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Abra Slivinski

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FETCHIN' THE TRUTH ABOUT DOG FOOD REGULATIONS

*Abra Slivinski**

INTRODUCTION

What would you do for a Scooby Snack? For those who have watched the animated children's show about a dog and his mystery-solving friends know that Scooby Doo will do just about anything for a Scooby Snack. But what if the ingredients in those Scooby Snacks were hidden beneath complex language and misleading labels allowed under the existing regulatory framework? It is doubtful that Scooby would be so eager to dig into that dog treat if he knew it contained chemicals and foreign products, or that it was made using unsafe manufacturing procedures. What is actually in our pet's food and how it is made is an unsolved mystery. It is time that the general public jumps into the Mystery Machine with the rest of the Mystery Gang and follow in their grand-old-tradition of debunking and unmasking the mysteries. At the end of every Scooby Doo Television Mystery episode, the criminals yell, "and I would have gotten away with it, if it weren't for you meddling kids!"¹ It is time the general public discovers the truth behind the deceit and trickery about what their pets are consuming.

The Food and Drug Administration ("FDA") is the federal agency responsible for regulating pet food, snacks, and treats.² The FDA's role in regulating pet

¹ Scooby-Doo, Where Are You! (Taft-Broadcasting 1969). In the final scenes of each television broadcast, the Mystery Gang unmask the offender that has been causing chaos the entire episode. Following the unveiling of the offender, each states "And I would have gotten away with it too, if it weren't for you meddling kids." After this the offender is taken away and the Mystery Gang closes the episode.

² *Animal & Veterinary: Pet Food*, FDA, <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/PetFood/default.htm>. (last visited Nov. 25, 2016).

food is similar to its role in regulating food for all other animals. In addition to regulating animal food, the FDA regulates food that is produced for human consumption.³ The FDA's responsibility to regulate products that enter the bodies of the majority of living beings in the United States is immense and imperative. Consumers generally put their faith in the industry and assume that the food they purchase is wholesome and safe.⁴ Consumers commonly assume the same standards apply for their pet's food, putting even more faith in the pet food industry because they are not consuming their pet's food and do not know what it tastes like, feels like, or even what is in it. The differences in the FDA's regulation of food produced for pets versus humans is significant.⁵ Until four years ago, the FDA did not have strict regulations on foreign-sourced pet foods and products. The FDA has attempted to address the areas that lack regulation, but has had limited success because pet food producers have been able to evade regulations. The focus of this Article will be on dog food.

Americans own an estimated 70 to 80 million dogs.⁶ 37-47% of all households in the United States own a dog and 30-37% of households own a cat.⁷ And 7.6 million dogs and cats enter American animal shelters every year.⁸ Each one of those mouths must be fed in order to survive. But, what are they eating? The FDA regulates food that pets consume⁹— to a certain extent.

³ *Animal & Veterinary: Pet Food*, *supra* note 2.

⁴ Denis W. Steams, *Pay No Attention to that Man Behind the Curtain: Concealment, Revelation, and the Question of Food Safety*, 38 SEATTLE U. L. REV. 1399 (2015).

⁵ *Animal & Veterinary: Pet Food*, *supra* note 2.

⁶ *Pet Statistics*, AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS (2016), <http://www.aspca.org/animal-homelessness/shelter-intake-and-surrender/pet-statistics>.

⁷ *Id.*

⁸ *Id.*

⁹ *Animal & Veterinary: Pet Food*, *supra* note 2. The FDA regulates food, drugs, biologics, medical devices, electronic products that emit radiation, cosmetics, veterinary products, and tobacco products. Some of the products the FDA does not regulate include water, alcohol, meat and poultry, pesticides, or vaccines for animal

Rather, it is the industry that dictates the production, ingredients, and labeling methods. The nearly half of American households that own pets are affected by the regulatory practices and industry blunders, which happen on a frequent basis. In the past decade, the pet food industry has hit all-time lows, forcing the government to take action in response to public outcry.¹⁰

In 2007, the pet food industry continually faced pet food recalls - both mandated and voluntary¹¹ - on products that endangered the lives of many pets nationwide. In response to the epidemic, Congress moved to amend the statutes in the Federal Food, Drug, and Cosmetic Act ("FFDCA") that regulate animal food. The legislation is still pending.¹² The FDA now sets processing and nutrition standards for pet food to avoid another preventable outbreak of animal illnesses and deaths similar to those that occurred in September 2007.¹³ But, the amendments to the FFDCA did not solve all of the problems that Congress sought to address. Consequential additions to the legislation, like mandatory recall authority and certification of foreign food systems, are still pending approval.¹⁴

Consumers and their pets are highly affected by the FDA regulations and requirements under the FFDCA. With 37-47% of households nationwide owning dogs, the average American is spending a portion of their earnings each month to provide food for their four-

diseases. For further information, as to what specific products fall under each category, see: <http://www.fda.gov/AboutFDA/Transparency/Basics/ucm194879.htm>.

¹⁰ May Hongmei Gao, *The 2007 Chinese Pet Food Crisis: On U.S. Media's Coverage and U.S. Pet-owners Reactions*, 3 J. OF EMERGING KNOWLEDGE ON EMERGING MKTS 1, 414 (2011).

¹¹ *Melamine Pet Food Recall- Frequently Asked Questions*, FDA, <http://www.fda.gov/AnimalVeterinary/SafetyHealth/RecallsWithdrawals/ucm129932.htm>. (last visited Nov. 25, 2016).

¹² Blair E. McCrory, *2007 Legislative Review*, 14 ANIMAL L. 265, 284 (2008).

¹³ *Id.*

¹⁴ *Id.* at 284.

legged friends.¹⁵ In 2015, pet owners in the United States spent \$23.05 billion on pet food alone.¹⁶ The American Pet Products Association estimated that the market will jump to \$24.01 billion in 2016.¹⁷ If the industry experiences any other quality issues, as it did in 2007, the amount Americans will spend in veterinary care will only increase from the \$14.28 billion already spent in 2015.¹⁸

This Article will be divided into seven parts. Part II will go over the background of the pet food recall crisis of 2007. Part III will review the background of the federal agencies, legislation, and regulations that govern the pet and human food industry. Part IV will discuss the Food and Drug Administration in depth, providing an overview of regulations on the food industry, with emphasis on pet food, and attempt to acknowledge the gaps that the pet food industry takes advantage of. Part IV is divided into two subsections in discussing those gaps. Subsection A will address foreign standards of production and how those standards affect pet food ingredients. Subsection B will scrutinize the "Made in the USA" label claim and explore the requisite criteria to obtain that certification. Part V will examine the development and implementation of the Food Safety Modernization Act. Part VI of this Article will analyze the current regulatory framework, how the pet food industry takes advantage of it, and how this affects consumers. Part VII concludes with a

¹⁵ *Pet Care Costs*, AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS, https://www.aspca.org/sites/default/files/upload/images/pet_care_costs.pdf. (last visited Nov. 15, 2016); Also see AMERICAN SOCIETY FOR THE PREVENTION OF CRUELTY TO ANIMALS, <http://lifehacker.com/this-aspca-chart-shows-you-the-cost-of-owning-a-pet-1700938002>. (last visited Nov. 15, 2016). The chart shows that the average cost of food for a dog ranges from \$55 to \$235 depending on its size.

¹⁶ *Pet Industry Market Size & Ownership Statistics*, AM. PET PRODUCTS ASS'N, (2016), http://www.americanpetproducts.org/press_industrytrends.asp.

¹⁷ *Id.*

¹⁸ *Id.*

synopsis of where FDA regulations leave consumers at this point and some suggestions for consumers to adapt to the existing pet food market.

2007 PET FOOD INDUSTRY RECALL AND CONTAMINATE CRISIS: BACKGROUND

In 2007 the FDA mandated¹⁹ serious recalls of a multitude of pet foods alleged to be poisoning dogs and cats in the United States. The pets developed severe illnesses from tainted pet food, that in some extreme cases, ended in death. After a large number of individual reports from pet owners across the country, a joint investigation uncovered contaminants in vegetable proteins imported from China that forced the FDA to impose a nationwide recall.²⁰

The FDA partnered with the United States Department of Agriculture ("USDA") to find the source of the contamination. The joint investigation led the agencies to a tainted animal feed that had been fed to livestock in China, which was later processed into food.²¹ Although the threat was professed to both human and pet foods, "government scientists determined that there [was] very low risk to human health from consuming food from animals that [had] ate [the] tainted feed."²² The FDA and USDA's further investigation found that vegetable proteins, identified as wheat gluten, were contaminated with melamine.²³ Melamine is a toxic component of fertilizers and plastic utensils.²⁴ According to the FDA, melamine is an industrial chemical that has no approved use as an ingredient in animal or human food in the United

¹⁹ *Melamine Pet Food Recall- Frequently Asked Questions*, *supra* note 11.

²⁰ *Melamine Pet Food Recall of 2007*, FDA, <http://www.fda.gov/animalveterinary/safetyhealth/recallswithdrawals/ucm129575.htm>. (last visited Nov. 15, 2016).

²¹ *Id.*

²² *Melamine Pet Food Recall of 2007*, *supra* note 20.

²³ *Melamine Pet Food Recall of 2007*, *supra* note 20.

²⁴ Katy Byron, *FDA Expands Pet Food Recall*, CNN (Apr. 18, 2007), <http://www.cnn.com/2007/US/04/18/pet.food/>.

States.²⁵ Melamine contains non-protein nitrogen as a substantial part of its molecular structure which was introduced into the wheat gluten and rice protein so that a crude protein analysis would conclude a protein content similar to that of wheat-gluten or rice-protein concentrate.²⁶ The Association of American Feed Control Officials ("AAFCO") found that China intentionally adulterated the proteins with melamine, a far less expensive ingredient, that gave the vendors a larger profit margin.²⁷

In March 2007, the FDA recalled more than 150 brands of pet food from store shelves²⁸ and prompted consumers to immediately cease feeding dogs those brands of food.²⁹ Menu Foods,³⁰ an entity that manufactures numerous well-known pet food brands, alerted the FDA to reports of animals that developed kidney failure after consuming certain products they produced.³¹ The suspected contaminate in the Menu Foods' products was melamine-tainted wheat gluten which was obtained from a supplier in China.³² The FDA expanded the recall after it discovered more instances of melamine contamination in products that contained

²⁵ *Melamine Pet Food Recall of 2007*, *supra* note 20.

²⁶ *When Things Go Wrong: Melamine Contamination*, ASS'N OF AM. FEED CONTROL OFFICIALS (2016), <http://talkspetfood.aaeco.org/thingsgowrong>.

²⁷ *Id.*

²⁸ *Melamine Pet Food Recall of 2007*, *supra* note 20.

²⁹ *Pet Food Recall: FDA's Ongoing Investigation*, FDA (Oct. 14, 2014), <http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm048192.htm>.

³⁰ Menu Foods Limited was purchased by Simmons Pet Food in 2010. All websites are redirected to Simmons Pet Food's main page or error page where consumers can no longer view which name-brands Menu Foods Limited contracted with. Archived website listed affects brand labels during the recall, *see*: https://web.archive.org/web/20070406195316/http://menufoods.com/recall/product_dog.html.

³¹ *Melamine Pet Food Recall of 2007*, *supra* note 20.

³² *Menu Foods' Tainted Pet Food Spurs Congressional and FDA Reforms*, THE HUMANE SOC'Y OF THE U.S. (2013), http://www.humanesociety.org/animals/resources/facts/menu_foods_recall.html.

rice proteins.³³ Following the recall, the U.S. Attorney's office reported twice the number of consumer complaints it received in one year, in a single month, totaling 14,000 reports.³⁴ At the end of the crisis, the tainted food killed 1,950 cats and 2,200 dogs.³⁵ This amounted to the largest pet food recall in United States history.

In the months following the crisis multiple animal-welfare and animal-rights groups, along with the general public, pressured Congress to address the foreign ingredients that were poisoning their family pets. In May 2007, Senator Dick Durbin (D-IL) And Representative Rosa DeLauro (D-CT) introduced the Human and Pet Food Safety Act of 2007 ("HPFSA") to their separate chambers of Congress.³⁶ The Senate approved the legislation as an amendment to the separately pending Food, Drug, and Cosmetic Act.³⁷ As a result of the HPFSA, the FDA is now required to set standards for pet food processing and ingredients in order to avoid a large-scale crisis in animal illnesses and deaths like the preceding incident of 2007.³⁸ Despite this small victory, portions of the HPFSA are still pending, yet to be enacted. Those portions are substantial and would contribute to the resolution of a plethora of problems still surrounding the pet food industry. Important portions yet to be enacted include mandatory recall authority, certification of foreign food systems, provisions that would authorize the Secretary of Health and Human Services to set processing, ingredient, and labeling standards, and surveillance procedures to detect early food contaminants.³⁹ Without the pending provisions of the HPFSA, the pet food industry maintains the upper hand on manufacturing and processing practices that may lead to more crises similar to the one in 2007.

³³ Byron, *supra* note 24.

³⁴ Menu Foods Tainted, *supra* note 32.

³⁵ Menu Foods Tainted, *supra* note 32.

³⁶ McCrory, *supra* note 12, at 284.

³⁷ McCrory, *supra* note 12, at 283-84.

³⁸ McCrory, *supra* note 12, at 283.

³⁹ McCrory, *supra* note 12, at 284.

BACKGROUND: WHAT FEDERAL AGENCIES,
LEGISLATION, AND REGULATIONS GOVERN THE PET
AND HUMAN FOOD INDUSTRY

The FDA is the federal agency responsible for regulating food that is produced for consumption by humans as well as for pets⁴⁰ and all other animals.⁴¹ The FDA's mission is to protect the public health by ensuring safety and security of human and veterinary drugs and the country's food supply.⁴² The FDA does not require pre-market approval for pet food products.⁴³ But, the FDA maintains that the ingredients used in pet foods are safe and serve appropriate functions within the pet food.⁴⁴ The scope of the FDA's authority reaches beyond nutritional standards to product labeling. Current FDA regulations require that products are properly identified, including a net quantity statement, the name and address of the manufacturer or distributor's business, and an accurate list of all the ingredients in the product on a decreasing scale based on weight.⁴⁵ The FDA's regulatory authority covers a large breadth of animal and veterinary matters beyond the scope of food. The FDA is also the regulatory agency for the medications and veterinary procedures that are imperative to the health of pets.⁴⁶

As a regulatory agency, the FDA enforces the Federal Food, Drug, and Cosmetic Act. The FFDCA⁴⁷ requires that food for both humans and pets be safe to eat, produced under sanitary conditions, contain no

⁴⁰ *Animal & Veterinary: Pet Food*, *supra* note 2.

⁴¹ *Food*, FDA (Nov. 30, 2016), <http://www.fda.gov/Food/default.htm>.

⁴² *What We Do*, FDA (Oct. 24, 2016), <http://www.fda.gov/AboutFDA/WhatWeDo/>.

⁴³ *Food*, *supra* note 41.

⁴⁴ *Animal & Veterinary: Pet Food*, *supra* note 2.

⁴⁵ *Food*, *supra* note 41.

⁴⁶ *Animal & Veterinary: Approved Animal Drug Products*, FDA (Feb. 1, 2016), <http://www.fda.gov/AnimalVeterinary/Products/ApprovedAnimalDrugProducts/default.htm>.

⁴⁷ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 9 (2015).

harmful substances, and be truthfully labeled.⁴⁸ The FFDCA defines the term "food" under its regulations published in the Code of Federal Regulations as any "articles used for food or drink for a man or other animals. . .,"⁴⁹ which means that any article intended to be used as an animal feed ingredient, to become part of an ingredient or feed, or added to animals' drinking water is considered to be "food" and subject to FDA regulation.⁵⁰ The FFDCA also regulates premarket approval, labeling, and claims of products. Pursuant to the FFDCA, the FDA has authority to regulate labeling and impose criminal liability for misbranding and labeling offenses pertaining to food.⁵¹

President Barack Obama signed the FDA Food Safety Modernization Act ("FSMA") into law in January 2011.⁵² The FSMA enables the FDA to better protect the public by modernizing the food safety system and focusing on more preventative measures. The goal⁵³ of the FSMA was to enable authorities to achieve higher compliance among risk-groups in terms of prevention and safety standards.⁵⁴ The FSMA bolsters a new tool to hold imported foods to the same standards as domestic foods for integration into a healthy national food system.⁵⁵ With positive prospective, the FSMA has been finalized and businesses, as of September 2016, are required to comply⁵⁶ with the Act. The FDA has taken

⁴⁸ *Animal & Veterinary: Pet Food*, *supra* note 2.

⁴⁹ *Animal & Veterinary: Product Regulation*, FDA (Feb. 23, 2015), <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm050223.htm>.

⁵⁰ *Id.*

⁵¹ Federal Food, Drug, and Cosmetic Act, 21 U.S.C. §333 (2015).

⁵² *Background on the FDA Food Safety Modernization Act (FSMA)*, FDA (July 13, 2015), <http://www.fda.gov/NewsEvents/PublicHealthFocus/ucm239907.htm>.

⁵³ Food Safety Modernization Act, Pub. L. 111-353, §303, 124 Stat. 3885, 3911-3912 (2011).

⁵⁴ *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 52.

⁵⁵ *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 52.

⁵⁶ *FSMA Final Rule for Preventive Controls for Human Food*, FDA

some progressive steps towards preventing another pet food disaster like that in 2007, but has not pushed far enough in production aspects and food manufacturing. With so many remedial amendments to the legislation still pending, some of the largest concerns and misfortunes that led to the crises are still possible through the existing regulatory framework.

FOOD AND DRUG ADMINISTRATION: REGULATIONS ON FOOD INDUSTRY AND LOOPHOLES OF INDUSTRY ADVANTAGE

The Food and Drug Administration is the oldest comprehensive protection agency appointed regulatory power by the United States, with its origins dating back to around 1848.⁵⁷ The FDA is the federal agency responsible for protecting the public health by assuring the safety, efficiency, and security of the nation's food supply, biological products, and human and veterinary drugs.⁵⁸ The FDA has the duty to enforce the law upon the various industries within its jurisdiction and to maintain public health.⁵⁹ As part of its responsibility to uphold public health, the FDA is required to publish proposed rules, regulations and food recalls in the *Federal Register*⁶⁰ to provide notice to the public of any action the Agency might take. Under the proposed rules notification, the FDA explains its intention and basis for a proposed rule and opens the forum to the public for comment and discussion.⁶¹ The public has a large

(Oct. 31, 2016), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm334115.htm>.

⁵⁷ *History*, FDA (Mar. 23, 2015), <http://www.fda.gov/AboutFDA/WhatWeDo/History/default.htm>.

⁵⁸ *What We Do*, *supra* note 42.

⁵⁹ *What We Do*, *supra* note 42.

⁶⁰ The Federal Register is the Government's official publication for notifying the public of many kinds of agency actions, *see* <http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm>.

⁶¹ *Rules & Regulation*, FDA (Apr. 23, 2014), <http://www.fda.gov/RegulatoryInformation/RulesRegulations/default.htm>.

impact on how the FDA responds to proposed rules. The FDA takes into account the public review and comment period when determining to act further on a particular issue.⁶² When issuing a final rule, the FDA interprets the impact that the rule will have on a particular industry and the public after review from other governmental agencies.⁶³

As of September 2016, the FDA has set a compliance timeline for businesses to implement the final ruling on the FSMA Preventative Controls for Human Food.⁶⁴ The rule is an extensive effort to impose stronger regulations on the human food industry. Public demand stemmed from the realization that profit-driven enterprises⁶⁵ (that is the Food Industry) have operated within the law while using misleading tactics in the production and safety of human food. Consumers are becoming more aware of what foods they put in their bodies as science continues to develop findings surrounding human health and food consumption.

Speculation around the difference between human and pet food regulations tends to be high and wavering. Lobbyists and groups of undercover pet food companies push the public to believe that pet food is a highly scientific and complex product that has convoluted ingredients and standards beyond that of human grade food.⁶⁶ This could not be further from the truth. The FDA's regulatory standards for pet food allow companies to mislead consumers when they buy their four-legged friend some dinner or snacks.

A. Foreign Standard of Production and the Veracity Behind Ingredient Claims

One of the biggest gaps that the FDA has failed to

⁶² *Id.*

⁶³ *Id.*

⁶⁴ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁶⁵ Steams, *supra* note 4.

⁶⁶ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

close with minimal restriction is the production of dog food, treats, and snacks produced outside of the United States. The FDA does not have direct authority to impose production regulations on foreign manufacturers, leaving out-sourcing and foreign production open to interpretation by pet food producers. The FDA loosely regulates imported food safety under the FSMA with "tools"⁶⁷ to ensure that imported foods meet domestic standards and are safe for consumers.⁶⁸ The FDA assures consumers that the Agency will accredit qualified third-party⁶⁹ auditors to certify that foreign food facilities are complying with domestic safety standards. However, the FDA has yet to address the foreign-sourced issues surrounding vitamins, minerals and premixes that are used in the production of dog food.

Apart from the FDA, the Association of American Feed Control Officials⁷⁰ ("AAFCO") imposes standards that pet food companies, who have obtained or wish to obtain membership, must meet when using synthetic vitamins and minerals to pet foods.⁷¹ When a pet food company claims that their food has added vitamins and

⁶⁷ The FDA claims that the FSMA provides the agency with "tools" for effective response when problems emerge. Some of the tools listed for response are mandatory recall, expanded administrative detention and suspension registration. For a complete list of tools that the FDA claims the FSMA grants, see: *Background on the FDA Food Safety Modernization Act (FSMA)*, *supra* note 52.

⁶⁸ *Frequently Asked Questions on FSMA*, FDA (July 13, 2016), <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm247559.htm>.

⁶⁹ *Id.*

⁷⁰ ASS'N OF AM. FEED CONTROL OFFICIALS, <http://www.aafco.org>. (last visited Nov. 15, 2016). The Ass'n of American Feed Control Officials has no regulatory authority, but provides a forum for the membership and industry representation to achieve three main goals (1) safeguarding the health of animals and humans, (2) ensure consumer protection, and (3) providing a level playing field of orderly commerce for the animal feed industry.

⁷¹ Dana Scott, *Class Action Lawsuit Filed Against Merrick and Purina*, DOGS NATURALLY MAGAZINE (2015), <http://www.dogsnaturallymagazine.com/class-action-lawsuit-filed-against-merrick-purina/>.

minerals to promote the health of your pet—most companies outsource the development of those added ingredients.⁷² Companies purchase “premises” from outside manufacturers most often located in China or India.⁷³ “Premises” are combinations of vitamins and minerals that are mixed together with edible ingredients (such as meats, vegetables, and fillers). The vitamins and minerals are produced overseas and added to the United States-based dog food company’s kibble mix. The problem with premises is that manufacturers in the United States do not have to disclose its foreign-sourced ingredients because the vitamins and minerals were not added directly to the food.⁷⁴ So long as the United States-based company claims that there are no dangerous foreign ingredients in the food,⁷⁵ it is complying with the Imported Food Safety section of the FSMA and does not alert any red flags to the FDA.

The AAFCO and the USDA have set the industry’s standard terminology for the definition of particular ingredients in pet food. For example, foods that are fit for human consumption can be officially labeled as “Edible,”⁷⁶ meaning that the product has been manufactured, packed and held in accordance with federal regulations,⁷⁷ and is safe for consumption.⁷⁸ Edible is a standard set by the USDA, but “human-grade” is not.⁷⁹ Therefore, any animal food label that claims to be “human-grade” has not passed any regulatory safety tests or processing standards. The AAFCO warns consumers against this marketing ploy and dedicates a portion of their website⁸⁰ that the consumer must seek out in order to make their own conclusions. AAFCO’s

⁷² *Id.*

⁷³ *Id.*

⁷⁴ *Id.*

⁷⁵ *Id.*

⁷⁶ *Human Grade*, ASS’N OF AM. FEED CONTROL OFFICIALS (2016), <http://talkspetfood.aaeco.org/humangrade>.

⁷⁷ *Id.*

⁷⁸ Current Good Manufacturing Practice in Manufacturing, Packing, or Holding Human Food. 21 C.F.R. § 110.5 (2016).

⁷⁹ *Human Grade*, *supra* note 76.

⁸⁰ *Human Grade*, *supra* note 76.

statements elude to the nutritional value of food for humans (as opposed to animals) and how the requirements are not the same. Foods that are safe for human consumption are not necessarily safe for pets.⁸¹ Like the amount of melamine introduced to the livestock in China—humans had the capacity to handle the miniscule dosages, but animals did not.⁸² Likewise, humans can safely consume foods such as chocolate, avocados, and tomatoes where dogs can die from eating even small portions of those foods. Therefore, the label claims and marketing tactics where food is defined as “human-grade” are simply deceptive tools that the industry utilizes to mislead consumers who are trying to feed their pets high-quality foods that they themselves would consume. The assumption that the food industry hopes pet owner’s make is that, “if it is good enough for me, it’s good enough for my pet.” But the reality is that the human-grade claim has no merit. The definition-less ingredient standard is just a claim that misleads consumers into purchasing products.

There are two more terms are of high importance to health-driven consumers. Human foods are labeled with terms such as “natural” and “organic” which carry a purity standard in their conveyance. However, the FDA has not defined either of those terms for pet food.⁸³ The FDA instead relies on the federal requirement that labeling not be false or misleading,⁸⁴ which enables the pet food industry to abide by that hopeful notion. But, consumers must ask themselves, if there is no definition of what constitutes natural—how could a company use it in a misleading or false way?

Similarly, “organic” is not defined as a pet food term in any FDA regulation. Rather, it is solely relied on to meet human standards of organic production.⁸⁵ In the absence of a definition for two popular terms, the FDA cannot enforce how producers use them to entice

⁸¹ *Human Grade*, *supra* note 76.

⁸² *Melamine Pet Food Recall of 2007*, *supra* note 20.

⁸³ *Natural*, ASS’N OF AM. FEED CONTROL OFFICIALS, (2016) *available at* <http://talkspetfood.aafco.org/natural>.

⁸⁴ *Id.*

⁸⁵ *Id.*

consumers. The food companies making these claims may or may not have merit to their organic or natural claims—and currently, no federal agency is looking out of their interest by setting policies.

B. Made in the USA: A Label Guise

If the hidden premixes and absence of term regulations are not enough to convince consumers that their pet's food might not be high-quality or made up of the safest ingredients—it is time to consider where the food is coming from. The average savvy American pet food purchaser, who is up-to-date on the foreign ingredient fear, is likely to pick up a bag of dog food and look for the “Made in the USA” stamp of assurance. But, that “Made in the USA” promise does not necessarily convey that the product is safe. Again, the pet food industry is imploring deceptive tactics and utilizing weak laws and regulations to entice consumers to purchase their products. The industry should deduce that after the 2007 crisis, consumers are becoming more aware of where and how Fido's food is being manufactured. But the regulations on “Made in the USA” labels and claims are weak at best and allow pet food producers to sneak in foreign ingredients.⁸⁶ The industry is capitalizing on the fears of American consumers by conducting deceptive marketing strategies to entice buyers.

The ugly truth behind the “Made in the USA” labels are that the ingredients do not all⁸⁷ have to be

⁸⁶ *Made in USA*, FTC, <https://www.ftc.gov/news-events/media-resources/tools-consumers/made-usa>. (last visited Oct. 30, 2016). “For most products, unless they are automobiles or items made from textile or wool, there is no law requiring manufacturers and marketers to make a “Made in USA” claim. But if a business chooses to make the claim, the FTC's Made in USA standard applies. Made in USA means that “all or virtually all” the product has been made in America. That is, all significant parts, processing, and labor that go into the product must be of U.S. origin. Products should not contain any - or should contain only negligible - foreign content.”

⁸⁷ *Id.* “[A]ll significant parts, processing, and labor that go into the product must be of U.S. origin. Products should not contain any - or should contain only negligible - foreign content.”

made in the United States.⁸⁸ The Federal Trade Commission ("FTC") is responsible for governing the labeling of products and the rule set forth states that "all or virtually all" of the significant parts and processing that go into the product must be of domestic origin.⁸⁹ But "all" and "virtually all" are not defined terms. The rule does not have percentages or a scale. The FTC's compliance sector makes no specific mention of food in its regulations definition.⁹⁰ This leaves a huge gap that allows pet food producers to manipulate their numbers and terms, which ultimately allows them to increase their profit margins. Companies may import foreign ingredients and add them to bases produced in the United States. Then the finalized pet food product was technically "Made in the USA." See how that works?

V. FOOD SAFETY MODERNIZATION ACT

The Food Safety Modernization Act⁹¹ was intended to shift the FDA's strategy from a responsive entity into a preventative entity that worked hard at the forefront to avoid food contamination. The legislation was intended to enable the FDA to aggregate a comprehensive plan towards the early steps of food production, such as setting more inspection guidelines

⁸⁸ Complaint at 1-10, *Sensenig et al. v. Wellpet, LLC*, (N.D. Ill. 2016) (No. 3:16-cv-50021).

⁸⁹ ASS'N OF AM. FEED CONTROL OFFICIALS, <http://petfood.aafco.org/Labeling-Labeling-Requirements#usa>. (last visited Nov. 26, 2016). The AAFCO's website links to the FTC for further information on labeling requirements AAFCO is a guideline and has not regulatory power of enforcement. FTC available at <https://www.ftc.gov/tips-advice/business-center/guidance/complying-made-usa-standard>. Makes no specific reference to food labeling in the guidance and compliance sections. The FTC utilizes generic language in which companies apply to their labels, as legally meeting definitions. Further information on labeling compliance is provided on the website. *Also see: Made In USA*, *supra* note 86.

⁹⁰ *Complying with the Made in USA Standard*, FTC (Dec. 1998), <https://www.ftc.gov/tips-advice/business-center/guidance/complying-made-usa-standard>.

⁹¹ Food Safety Modernization Act, Pub. L. 111-353, §303, 124 Stat. 3885, 3956-3957 (2011).

and quality standards that must be met before moving forward with production. However, the rule did not pass when it was introduced the first time, leaving the FDA to produce more concrete strategies and reach out to the industry and public for feedback.⁹² The comment period allowed for a rigorous discussion on how to improve the rule and also highlighted faults with previously implemented tactics.

Therefore, in 2014 the FDA issued a supplement provision section that allowed the FSMA to be more flexible, practical, and effective for the industry while maintaining the FDA's advancement of safety for the industry.⁹³ The new rule began to impose the new regulations on businesses in the industry in September 2016.⁹⁴ Four main requirements⁹⁵ of the provisions address concerns that have been neglected in the past, left in brevity, or completely overlooked. Now, the FDA recognizes these as areas of improvement and has built more specific language in the FSMA to address these topics.⁹⁶ For animal food, Current Good Manufacturing

⁹² *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁹³ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56. FDA comment on the FSMA "The law applies to human food as well as to food for animals, including pets," at <http://www.fda.gov/AnimalVeterinary/Products/AnimalFoodFeeds/ucm347941.htm>.

⁹⁴ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁹⁵ The four key requirements are (1) Current Good Manufacturing Practices (CGMPs) established for animal food production, (2) covered facilities must establish and implement a food safety system that includes an analysis of hazards and risk-based preventive controls, (3) supply-chain program is more flexible, with separate compliance dates established, and (4) The definition of a 'farm' is clarified in the Preventive Controls for Human Food final rule to cover two types of farm operations. Operations meeting the definition of 'farm' are not subject to the preventive controls rule. For details, see: FDA, <http://www.fda.gov/food/guidanceregulation/fsma/ucm366510.htm>.

⁹⁶ See Current Good Manufacturing Practice, Hazard Analysis, and Risk-Based Preventive Controls for Food for Animals, 80 Fed. Reg. 56169 (Nov. 16, 2015) (to be codified at 21 C.F.R. pts. 11, 16,

Practices ("CGMP") have provided a baseline standard for producing animal food that would be considered safe in a wide diversity of animal food facilities. The FDA explains this provision as the prohibition of contamination in containers holding by-product with physical or chemical contaminants.⁹⁷ It is somewhat troubling that in 2016, this has just become a provision of the FDA's control over the pet food industry. Better late than never, but if this slow pace of progress continues, our four-legged friends will be waiting a long time for *real* improvements.

The FSMA also lists implementing food safety systems as a main requirement of the 2014 provisions. It states that covered facilities must establish and implement safety systems for the analysis of hazards and risks in their facilities.⁹⁸ Then, the FSMA states that these facilities must take preventative measures and set forth written food safety plans with specifications such as monitoring of manufacturing and recall plans. The objective of this key requirement is to ensure that facilities recognize their own risks and hazards. Hopefully companies, as a response to recognizing these issues, will try to minimize and prevent any foreseeable consequences. Again, this requirement seems generic and allows for the facilities themselves to dictate their own risk analysis, conceive their own prevention plans, and establish an inside recall procedure.

The provisions to the FSMA also address the definition of a "Farm"⁹⁹ facility and clarifies what

117, 500, 507, 579) available at <https://www.federalregister.gov/documents/2015/09/17/2015-21921/current-good-manufacturing-practice-hazard-analysis-and-risk-based-preventive-controls-for-food-for>; *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁹⁷ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁹⁸ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56.

⁹⁹ *FSMA Final Rule for Preventive Controls for Human Food*, *supra* note 56. "The supplemental rule proposed, and the final rule includes, a change to expand the definition of 'farm' to allow farms to pack or hold raw agricultural commodities (food in its raw or

constitutes that type of production location. Supply-chain program regulations were loosened to allow for flexible identification of hazards for use of raw materials and other ingredients identified as hazards.¹⁰⁰ Basically, facilities are not required to have preventative controls if there are other links in the chain, such as distributors, that will follow precautions for hazards. The key requirements to the FSMA explicitly recognize that feed mills that are associated with farms¹⁰¹ are not covered by the final rule. The FDA states its own concern that not having these operations subject to the rule leaves a gap in the protection of human and animal health because these entities manufacture a significant amount of animal food.¹⁰² So if the FDA is concerned about a gap left open in the FSMA, it must be a pretty big gap, or at least highly criticized in its own realm, to circulate fears within the Agency.

All of the provisions to the FSMA as final rulings are progressive movements towards the ultimate safety standards for pet food. But, the key requirements are vague and non-penalizing. The rules leave gaps for the industry to fill in with their own advancement at the forefront. The FDA still has major work to do if the implementing these few critical provisions were the only serious reactions to the crisis of 2007. With the regulations in place now under the FSMA and other legislation responsive to the recall disaster, it is fairly likely that the industry may have even more opportunities to work the system under the loosely

natural state) that are grown on a farm under a different ownership. The final rule also includes within the 'farm' definition companies that solely harvest crops from farms"

¹⁰⁰ *FSMA Final Rule for Preventive Controls for Animal Food*, *supra* note 56.

¹⁰¹ *FSMA Final Rule for Preventive Controls for Animal Food*, *supra* note 56. "Feed mills associated with fully vertically integrated farming operations (i.e., farms where the feed mill, animals, land, and establishment are all owned by the same entity) generally meet the definition of a farm and are therefore not subject to the Preventive Controls for Animal Food final rule."

¹⁰² *FSMA Final Rule for Preventive Controls for Animal Food*, *supra* note 56.

defined and poorly articulated rulings.

VI. RATIONALE AND IMPACT

With all of the provisions, regulations, and new legislation introduced in response to the 2007 recall crisis, one would assume that the pet food industry has adopted major changes. It would be a reasonable correlation to assume that problems arising from the foreign-sourced pet foods would be decreasing as supposedly helpful rules are being implemented. But, that does not seem to be the case. In fact, a plethora of claims and lawsuits are still arising from problems that were cited in 2007.¹⁰³ And the frightening part is that there are also problems arising as a result of the new provisions—the consumers are responding to the way the industry is inventing new ways around the rules and utilizing gaps in the policies.¹⁰⁴

The well-known pet food brand, Nestle Purina,¹⁰⁵ has had its fair share of spotlight in the past few years.¹⁰⁶ Purina's line of Beneful dog food has been criticized for containing harmful ingredients that are toxic and poisonous to dogs.¹⁰⁷ Well over 3,000 pet

¹⁰³ *Veterinary: Recalls & Withdrawals*, FDA (Nov. 24, 2016), <http://www.fda.gov/animalveterinary/safetyhealth/recallswithdrawals/>. A continuing list of the most recent recalls in the pet food industry are listed by product and reason for recall.

¹⁰⁴ See Generally, Patrick Harrington and Sandra K. Jones, *Made in the USA: Labeling Lawsuits in America's Pet Food Industry*, DRINKER BRIDDLE, LLP (Mar. 8, 2016), http://www.drinkerbiddle.com/insights/publications/2016/03/made-in-the-usa-labeling-lawsuits-in-americas-pe__.

¹⁰⁵ Nestle Purina Petcare Company (est. 1894). More information on the history of the company is available at <https://www.purina.com/meet-purina/about-us#/past-and-present>.

¹⁰⁶ See, Ralph Ellis, *Lawsuit says Purina food harms dogs; company denies allegations*, CNN (Feb. 25, 2015), <http://www.cnn.com/2015/02/24/us/dog-food-lawsuit/>; Daniella Silva, *Dog Owners Alarmed at Beneful Lawsuit as Purina Denies Claims*, NBC NEWS (Mar. 8, 2015), <http://www.nbcnews.com/news/us-news/dog-owners-alarmed-beneful-lawsuit-purina-denies-claims-n316856>.

¹⁰⁷ Morgan & Morgan, *Lawsuit Alleges Purina Beneful Sickened:*

owners have reported that their dogs have contracted illnesses or have died after consuming the Beneful line of dog food.¹⁰⁸ After more than 1,000 reported American dog deaths, the FDA addressed the allegations by distributing a preliminary advisory in 2011 announcing their investigation.¹⁰⁹ The FDA, again, originally blamed the deaths on the foods that were imported from China and ordered a voluntary recall of the products from store shelves in 2013.¹¹⁰ One of several lawsuits filed alleged that the toxins contained in the food were poisonous chemicals propylene glycol and mycotoxins.¹¹¹ Propylene glycol contains antifreeze components that are harmful for ingestion and mycotoxins are a group of toxins that occur in grains that produce fungus.¹¹² A class action lawsuit arose from the poisonous Beneful product line which alleged that the Chinese-made treats were not safe for animal consumption and resulted in death of consumers' dogs.¹¹³ The consumers in the class stated that they had relied on the claims that Purina placed on the product labeling that read the pet food was "wholesome," "nutritious," and "healthy."¹¹⁴ The class action suit settled when Purina offered the consumers a \$6.5 million fund to compensate the pet owners for their deceased pets.¹¹⁵ At the conclusion of the lawsuit, neither Purina nor the FDA ever admitted that there was any contamination in the product line and denied any

Killed Dogs, ForThePeople.com, <https://www.forthethepeople.com/class-action-lawyers/purina-beneful-dog-food-deaths/> (last visited Dec. 17, 2016).

¹⁰⁸ Morgan & Morgan, *supra* note 104.

¹⁰⁹ *Adkins v. Nestle Purina Petcare Co.*, 973 F. Supp.2d 905, 911 (N.D. Ill. 2013).

¹¹⁰ Danielle Silva, *Lawsuit Alleges Purina Beneful Sickened: Killing Dogs*, NBC NEWS (Feb. 24, 2015), <http://www.nbcnews.com/news/us-news/lawsuit-claims-purinas-beneful-poisoning-killing-dogs-n312176>.

¹¹¹ Morgan & Morgan, *supra* note 104.

¹¹² Morgan & Morgan, *supra* note 104.

¹¹³ *Adkins et al.*, 973 F. Supp.2d at 906. Manufacturer of the dog treats Waggin' Train LLC was joined as a defendant in the suit.

¹¹⁴ *Id.* at 8.

¹¹⁵ Silva, *supra* note 110.

safety concerns that were associated with the pet food.

In addition to the risk of poisonous imported pet food, product mislabeling may lead consumers to believe that the pet food they purchase is produced in the United States, making it seem like they are avoiding potentially dangerous foreign ingredients. Consumers are taking initiatives and seeking legal action in response to the pet food industry's labeling practices. Claims such as the "Made in the USA" are receiving attention due to the existing regulatory framework associated with that claim. Companies are putting the "Made in the USA" stamp of assurance on products that have substantial amounts of ingredients imported from foreign countries.¹¹⁶ As long as companies are meeting that "all or virtually all"¹¹⁷ threshold, they are allowed to make such American-based claims on their labels. Companies are still utilizing the deceptive "Made in the USA" label to hide their foreign-sourced vitamins and minerals under an ambiguity in legal jargon. For the companies to make the claim that their product was produced in the United States, they assert that a "significant portion" of their food is produced in the United States, meaning their kibble or base product is manufactured domestically, but their additives are outsourced.¹¹⁸ An example to illustrate this point is a claim that chocolate chip cookies are "Made in the USA" even though the eggs used in the dough are imported from Mexico. Assuming Mexico has lower standards for antibiotic treatment and handling of eggs, it is not guaranteed that the eggs are free from contaminants like salmonella. Therefore, a claim that the chocolate chip cookies were substantially or virtually all produced in the United States is not a lie. This is how the labeling under the FTC and FDA for "Made in the USA" is deceptive and to this day are still taking advantage of by the industry.

Since 2007, pet food companies have received criticism for false advertising, poor manufacturing

¹¹⁶ Complaint at 1-10, *Sensenig et al. v. Wellpet, LLC*, (N.D. Ill. 2016) (No. 3:16-cv-50021).

¹¹⁷ *Made in USA*, *supra* note 73 ("all or virtually all" claims).

¹¹⁸ Scott, *supra* note 71.

practices, and abusing the "Made in the USA" claims.¹¹⁹ However, it is not a new strategy that in order to leverage their own interests, companies attempt to undermine each other's manufacturing and marketing procedures.¹²⁰ This is a clear advantage to the consumers aimed at pressing for further improvement and higher standards because companies in the industry have the knowledge to address these issues and hold other players on the field accountable.¹²¹ The industry as a whole has to gain back the trust of consumers since dependable name brands went down for the crisis in 2007.

In 2015, the FDA attempted to circumvent some responsive strategies by issuing a provision to the FSMA called the Foreign Supplied Verification Program.¹²² This program sought to require importers to verify that food imported to the United States has been produced in a manner consistent with the public health protections required of United States manufacturers.¹²³ The addition of the Foreign Supplied Verification Program was a supplement to a 2013 provision that intended for the verification measures to be determined appropriately and flexibility. The final ruling was issued in late 2015.¹²⁴ Although this provision seems to have been the step that the food

¹¹⁹ See generally, Lisa Brown, *Purina, Blue Buffalo Settle False Advertising Lawsuit*, ST. LOUIS POST-DISPATCH (Nov. 3, 2016), [http://abcnews.go.co.](http://abcnews.go.co.;); Edi Lau, *Purina v. Blue Buffalo court fight sprawls*, VIN NEWS (Sept. 11, 2015), <http://news.vin.com/VINNews.aspx?articleId=38069>.

¹²⁰ *Iams Co. v. Nutro Prods., Inc.*, No. C-3-00-566, 2004 WL 5780000, 2 (S.D. Ohio July 19, 2004).

¹²¹ Scott Holland, *Class actions says Purina, Wellpet brand 'made in USA' dog foods actually aren't*, COOK COUNTY RECORD (Feb. 2, 2016), <http://cookcountyrecord.com/stories/510661106-class-actions-say-purina-wellpet-brand-made-in-usa-dog-foods-actually-aren-t>.

¹²² *FSMA Final Rule on Foreign Supplier Verification Programs (FSVP) for Importers of Food for Humans and Animals*, FDA, <http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm361902.htm>

¹²³ Food Safety Modernization Act, Pub. L. 111-353, §303, 124 Stat. 3885, 3956-3957 (2011).

¹²⁴ *Frequently Asked Questions on FSMA*, *supra* note 68

industry needed to set safety standards for foreign food, consumers are still being misled by labels and foreign additives. Pet brands are still hiding behind tricky language and upmarket ingredient language.

In 2016, a multiple class action suits were filed against Nestle Purina. In one of the class action suits, the class alleged that Nestle Purina utilized aggressive marketing, mislabeling, and asserted fraudulent claims in its retailing of "Beggin" dog treat products.¹²⁵ The suit challenged language that suggested the Beggin' products were primarily made out of bacon.¹²⁶ The suit was terminated on procedural grounds after a motion to dismiss was denied in part and granted in part.¹²⁷ In a separate pending class action suit, the class alleged that Purina wrongfully utilizes the "Made in the USA" label claim under the FTC and deceives consumers into purchasing their products that are purportedly free of foreign ingredients.¹²⁸ It remains to be seen whether similar suits will be filed against other major brands. Even though standards have been raised in the FSMA the implications have yet to catch up to the pace of the industry. It is going to take time before the FDA can implement all of the changes in the legislation, but it still has vast improvements to make.

VII. CONCLUSION

The FDA's mission is to promote, protect, and advise the public health. The Agency regulates the vast majority of consumer products that affect the well-being of humans in the United States. As science continues to advance in the production of pet food, findings still show room for improvement. The improvement for human regulations and safety standards show promise that it is possible for the field to advance. Public outcry and social movements have led the FDA to intervene and take control in the human

¹²⁵ *Kacocha v. Nestle Purina Petcare Co.*, No. 15-CV-5489 KMK, 2016 WL 4367991 1 (N.Y. Dist. Ct. Aug. 11, 2016).

¹²⁶ *Id.*

¹²⁷ *Id.* at 16.

¹²⁸ Holland, *supra* note 118.

food industry. Since the slaughterhouse practices were exposed in the early 1900s, there has been a complete turnaround and food safety has improved. That was a result of consumers pressuring the government to implement changes. However, pet food manufacturers have a clear advantage to fly below the radar because their biggest consumer cannot talk.

At this point, it is clear that the pet food industry is using elusive tactics to victimize consumers. Pet food companies hide their foreign-sourced ingredients behind incomplete regulations and misleading labels. The evidence that pet food companies use foreign-sourced ingredients in their pet food and hide them behind misleading claims has been proven. Consequences of having foreign ingredients in pet foods have led to severe illness and death. Foreign suppliers do not have the same quality, safety, and handling standards as the United States. Their tactics to hide chemical ingredients behind crude protein analyses and vitamin and mineral additives have been successful. It is a matter of time before the United States sees another disaster resulting from loose regulations.

Consumers should be aware of where their pet food comes from and how it is made. Labels are deceiving, so research is necessary to ensure that our pets are getting the highest quality, most nutritious and beneficial food that they can. For the time being, consumers will need to perform due diligence in investigating the source of their pet food ingredients or be willing to prepare homemade meals for their pets.

Until a time where labels are clearly marketed free of misleading information, pressure needs to be put on the FDA to crack down on the industry and impose penalties on companies that are not following the standards set forth in legislation and provisions executed since the 2007 food crisis. The pet food industry remains a mystery hidden behind deceptive marketing ploys and strategies. The public must channel their inner investigator as a member of the Mystery Gang to ensure that their very own Scooby Doo at home will remain healthy and strong as a result of eating his Scooby Snacks – and not sick as a result of

the poorly regulated pet food industry.