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Man's Best Friend? FDA Adopts New Rule in Wake of Pet Deaths, But Will it Have a Significant Impact on the Pet Food Industry?

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MAN’S BEST FRIEND?
 FDA ADOPTS NEW RULE IN WAKE OF PET DEATHS,
 BUT WILL IT HAVE A SIGNIFICANT IMPACT ON THE PET FOOD INDUSTRY?

*Amanda Paige Marcum**

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I. INTRODUCTION

Eight years after the largest pet food recall in U.S. history,¹ pet owners are still grappling with mysterious pet illnesses and deaths associated with commercial pet food.

Alfredo Gude knew his spunky four-year-old West Highland white terrier, Andy, was in trouble after he started showing symptoms of an

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1. FDA, *The Melamine Story*, YOUTUBE (May 20, 2010), <https://www.youtube.com/watch?v=l4Uudb3WOOs>.

illness.² It began with a loss of appetite, vomiting, an unquenchable thirst, a constant need to urinate, and after everything had transpired, Andy lost more than ten percent of his weight.³ After rushing Andy to his veterinarian, Gude and his wife were referred to a clinic fifteen miles away.⁴ Doctors at the clinic sent a urine sample to a specialized metabolic lab at the University of Pennsylvania.⁵ After waiting for an answer for days, Gude and his wife received Andy's diagnosis: Fanconi syndrome, a rare, often fatal disease that affects the kidneys.⁶ The alleged culprit: chicken jerky pet treats manufactured in China.⁷

In response to cases like Andy's, the U.S. Food and Drug Administration's ("FDA") Center for Veterinary Medicine ("CVM") has "conducted more than 1,200 tests, visited jerky pet treat manufacturers in China and collaborated with colleagues in academia, industry, state labs and foreign governments."⁸ Despite its investigation, the FDA has failed to pinpoint the origin of the problem.⁹ Bernadette Dunham, director of the CVM, describes it as "one of the most elusive and mysterious outbreaks we've encountered."¹⁰

Although Andy the terrier was fortunate enough to survive after months of expensive treatments to restore his kidney function,¹¹ other pets have not been as lucky. As of September 30, 2014, the FDA had received approximately 5,000 reports of pet illnesses, some involving more than one pet, which were believed to be associated with the consumption of jerky pet treats.¹² The reports involved more than 5,800 dogs, 25 cats and included

2. Brady Dennis, *Mystery of Pet Deaths Related to Jerky Treats Made in China Continues to Stump FDA*, WASH. POST (Mar. 28, 2014), http://www.washingtonpost.com/national/health-science/mystery-of-pet-deaths-related-to-jerky-treats-made-in-china-continues-to-stump-fda/2014/03/28/c860002a-b39b-11e3-8cb6-284052554d74_story.html.

3. *Id.*

4. *Id.*

5. *Id.*

6. *Id.*

7. Dennis, *supra* note 2.

8. *Why Are Jerky Treats Making Pets Sick?*, FDA CONSUMER HEALTH INFO. 1 (Oct. 2013), <http://www.fda.gov/downloads/ForConsumers/ConsumerUpdates/UCM371677.pdf>.

9. *Id.*

10. *Id.*

11. Dennis, *supra* note 2.

12. *Questions and Answers Regarding Jerky Pet Treats*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm295445.htm> (last updated Feb. 19, 2015).

more than 1,000 canine deaths.¹³ Pet owners would agree that one preventable pet death is one too many.

The largest pet food recall in U.S. history occurred in 2007 after the FDA learned that more than 200 brands of pet foods were linked to illnesses and deaths of cats and dogs.¹⁴ On March 15, 2007, Menu Foods, a Canadian-based manufacturer of pet food, notified the FDA of its decision to issue a massive recall of its products.¹⁵ The company learned through its routine quarterly palatability tests and customer reports that something in its foods—later identified as wheat flour laced with melamine—was causing so much damage to the kidneys of cats and dogs that the animals had to be euthanized.¹⁶ Menu Foods initially suspected that the issue could be traced to the wheat gluten in its pet foods because the ingredient came from a new source.¹⁷ The company had recently switched suppliers in November 2006 and began buying wheat gluten from ChemNutra, which obtained the ingredients it sold from China.¹⁸

The recall came as a shock to pet owners, as it affected pet foods marketed under the most trusted and well-known brand names.¹⁹ The recall also revealed that Menu Foods was the largest North American manufacturer of private-label “wet” pet foods.²⁰ Menu Foods manufactured canned and pouched foods for seventeen of the top twenty North American pet food retailers under an array of brand names.²¹

Although there were approximately 17,000 complaints from pet owners concerning pet illnesses and deaths associated with the contaminated food,²² the exact number of pet deaths is unclear. Consumer complaints included reports of approximately 1,950 deaths of cats and 2,200 deaths of dogs related to contaminated food.²³ However, the FDA claimed only

13. *Id.*

14. *Melamine Pet Food Recall of 2007*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129575.htm> (last updated July 14, 2014).

15. MARION NESTLE, *PET FOOD POLITICS: THE CHIHUAHUA IN THE COAL MINE* 1 (2008).

16. *Id.* Melamine is an industrial chemical used in cookware, furniture, and industrial fertilizers. Kate Paulman, *See Spot Eat, See Spot Die: The Pet Food Recall of 2007*, 15 *ANIMAL L.* 113, 114 (2008).

17. NESTLE, *supra* note 15, at 88.

18. *Id.*

19. *Id.* at 13.

20. *Id.*

21. *Id.*

22. *Import Alert 99-29*, FDA (Oct. 2, 2015), http://www.accessdata.fda.gov/cms_ia/importalert_267.html.

23. *Id.*

seventeen or eighteen confirmed deaths among pets related to contaminated pet food.²⁴

Six years later, the FDA decided to take action by proposing a rule under the Food Safety Modernization Act (“FSMA”) aimed at improving the safety of food for animals and preventing foodborne illness among pets and their owners.²⁵ The final rule, Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, was adopted on September 17, 2015²⁶ and requires certain domestic and foreign facilities to establish and implement food safety practices for animal food comparable to those in the human food industry.²⁷

While the rule seems to be a step in the right direction, many special interest groups are worried that the requirements imposed are likely to lead to unintended consequences. In its comments to the FDA, the National Association of State Departments of Agriculture (“NASDA”) noted that if the animal food manufacturing industry were to find the requirements of the rule too burdensome, it may be “forced to withdraw these products from the animal production continuum which would result in consequences . . . that could result in increased consumer prices or may push [the] industry to obtain ingredients from less regulated or safe sources.”²⁸ However, NASDA was founded to “represent the state departments of agriculture in the development, implementation, and communication of sound public policy and programs which support and promote the American agricultural industry, while protecting consumers and the environment.”²⁹ Therefore, NASDA’s perspective on the rule is primarily focused on the agricultural interest, which is protective of the animal feed and pet food manufacturers.

This comment discusses a number of issues related to the rule. First, it looks at a brief history of pet food industry regulation. Second, it examines the mystery of pet deaths related to jerky treats made in China. Third, it discusses recent developments in the law in response to those pet deaths. Fourth, it considers the implications of the rule and how it will affect the

24. NESTLE, *supra* note 15, at 60.

25. *FDA Issues Proposed Rule to Help Ensure the Safety of Food for Animals*, FDA (Oct. 25, 2013), <http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm372215.htm>.

26. 21 C.F.R. § 507 (2015).

27. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56,170 (Sept. 17, 2015) (to be codified at 21 C.F.R. pt. 507).

28. *NASDA Comments: Part 507-Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, NAT’L ASS’N OF ST. DEP’TS OF AGRIC. 7 (Mar. 31, 2014), <http://www.nasda.org/File.aspx?id=25943>.

29. *What is NASDA?*, NAT’L ASS’N OF ST. DEP’TS OF AGRIC., <http://www.nasda.org/File.aspx?id=29929> (last visited Nov. 20, 2015).

standards applicable to the manufacturing and processing of pet food. Finally, this comment proposes additional changes that should be promulgated in the wake of frequent recalls.

II. REGULATION OF THE PET FOOD INDUSTRY

It is estimated that nearly three-quarters of U.S. households own pets.³⁰ There are approximately 218 million pets in the United States.³¹ In 2014, \$58.04 billion was spent on pets in the United States, with \$22.26 billion spent towards pet food.³² Additionally, according to data from the 2012 U.S. Pet Ownership & Demographics Sourcebook maintained by the American Veterinary Medical Association, 63.2% of U.S. pet owners reported that they considered their pets to be family members.³³ In essence, the pet food industry is booming, and with that growth comes demanding pet owners who are concerned about providing safe and healthy food for their pets.

Up until the Melamine Pet Food Recall of 2007, a majority of pet owners did not question the ingredients that went into their chosen pet food.³⁴ Presumably, most consumers trusted recommendations by their veterinarians and the health information printed on the pet food packaging. Further, pet owners likely expected that the FDA regulated the pet food industry with the same stringent standards as human food. Indeed, the Pet Food Institute claims that in the United States, "cat and dog food products are the most highly regulated food product, with the exception of infant formula."³⁵ However, with the number of recent pet food recalls and subsequent illnesses, pet owners have come to question the safety of commercial pet food in the United States,³⁶ and rightly so.

30. Steven Henderson, *Spending on Pets: "Tails" from the Consumer Expenditure Survey*, 2 BEYOND THE NUMBERS 1 (May 2013), <http://www.bls.gov/opub/btn/volume-2/pdf/spending-on-pets.pdf>.

31. *Id.*

32. *Pet Industry Market Size & Ownership Statistics*, AM. PET PRODUCTS ASS'N, http://www.americanpetproducts.org/press_industrytrends.asp (last visited Nov. 20, 2015).

33. Katie Burns, *Vital Statistics*, AM. VETERINARY MED. ASS'N (Jan. 16, 2013), <http://www.avma.org/news/javmanews/pages/130201a.aspx>.

34. See generally MICHAEL W. FOX ET AL., NOT FIT FOR A DOG!: THE TRUTH ABOUT MANUFACTURED CAT AND DOG FOOD ix (2009) (discussing the trust that pet owners have in the various brands of commercial pet foods).

35. *Pet Food is Highly Regulated, Contrary to Common Misunderstandings*, PFI MONITOR, Fall 2011, at 18.

36. See, e.g., NESTLE, *supra* note 15, at 158 ("In the immediate aftermath of the recall, sales of pet foods dropped by more than 30%.").

A. Federal Regulation by the FDA

Pet food is regulated under the Federal Food, Drug, and Cosmetic Act (“FDCA”), which defines food as “articles used for food or drink for man or other animals. . . .”³⁷ Under the FDCA, the adulteration or misbranding of pet food is prohibited.³⁸ Adulterated food includes, among other things, products or materials that are defective and unsafe because they are contaminated or were produced under unsanitary conditions.³⁹ A food is considered misbranded if its labeling is false or misleading in any way or lacks required information.⁴⁰ Therefore, the FDCA requires that pet foods be “safe, wholesome, sanitary, and properly labeled.”⁴¹

The FDA, an agency within the Department of Health and Human Services, is tasked with promoting the public health by ensuring that “foods are safe, wholesome, sanitary, and properly labeled; human and veterinary drugs are safe and effective; there is reasonable assurance of the safety and effectiveness of devices intended for human use; cosmetics are safe and properly labeled; and public health and safety are protected from electronic product radiation.”⁴² Thus, the FDA’s regulatory authority is particularly broad,⁴³ making its role in pet food oversight fairly limited.⁴⁴ In carrying out its responsibilities, the FDA “distinguishes oversight of food for people from that of farm animals and pets,” and it oversees foods for these groups through delegation of authority to two distinct departments.⁴⁵ Human food is regulated by the FDA’s Center for Food Safety and Applied Nutrition (CFSAN), whereas animal feed and pet food is regulated by the CVM.⁴⁶

The CVM “monitors feed contaminants, oversees the labeling of feed contents, and approves the safety of feed additives.”⁴⁷ However, one of the CVM’s highest priorities is “assuring the safety of the [human] food supply through elimination of violative residues in meat and milk.”⁴⁸ Thus, while

37. 21 U.S.C. § 321(f)(1) (2012).

38. 21 U.S.C. § 331(b) (2012).

39. 21 U.S.C. § 342(a)-(i) (2012).

40. 21 U.S.C. § 343(a) (2012).

41. 21 U.S.C. § 393(b) (2012).

42. *Id.*

43. *What Does FDA Regulate?*, FDA, <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm> (last updated June 12, 2014).

44. MARION NESTLE & MALDEN C. NESHEIM, *FEED YOUR PET RIGHT* 91 (2010).

45. *Id.*

46. *Id.*

47. *Id.*

48. *Structure and Responsibilities*, FDA, <http://www.fda.gov/AboutFDA/CentersOffices/OfficeofFoods/CVM/WhatWeDo/ucm072570.htm> (last updated Aug. 21, 2014).

the CVM is responsible for ensuring the safety of animal food and drugs, the organization is primarily concerned that “food from treated animals is safe for human consumption.”⁴⁹

B. Coordination with the AAFCO

The CVM also works with state and local partners, such as the Association of American Feed Control Officials (“AAFCO”), to regulate pet food.⁵⁰ The AAFCO is a voluntary organization, which is comprised largely of “local, state and federal agencies charged by law to regulate the sale and distribution of animal feeds and animal drug remedies.”⁵¹ The FDA coordinates with the AAFCO and the states for the “implementation of uniform policies for regulating the use of animal feed products.”⁵² The FDA describes its partnership with the AAFCO as “vital to the effective regulation of pet food products” due to the fact that the FDA has limited resources that are focused primarily on human food safety issues.⁵³ It seems that the safety of pet food is not a priority for the FDA. Consequently, it has delegated its authority to the CVM, which in turn coordinates with the AAFCO to carry out the FDA’s responsibilities.⁵⁴

Although the AAFCO has no regulatory authority, it “brings together state and federal regulators so they can develop consensus on matters relating to the formulation, manufacture, labeling and marketing of pet food and animal feed products.”⁵⁵ While industry experts may be involved in the deliberations of the AAFCO committees as advisors, “they are not permitted to vote.”⁵⁶ Indeed, the AAFCO advisors include representatives from major feed manufacturers, such as Nestle Purina, Hills Pet Nutrition, Nutro Products, and Cargill Animal Nutrition.⁵⁷

49. *Id.*

50. *Product Regulation*, FDA, <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm050223.htm> (last updated on Feb. 23, 2015).

51. *Welcome to AAFCO*, ASS’N OF AM. FEED CONTROL OFFICIALS, <http://aafco.org/> (last visited Nov. 20, 2015).

52. *Product Regulation*, *supra* note 50.

53. *FDA’s Regulation of Pet Food*, FDA, <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047111.htm> (last updated on Feb. 13, 2015).

54. *Id.*

55. *AAFCO, A Colorful History*, PFI MONITOR, Fall 2011, at 4, 5.

56. *Id.*

57. Lucy Postins, *What is AAFCO?*, DOGS NATURALLY, <http://www.dogsnaturallymagazine.com/what-is-aafco/> (last visited Nov. 20, 2015); *see also Pet Food Committee*, ASS’N OF AM. FEED CONTROL OFFICIALS,

The AAFCO publishes its *Official Publication* annually, which contains “information on individual state feed law requirements, and the text of the Model Feed Bill and feed and pet food regulations.”⁵⁸ In fact, “[m]ost states have adopted all or part of the [M]odel [F]eed [B]ill and allow feed ingredients listed in the publication to be used in their respective territories.”⁵⁹

Ultimately, the AAFCO only establishes the nutritional standards for pet food and “[i]t is the state feed control official’s responsibility in regulating pet food to ensure that the laws and rules established for the protection of companion animals and their custodians are complied with so that only unadulterated, correctly and uniformly labeled pet food products are distributed in the marketplace”⁶⁰

C. Problems with the Pet Food Regulatory Scheme

There are several problems with the regulatory scheme of the pet food industry in the United States. First, while it appears that the pet food industry would be heavily regulated, the fact is that the FDA has delegated its responsibilities mainly to the CVM and the AAFCO as a result of limited resources. This becomes problematic because the AAFCO consists not only of local, state, and federal agencies, but it is also advised by people from the pet food industry,⁶¹ which means that the people who are influencing model regulations for pet foods are also directly benefiting from the sale of pet food. As one exasperated veterinarian described it, “talk about the fox guarding the henhouse.”⁶²

Second, although the FDCA stipulates that pet food be held to the same standard as food for human consumption, the reality is that pet food safety is not treated as a priority. This harsh truth is demonstrated by the FDA’s decision to delegate its responsibility of regulation to the CVM.

Third, because the FDA has limited resources and has abdicated its authority, there is no federal entity with the authority to enforce regulations,

<http://www.aafco.org/Regulatory/Committees/Pet-Food> (last visited Nov. 20, 2015) (listing the names of members and advisors of the AAFCO Pet Food Committee).

58. FOOD & DRUG L. INST., FOOD AND DRUG LAW AND REGULATION 249 n.16 (David G. Adams et al. eds., 2011).

59. *Ingredients & Additives*, FDA, <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/IngredientsAdditives/default.htm> (last updated June 5, 2014).

60. *The Business of Pet Food*, ASS’N OF AM. FEED CONTROL OFFICIALS, <http://petfood.aafco.org/> (last visited Nov. 20, 2015).

61. Postins, *supra* note 57; see also *Pet Food Committee*, *supra* note 57.

62. Douglas Knueven, *The Five Supplements Every Dog Needs*, CLEAN RUN, Dec. 2005, at 35.

leaving a gap between the creation, implementation, and enforcement of regulations. Thus, it is left to the state feed control official to ensure that manufacturers comply with all applicable regulations—a nearly impossible task.

Lastly, it should be noted that damages recoverable in a pet death lawsuit are generally limited to replacement value.⁶³ In essence, the life of a pet is valued as a commodity in the eyes of the law. The result is the emasculation of the deterrent effect that litigation and significant monetary judgments provide for non-pet product manufacturers. Unlike automobile manufacturers, for example, pet food manufacturers need not worry about significant monetary judgments to motivate them to make their products safe. Thus, rather than worrying about purchasing safe ingredients for pet food, manufacturers justify cutting corners because from their perspective, it is cheaper to pay a nominal judgment for the death of a pet than to invest in safe ingredients.

Given the history of recalls and the sheer number of pets who have lost their lives, it seems that drastic measures must be taken to ensure the safety of pets. It is obvious that these regulating groups and commercial pet food manufacturers have failed pets and their owners. If pet food manufacturers were held to the same standards as human food manufacturers, it is likely that the thousands of reports of pet illnesses related to the consumption of pet food would be greatly reduced.

III. PET DEATHS RELATED TO JERKY TREATS

Most of the pet food products mentioned in consumer complaints involved chicken jerky treats, but also included are treats in which chicken or duck jerky is wrapped around dried fruit, sweet potatoes or yams.⁶⁴ To date, there is no clear pattern based on breed or geography of animals affected, and the problems have not been traced to a specific brand or manufacturer.⁶⁵

63. William C. Root, "Man's Best Friend": Property or Family Member? An Examination of the Legal Classification of Companion Animals and Its Impact on Damages Recoverable for Their Wrongful Death or Injury, 47 VILL. L. REV. 423, 423-24 (2002).

64. Dennis, *supra* note 2.

65. *Id.*

A. Chronology of the Illnesses and Deaths

The FDA first became aware of growing numbers of illnesses in pets associated with the consumption of jerky pet treats in 2007.⁶⁶ As of September 14, 2012, approximately 2,200 reports of pet illnesses had been reported to the FDA in relation to consumption of jerky treats.⁶⁷ The reports contained information on 360 canine deaths and one feline death.⁶⁸ With reports ranging from all fifty states and six Canadian provinces, there does not appear to be a geographic pattern.⁶⁹ Despite working with laboratories across the country to investigate a cause of the illnesses, FDA testing for contaminants has not revealed a cause for the illnesses.⁷⁰

The long-running investigation of pet illnesses has corresponded with a remarkable increase in the amount of pet food China exports to the United States.⁷¹ According to the FDA, that volume increased from less than one million pounds in 2002 to an estimated eighty-six million pounds by 2011.⁷² As the purchase of pet-related products has increased among American consumers, so too have the sales of pet treats, including the jerky treats in question.⁷³ With the knowledge that nearly all of the complaints stem from Chinese-made treats,⁷⁴ it is astonishing that no action has been taken by the FDA to more closely monitor and regulate the sale of jerky treats originating from China.

66. *FDA Investigates Animal Illnesses Linked to Jerky Pet Treats*, FDA (Sept. 14, 2012), <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm319463.htm>.

67. *Id.*

68. *Id.*

69. *Id.*

70. *Jerky Pet Treats*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm360951.htm> (last updated Apr. 29, 2015).

71. *FDA Investigates Animal Illnesses Linked to Jerky Pet Treats*, *supra* note 66.

72. *Id.*

73. Andrew Martin, “*For the Dogs*” *Has a Whole New Meaning*, N.Y. TIMES (June 4, 2011), http://www.nytimes.com/2011/06/05/business/05pets.html?pagewanted=all&_r=1&.

74. Christian Gomez, *Petco and PetSmart Stop Sale of Pet Treats Made in China*, THE NEW AM. (May 22, 2014), <http://www.thenewamerican.com/economy/markets/item/18321-petco-and-petsmart-stop-sale-of-pet-treats-made-in-china>.

B. Reaction by the Public

Pet owners share the same frustration. Susan Thixton, who serves as an advisor to the AAFCO'S Pet Food Committee⁷⁵ and runs the website TruthAboutPetFood.com, which has demanded the FDA do more, thinks "[i]t's maddening that it has gone on this long."⁷⁶ The home page of her website shows a clock tracking how long jerky treats from China have been harming pets.⁷⁷ The most recent count stood at 3,245 days.⁷⁸

Furious pet owners have also criticized "U.S. companies that continue to manufacture jerky treats with ingredients from China."⁷⁹ While some pet owners have responded with complaints to the FDA, others have filed lawsuits alleging harm.⁸⁰ Terry Safranek, whose 9-year-old fox terrier, Sampson, died of kidney failure in 2012 after eating jerky treats,⁸¹ became a plaintiff in a class-action lawsuit against Nestlé Purina and retailers including Target and Wal-Mart.⁸² Safranek was also instrumental in the creation of Animal Parents Against Pet Treats and Food Made in China,⁸³ a group of pet owners "working proactively to keep . . . pets safe by removing pet treats and foods that have been manufactured in China, or using predominantly Chinese sourced ingredients, from the marketplace."⁸⁴ The group has petitioned the FDA to make improvements in "alerting people about the potential dangers of jerky treats produced in Chinese factories."⁸⁵

In Safranek's class-action lawsuit, *Adkins v. Nestlé Purina PetCare Co.*, U.S. District Judge Robert Gettleman denied a motion to dismiss the lawsuit, saying that the plaintiffs sufficiently alleged that "the product was defective, and that no other secondary cause was responsible for the dogs' illnesses."⁸⁶ However, Judge Gettleman dismissed most of the allegations against Wal-Mart, Costco, Target, BJ's, CVS, Walgreens, Pet Supplies and other retailers who sold the treats because the plaintiffs failed to allege any

75. *Pet Food Committee*, *supra* note 57.

76. Dennis, *supra* note 2.

77. *FDA Has Been Investigating Pet Deaths and Illnesses Linked to Chinese Jerky Treats For*, <http://truthaboutpetfood.com/> (last visited Nov. 21, 2015).

78. *Id.*

79. Dennis, *supra* note 2.

80. *Adkins v. Nestlé Purina PetCare Co.*, 973 F. Supp. 2d 905, 905 (N.D. Ill. 2013).

81. Dennis, *supra* note 2.

82. *Adkins*, 973 F. Supp. 2d at 911.

83. Dennis, *supra* note 2.

84. *Animal Parents Against Pet Treats and Food Made in China*, FACEBOOK, http://www.facebook.com/pages/Animal-Parents-Against-Pet-Treats-and-Food-Made-in-China/235390426550583?sk=info&tab=page_info (last visited Nov. 21, 2015).

85. Dennis, *supra* note 2.

86. *Adkins*, 973 F. Supp. 2d at 916.

actionable false statements made by the merchants.⁸⁷ In addition, the plaintiffs failed to allege sufficient facts to hold the merchants liable under strict products liability.⁸⁸

Although Nestlé Purina and Waggin' Train LLC denied any wrongdoing, they agreed to pay \$6.5 million to settle the class-action lawsuit, as well as two other lawsuits related to the legal battle between pet owners and the makers of two of the nation's top brands.⁸⁹ Under the settlement agreement, Nestlé Purina agreed to "use a single-source supplier of meat for its treats, and to conduct new and rigorous testing of every batch of products."⁹⁰ Additionally, the company would include bold labels on every package specifying the origin of the product.⁹¹ The settlement still has to be approved, but pet owners who initiated the lawsuit view the agreement as a "bittersweet victory."⁹² Robin Pierre, whose 2-year-old pug, Bella, died in 2011 from kidney failure after eating Waggin' Train treats, lamented that "[n]o amount of money, no amount of anything, is going to make any of this right."⁹³

On the other hand, some major retailers have taken a proactive approach without the pressures of a class-action lawsuit. Petco and PetSmart became the first major pet food and supply retailers to announce they would "discontinue the sale of dog and cat treats made in China in order to ensure the 'wellbeing of pets.'"⁹⁴ Regardless of the medium used to voice their outrage, pet owners have certainly made their opinions known and have perhaps been the reason for such a bold response by retailers such as PetSmart.

C. FDA Investigation

The FDA has responded to reports of pet illnesses in relation to consumption of the jerky treats by working with colleagues in academia, industry, foreign governments and state labs.⁹⁵ However, the investigation has proved to be a puzzling one for the FDA for several reasons.

87. *Id.* at 921.

88. *Id.* at 924.

89. Jonel Aleccia, *Pet Jerky Treat Deal: Six Things You Need to Know*, NBC NEWS (June 2, 2014), <http://www.nbcnews.com/health/health-news/pet-jerky-treat-deal-six-things-you-need-know-n120576>.

90. *Id.*

91. *Id.*

92. *Id.*

93. *Id.*

94. Gomez, *supra* note 74.

95. *Why Are Jerky Treats Making Pets Sick?*, *supra* note 8.

First, there are some “fundamental differences between investigations into illnesses in people versus those in pets.”⁹⁶ While the FDA collaborates with the Centers for Disease Control and Prevention when investigating human illness outbreaks, there is no equivalent for pets, making it difficult to correctly assess the scope of an outbreak.⁹⁷

Second, there is a “lack of adequate post-mortem information in most cases.”⁹⁸ When a pet dies, a qualified veterinary pathologist rarely has the opportunity to inspect the body.⁹⁹ Usually by the time the FDA receives a report of a pet death, the body has either been buried or cremated, which eliminates the opportunity for scientists to gather information about potential causes for the pet’s illness.¹⁰⁰

Finally, the FDA “does not have access to market data about food items for pets [because] FDA regulations do not require product registration for foods, whether they are intended for people or animals.”¹⁰¹ This lack of market data makes it difficult to assess the scope of the jerky pet treat market.¹⁰²

IV. FOOD SAFETY MODERNIZATION ACT

The FSMA, which was signed into law on January 4, 2011, provides that, within 18 months after the date of enactment, the Secretary of Health and Human Services (and by delegation, the FDA) shall promulgate regulations: “to establish science-based minimum standards for conducting a hazard analysis, documenting hazards, implementing preventive controls, and documenting the implementation of the preventive controls under this section; and to define . . . the terms ‘small business’ and ‘very small business’”¹⁰³ Thus, pursuant to requirements under the FSMA and in response to the increased complaints stemming from pet illnesses and deaths, the FDA adopted regulations that “govern the production of pet food and farm animal feed for the first time.”¹⁰⁴

96. *FDA Progress Report on Ongoing Investigation into Jerky Pet Treats*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/ProductSafetyInformation/ucm371465.htm> (last updated Feb. 19, 2015).

97. *Id.*

98. *Id.*

99. *Id.*

100. *Id.*

101. *FDA Progress Report on Ongoing Investigation into Jerky Pet Treats*, *supra* note 96.

102. *Id.*

103. 21 U.S.C. § 350g(n) (2012).

104. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56,170 (Sept. 17, 2015) (to be

A. Final Rule

The final rule was adopted on September 17, 2015 and requires certain facilities to undertake a two-pronged approach to food safety by establishing and implementing food safety practices for animal food comparable to those in the human food industry.¹⁰⁵

Under the rule, domestic and foreign facilities are required to “establish requirements for the current good manufacturing practice” (“CGMP”) in the manufacturing, processing, packing, and holding of animal food.¹⁰⁶ The regulation also requires that certain facilities “establish and implement hazard analysis and risk-based preventive controls” (“HARBPC”) for food for animals.¹⁰⁷

To clarify further, under Subpart B, CGMPs are required for the following areas: personnel; plant and grounds; sanitation; water supply and plumbing; equipment and utensils; plant operations; holding and distribution; and holding and distribution of human food by-products for use as animal food.¹⁰⁸ The CGMPs serve as a framework to prevent contamination or adulteration of pet food.¹⁰⁹ Under Subpart C, each animal food facility is required to have and implement a written food safety plan that includes a hazard analysis; preventive controls; a supply-chain program; a recall plan; monitoring procedures; corrective action procedures; and verification procedures.¹¹⁰ The HARBPC is essentially the heart of the rule, requiring that facilities be held responsible for food safety issues.¹¹¹

The rule applies to all animal food facilities that are required to register with the FDA under the FDCA, unless subject to an exemption.¹¹² This would include facilities involved in the “manufactur[ing], process[ing], pack[ing], or hold[ing] [of] animal food for sale in the United States”¹¹³

codified at 21 C.F.R. pt. 507); Sabrina Tavernise, *F.D.A. Bids to Regulate Animal Food, Acting After Recall and Deaths*, N.Y. TIMES (Oct. 25, 2013), http://www.nytimes.com/2013/10/26/health/fda-moves-to-regulate-food-for-animals.html?_r=1&.

105. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. at 56,170.

106. *Id.*

107. *Id.*

108. 21 C.F.R. §§ 507.14-507.28 (2015).

109. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. at 56,185.

110. 21 C.F.R. § 507.31 (2015).

111. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. at 56,179.

112. *Id.* at 56,173. See 21 U.S.C. § 350d(a)(1) (2012).

113. 21 C.F.R. § 507.1(b) (2015).

The rule does not apply to farms, including primary production farms and secondary activities farms.¹¹⁴

B. Implications of the Rule

The rule has the potential to make great changes in the regulation of the pet food industry. The FDA gave the public nearly four months to submit written comments on the proposed rule.¹¹⁵ After receiving 529 comments by the end of the comment period,¹¹⁶ the FDA published revised provisions, based on the feedback received from the industry during meetings and in the comments submitted on the proposed rule.¹¹⁷ The FDA also decided to offer an additional 75-day commenting period for the proposed revisions before issuing the final rule in 2015.¹¹⁸ According to Michael Taylor, FDA Deputy Commissioner for Foods and Veterinary Medicine, the decision to take comments on revised proposals before issuing the final rule was “a very unusual step.”¹¹⁹ Perhaps the reissuance illustrates the FDA’s understanding of the importance of the rule and the agency’s “determination to get the rules right.”¹²⁰

114. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. at 56,183 (“A primary production farm is ‘under one management’ rather than ‘under one ownership.’ . . . A ‘secondary activities farm’ is an operation, not located on a primary production farm, devoted to harvesting (such as hulling or shelling), packing, and/or holding of [raw agricultural commodities (RACs)], provided that the primary production farm(s) that grows, harvests, and/or raises the majority of the RACs harvested, packed, and/or held by the secondary activities farm owns, or jointly owns, a majority interest in the secondary activities farm.”).

115. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 78 Fed. Reg. 64,736 (proposed Oct. 29, 2013) (to be codified at 21 C.F.R. pt. 507).

116. *Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, REGULATIONS.GOV, <http://www.regulations.gov/#!documentDetail;D=FDA-2011-N-0922-0002> (last visited Nov. 22, 2015).

117. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 79 Fed. Reg. 58,476 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 507). See Michael J. O’Flaherty, *FDA Updates 4 Proposed Rules Implementing FSMA*, OFW LAW (Sept. 19, 2014), <http://www.ofwlaw.com/2014/09/19/fda-updates-4-proposed-rules-implementing-fsma/> (discussing the proposed revisions).

118. O’Flaherty, *supra* note 117.

119. Lydia Zuraw, *FDA Releases Four Revised FSMA Rules*, FOOD SAFETY NEWS (Sept. 19, 2014), http://www.foodsafetynews.com/2014/09/fda-releases-four-revised-fsma-rules/#.VGbavPnF_nh.

120. *Id.*

There are several potential implications of the rule that must be considered. In particular, it is imperative to consider how the rule would affect the standards for the manufacturing and processing of pet food. The following section of the comment will focus on specific provisions within the rule.

1. Modified Requirements

The rule provides for modified, or less stringent, requirements for entities that the FDA deems “qualified facilities.”¹²¹ These would include small businesses and very small businesses; low-risk, on-farm activities undertaken by small and very small businesses; canned pet food manufacturers; and facilities solely engaged in the storage of packaged animal food.¹²²

Under the rule, qualified facilities are exempt from the requirements for the HARBP. ¹²³ Modified requirements, however, apply to a qualified facility.¹²⁴ Therefore, a qualified facility is required to:

[N]otify FDA about its status and [e]ither: [n]otify FDA that it is addressing hazards through preventive controls and monitoring; or [n]otify FDA that it complies with applicable non-Federal food safety regulations, and [n]otify consumers of the name and complete business address of the facility where the animal food was manufactured or processed.¹²⁵

In the original proposed rule, three options were suggested for the definition of a very small business: annual sales of less than \$500,000; less than \$1 million; or less than \$2.5 million.¹²⁶ In the revised provisions, the new proposed definition of a very small business would have a \$2.5 million

121. Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56,170, 56,175 (Sept. 17, 2015) (to be codified at 21 C.F.R. pt. 507).

122. *Id.*

123. 21 C.F.R. § 507.5(d) (2015).

124. 21 C.F.R. § 507.7 (2015).

125. *Id.*; Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. at 56,175.

126. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 78 Fed. Reg. 64,736, 64,738 (proposed Oct. 29, 2013) (to be codified at 21 C.F.R. pt. 507).

threshold,¹²⁷ which would exempt from the requirements for the HARBPC “less than two percent of the dollar value of all animal food produced in the United States.”¹²⁸ According to the FDA, it is estimated that 4,325 facilities would be covered by the revised provision, compared to 6,124 under the \$1,000,000 threshold and 6,603 under the \$500,000 threshold.¹²⁹

Although the final rule adopts the \$2.5 million threshold,¹³⁰ a strong argument can be made that a “very small business” should be defined as no greater than annual sales less than \$500,000. Corresponding with the consumer shift towards natural and organic pet food and treats has been an influx of smaller pet specialty manufacturers entering the market.¹³¹ These smaller, independent pet food manufacturers should be held just as accountable as large manufacturers. By requiring only businesses with annual sales of \$2.5 million or more to be subject to the HARBPC, the safety of pets could be put at risk, if smaller manufacturers do not implement the same safeguards as larger manufacturers.

Another exemption from the requirements for the HARBPC applies to facilities “solely engaged in the storage of unexposed packaged animal food.”¹³² While these facilities would be subject to the modified requirements mentioned previously as applied to the storage of refrigerated packaged animal food,¹³³ these less stringent requirements are not adequate to protect the health and safety of pets.

A persuasive argument can be made that all pet food storage facilities should be required to meet the HARBPC requirements. The need for the protection of pet food while in storage is crucial, as a 2008 Petco warehouse raid demonstrated. Various pet products stored in “unsanitary conditions” were seized by U.S. Marshals at Petco’s Animal Supplies Distribution Center in Joliet, Illinois.¹³⁴ An FDA inspection of the warehouse revealed a

127. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 79 Fed. Reg. 58,476, 58,477 (proposed Sept. 29, 2014) (to be codified at 21 C.F.R. pt. 507).

128. *FDA Proposes Revised Rule for Animal Food*, RENDER, <http://www.rendermagazine.com/articles/2014-issues/december-2014/fda-proposes-revised-rule/> (last visited Nov. 22, 2015).

129. *Id.*

130. 21 C.F.R. § 507.3 (2015).

131. Lindsay Beaton, *Natural, Organic Pet Foods Lead Specialty Market*, PETFOODINDUSTRY.COM (Apr. 15, 2015), <http://www.petfoodindustry.com/articles/5080-natural-organic-pet-foods-lead-specialty-market>.

132. 21 C.F.R. § 507.10 (2015).

133. *Id.*

134. *FDA Requests Seizure of Animal Food Products at PETCO Distribution Center*, FDA (June 19, 2008),

widespread bird and rodent infestation, which “could affect the food’s integrity and quality” and put consumers at risk.¹³⁵ To allow an exemption for these facilities would likely provide the impetus for more cases of pet food contamination, which could have a significant impact on both consumers and pets.

2. Reference to Existing Federal Law

Throughout the rule, the FDA references section 402 of the FDCA, which defines adulteration.¹³⁶ The following language from the FDCA definition of adulteration was omitted from the rule:

(2)(A) if it bears or contains any added poisonous or added deleterious substance (other than a substance that is a pesticide chemical residue in or on a raw agricultural commodity or processed food, a food additive, a color additive, or a new animal drug) that is unsafe within the meaning of section 346 of this title; . . . or (5) 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; or (6) 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 (7) if it has been intentionally subjected to radiation, unless the use of the radiation was in conformity with a regulation or exemption in effect pursuant to section 348 of this title.¹³⁷

In addition, “(b) Absence, substitution, or addition of constituents” was excluded:

(1) If any valuable constituent has been in whole or in part omitted or

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/2008/ucm116915.htm>.

135. *Id.*

136. 21 C.F.R. § 507.1(a)(1)(i)-(ii) (2015).

137. 21 U.S.C. § 342 (2012).

abstracted therefrom; or (2) if any substance has been substituted wholly or in part therefor; or (3) if damage or inferiority has been concealed in any manner; or (4) if any substance has been added thereto or mixed or packed therewith so as to increase its bulk or weight, or reduce its quality or strength, or make it appear better or of greater value than it is.¹³⁸

While these exclusions may seem insignificant, the FDA certainly does not have the discretion to omit circumstances in which food is deemed adulterated under the FDCA. The FDCA should be applied as it is written, and the FDA's decision to exclude these provisions only works to undermine the authority of the FDCA and diminish the effort to ensure the safety of pet food.

3. Monitoring and Recalls

The FDA's monitoring system of adverse food events is described as utilizing numerous sources, including the Reportable Food Registry, the Pet Food Early Warning Surveillance System, consumer complaints, industry recalls and FDA and State inspection findings.¹³⁹ While those options are helpful in monitoring pet food incidents, an argument can be made that it would be more beneficial to include those who are directly involved, such as veterinarians and pet food retailers. The FDA should create a forum, allowing veterinarians and pet food retailers to report pet food incidents directly to the FDA as they occur. There should also be a system in place to notify pet food retailers once a safety issue arises. Further, once a pet food retailer is made aware of a safety issue related to a food product sold in its store, the retailer should be required to pull the product from the shelves until a thorough investigation is completed by the FDA.

In addition, under the HARBPC, appropriate facilities are required to develop a written recall plan for animal food with a significant hazard.¹⁴⁰ It would be helpful if the rule specified a process for evaluating health hazards and examples of significant hazards. For instance, the USDA provides factors to take into account when assessing health hazards for meat and

138. *Id.*

139. Current Good Manufacturing Practice and Hazard Analysis and Risk-Based Preventive Controls for Food for Animals, 78 Fed. Reg. 64,736, 64,747 (proposed Oct. 29, 2013) (to be codified at 21 C.F.R. pt. 507).

140. 21 C.F.R. § 507.38 (2015).

poultry products, including “[w]hether any illness or injuries have already occurred from eating the product; [w]hat hazards target various segments of the population . . . with particular attention paid to those individuals at greatest risk; [h]ow serious is the health hazard to which the at-risk population would be exposed; [h]ow likely is the hazard to occur; and [w]hat would happen if it did.”¹⁴¹ A few guidelines would go a long way in ensuring that the appropriate facilities develop a written recall plan that addresses a wide range of potential hazards. Further, it would be extremely beneficial to consumers if the FDA were to implement strict deadlines for issuance of recall notices. Consumers should be notified of pet food recalls promptly to have the opportunity to make important decisions on behalf of their pets before it is too late to take action.

V. SUGGESTED ADDITIONAL CHANGES

In addition to the enhanced protections of the rule that have been discussed, additional changes that should be promulgated in the wake of consistent recalls should be mentioned.

First, the FDA should prohibit the importation of pet food products from China. Over the last seven years, thousands of pets have died from the consumption of treats, nearly all of which are imported from China.¹⁴² Not surprisingly, China does not have a significant body of pet food law, regulations, and standards.¹⁴³ Rather, what it has is strewn within “regulations and standards administered by different agencies, with no one agency taking the lead in resolving problems.”¹⁴⁴ It is nearly impossible to assure consumers of the safety of pet food when it is being imported from a country that has no laws or regulations established for pet food.¹⁴⁵ If prohibiting pet food products from China is not feasible, perhaps the United States could require that Chinese companies be held to the same standard as United States companies. Either way, the FDA needs to take action regarding foreign suppliers of pet food.

Second, there needs to be more stringent labeling requirements to ensure that stated ingredients are actually in the product as it is advertised. Currently, under the AAFCO’s Model Regulations for Pet Food and

141. *How to Develop a Meat and Poultry Product Recall Plan*, USDA 9 (May 2013), http://www.fsis.usda.gov/shared/PDF/RecallPlanBooklet_0513.pdf.

142. *More Dogs Sick From Imported Pet Treats From China*, ECOWATCH.COM (May 19, 2014), <http://ecowatch.com/2014/05/19/dogs-sick-pet-treats-china/>.

143. John Balzano, *China’s Elusive Pet Food Regulation*, FORBES (June 25, 2014), <http://www.forbes.com/sites/johnbalzano/2014/06/25/chinas-elusive-pet-food-regulation/>.

144. *Id.*

145. *Id.*

Specialty Pet Food, pet food products are expected to contain: (1) an appropriate product name; (2) the species of pet(s) for which the product is intended; (3) a quantity statement for the amount of food in the package or container; (4) a guaranteed analysis; (5) a list of ingredients in the product; (6) a statement of nutritional adequacy, if required; (7) feeding directions, if required; and (8) name and address of manufacturer or distributor.¹⁴⁶ It would be helpful to consumers if pet food labeling were held to the same standards as those applicable to human food labeling. Pet food labels should be as easy to understand as human food labels, so consumers can make educated decisions which impact the health of their pets.

Last, the USDA should change its inspection standards relating to Salmonella. Currently, the United States Department of Agriculture ("USDA") and the FDA have different policies.¹⁴⁷ The FDA has a higher standard (zero-tolerance)¹⁴⁸ than the USDA (7.5 percent).¹⁴⁹ Therefore, "a pet food facility can pass a USDA inspection and still produce a food that might turn up positive for Salmonella if tested by the FDA."¹⁵⁰ This distinction could be confusing to consumers. The USDA and the FDA should be consistent, and the USDA should adopt the FDA zero-tolerance standard.

VI. CONCLUSION

Unless the FDA guarantees that the changes under the rule will be implemented, consumers and pets will continue to suffer from unnecessary pet food recalls. The health and safety of pets rest in the hands of the FDA and pet food manufacturers, which is not reassuring to the hundreds of pet owners who have lost members of their families due to the breakdown in the pet food regulatory system. It is imperative that the FDA and pet food manufacturers come to the realization that pets are not merely widgets with a fair market value. A pet is an irreplaceable part of the family and should

146. *Information on Marketing a Pet Food Product*, FDA, <http://www.fda.gov/AnimalVeterinary/ResourcesforYou/ucm047107.htm> (last updated Jan. 13, 2015).

147. Carlotta Cooper, *Changes Ahead for the Pet Food Industry*, HUFFINGTON POST (Apr. 14, 2014), http://www.huffingtonpost.com/carlotta-cooper/changes-ahead-for-the-pet-food_b_5135233.html.

148. *FDA Issues Compliance Policy Guide for Salmonella in Food for Animals*, FDA (July 16, 2013), <http://www.fda.gov/AnimalVeterinary/NewsEvents/CVMUpdates/ucm360834.htm>.

149. *Salmonella Verification Testing Program: Monthly Reports for Establishments by Performance Category*, USDA, <http://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/salmonella-verification-testing-program> (last visited Nov. 22, 2015).

150. Cooper, *supra* note 147.

be protected as such. The rule represents a significant first step in changing the way the FDA treats our pets. Ultimately, though, the responsibility is on the FDA to do its job and ensure that the regulations applicable to pet food be enforced to the letter of the law.