Death by Dog Food: A Critical Examination of Pet Food Regulation in the United States

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I. INTRODUCTION

When you feed Fido a scoop of wholesome and nutritious dog food, you may actually be giving him a bowl of road kill, dead zoo animals, grocery store garbage including Styrofoam trays and plastic wrap, and even euthanized cats and dogs. While most Americans assume the federal government is protecting their pets from consuming diseased animals and harmful substances, the unfortunate reality is that a lack of resources and a combination of industry pressure has left pet food safety in peril. Many pet owners are unaware of the hidden dangers lurking inside the food they feed their pet every day.

Pet ownership in the United States has steadily increased over the past twenty years. In 1988, fifty-two percent of U.S. households owned a pet, and in 2012 that figure grew to sixty-two percent. Additionally, in a 2009 poll conducted by Petside.com, fifty percent of American pet owners reported that they considered their pets to be a part of their family. As their importance continues to grow, so does the amount of money that pet owners spend on their pets, for items such as veterinary care, grooming, boarding, and supplies. In fact, in 2012, total U.S. pet industry expenditures were $52.87 billion. Of that amount $20.46 billion was spent on pet food alone.

Recent pet food recalls and illness outbreaks have led many consumers to question the safety of pet food in the U.S. At first glance, it appears that pet food is heavily regulated but closer examination reveals a complex web of industry-dominated groups promulgating self-serving rules and regulations that will continue to ensure a healthy profit. While some of the

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1 See ANN M. MARTIN, FOOD PETS DIE FOR: SHOCKING FACTS ABOUT PET FOOD 16 (3d ed. 2008).
5 Id.
most recent pet food crises have led Congress to pass federal legislation designed to increase food safety regulations, much has yet to be done to implement the measures. Additionally, some areas of concern have not been addressed at all, leaving serious gaps in the regulatory system.

In an effort to restore consumer confidence in pet food safety, the United States Food and Drug Administration (FDA) should re-examine mandates given to them by Congress in recent years. Instead of allowing pet food industry representatives to secure legislation allowing a non-governmental organization, dominated by industry insiders, to take over some of these responsibilities, the FDA should promulgate appropriate regulations itself. While the FDA is not immune from industry pressure, at the least, the federal rulemaking process will invite public comment and discussion from a wide array of interested parties, including pet owners and consumer protection groups. In addition, the ability to evaluate and comment on potential regulations will allow consumers to better educate themselves about current pet food ingredient and labeling standards, which will allow them to make more informed choices in the future.

In addition to carrying out responsibilities given to it by Congress, the FDA should take proactive steps to eliminate some of the most concerning gaps in pet food regulation. As will be discussed below, the FDA is aware that potentially dangerous substances are entering pet foods through the rendering process. Although resources are scarce and industry pressure is difficult to overcome, the FDA has displayed its ability to address such issues in the past. In fact,

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7 As part of the federal rulemaking process, an agency must issue a notice of the proposed regulation, allow public comments, and respond to the comments before developing a final rule. CURTIS W. COPELAND, CONG. RESEARCH SERV., RL32240, THE FEDERAL RULEMAKING PROCESS: AN OVERVIEW 2 (2011).

8 Despite industry opposition, the FDA banned the use of cattle that tested positive for Bovine Spongiform Encephalopathy and the brains and spinal cords of cattle 30 months or older from use in animal feed. See Substances Prohibited from Use in Animal Food or Feed, 21 C.F.R. § 589 (2009).
addressing some of the known risks does not have to be extensive or cost-prohibitive. The FDA can take relatively simple steps, similar to recent regulations adopted in the European Union.

As part of its new proactive approach to food safety in general, as mandated by the Federal Food Safety Modernization Act of 2011, the FDA should prohibit certain production practices that allow risky substances to enter pet food before there is another national crisis. Numerous pets should not have to die because the FDA could not muster the will to stand up to the pet food industry.

II. BACKGROUND AND HISTORY OF PET FOOD REGULATION IN THE UNITED STATES

Pet food regulation in the United States is complex and involves a number of different organizations. Primary to this discussion are the United States Food and Drug Administration (FDA) and the Association of Animal Feed Control Officials (AAFCO). The FDA is the primary governmental organization charged with regulating pet food in the United States; however, due to “limited enforcement resources that are focused on human food safety issues,” they do so in partnership with the AAFCO, a private non-governmental organization. Additionally, each state has the ability to regulate pet food on a local level.

A. United States Food and Drug Administration

The United States Food and Drug Administration (FDA), an agency within the United States Department of Health and Human Services, is responsible for regulating food safety in the United States. Pursuant to the Federal Food, Drug, and Cosmetic Act (Act), the FDA is charged with ensuring that all foods are safe to eat, wholesome, sanitarily produced, and properly

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labeled.\textsuperscript{13} The Act defines food as “articles used for food or drink for man or other animals, and articles used for components of any such article.”\textsuperscript{14} Within the FDA, the Center for Veterinary Medicine (CVM), manages the FDA’s pet food programs.\textsuperscript{15} As part of this responsibility, the CVM is responsible for regulating pet food additives and ingredients.\textsuperscript{16}

Federal law does not require pet foods to have pre-market approval by the FDA, however, similar to foods intended for human consumption, pet foods must be safe to eat, sanitarily produced, and properly labeled.\textsuperscript{17} Additionally, the FDA is required to approve any substance intentionally added to pet food if it is not generally recognized as safe (GRAS).\textsuperscript{18} A food additive may be established as GRAS if the substance is generally available and there is a consensus among qualified experts about the safety of the substance for its intended use.\textsuperscript{19} If the substance is not GRAS, the manufacturer can submit a food additive petition to the FDA that describes such things as the chemical identity, manufacturing process and controls, analytical methods, and target animal safety data.\textsuperscript{20} If a product contains a food additive that is not GRAS and the substance has not been pre-approved by the FDA, the product may be deemed adulterated and the manufacturer subject to penalties.\textsuperscript{21}

\begin{flushright}
\textsuperscript{13} Id.
\textsuperscript{15} FDA’s Regulation of Pet Food, supra note 10.
\textsuperscript{16} Id.
\textsuperscript{17} Id.
\textsuperscript{20} FDA’s Regulation of Pet Food, supra note 10.
\end{flushright}
Although the FDA is required to pre-approve food-additives that are not GRAS, the CVM has decided not to require food additive petitions for substances that do not raise any safety concerns.\textsuperscript{22} Citing the time-consuming approval process, the CVM claims to be conserving agency resources by asking manufacturers to submit information about the proposed food-additive to the Association of American Feed Control Officials, a non-governmental organization described below, for publication on its list of ingredients that are appropriate for use in animal feed.\textsuperscript{23} Admittedly, these ingredients are not approved food additives but the CVM has agreed not to take regulatory action in these instances.\textsuperscript{24}

\textbf{B. Association of American Feed Control Officials}

The Association of American Feed Control Officials (AAFCO) is a voluntary membership organization composed of local, state, and federal agencies, as well as government agencies from other countries that are responsible for executing laws and regulations pertaining to animal feed or feed ingredients.\textsuperscript{25} In addition, the AAFCO invites representatives of industry and trade associations to serve as advisors to its committees, task forces, and work groups.\textsuperscript{26}

The AAFCO does not have any regulatory authority in the U.S., but provides a forum for industry representatives to achieve three stated goals of “ensuring consumer protection, safeguarding the health of animals and humans, and proving a level playing field of orderly

\begin{itemize}
\item If a person violates § 331, they are subject to “imprisonment for not more than one year or fined not more than $1,000, or both.” 21 U.S.C. § 333 (2010).
\item FDA’s Regulation of Pet Food, supra note 10.
\item Id.
\item Id. The CVM has agreed not to take regulatory action for the use of these un-approved feed ingredients “as long as the labeling is consistent with the accepted intended use, the labeling or advertising does not make any drug claims, and new data are not received that raise questions concerning safety or suitability.” Id.
\item Committee Advisors, ASS’N OF AM. FEED CONTROL OFFICIALS, http://www.aafco.org/Directory/CommitteeAdvisors.aspx (last visited Nov. 28, 2012). For example, advisors for the Feed and Feed Ingredient Manufacturing Committee include representatives from the National Renderers Association, the American Pet Products Association, and the American Feed Industry Association. Id.
\end{itemize}
commerce for the animal feed industry.” Additionally, the AAFCO develops model laws and regulations for the manufacture, distribution, and sale of animal feeds and ingredients. Many states in the U.S. have adopted AAFCO’s model regulations as the basis for their statewide feed control programs.

Although the AAFCO does not regulate pet food, the organization establishes nutritional standards for “complete and balanced pet foods” based on recommendations of the National Research Council (NRC). In order for a manufacturer to market their product as complete and balanced under AAFCO’s standards, the pet food must meet one of the AAFCO’s nutrient profiles, pass a feeding trial, or be established as a member of a “product family.”

Conceptually, a feeding trial sounds like a good method to determine nutritional adequacy, however, the AAFCO’s guidelines for these trials seem woefully inadequate. A feeding trial need only use a minimum of eight animals and last a mere twenty-six weeks. To successfully complete the trial, animals cannot lose more than fifteen percent of their body weight.

27 ASS’N OF AM. FEED CONTROL OFFICIALS, supra note 25.
29 Id.
32 Patrick, supra note 30.
Further, the AAFCO allows twenty-five percent of the animals involved in the trial to be removed for non-nutritional reasons or poor food intake.\(^3^4\)

The third method of qualifying as complete and balanced is being established as a member of a “product family.” To qualify, the lead product member must pass an AAFCO feeding trial. Other members of the product family can thereafter be deemed nutritionally similar to the lead product by meeting specified nutrient and calorie criteria. If the product successfully meets the above guidelines, the manufacturer can market the product as a complete and balanced pet food.\(^3^5\)

In addition to creating model regulations and establishing nutritional standards, the AAFCO issues an Official Publication each year that includes a list of ingredients that are appropriate for use in animal feed.\(^3^6\) Through its “New and Modified Feed Ingredient Definitions Process,” the AAFCO determines the suitability of feed ingredients and establishes standard ingredient names.\(^3^7\) AAFCO investigators review petitions for new feed ingredients and modifications to existing feed ingredients to determine the suitability of the ingredient for its proposed use.\(^3^8\) The FDA is a member of the AAFCO and acts as a scientific advisor during the ingredient review process.\(^3^9\)

In 2007, the FDA entered into a memorandum of understanding (MOU) with the AAFCO to allow the FDA to formally recognize the AAFCO process and clarify the FDA’s role in

\(^{3^3}\) Martin, supra note 1, at 52-53. Animals must be of normal weight and health prior to starting the feeding trial. Id. While animals cannot lose more than 15 percent of their body weight during a feeding trial, there is no limit on the amount of weight an animal may gain during the trial. Patrick, supra note 30.

\(^{3^4}\) Patrick, supra note 30. The manufacturer does not have to disclose data from the dispatched animals in the final study report to the AAFCO. Id.

\(^{3^5}\) The Business of Pet Food, supra note 30.

\(^{3^6}\) FDA, AAFCO Sign Agreement on Feed Ingredient Listing, U.S. FOOD AND DRUG ADMIN. (Nov. 19, 2007), http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm048025.htm.

\(^{3^7}\) Id.


\(^{3^9}\) FDA, AAFCO Sign Agreement on Feed Ingredient Listing, supra note 36.
reviewing ingredients for the list. Specifically, the MOU requires the AAFCO to seek advice and a letter of concurrence regarding the suitability of the proposed ingredient from the FDA prior to adopting the ingredient definition or modification. Additionally, the MOU directs the AAFCO to accept requests from the FDA to remove ingredient definitions from the list if the FDA presents information or scientific evidence showing the ingredient is no longer suitable for its intended use.

When the MOU expired on September 1, 2012, the FDA agreed to extend the agreement for one year. According to the FDA, the MOU was extended to allow adequate time to transition to new ingredient approval processes that are in development. At the conclusion of the one-year extension, the FDA will transition from being an active participant in AAFCO’s ingredient review process to merely serving as a liaison and advisor to the AAFCO Ingredient Definition Committee. Additionally, the FDA will stop accepting requests to review new ingredient definition submissions in February 2013 because of the increasing amount of resources needed to address such submissions. Although the FDA referred to new approval processes that are in development, it appears that the MOU was extended to allow the feed industry to obtain a legislative amendment to gain formal recognition of AAFCO’s ingredient definitions in the Federal Food, Drug, and Cosmetic Act. Accordingly, this would leave

40 FDA, AAFCO Sign Agreement on Feed Ingredient Listing, supra note 36.
41 MOU, supra note 38.
42 Id.
43 Id.
45 Id.
46 Id.
AAFCO’s ingredient approval process intact and open the door to the AAFCO legally setting standards for the feed industry.\textsuperscript{48}

While it is unknown if the feed industry will be able to successfully amend federal law, the prospect of allowing the AAFCO to regulate pet food raises some significant concerns. First, the AAFCO is a private organization and is not subject to governmental oversight. Further, industry interests dominate the AAFCO and its Ingredient Definition Committee.\textsuperscript{49} While the AAFCO purports to invite representatives of consumer groups, in addition to industry and trade associations, to serve as advisors to its committees, task forces and work groups, there are only two representatives from one consumer group serving as advisors to one of the AAFCO’s thirteen committees.\textsuperscript{50}

Allowing the AAFCO to regulate pet food ingredients will essentially formalize the process of allowing the feed industry to regulate itself. This has the potential of further eroding already shaky public confidence in pet food safety.

\textbf{C. State Regulation}

As mentioned above, each state is also permitted to regulate pet food on a local level. Many states have enacted their own ingredient and labeling requirements and, in addition, some states require pet food companies to register locally prior to selling their products in that particular state.\textsuperscript{51} Many states have utilized the AAFCO model rules and regulations in adopting their own regulatory regimes, and in fact, the Pet Food Institute reported in 2007 that at least

\textsuperscript{49} See Id.

\textsuperscript{49} Advisors for the Ingredient Definitions Committee include representatives from the American Feed Industry Association, the American Pet Products Association, the National Grain and Feed Association, the Enzyme Technical Association, the National Oliseed Processors Association, the National Renderers Association, and the Pet Food Institute. While the AAFCO claims that consumer industry groups may also serve as committee advisors, there are currently none serving the Ingredient Definitions Committee. Committee Advisors, supra note 26.

\textsuperscript{50} Id. Two representatives from Defend Our Pets serve as advisors to the Pet Food Committee, however one of those representatives is listed as an alternate. Id.

\textsuperscript{51} See Hillestad, supra note 11.
thirty-eight states adopted the AAFCO model regulations into law in whole or in part.\textsuperscript{52} There are also some states that have chosen not to adopt any additional pet food regulations, relying instead on federal requirements.\textsuperscript{53}

III. \textbf{Current Regulatory Measures and Their Adequacy}

In response to a large-scale recall of pet food in 2007 and as a result of other safety issues identified apart from the recall, there have been some significant changes to the way the federal government regulates pet food in recent years. While many of these changes represent a positive step for pet food safety, the current status of those regulations leave a lot to be desired. Some of the most relevant changes are detailed below, followed by an examination of why these steps are inadequate.

A. \textit{Federal Food and Drug Administration Amendments Act of 2007}

In 2007, United States consumers experienced the largest pet food recall in the country’s history. The recalled foods, sold primarily by Menu Foods Income Fund, contained wheat gluten that was contaminated with melamine, an industrial chemical used in products such as plastics and cleaning products.\textsuperscript{54} While not highly toxic on its own, melamine can cause renal failure in pets when combined with cyanuric acid, another contaminate found in the recalled products.\textsuperscript{55} Although there were upwards of 14,000 complaints from pet owners about pet illnesses or deaths associated with the contaminated food, it is unclear exactly how many animals were affected

\textsuperscript{52} S.B 1773, 2007-2008 Leg., Reg. Sess. (Ca. 2007). For example, California has only adopted some of the AAFCO model rules and regulations as part of their regulatory regime. \textit{Id.}

\textsuperscript{53} Patrick, \textit{supra} note 30. As of 2008, Florida, Nebraska, and Nevada did not have any state regulations for pet food. \textit{Id.}


because the FDA does not have a surveillance network to confirm pet illnesses or deaths. The FDA’s complaint system “is designed to identify emerging problems and does not provide data on the patterns and causes of disease that would enable FDA to conclusively link illness or death with a specific product.”

In response to the public outcry linked to the recall, U.S. Senator Durbin and U.S. Representative DeLauro introduced the Human and Pet Food Safety Act of 2007. The legislation would have required the FDA to recall contaminated food in addition to developing ingredient and labeling standards for pet food. While this legislation was ultimately unsuccessful, Senator Durbin amended several of the food safety provisions contained in his original bill to the Federal Food and Drug Administration Amendments Act (FDAAA) of 2007.

The FDAAA directed the Secretary of Health and Human Services, in consultation with the AAFCO and other relevant stakeholder groups, to establish ingredient standards and definitions, processing standards, and updated labeling standards for pet food within two years of the date of enactment of the legislation. Additionally, the FDAAA directed the Secretary, within one year of the date of enactment, to establish an early warning and surveillance system to identify adulteration of the pet food supply and outbreaks of illness associated with pet food. President Bush signed the FDAAA of 2007 into law on September 27, 2007.

i. Progress on Ingredient Standards and Definitions

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On January 7, 2008, the FDA established a docket in the Federal Register to receive comments from stakeholders about section 1002(a) of the FDAAA, which mandated the FDA to establish ingredient standards and definitions, processing standards and updated labeling standards for pet food. Additionally, four months later, the FDA held a public meeting to gather input from the AAFCO and other stakeholder groups about the development of the required ingredient and labeling standards. In its public meeting notice for the May 2008 gathering, the FDA expressed concerns about the new mandated regulations. Specifically, the FDA stated:

[T]hat certain new requirements, if limited to pet food only, would be impractical to implement, difficult to enforce, and would not effectively provide the safety enhancements intended by FDAAA. Furthermore, because the standards mandated by FDAAA do not currently exist for any animal food or feed, limiting new requirements to pet food only would fail to address the broader food safety concerns associated with food intended for other animal species, particularly food-producing animals.

Despite these concerns, the FDA held the public meeting, as planned, on May 13, 2008, at which they received oral and written comments. Unfortunately, since the May 2008 meeting, the FDA has taken no additional steps in the rulemaking process.

Although the FDAAA set a two-year deadline for the promulgation of regulations to ensure pet food safety, no such regulations exist. According to the FDA, more than three years past the deadline set by Congress, they are “reviewing the comments to the docket and determining the intent of the mandate to establish standards and definitions.” Not surprisingly many comments submitted by pet food industry groups encouraged the FDA to either model any new ingredient definitions after or formally adopt the AAFCO ingredient list citing “regulatory

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64 Overview of FDA Animal Feed Safety System, supra note 62.
confusion” and “marketplace chaos” should the FDA adopt ingredient definitions that differ from AAFCO’s list. Additionally, industry comments encouraged the FDA to seek input from pet food suppliers, manufacturers, and representatives of the animal feed business before attempting to redefine any existing definitions.

While the FDA did sign an MOU with the AAFCO to formally recognize its list of suitable pet food ingredients shortly after the FDAAA was signed into law, this is no substitute for regulations that have the force of law. Additionally, as discussed above, allowing the pet food industry to seek an amendment to gain formal recognition of AAFCO’s ingredient definitions in federal law rather than creating the regulations called for in the legislation is not the appropriate solution.

ii. Progress on Updated Labeling Requirements and an Early Warning and Surveillance System

Although the FDA does not seem to be moving forward with regulations regarding ingredient definitions and processing standards, the FDA is not doing as poorly with respect to the updated labeling requirements, also mandated by the FDAAA. Though well past the two-year deadline required by the legislation, the FDA has acknowledged – and the public, pet food industry, government agencies, and the AAFCO agree – that current pet food labeling standards “can be improved to provide more meaningful information to pet owners about the nutrition and

66 COMMENTS OF AM. FEED INDUS. ASS’N, supra note 65.
safe use of the food they purchase for their pets. The FDA has indicated that a proposed regulation is expected in 2012. As of the writing of this article, no further action has been taken by the FDA.

In fact, the only mandate that the FDA has complied with to date is the establishment of an early warning and surveillance system, however the FDA already had an existing consumer products complaint system that has been in operation since at least 1994. The FDA’s Consumer Complaint Reporting system is a telephone-based system that allows consumers to report complaints about an FDA-regulated product, including problems related to pet food and treats. The FDA follows up on complaints received as necessary.

While the FDA may not agree with or like the mandate given to them by Congress, they had a duty to meet their entire obligation and promulgate all of the appropriate regulations called for in the FDAAA. Partial compliance is not acceptable for a federal agency charged with protecting the nation’s food supply. At the expense of animal welfare, the FDA has decided to ignore this deadline and continues to allow the industry to self-regulate.

B. Food Safety Modernization Act and the CVM’s Animal Feed Safety System

In a continued effort to ensure safety of the food supply, Congress passed the Food Safety Modernization Act (FSMA) in 2011, which significantly changed the way the FDA regulates

67 Overview of FDA Animal Feed Safety System, supra note 62 at 19.
68 Id. at 20.
human and animal feed.\textsuperscript{71} One of the most noteworthy effects of the FSMA is a shift in the FDA’s regulatory approach. The law encourages the FDA to adopt preventative control regulations instead of responding to food crises as they occur.\textsuperscript{72}

Prior to passage of the FSMA, the CVM began development of a program designed to make the FDA’s feed regulatory program “comprehensive and risk-based.”\textsuperscript{73} Initially, the goal of the Animal Feed Safety System (AFSS) was to describe how animal feeds should be manufactured and distributed to minimize risks to animals that consume animal feeds and humans that consume food products from animals.\textsuperscript{74} The AFSS sought to accomplish these goals by identifying gaps in animal food regulations and offering proposals for ways to fill the identified gaps.\textsuperscript{75} After passage of the FSMA, the CVM decided to “use AFSS as the title of FDA’s program aimed at protecting human and animal health by ensuring production and distribution of feed that is safe.”\textsuperscript{76} According to the FDA, “as the FSMA is implemented, the AFSS team will continue to pursue projects previously identified, to work on assignments to implement FSMA, and to develop new projects which would benefit from having input from a cross section of the FDA and state feed safety expertise.”\textsuperscript{77}

\textsuperscript{72} See FDA Animal Feed Safety System Update #8, supra note 9. In addition to shifting the FDA’s regulatory approach, the FSMA expanded the FDA’s food safety activities and improved the FDA’s capacity to detect and respond to food safety problems. Further, the legislation authorized the Secretary to order a recall of an article of food if the manufacturer of the unsafe food product does not voluntarily recall the product in a timely manner. Id.
\textsuperscript{73} Animal Feed Safety System Update #9, U.S. FOOD AND DRUG ADMIN., http://www.fda.gov/AnimalVeterinary/SafetyHealth/AnimalFeedSafetySystemAFSS/ucm314014.htm (last updated Aug. 1, 2012). Prior to implementation of the AFSS, the FDA’s feed program focused on specific safety issues but did not address feed safety in a comprehensive manner. According to the FDA, risk based decision making will allow the FDA to direct regulatory resources to feed hazards that pose the greatest risk to animal and public health. Overview of FDA Animal Feed Safety System, supra note 62 at 4.
\textsuperscript{75} FDA Animal Feed Safety System Update #8, supra note 9.
\textsuperscript{76} Animal Feed Safety System Update #9, supra note 73.
\textsuperscript{77} Id.
As part of its transition to a preventative system, the CVM issued an Overview document that, among other things, details a number of operating principles that will form the basis of the AFSS going forward. While a number of these principles appear to be positive steps toward safer pet foods, the principles continue to articulate a reliance on the pet food industry to self-regulate, charging the feed and animal production industries with responsibility for the production, distribution, and use of safe feed.

C. Ruminant Feed Ban

In the mid 1980’s Bovine Spongiform Encephalopathy (BSE), also known as “mad cow disease,” was discovered in 18,000 cattle in the United Kingdom and approximately 1,800 cattle elsewhere in the European Union. The outbreak was linked to contaminated cattle feed. After cows and sheep are slaughtered and their edible parts removed, the inedible parts are rendered into fat and meat and bone meal. Although the ruminant parts are cooked at high temperatures, the BSE agent is able to survive. When the contaminated meat and bone meal are fed to cattle, the disease can be passed on.

To prevent the spread of BSE in the United States, the FDA passed a ban in 1997 on the use of certain mammalian proteins in feed for ruminant animals, which include cattle and sheep. Use of these materials was still permitted in feed for non-ruminant animals, including pets.

While dogs, birds, reptiles, and horses are not known to be susceptible to BSE, cats are susceptible and approximately ninety cats in the European Union were diagnosed with the feline

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78 FDA Animal Feed Safety System Update #8, supra note 9.
79 For example, the Overview document specifies that “Feed intended for non-food producing animals, such as pets, is included along with feed for food-producing animals.” Overview of FDA Animal Feed Safety System, supra note 62 at 5.
80 Id.
81 Linda Bren, Trying to Keep “Mad Cow Disease” Out of U.S. Herds, XVI No. II FDA VETERINARIAN, 1, 3 (Mar./Apr. 2001).
82 Id.
83 Substances Prohibited from Use in Animal Food or Feed, 21 C.F.R. § 589 (2009).
version of BSE. As a result, the FDA expanded the ruminant feed ban to prevent the use of certain cattle materials, including entire carcasses of BSE-positive cattle and the brains and spinal cords of cattle thirty months of age or older, in the food of all animals.

i. Continued Use of Animal By-Products and Other Ingredients Not Fit for Human Consumption

While the ruminant feed ban was a positive step, the use of animal by-products and other ingredients not fit for human consumption still poses a substantial risk to pet food safety. Although the FDA has not yet established ingredient standards and definitions for pet food, most ingredients included on pet food labels have a corresponding definition in the AAFCO’s Official Publication. One of these products is meat meal. The AAFCO defines meat meal as “the rendered product from mammal tissues, exclusive of any added blood, hair, horn, hide trimmings, manure, stomach and rumen contents.” It is not the use of meat meal itself that is a cause for concern, as meat meal seems to have nutritional benefits when used in pet food. Rather it is the types of animals that are processed into meat meal used in pet food.

Rendering is the process used to convert dead animals and animal parts that are not fit for human consumption into a variety of materials, including meat and bone meal. Renderers convert more than forty seven billion pounds of raw animal materials into approximately eighteen billion pounds of product annually, valued at more than $3 billion. Of the eighteen billion pounds of product produced, more than six billion pounds were meat and bone meal.

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85 21 C.F.R. § 589.
Poultry operations and pet food manufacturers accounted for more than sixty-six percent of the meat and bone meal market in 2000.  

Renderers receive animal material from meat slaughtering and processing plants; dead animals from farms, ranches, feedlots, marketing barns, animal shelters, and other facilities; and fats, grease, and other food waste from restaurants and grocery stores. During the rendering process, the raw materials are put into batch cookers, which evaporate moisture. The fat is separated from protein and bone and the solid protein is pressed into cake for processing into feed. Restaurant grease is rendered in a separate process and used in non-human products, including animal feeds.

During the meat slaughter and packing process, animal carcasses are inspected for indications of disease and suitability for human consumption. Animal carcasses that are condemned are separated and either destroyed or denatured with a substance, such as crude carbolic acid or cresylic disinfectant. These denatured animal materials can then be rendered for use in pet food.

In addition to these denatured animal products, euthanized companion animals can also be rendered for use in pet food. There is no law prohibiting the rendering of companion animals in the U.S., which was confirmed by the FDA. Christine Richmond, a spokesperson for the FDA Division of Animal Feed, stated that “[i]n recognizing the need for disposal of a large number of unwanted pets in this country, CVM has not acted to specifically to prohibit the

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89 Id.
90 Id.
91 Id.
92 Id.
94 9 C.F.R. § 314.3 (2012).
95 See Baker, supra note 88 at 3. See also EPA, supra note 93.
96 See Martin, supra note 1.
rendering of pets. However, that is not to say that the practice of using this material in pet food is condoned by CVM.\(^9^7\)

This reality is further illustrated by a 2002 investigation by the CVM into reports of sodium pentobarbital in dog food. Sodium pentobarbital is a chemical used to euthanize animals in the U.S. and according to a University of Minnesota study the chemical survives the rendering process without undergoing degradation.\(^9^8\) In its study, the CVM did find sodium pentobarbital in some samples of dog food and concluded that the residues are entering pet foods from euthanized, rendered cattle or horses.\(^9^9\) Although, in their report, the scientists who conducted the CVM studies revealed that none of the samples tested positive for equine derived proteins. In fact, the samples did not point to a single protein source responsible for the contamination.\(^1^0^0\) The only common feature of the samples was the presence of animal fat.\(^1^0^1\)

During the study, the CVM also developed a method for testing the DNA of rendered material used in pet foods and inspected some of the samples for remnants of dogs and cats.\(^1^0^2\) While they did not find any dog or cat DNA in any of the samples tested, the study was rather limited. The CVM only tested seventy-five dry dog food samples for the presence of sodium pentobarbital, all purchased from the same geographic region.\(^1^0^3\) Of those seventy-five samples, only thirty-one were tested for the presence of canine DNA.\(^1^0^4\) Additionally, while the results


\(^{100}\) Id.

\(^{101}\) Id.

\(^{102}\) Id.

\(^{103}\) Id. at 43.

\(^{104}\) Id.
demonstrated an absence of canine DNA in all thirty-one samples, at the level of detection tested, the scientists who conducted the study could only say “if there is any canine material in the dog food, it is present at a rate of less than 7 lb. per 500 tons.” It is conceivable that these types of animals can be included in pet food because as noted above, the CVM has not taken any steps to make the practice illegal.

Despite the discovery of sodium pentobarbital, the CVM did not take any action to eliminate this chemical from pet foods. The CVM concluded that the low level of sodium pentobarbital found in dry dog food was unlikely to cause any adverse affects based on the amount of food a dog would need to eat in one day to reach a toxic level. While one day’s worth of pet food may not have a toxic level of sodium pentobarbital, the CVM study did not contemplate exposure to the chemical on a long-term basis. The study only lasted for an eight-week period. The median life expectancy for a dog is twelve and one-half years.

There is already evidence that sodium pentobarbital and the agent that causes BSE are able to survive the rendering process. It is plausible there are additional substances that can also survive rendering. Because pet food does not need to receive pre-market approval prior to being sold in the U.S., other harmful substances may be entering pet food undetected by the FDA.

D. Lack of Uniformity Throughout the United States

As discussed in section II. C., each state is free to adopt its own pet food regulations, and many have adopted all or part of the AAFCO model regulations. This can be problematic as pet foods are sold throughout the U.S. and even exported to other countries. Industry groups have

105 Id.
106 Id.
107 *See* Martin, *supra* note 1 at 44-45.
108 Id.
warned the FDA that national regulations that vary from AAFCO’s model regulations have the
potential to be costly and confusing for federal and state regulators.111 While the AAFCO has
attempted to put forward a comprehensive, uniform approach to pet food regulation,112 the reality
remains that each state can, and most do, vary in their approach. The only way to ensure a
comprehensive, uniform system is to establish one at the federal level rather than rely on
individual states to adopt the model rules of a non-governmental organization with no regulatory
authority themselves.

IV. RECOMMENDATIONS

Although the FDA has taken steps in recent years to eliminate some risks in pet food, its
efforts seem incomplete. As the FDA continues to implement the AFSS and shift its regulatory
approach, it should continue to focus on prevention, rather than reaction. Comprehensive,
preventative measures regulating the pet food industry can prevent needless deaths of companion
animals throughout the country.

A. Fully Implement the FDAAA of 2007

Congress directed the FDA to adopt regulations to ensure the safety of pet food more
than five years ago. To date, many of the mandates have been left unanswered despite
widespread public support. In response to the FDA’s call for input regarding potential
implementation of the FDAAA of 2007, more than 200 comments were received.113 Though the
remarks from industry groups displayed resistance to proposed changes, many of the comments

111 COMMENTS OF AM. FEED INDUS. ASS’N, supra note 65.
112 See COMMENTS OF PET FOOD INST., supra note 65.
113 Meeting Being Planned to Obtain Public Input for Ensuring the Safety of Pet Food, REGULATIONS.GOV,
http://www.regulations.gov/#!docketBrowser;dct=PS;rpp=25;po=0;D=FDA-2007-N-0442 (last visited Nov. 20,
2012).
from concerned pet owners and consumer interest groups displayed hope that the FDA would finally address some of the safety issues plaguing pet food.\textsuperscript{114}

The FDA should re-invest efforts to finally come into full compliance with the statute and adopt comprehensive regulations for pet food ingredient and processing standards as well as labeling requirements. Furthermore, the FDA should not step aside and allow the pet food industry to seek formal approval of AAFCO processes in place of establishing a comprehensive, uniform system of regulation that reflects industry and consumer interests.

In passing the FDAAA of 2007, Congress recognized that further steps to ensure the safety of the food supply are needed. However, they also acknowledged that the FDA’s resources are limited. In their findings, Congress stated that it is:

\begin{quote}
\begin{center}
vital for Congress to provide the Food and Drug administration with additional resources, authorities, and direction with respect to ensuring the safety of the food supply in the United States; additional inspectors are required to improve the Food and Drug Administration’s ability to safeguard the food supply of the United States.\textsuperscript{115}
\end{center}
\end{quote}

While economic realities may prevent Congress from providing the FDA with additional resources in the immediate future, the FDA should work with Congress to identify and implement cost-saving measures and agency-wide initiatives so that they are able re-direct funds to protecting the nation’s food supply. When the economic situation improves, the FDA and interested stakeholder groups should lobby Congress and the Administration for additional funding for food protection measures.

\textsuperscript{114} For example, Lyn Dvorak stated: “I was one of the many people that lost a loving pet due to the inadequate testing of food products. Not only should products be tested better, but shipping regulations should be increased for better protection.” U.S. FOOD AND DRUG ADMIN., FDA-2007-N-0442-0040, PUBLIC SUBMISSION FROM LYN DVORAK ON DOCKET NO. 2007-N-0442 (May 14, 2008) \textit{available at} http://www.regulations.gov/#\documentDetail;D=FDA-2007-N-0442-0040. Further, Michael Floyd, found of Defend Our Pets stated: “Virtually the entire infrastructure of the pet food industry is decayed and unresponsive to the demands of consumers for safe and healthy pet food, AND fair and accurate labeling.” U.S. FOOD AND DRUG ADMIN., FDA-2007-N-0442-0042, PUBLIC SUBMISSION FROM DEFENDOURPETS.ORG ON DOCKET NO. 2007-N-0442 (Apr. 5, 2008) \textit{available at} http://www.regulations.gov/#\documentDetail;D=FDA-2007-N-0442-0004.

B. Adopt a Standard Similar to the European Union for Use of Animal By-Products in Pet Food

All countries have their own approach to pet food regulation, some which may be better or worse than the U.S. Regime. One set of regulations, promulgated by the European Union, is a good example of a simple change that could eliminate many of the risks posed by the use of ingredients not fit for human consumption in animal food.

In 2003, the Scientific Steering Committee for the European Parliament and Council concluded that animal by-products derived from animals not fit for human consumption should not enter the feed chain and their uses should be limited.116 To this end, the Council adopted a regulation dividing animal by-products into three categories based on their potential risk to humans, animals, and the environment. The regulation limited the use of animal by-products in pet food to Category three materials, which include by-products derived from healthy animals slaughtered for human consumption.117

Prior to passage of the regulation, raw material of a lower standard was permitted in pet food. The practice of recycling cadavers and material unfit for human consumption in the feed chain was a factor in spreading BSE and other epidemics in European countries.118

The FDA should consider a ban similar to that imposed in the EU on the use of animals not fit for human consumption in pet foods. Animals in the U.S. are being exposed to harmful chemicals and other ingredients due to the type of animals rendered into meat meal and the practices of the rendering industry. As discussed above, condemned animals, road kill, grocery store garbage, and euthanized cats and dogs are just some of the substances permitted for use in pet food. Additionally, in her book Food Pets Die For, Ann Martin details the practices of the

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117 Id. at 11, 19-20.
118 Id. at 2-3.
rendering industry, including putting the remains of dead animals into rendering vats along with flea collars and id tags.\textsuperscript{119} Simply prohibiting the use of materials not fit for human consumption in pet food can eliminate many of the risks associated with these unsavory materials.

The rendering industry is a huge political force in the country, and based on past experiences, the FDA can anticipate strong resistance if a similar ban is proposed in the U.S. For instance, when the FDA sought public comments on its expansion of the 1997 ruminant feed ban, industry groups expressed concerns about increased financial burdens and difficulties associated with removing brains and spinal cords from dead cattle.\textsuperscript{120} In fact, the National Cattleman’s Beef Association circulated materials encouraging opposition to the feed ban because of increased production costs and diminished market value of finished rendered products.\textsuperscript{121} Despite such resistance, the FDA was successful in initiating and implementing the expanded ruminant feed ban, showing it has the political will to withstand industry pressure. The FDA must do so again and keep the welfare of animals as its first priority.

In the alternative, the FDA should work with the rendering industry to improve their operating standards. At the least, the FDA should ban the use of euthanized companion and other animals in pet food.

\textit{C. Standardize Regulations Throughout the United States}

Because each state is permitted to promulgate its own pet food regulations, pet food manufacturers in the U.S. are forced to navigate a complex web of rules and requirements when formulating, labeling, and offering their products for sale in retail establishments throughout the country. While the AAFCO has attempted to establish a comprehensive, uniform approach to

\begin{footnotes}
\item[119] Martin, \textit{supra} note 1, at 28.
\end{footnotes}
pet food regulation, only thirty-eight states have adopted all or a portion of the AAFCO’s model rules and regulations.\footnote{S.B. 1773, 2007-2008 Leg., Reg. Sess. (Ca. 2007).} The only way to ensure a complete and comprehensive system is to establish one at the federal level.

As a first step, the FDA should strive to implement the mandates already handed to them by Congress. The existence of a uniform ingredient list, processing standards, and labeling requirements for all fifty states will make it easier for pet food companies to produce a standard product that can be sold throughout the country.

V. CONCLUSION

As consumers become aware of pet food safety issues, many are seeking healthier options for their pets. For instance, nationwide sales of organic and natural pet foods are expected to grow three times as fast as other pet foods through 2015.\footnote{Organic Pet Food Sales Growth Outpacing Other Pet Foods, ALLPETNEWS (Feb. 8, 2011), http://www.allpetnews.com/organic-pet-food-sales-growth-outpacing-other-pet-foods/.} However, these options may be significantly more expensive and less convenient for consumers to locate than traditional brands. Pet owners should not have to seek out goods that are substantially more expensive to ensure the safety of their animals. Consumers ought to be able to feel confident that a commercially available food contains wholesome ingredients that will not harm their pet. In fact, many pet owners would probably be willing to spend a few more dollars for a bag of pet food if they could do so with the knowledge that it does not contain sordid ingredients. “The greatness of a nation and its moral progress can be judged by the way its animals are treated.” Mahatma Gandhi.

Feeding our pets diseased and condemned leftovers from the human food supply does not constitute the good, or even adequate, treatment these animals deserve.