Atwater” formula:

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

      Where: ME = Metabolizable Energy
      CP = % crude protein “as fed”
      CF = % crude fat “as fed”
      NFE = % nitrogen-free extract (carbohydrate) “as fed”

      And the percentages of CP and CF are arithmetic averages from proximate analyses of at least four production batches of the product, and 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 accompany 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 claim 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 claim 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, and the value of calorie content stated on the label which is determined in accordance with Regulation PF9(a)(3)B shall not exceed or understate the value determined in accordance with PF9(a)(3)A by more than 15%.

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

As originally proposed in 2005 (some revisions have been made as deliberations continue). Proposed additions and deletions are in underline and strikethrough, respectively.
lished a new document on the nutrient requirements of dogs and cats, including updated scientific information as well as practical considerations pertaining to pet food production. Currently, AAFCO has convened a new panel of experts to review the NRC publication and update the profiles as appropriate, as well as to review and revise the feeding protocols to further their scientific soundness. Some portions of the panel's report are expected to be released for public comment in 2010.

**Calorie Content**

Presently, except for dog and cat food products labeled *lite, low calorie, less calories,* or like terms, calorie content declarations on pet food labels are voluntary. As a result, many dog and cat food labels do not contain this information, and these values are often difficult to obtain from other sources. Calorie content statements are mandatory for “lite” and similarly labeled pet foods. However, some product labels avoid these specific terms and instead use wording such as *weight management formula,* *for less active dogs,* or other, similar phrases. These alternative phrases still imply control of energy intake, but because they do not expressly refer to calories, the labels do not have to declare caloric content.

In 2005, ACVN submitted a proposal to AAFCO that, among other things, would mandate calorie content statements on all dog and cat food labels, including snacks and treats *(BOX 2).* In light of the reported high incidence of overweight and obese pets in the United States, this is a prudent action. Knowledge of calorie content in all types of foods could help veterinarians and owners prevent excess pet weight gain, not just treat the aftermath. Beyond the issue of obesity, knowledge of calorie content for a given product is helpful when determining appropriate feeding amounts for dogs and cats at any life stage, be they growing kittens, working dogs, or lactating dams; hence, limitation of the required label statement to just the “lite” and “less calories” categories of food is insufficient.

The ACVN proposal has been endorsed by AAVN, AVMA, and the American Animal Hospital Association. A statistically sound survey of practicing veterinarians found that an overwhelming proportion (97%) would like to see calorie content statements on pet food labels. Despite these facts, the ACVN proposal has been vigorously opposed by segments of the pet food industry. As a result, after 4 years of debate within AAFCO, deliberations on this matter are ongoing.

**Good Manufacturing Practices**

Historically, safety of pet foods has been monitored by regulators through inspection (including sampling for analysis) of the finished product. Under this practice, a laboratory finding of product contamination with a pathogenic organism or chemical toxin could be used as evidence of adulteration so that regulatory action could be taken. However, in
the past, regulatory officials have spent little effort on monitoring the processes that may lead to contamination. GMPs are in place for canned products to help prevent safety issues specifically related to the complicated sterilization process, as well as for medicated feeds (feeds containing an approved drug, such as an antibiotic or coccidiostat), but not for animal feeds or pet foods in general.

After a number of years of deliberation, AAFCO has recently enacted new model regulations for GMPs that affect all animal feeds, including pet foods. These new rules establish additional requirements regarding handling of materials, training of personnel, sanitation, processing, transportation, and record keeping. A violation of the GMPs could be de facto evidence that a product manufactured under these conditions was adulterated, irrespective or in lieu of a negative laboratory finding of contamination.

**Conclusion**

As evidenced by recent changes, steps to further ensure the safety of pet foods have become a high-priority matter for regulators. Other concerns to be addressed in the near future may include establishment of FDA mandatory recall authority and increased oversight of imported products. By virtue of their expertise in the field of animal health, veterinarians are in a unique position to contribute their viewpoints as these deliberations continue.

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**References**


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**QuickNotes**

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