Regulation of Pet Foods in the United States

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Dr. Dzanis with his bloodhound, Cooper.

Abstract: *In the United States, pet foods (including treats, edible chews, and supplements) are subject to regulation at both federal and state levels. Products found to be adulterated or misbranded are subject to enforcement action. Veterinarians play a key role in helping ensure pet food safety by reporting possible adverse effects to authorities in a timely manner.*

At a Glance

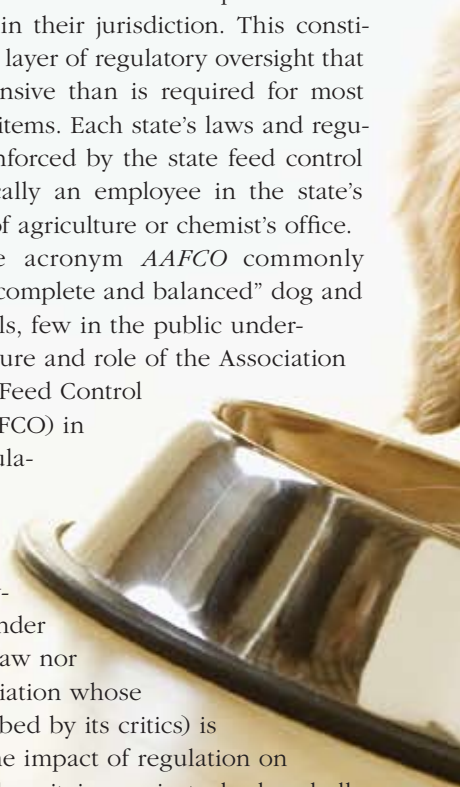
In 2007, the widely reported recall of dog and cat foods due to contamination with melamine and related compounds brought renewed public scrutiny of the pet food industry. The Internet is replete with sites that disparage the nutritive value and safety of commercial pet food products, often implicating poor regulatory oversight. Because pet owners often consult veterinarians on matters relating to pet food, it behooves practitioners to be familiar with the topic of pet food regulation.

Who Regulates Pet Foods?

The US Department of Agriculture oversees meat and poultry products intended for human consumption; however, the same products, intended for animal consumption, fall within the authority of the US Food and Drug Administration (FDA). FDA's Center for Veterinary Medicine has primary jurisdiction over all animal feed in interstate commerce (including imports).[1] "Animal feed" includes pet food, which further encompasses complete and balanced foods, treats and snacks, supplements, edible chews (e.g., rawhides, bones), and the ingredients intended to be incorporated into these products. "Interstate commerce" of a product is determined by the origins of its ingredients, the location where the product was manufactured, and the point of sale or receipt of the product. Most pet foods contain at least some ingredients obtained from sources outside of the state where they are manufactured; therefore, virtually all pet foods fall under federal authority.

Individual state governments also exercise authority over animal feed and pet food distributed within their jurisdiction. This constitutes another layer of regulatory oversight that is more extensive than is required for most human food items. Each state's laws and regulations are enforced by the state feed control official, typically an employee in the state's department of agriculture or chemist's office.

While the acronym *AAFCO* commonly appears on "complete and balanced" dog and cat food labels, few in the public understand the nature and role of the Association of American Feed Control Officials (AAFCO) in pet food regulation. AAFCO is neither a government body empowered to act under authority of law nor a trade association whose goal (as ascribed by its critics) is to mitigate the impact of regulation on industry. Rather, it is a private body wholly comprised of federal, state, and foreign gov-



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ernment officials.[2] Essentially, its role is to provide a Model Bill and Regulations, establish ingredient definitions, and set other standards (such as guidelines for use of the term *natural* and the AAFCO Dog and Cat Nutrient Profiles and feeding trial protocols), via policy or guidance, that represent a consensus among regulators about what constitutes the appropriate regulation of animal feed. Nothing AAFCO publishes has any power of law unless subsequently adopted by individual state legislatures, and not all states follow AAFCO models. However, enough do that AAFCO has nationwide influence.

Representatives of industry and consumer groups can provide information to committees and working groups within AAFCO and are free to voice their opinions at public AAFCO meetings. However, they are not allowed to be members of AAFCO and hence, cannot hold office, make motions, or cast votes on any matter under consideration.

About ACVN

Founded in 1988, the primary objective of the American College of Veterinary Nutrition (ACVN) is to advance the specialty area of veterinary nutrition and increase the competence of those who practice in this field by establishing requirements for certification in veterinary nutrition, encouraging continuing professional education, promoting research, and enhancing the dissemination of new knowledge of veterinary nutrition through didactic teaching and postgraduate programs.

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Government Oversight of Pet Foods

With regard to pet food, the federal and state governments' mandate is to enforce pertinent laws relating to pet food manufacture and distribution. This includes products sold through retail outlets, veterinary clinics, catalogs, and Web sites. The Federal Food, Drug, and Cosmetic Act of 1938 (FFDCA) and equivalent state laws prohibit the distribution of foods that are either adulterated or misbranded.[3] The term *adulterated* may refer to the presence of a chemical, microbiologic, or physical contaminant, including any substance that is not generally recognized as safe, an approved food additive, or an otherwise sanctioned ingredient (e.g., via the AAFCO Feed Ingredient Definition process) for use in pet foods. Failure of a product to meet stated nutrient guarantees or conform to ingredient or nutritional representations is also a form of adulteration.[2] The term *misbranded* relates to false or misleading claims and to labeling that is not in compliance with federal or state regulations. "Drug claims," which are defined as claims that a product can (1) treat, prevent, mitigate, or otherwise affect a disease or condition or (2) affect the structure or function of the body in a manner beyond what is normally ascribed to food, for which the product is not approved, can be considered a form of misbranding.[1]

Most enforcement efforts are conducted by state feed control officials. This is because many state laws (particularly those that follow AAFCO models) mandate periodic (usually annual) product registration and/or company licensure as a condition of distributing in the state.[2] Typically, the process requires submission of product labels for review by the feed control official. Sale of any product found to be misbranded may be denied in that state, affecting not only distribution of the product within the state, but also deliveries from outside the state based on catalog or online sales. While this action would appear to affect only one jurisdiction, in practice, it is infeasible for pet food companies to distribute products in different states with different labels. Hence, labeling found to be objectionable by one state may result in revision of the labeling for nationwide sale of a product.

In addition to their registration/licensure functions, state feed control officials often inspect pet stores and other retail outlets that sell pet foods, including veterinary clinics. Wholesale distribution points within the state are also subject to inspection. Inspectors may search for products that are not properly registered or have been previously denied sale. Samples of products may be obtained from the location for label review and/or laboratory analysis for nutrient content and contamination. Depending on the egregiousness of any violations found, the product may be seized by the regulator, or the company may be notified and allowed time to remedy the violation.

Compared with individual states, FDA conducts little direct enforcement. While FDA can seize product or take other enforcement measures, there are no federal product registration or company licensure requirements at this time (except registration of food manufacturing facilities under the Bioterrorism Act). However, FDA is intimately involved in the process of state enforcement efforts, assisting states with scientific, technical, and regulatory expertise in support of contemplated enforcement actions. For example, feed control officials often refer questionable claims or ingredients to FDA for assessment before taking action, or they may require a company to first obtain FDA's acceptance as a condition of distribution of its product in their state. Also, FDA has taken direct action when it was deemed more effective than a single state's action, such as in cases involving catalog and online sales.

Oversight of Veterinary-Dispensed Products

Veterinarians frequently dispense therapeutic pet foods as part of normal practice. As noted

*Quick*Notes

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above, a pet food label bearing a drug claim is subject to enforcement action. However, FDA often exercises "enforcement discretion" in the case of veterinary therapeutic diets. In other words, it allows companies to convey information to veterinarians on the function of a product as it relates to disease processes, provided that the product is sold under a valid veterinarian/client/patient relationship.[4] This discretion is based on the premise that veterinarians' medical and scientific training is sufficient to enable safe and appropriate use of the product by clients. However, most veterinarians are not aware that the diet/disease claims made by the company most often have not been reviewed and verified by FDA. This is not to imply that such products lack benefit or are unsafe when used as clinically appropriate. On the contrary, manufacturers of therapeutic diets may have extensive documentation. The Veterinary Oral Health Council (VOHC), an organization under the auspices of the American Veterinary Dental College, provides protocols and reviews data from companies with regard to dental plaque and tartar control claims and allows use of its seal of acceptance for products that pass muster in this regard. However, other than VOHC, there are no independent organizations that scrutinize therapeutic diet claims for products sold in the United States.

Many veterinarians also distribute pet supplement products to clients. The Dietary Supplement Health and Education Act of 1994 (DSHEA) diminished FDA's authority over dietary supplements (a subcategory of foods) by allowing the inclusion of ingredients that were previously prohibited in food products as well as broadening the scope of permissible claims relating to function. This act affects only products that meet the statutory definition of dietary supplements, not foods in "conventional" form. Regardless, FDA has given notice of its determination that DSHEA only applies to products intended for human consumption, so that FFDCA still applies to all pet products, whether in conventional (e.g., a complete and balanced pet food) or supplement (i.e., "dosage") form.[5] In response, some manufacturers of pet supplement products containing unapproved food additives (such as many herbs, botanicals, metabolites, and other compounds) have opted for labeling such products as drugs rather than as foods. While still under the authority of FDA and "animal remedy" laws in some states, products so labeled may escape scrutiny by many state feed control officials. Further, although FDA does allow some products on the market as "unapproved drugs of low regulatory priority" based on its determination of reasonable expectations of safety, it is not obvious by their labeling which products have passed FDA muster in this regard and which have not. As a result, some products on the market may not have received adequate review by regulatory officials.

The Veterinarian's Role

Notwithstanding the adverse attention pet foods have received since the 2007 recall, in general, pet foods have a good safety record.[6] Regardless, future contamination incidents are always possible. Clinicians are in an excellent position to detect and report potential pet foodborne illness before a larger outbreak occurs. Suspected or confirmed contamination should be reported to appropriate regulatory agencies (**TABLE 1**)

*Quick***Notes**

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TABLE 1

Reporting Suspected or Confirmed Pet Food Contamination or Adverse Events[a]

Whom to Contact	How to Contact	Alternate Contact Method
Pet food manufacturer	Call "800" telephone number on label.	Visit company Web site.
FDA	Call your FDA district office consumer complaint coordinator. Telephone numbers for district offices are listed at fda.gov/opacom/backgrounders/complain.html.	Call the telephone number listed in the blue pages (for federal agencies) in the telephone directory.
State feed control official (state agency varies but is usually the department of agriculture or chemist's office)	Call an AAFCO member in your state. Telephone numbers are listed in the AAFCO membership directory at www.aafco.org/Directory/MembershipDirectory/tabid/62/Default.aspx.	Call the telephone number listed in the blue pages (for state agencies) in the telephone directory.

[a]Dzanis DA. Anatomy of a recall. *Topics Companion Anim Med* 2008;23(3):133-136. Reproduced with permission.

as well as the manufacturer, which may be in the best position to recognize a pattern of complaints suggesting a safety problem. Pertinent information to relate to regulators and companies includes the product name (including variety) and package size, as well as the universal product code (UPC) number to help identify the exact product in question. Regulators and companies can also use lot or date codes to help pinpoint the production batch(es) of highest concern. The date and place of purchase of the suspect food, as well as relevant medical information regarding the animal, are also helpful. Proper handling of samples of the suspect food as legal evidence may be critical if there is a possibility of a lawsuit at a later date.[6]

Therapeutic pet foods must meet the same processing, ingredient, and labeling standards as any other pet food, including substantiation of nutritional adequacy. A food labeled "This product is intended for intermittent or supplemental feeding only" should not be considered sufficient for long-term feeding as the sole source of nutrition. In consideration of the lack of regulatory review of efficacy claims for therapeutic diets, it is prudent for clinicians to carefully scrutinize data supplied by companies in support of the reported benefits of their products. Outcomes of feeding these diets should be closely monitored.

Before using or recommending any supplement product, veterinarians must practice due diligence in assessing the clinical need for a given supplement in an individual animal; evaluating the strength, quality, and source of data to support the use of the supplement; and judging the integrity and competence of the manufacturer. Veterinarians must also objectively assess outcomes of supplement administration and be open to revising use or recommendations as necessary. Any observed adverse effects should be reported to the appropriate regulatory officials as well as the manufacturer. Members of the National Animal Supplement Council (NASC)—a trade organization representing the interests of supplement manufacturers—that receive adverse event reports must convey that information to the council to be included in its database.[7] NASC allows federal and state regulators, but not the general public, to review this database. C

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Veterinarians must practice due diligence in assessing the clinical need for a given supplement in an individual animal.

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