Dog Food Production from Farm to Food Bowl:

Evaluating FDA's Regulatory Oversight and the Impact on Food Safety

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Abstract

With the introduction of the Food and Drug Administration's Food Safety Modernization Act (FSMA) regulatory oversight of dog food production is becoming clearer, and it is important for consumers and manufacturers to understand the effect of regulatory oversight on the safety of their pet's food. This review of guidance documents, laws and regulations, news articles and scholarly research aims to educate the consumer on how their dog's food is regulated at each stage of its production. Additionally, this review aims to assist manufacturers in understanding the regulations and/or authorities the finished products and ingredients may be subject to thus providing the manufacturers with the tools to perform a more complete and accurate review of their food safety procedures. To convey this information three educational fact sheets were developed that focused on explaining how dog food is produced, educating on the regulatory oversight of dog food production, and illustrating how consumers can protect both themselves and their pets from contaminated pet food. It is recommended that additional materials aimed at consumers be developed to cover trends in dog food diets, pet food labelling including medical claims, and tips on safely creating home-made pet food.

Keywords: Preventive Controls for Animal Food, Food Safety Modernization Act, dog food safety, animal feed safety

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Introduction

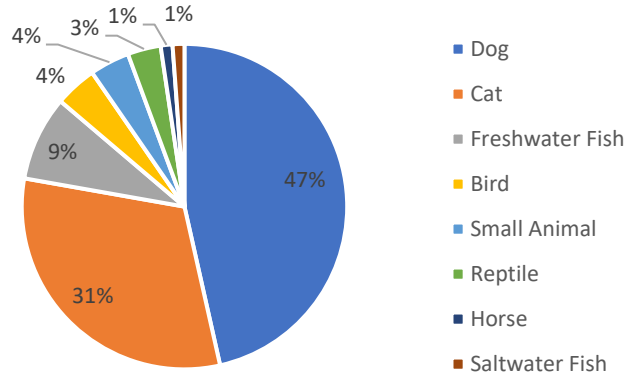
Background and Setting, Statement and Significance of the Problem

Pets play a role in most Americans' lives as a faithful companion, a close friend, a treasured family member, and an important lifesaver. With such a strong relationship between animals and humans, in some cases bordering on anthropomorphism, it is important for consumers to understand what they feed their pets and for pet food manufacturers to take care in what they produce. From the industry perspective, understanding the consumer's wants and needs could be the key to selling their product. In 1999 Aylesworth et al. presented a framework that demonstrated three facets to understand how pets impact a consumer's consumption activities. Within this framework they discussed the three stages of acquisition, consumption, and disposition: Acquisition sets the consumer on a certain path depending on the species or breed adopted, for example, a consumer who adopted a cat may have less frequent play sessions compared to a consumer who adopted a dog; consumption encompasses choices made during the pet's lifetime with the consumer such as their interaction with the consumer, the food choices made by the consumer, and the medical choices in response to the pet's needs; finally, disposition focuses on the termination of the animal-human relationship whether voluntary, human's choice to give up the pet or animal's choice to run away, or involuntary, if the animal dies or is lost (Aylesworth et al., 1999). While the study itself focused on consumption for future research topics, this paper will utilize the impact of the consumer's relationship on their pet's food choices to describe dog food production, educate consumers on the regulatory oversight, and explain how regulations and manufacturers work for and against each other in order to produce a safe dog food product.

According to the 2019-2020 APPA National Pet Owners Survey, a majority, 67% or 84.9 million homes of U.S households own a pet whether it's a dog, cat, bird, horse, fish, reptile, or

Figure 1

Pet ownership in the United States



[a]Breakdown of pet ownership in the U.S. according to the 2019-2020 APPA National Pet Owners Survey (Percentage of the 84.9 million pet households)

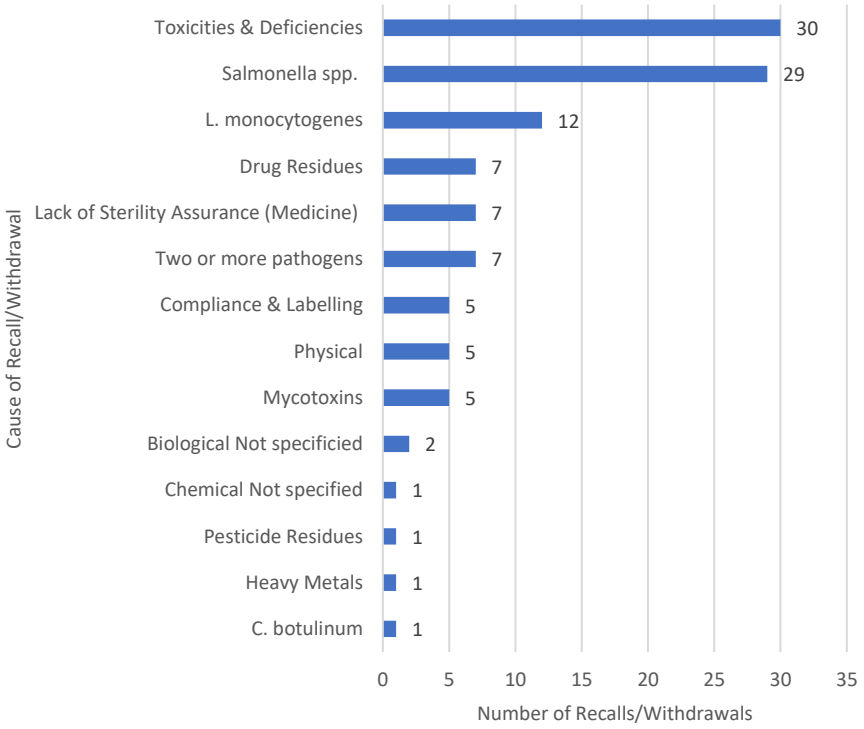
other small animal and have spent an estimated $99.0 billion on our pets for 2020, higher than the $95.7 billion spent in 2019 (American Pet Products Association [APPA], n.d.). Dogs as pets are responsible for 63.4 million of the 84.9 million pet households (see Figure 1). With a majority of the United States owning a dog, it is important for those pet owners to know and understand what they are feeding their puppy. In a recent study by Schleicher, Cash, & Freeman they found that the highest-ranking pet food characteristics pet owners look for were health and nutrition, quality, ingredients, and freshness (2019). Additionally, these characteristics mirror the choices made by consumers for their own food consumption (Schleicher et al., 2019). Consumers that take care of their own bodies typically want what is best for their dog as well, however, knowing the characteristics you want in your pet's food is half the battle. With so many choices for consumers choosing the right food for your pet dog can be overwhelming, with multiple brands to choose from and multiple products within those brands depending on your dog's size, health & nutrition, eating habits, and in some cases their breed. Understanding your dog's needs assists consumers in choosing the right dog food, however, consumers should also be aware of how their pet's food is processed and regulated to ensure they are providing the safest and healthiest food to their pets.

The safety of pet food is important as it not only protects the animal but also the owner and it is the industry's responsibility to ensure the final product does not cause harm to the consumer. In addition to the industry's responsibility for safety, the Food and Drug Administration (hereinafter

"FDA") is responsible for regulating the production of animal feed and veterinary medicine. As a component of their responsibility the FDA monitors and tracks recalls ensuring a safe supply of animal feed and veterinary medicine for the consumer. Since 2017, animal food and veterinary medicine products have been implicated in 114 recalls (see Figure 2) (Center for Veterinary Medicine [CVM] [Data set], 2020). Based on the information provided by the U.S. FDA, implicated biological hazards included contamination with *Salmonella* spp., *Listeria monocytogenes*, *Clostridium botulinum*, and *Escherichia coli* O128. There is a high human health risk involved due to the increased likelihood of direct human contact with contaminated pet food. In regard to *Salmonella* spp., pets can be affected by any *Salmonella* serotype increasing the risk of foodborne illness, whereas animal feed for non-pets is considered adulterated when contaminated with a *Salmonella* serotype that is considered pathogenic to the intended animal species (Schertz, 2018). One example of a species-specific *Salmonella* serotype is *Salmonella abortusequi (abortivoequina)*

Figure 2

Number of Recalls & Withdrawals for Animal Feed & Veterinary Medicine Products from January 2017 to November 2020 Categorized Based on Recall Cause

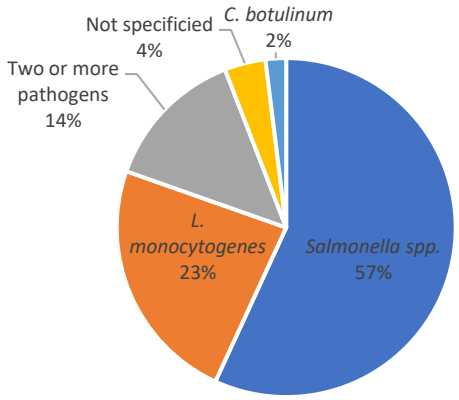


[a]Data taken from the FDA's Recalls and Withdrawals webpage, includes all animal-related recalls from January 2017 to November 2020.

(also known as *Salmonella enterica* serovar Abortusequi) which causes abortion in mares and donkeys (Saunders, 2017). According to Albright's Raw Dog Food company announcement, "pets with *Salmonella* infections may be lethargic and have diarrhea or bloody diarrhea, fever, and vomiting [while] some pets will have only decreased appetite, fever and abdominal pain" and humans contaminated by *Salmonella* may experience similar symptoms (CVM, 2020 Nov). Of the pathogenic bacteria implicated since January 2017 *Salmonella* spp. is responsible for a majority, 57%, of the foodborne pathogen related recalls (see Figure 3). Implicated chemical contamination include nutrient toxicities and deficiencies, lack of sterility assurance (for veterinary medicine), drug residues, heavy metals, mycotoxins, and pesticide residues with toxicities and deficiencies responsible for a majority of the chemical hazard related recalls (See Figure 4) (CVM [Data set], 2020). The key difference between *Salmonella* spp. and toxicities and deficiencies as hazards is their capability to infect humans with toxicities and deficiencies affecting only the animal consuming the pet food product. Based on multiple recall reports received through the reportable food registry (hereinafter "RFR") the FDA was able to compile a list of examples identified under nutrient toxicities and deficiencies. These examples include: "low levels of thiamine in cat food, low levels of vitamin D in food for swine, elevated levels of copper in food for sheep, elevated levels of vitamin D in dog, guinea pig,

Figure 3

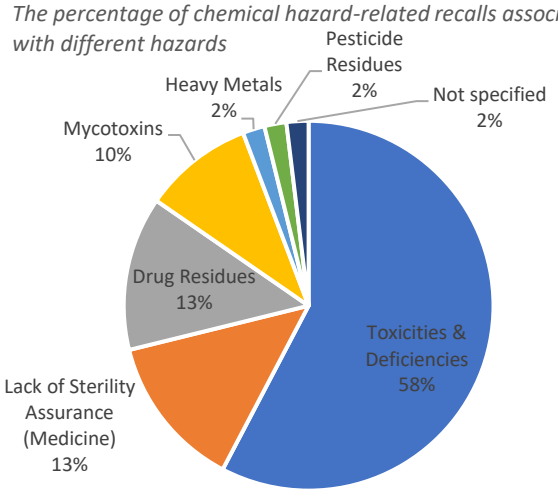
The percentage of biological hazard-related recalls associated with a specific pathogen



[a]Data calculated from the FDA's Recalls and Withdrawals webpage, includes all animal-related recalls from January 2017 to November 2020.
[b]n = 52

Figure 4

The percentage of chemical hazard-related recalls associated with different hazards



[a]Data calculated from the FDA's Recalls and Withdrawals webpage, includes all animal-related recalls from January 2017 to November 2020.
[b]n = 52

and fish food, elevated levels of calcium and phosphorus in food for broiler chickens and turkeys, and elevated levels of urea in food for cattle" (CVM, 2018 January). Of the 30 nutrient related recalls from the dataset, 13 were related specifically to elevated levels of vitamin D, and of those 13 recalls 12 were specifically related to dog food products, accounting for 11% of the overall recalls from January 2017 to November 2020 (CVM [Date set], 2020). Recently, December 2020, a recall of dog and cat food products from Midwestern Pet Foods, Inc. began because some products were found to contain aflatoxin as a result of contaminated corn product ingredients used in the formulations (CVM, 2021). According to Gibson at CBS News, as of January 28, 2021, the aflatoxin-contaminated products have left more than 110 dogs dead and more than 210 dogs sick, however, the FDA stated that this number "is approximate and may not reflect the total number of pets affected" (Gibson, 2021). This explanation of the recalls from the past three years demonstrates to consumers the need to understand how their dog's food is regulated and what to look for when choosing the best pet food based on the labelling and ingredient components.

Purpose of the Project

The purpose of the project is to describe dog food production, educate consumers on the regulatory oversight in the United States from farm to dog bowl, and assist the entities in the dog food supply chain understand their responsibility.

Project Objectives

1. Evaluate the dog food supply chain in terms of regulation and jurisdiction.
2. Evaluate the preventive controls manufacturers may implement as a major component in ensuring the safe production of pet food products.
3. Develop educational material for (1) consumers and the public on how the dog food is produced from farm to dog bowl, (2) for manufacturers and suppliers on how the FDA regulates pet food, and (3) for consumers on how they can play a food safety role for pet food.

Definition of Keywords/Terms

1. *Adulterated Food*: food that is generally, impure, unsafe, or unwholesome. The main federal laws governing adulterated foods are the Federal Food, Drug, and Cosmetic Act, the Federal Meat Inspection Act, and the Poultry Products Inspection Act. These laws contain separate language defining in very specific terms how the term "adulterated" will be applied to the foods each of these laws regulates. Products that are adulterated under these laws' definitions cannot enter into commerce for human food use. Under U.S. law, using an ingredient not approved by the Food and Drug Administration (FDA) is one form of food adulteration (U.S. Legal, n.d.).

2. *Code of Federal Regulations (C.F.R.)*: the codification of the general and permanent rules published in the Federal Register by the departments and agencies of the Federal Government (University of Michigan, 2020). The FDA has officially published the Food Safety Modernization Act components in the Code of Federal Regulations. References or citations to the Code of Federal Regulations are written as follows: ## (Title) C.F.R. ###### (Section).
3. *Covered Produce*: Produce that is considered a raw agricultural commodity (RAC) and that is grown domestically or that is imported or offered for import (Rogers, 2020). Fruits and vegetables that are typically consumed raw.
4. *Food Safety Modernization Act (FSMA)*: FSMA overhauled regulations regarding food production and gave the Food and Drug Administration more authority to oversee and enforce supply chains. FSMA shifts the focus from responding to foodborne illnesses to preventing them and affects almost every business that must register with the FDA (Thatte, 2019).
5. *Food Safety Plan*: A food safety plan consists of the primary documents in a preventive controls food safety system that provides a systematic approach to the identification of food safety hazards that must be controlled to prevent or minimize the likelihood of foodborne illness or injury. It contains a collection of written documents that describes activities that ensure the safety of food during manufacturing, processing, packing, and holding (CFSAN, 2018 Jan).
6. *Foodborne Disease Outbreak Surveillance System (FDOSS)*: collects information from state and local health departments about foodborne disease outbreaks.

Outbreaks are occurrences in which two or more people get the same illness from the same contaminated food or drink (CDC, 2018).

7. *Good Agricultural Practices (GAPs)*: a set of best management practices for the production of fresh fruits and vegetables. When correctly used and put in place, GAPs are intended to minimize the risk of microbial food safety hazards (Long, 2016).
8. *Hazard Analysis and Critical Control Points (HACCP)*: a management system in which food safety is addressed through the analysis and control of biological, chemical, and physical hazards from raw material production, procurement and handling, to manufacturing, distribution and consumption of the finished product (U.S. FDA, 2018).
9. *Preventive Controls for Animal Feed (PCAF)*: The rule is intended to ensure safe manufacturing/processing, packing and holding of food products for animal consumption in the United States. Also referred to as *The Current Good Manufacturing Practice, Hazard Analysis, and Risk-based Preventive Controls* for Animal Food regulation (FSPCA, n.d.).
10. *Produce Safety Rule (PSR)*: the rule is a collection of science-based standards for the growing, packing, harvesting and storing practices of produce grown for human consumption. The final rule is a collection of the original rule and all the subsequent revisions, amendments and modifications (Long, 2016).

Review of Literature

A Brief History of Dog Food

To understand the present-day situation regarding the safety of dog food and how it is regulated, it is important to first learn the history of commercial dog food production in the United States. In the 1870s an American by the name of James Spratt introduced the United States market to fortified dog biscuits, a product he had produced and sold in Great Britain during the 1860s (Case et al., 2011). After observing Spratt's success, other companies in the United States began to develop and sell their own variety of commercial pet food products. One such product that is still popular today is Milk-Bones, originally produced in 1908 under the name "Maltoid" biscuits by F.H. Bennett Biscuit Company and advertised as a way for pet owners to provide nutrition to their dogs (Case et al., 2011). The popularity of commercial dog food grew as the relationship between dog and owner developed from task animal for hunting and guarding to beloved companion and family member (Kelly, 2012).

In 1922 canned dog food was introduced into the United States market as a product called Ken-L Ration, made primarily from horse meat which was "carefully marketed as 'lean, red meat' and only disclosed in much smaller letters at the bottom of the packaging" (The Farmer's Dog, 2017), and accounted for 90% of commercial pet food sales by 1941 (Podolsky, n.d.; Case et al., 2011). The popularity of canned dog food lived until World War II when tin was utilized for weapons manufacturing leaving a shortage for the canned dog food industry and did not return back to the market until the war was over (Podolsky, n.d.; Case et al., 2011). Horse meat was utilized in the production of canned dog food due to its affordability until it was banned as an ingredient in 1970 as a result of food politics and humans' evolving relationship with horses (AKC

Studio, 2018). Canned dog food, without the horse meat, has maintained its position in the commercial dog food market and is purchased today as part of a pet's diet.

Around the same time dry dog food was introduced by Gaines Dog Food Co. in 1928 as a complete meal for pets which consisted of dried, ground ingredient mixed together and sold in 100lb bags (Case et al., 2011.; Clarence F. Gaines obituary, 1986). The idea of 'kibble' however was not introduced until 1956 when the Ralston Purina Company experimented with their Chex breakfast cereal machines to extrude a pre-mixed dog food product through a die cut machine after it was subjected to extreme pressurized steam and high temperatures, more commonly known as an extrusion process (The Farmer's Dog, 2017; Case et al., 2011). Beginning in World War II and skyrocketing after the introduction of extruded kibble, dry dog food's popularity rose, and it has maintained its dominance in the market until recent years when a call for healthier pet food has been heard (Podolsky, n.d). With multiple changes to the commercial pet food industry in the past century, introducing and advancing regulations was and continues to be imperative in ensuring a safe production of dog food from farm to food bowl.

With the advancements of animal feed production and commercially processed dog food, state and federal governments took note and enacted laws and regulations for the animal feed industry. In the history of feed regulations in the United States, state regulatory agencies took the first step with Connecticut leading the way in 1885 when they passed a general food law that included regulations of food sales for animals (American Feed Industry Association [AFIA], n.d.b). This regulation specifically targeted adulteration and misbranding in the sale of "every article used for food or drink by man, horses, or cattle" (Connecticut Agricultural Experiment Station, 1897). The first feed-specific law was passed in 1896 in Massachusetts that stipulated penalties for those "feeding, or keeping with intent to feed, garbage, offal, etc. to milch [milk]

cows and certain food animals" (Boston: Secretary of the Commonwealth, 1896). Other states followed the trend of enacting feed-directed laws and today all U.S. states have feed laws in place, except for Alaska which follows the Federal "Truth in Labeling" laws and does not have a commercial feed law (Association of American Feed Control Officials [AAFCO], 2019; AFIA, n.d.b; State of Alaska Department of Natural Resources, n.d.).

The federal government did not enter the feed regulatory landscape until the enactment of the Federal Pure Food and Drug Act of 1906 which granted federal authorities the ability to regulate interstate feed commerce and permitted the FDA the ability to start development of safety regulations for feed for animals (AFIA, n.d.b; U.S. Food and Drug Administration [U.S. FDA], 2019 July). The FDA would not be granted the authority to regulate food and drugs for animals until the passage of the Federal Food, Drug, and Cosmetic Act (hereinafter "FD&C Act") in 1938, approximately 70 years after the introduction of commercial pet food into the United States market (U.S. FDA, 2019 July). The FD&C Act defines food as "articles used for food or drink for man or other animals…" (Federal Food, 2021). Under the FD&C Act all animal food must be safe to consume, manufactured under sanitary conditions for both domestic and foreign facilities, may not contain any harmful substances, must be properly labelled, be unadulterated and not misbranded (Haskell, 2020). Throughout the years, since the passage of the 1938 FD&C Act, updates have been made related to: specific ingredients, such as the passing of the Delaney Amendment in 1958 which set a zero-tolerance policy for any feed additive known to cause cancer; hazards, such as the FDA issuing guidance on the acceptable limits of aflatoxin for animal feed in 1989; and, practices, such as the FDA issuing the first Good Manufacturing Practice (hereinafter "GMP") regulations for medicated animal feed (AFIA, n.d.c). In 2011 the most sweeping change to animal feed safety came when former President

Barack Obama signed into law the Food Safety Modernization Act (hereinafter "FSMA") which shifted the focus of feed safety from reaction to prevention (U.S. FDA, 2019 July; AFIA, n.d.d). In addition to this focus shift, the law granted the FDA new authority "including the promulgation of rules for preventive controls, development of performance standards, strengthening of administrative detention rules and mandatory recall authority of adulterated products" (AFIA, n.d.d). The impact of FSMA and other feed safety regulations on separate aspects of the feed supply chain will be evaluated in the Evaluation of the Dog Food Supply Chain.

Multiple groups, agencies and organizations work together to regulate the pet food industry (see Appendix B). As discussed previously the most notable agency is the FDA with its power to regulate animal feed at the federal level. Within the FDA, the Center for Veterinary Medicine (hereinafter "CVM") bears the responsibility for regulating animal feed products, with the Center for Food Safety and Nutrition responsible for human food products. In the past the CVM's focus was on animal drugs, medicated feeds and feed additives, and with most drugs or medications intended for livestock the pet food industry was not heavily regulated (Patrick, 2006). With the introduction of FSMA, the CVM has taken on more responsibility in regulating pet food by implementing and enforcing FSMA's requirements of pet food manufacturing facilities to create and implement a food safety plan and comply with GMPs in accordance with 21 C.F.R. § 507, unless exemptions apply (Current Good…Animals, 2021; U.S. FDA, 2020 May). Alongside the FDA one of the most important organizations in the regulation of commercial pet food products is the Association of American Feed Control Officials (hereinafter "AAFCO"), a private non-profit which was first formed in 1909 as a way to harmonize the laws that governed the sale of animal feed and pet food (AAFCO, 2019; Case et al., 2011; U.S. FDA,

2019 July). AAFCO is a volunteer organization that aids the industry in a non-regulatory capacity by providing definitions for approved feed ingredients, current labeling requirements, and model guidance, bills, and regulations that states may adopt as state laws (AAFCO, 2019). The association itself consists of local, state, and federal feed control officials working closely to "safeguard the health of animals and people; ensure consumer protection; and provide a level playing field of orderly commerce for the animal feed industry" (U.S. FDA, 2020 May). In 1909, alongside AAFCO, the American Feed Manufacturers Association, the predecessor to the American Feed Industry Association (hereinafter "AFIA"), was established to represent the business, legislative, and regulatory interests of the U.S. animal food industry and its suppliers (AFIA, n.d.a; AFIA, n.d.c). While the FDA and AAFCO play the largest roles in regulating pet food in the U.S. pet food industry, it is important to acknowledge how multiple agencies and organizations come together to regulate pet food from farm to food bowl.

Evaluation of the dog food supply chain

The idea of farm-to-fork can be traced back to the 1970s when a Chef Alice Waters opened a restaurant in Berkeley, California with the concept of locally sourcing her ingredients (Janzer, 2018; Traylor, n.d.; Witkowski & Witkowski, n.d.). While the farm-to-fork social movement focuses mostly on sourcing from local areas for local restaurants, the concept of farm-to-fork can be applied broadly to encompass the production of a product for humans and animals from the farm to the manufacturer and ultimately to the consumer. With the product changing hands many times throughout the process from farm to food bowl the responsibility for food safety will not lie with a single entity. The horizontal responsibility of food safety, from farm to manufacturer to consumer, goes hand-in-hand with vertical responsibility, the degree to which each entity in the supply chain achieves food safety. According to Wallace and Oria (2010), "the

degree of food safety that is attainable also depends on management and oversight practices, on costs versus benefits, and on such factors as regulatory limits, public perceptions, consumer education and responsibility, and public communication" (Limits on Food Safety section, para. 1). While food safety is not guaranteed maintaining a culture of food safety can reduce the risk of foodborne-related outbreaks. Much like a 4x4 relay race the responsibility for completing the race is the work of the whole and the individual. If food safety is the baton passed between entities than it is the obligation of each "leg" of the journey to ensure the baton is well-received, maintained properly, and passed along successfully to next.

Primary Producers

The first "leg" in the production of a safe pet food product is the primary producers who create the base ingredients used in pet food manufacturing. The FDA defines a primary production farm as "an operation under one management in one general (but not necessarily contiguous) physical location devoted to the growing of crops, the harvesting of crops, the raising of animal (including seafood), or any combination of these activities" (Standards, 2021). The commodity grown, animal raised, or processing performed determines which agency and regulation(s) the primary producer must comply with in order to produce a safe product. For the purpose of this section primary production includes the growing and harvesting of crops, slaughter of livestock and seafood processing, essentially the preparation of ingredients used in pet food.

Farm and mill-based ingredients

As stated previously FSMA is one of the most revolutionary and sweeping changes to the food safety laws in the United States with one of the provisions addressing the on-farm safety of produce grown and harvested, the first of its kind for produce sold and consumed raw in the

United States (Astill et al., 2018). Named the "Standards for the Growing, Harvesting, Packing, and Holding of Produce for Human Consumption," or more commonly referred to as the "Produce Safety Rule," it was also the first time that science-based food safety standards were established related to fruits, vegetables, and sprouts (LaBorde, 2018). The Produce Safety Rule is specific to produce intended for human consumption and does not regulate produce grown for animal feed and pet food, however the rule comes into play for pet food when a covered produce grower might re-purpose their by-products for the pet food industry. Covered produce refers to produce that is both a raw agricultural commodity and is within the scope of the Produce Safety Rule, e.g. almonds, blueberries, spinach, and watermelons (Center for Food Safety and Applied Nutrition [CFSAN], 2018 Oct). A more complete list of covered produce can be found at 21 C.F.R. § 112.1(b)(1). The impact of the Produce Safety Rule standards on pet food production can be discerned from a pet food production and ingredient analysis report published in March 2020. From June 2018 to June 2019 Decision Innovation Solution, commissioned by the Institute for Feed Education and Research (IFEEDER), North American Renderers Association (NARA), and Pet Food Institute (PFI), analyzed data on ingredients used in pet food production to better understand what goes into producing pet food products (2020). Based on the analysis, farm and mill-based products constituted 46.8%, based on tonnage, of the ingredients used in pet foods, see Table 2 (Decision Innovation Solution

Table 2

U.S. Total Pet Food Ingredient by Category

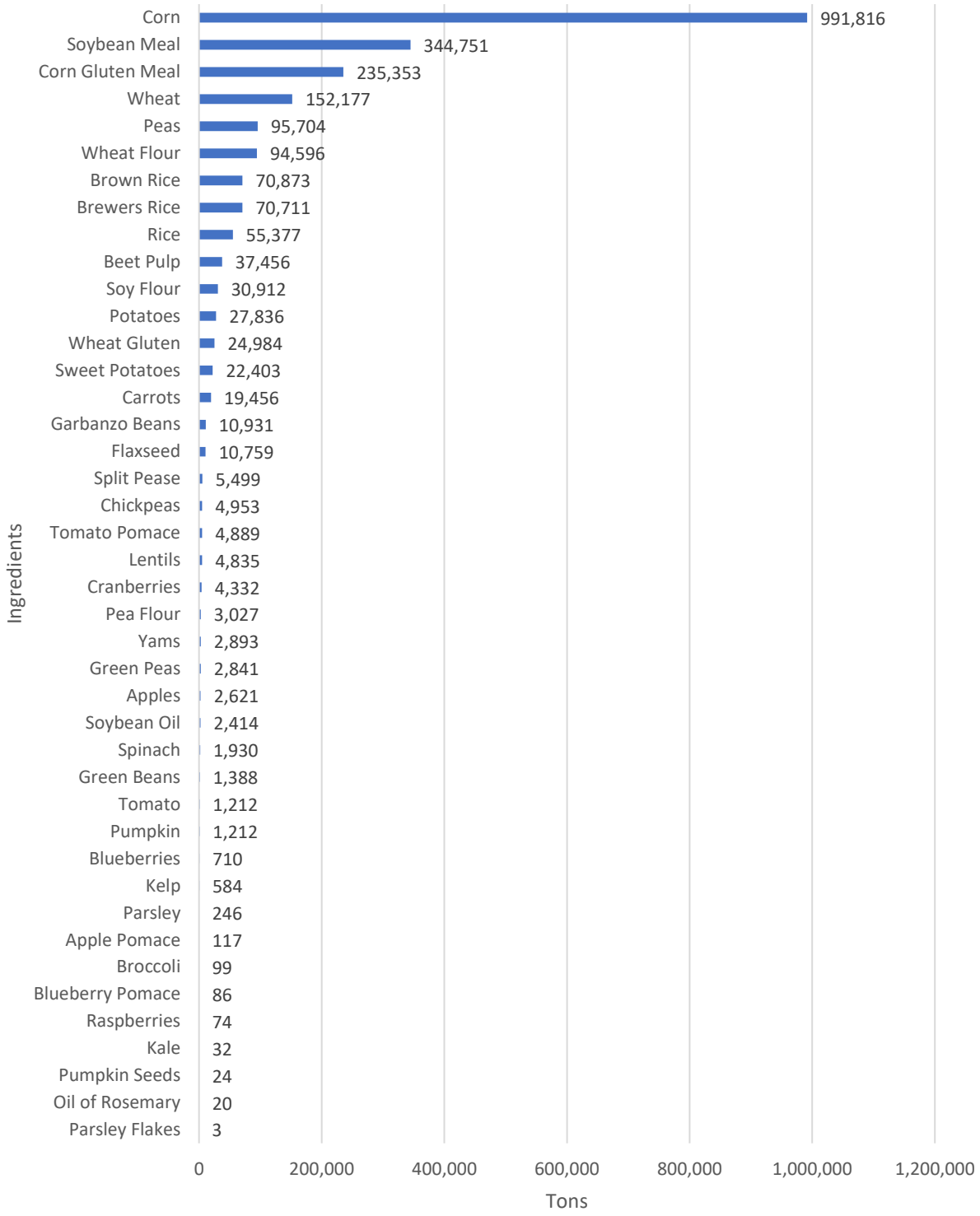
U.S. Total Pet Food Ingredients by Category		
Commodity Type	**Tons**	**$ Value**
Meat and Poultry Products	2,123,698	$3,242,773,275
Farm and Mill-based	4,042,698	$1,394,879,026
Fishery	198,671	$893,153,404
Broth	166,851	$834,255,514
Rendered Protein Meals	1,543,129	$562,588,878
Minerals and Others	3,663	$12,520,150
Water	567,501	$1,135,003
Grand Total	**8,646,211**	**$6,941,305,251**
Note: Data factored up from Nielsen Data to represent National Data		
Note: Commodity Type of all ingredients Items are listed in the Appendix		

Note. Retrieved from "Pet Food Production and Ingredient Analysis" by Decision Innovation Solution, 2020, p. 14.

[DIS], 2020). With such a large percentage of farm and mill-based ingredients used in pet food production, it begs the question as to why the Produce Safety Rule did not consider produce grown for pet food. The answer lies in the specific ingredients and quantities used to produce pet food, specifically dog food. The top five farm and mill-based ingredients used in dog food are corn, soybean meal, corn gluten meal, wheat, and peas, see Figure 5 on the following page (DIS, 2020; Institute for Feed [IFEEDER], 2020). Of the top five ingredients, peas are the only ingredient that would be subject to the Produce Safety Rule, and, based on the data collected, covered produce ingredients constitute just 5.4% of the total farm and mill-based ingredients and 1.8% of all ingredients (7.1M tons) used in dog food production. With such a negligible volume of ingredients coming from covered produce the impact of the Produce Safety Rule on pet food may also be considered trivial leaving the main compliance structure, from which farm and mill-based ingredients may operate for food safety, of Good Agricultural Practices (hereinafter "GAP"). GAPs are a result of President Bill Clinton's Food Safety Initiative in 1997, when produce was identified as an area of concern for food safety, as a way to provide assurance that domestic and foreign produce meets health and safety standards (NC State Extension, 2016). It is important to note that GAPs are simply guidance and not regulation, therefore, while they are strongly recommended, they are voluntary and not enforced by law. The United States Department of Agriculture (hereinafter "USDA") offers voluntary GAP audits to producers "to verify that fruits and vegetables are produced, packed, handled, and stored in the safest manner possible to minimize risks of microbial food safety hazards" (Agricultural Marketing Service [AMS], n.d.). In 2018 the USDA upgraded its GAP program to consider the food safety technical requirements of the Produce Safety Rule through a Harmonized GAP audit program (Petersen, 2018); and the USDA and FDA aligned the USDA's voluntary Harmonized GAP audit program

Figure 5

Farm and Mill-Based Volumes by Ingredient



Note. Data retrieved from "Pet Food Production and Ingredient Analysis" by Decision Innovation Solution, 2020, pp. 69 & 71.

with FDA's Produce Safety Rule as a method to practically help growers maintain the safety of the food supply whether they are subject to the Produce Safety Rule or not (AMS, 2018). Based on data from the Center for Disease Control's National Outbreak Reporting System, from 1998 to 2016 produce-related outbreaks ranged from 30 to 60 per year and sickened 900 to 3,000 people annually with leafy greens specifically being targeted as the "highest priority" for biological hazards by a 2008 United Nations study (Johnson, 2019). While leafy greens are not a common ingredient in dog food products, see figure 5 on the previous page, produce ingredients as a whole are cause for concern as they present the potential for biological, chemical and physical hazards to be introduced into the supply-chain. For manufacturers, evaluating the safety of the received ingredients is a critical component in maintaining a safe pet food product and is a requirement of FSMA's animal feed regulation. For producers not subject to FSMA's Produce Safety Rule demonstrating a history of GAP compliance, while not mandatory, offers a way for them to assure their buyers (manufacturers) that they follow adequate food safety practices thus reducing food safety risks in the ingredient(s) which can result in lessened economic risk for both parties (Rejesus, n.d.). Overall, produce grown only for pet food is not regulated, but regulations and guidance for produce for human consumption and produce by-products for animal food can be applied to produce intended for pet food production as well as providing added assurance of ingredient safety from the producer to the manufacturer.

Meat and Poultry

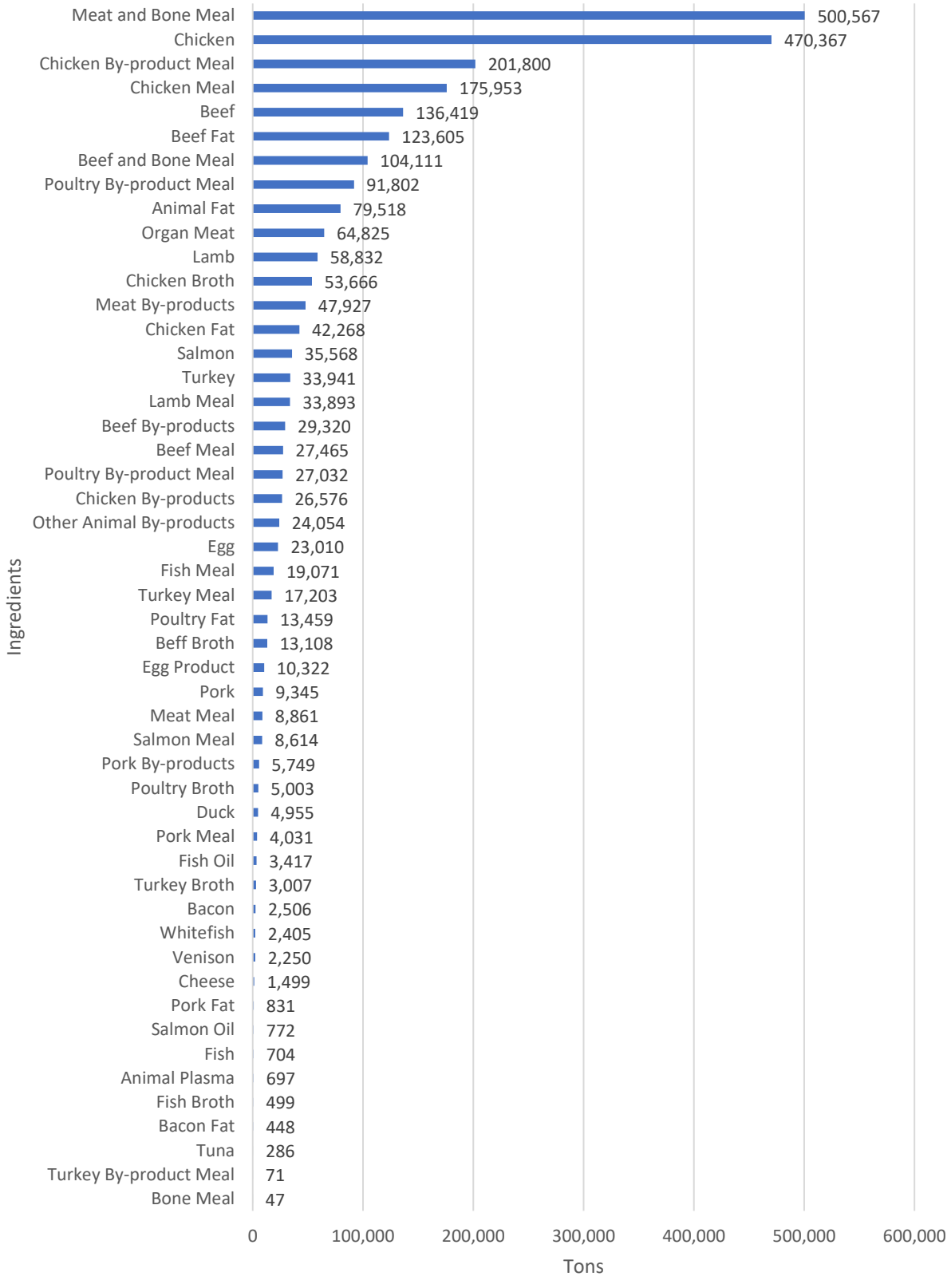
When consumers read meat and poultry products as ingredients in their dog's food, they may not think twice about whether the ingredient is USDA approved or not as the United States has a history of keeping up with the dynamic livestock industry. In the early 1900s there was public outcry over the inadequacy of the meat industry in maintaining a sanitary environment

and of the government not conducting adequate inspections which only increased in 1906 when Upton Sinclair published his revolutionary novel *The Jungle* (Institute of Medicine [IoM], 1990). The direct result of the novel and outcries was the Federal Meat Inspection Act of 1906 (hereinafter "FMIA") "which strengthened requirements for sanitary conditions in packing houses and required inspection of meat for interstate commerce" and became law on the same day as the Pure Food and Drug Act (IoM, 1990; Food Safety Inspection Service [FSIS], 2012). The FMIA of 1906 was further built upon in the 1960s with The Wholesome Meat Act of 1967 which granted the USDA additional authorities, increased importation requirements, and mandatory antemortem inspections (IoM, 1990). Poultry products gained a similar regulation in the 1950s with the Poultry Products Inspection Act (hereinafter "PPIA") of 1957 which required inspection of poultry products antemortem slaughter, postmortem slaughter, before processing, of plant facilities and all operations, and of imported poultry products at point of entry, as well as product label verification (National Research Council [NRC], 1987). This act gave the USDA the authority to inspect all poultry products intended for interstate commerce, similar to the authorities granted in the FMIA of 1906. The PPIA was further amended in 1968 with the Wholesome Poultry Products Act which established mandates similar to the Wholesome Meat Act of 1967 and required inspection of all poultry sold to consumers (FSIS, 2012; NRC, 1987). To this day the USDA follows the regulations laid out in FMIA and PPIA with the inclusion of a science-based system more commonly known as Hazard Analysis and Critical Control Points (hereinafter "HACCP") in 1996 (FSIS, 2012). The HACCP system itself places part of the responsibility of safe meat and poultry products on the manufacturer as it requires them to assess hazards in their production, determine critical control points in order to control the identified hazards, and establish procedures to monitor the identified critical control points, on top of the

mandatory inspections (IoM, 1990). Finally, FSIS increased their efforts to prevent foodborne pathogen outbreaks from contaminated meat and poultry products by testing for *Listeria monocytogenes*, implementing stricter *Salmonella* and new *Campylobacter* performance standards for poultry products, and identifying six additional serogroups of *Escherichia coli* as adulterants in non-intact raw beef (FSIS, 2012). Even with such stringent regulations and inspections in place contaminated meat and poultry products still find their way into the United States market. Based on data collected by USDA's Food Safety and Inspection Service, the year 2019 saw 124 recalls for USDA-regulated products totaling 20.4M pounds of product with poultry products contributing the most at 37 recalls for 17.1M pounds (FSIS, 2020). Appendix A includes the complete summary for recall cases from 2019. Of the 2019 recalls 13% were attributed to STEC, *L. monocytogenes*, and *Salmonella*, three of the five most common pathogens associated with meat and poultry products and linked to products such as raw ground beef and diced/mechanically separated chicken, (FSIS, 2020; The Pew Charitable Trusts [PEW], 2016). In pet food production, meat and poultry products account for 44.3% of all ingredients used with fresh and frozen meat and poultry at 24.6%, rendered protein at 17.8%, and broth at 1.9%, see table 2 (DIS, 2020). Of the ingredients within these combined categories meat and bone meal, chicken, chicken by-product meal, chicken meal, and beef are the top five used in dog food production, see figure 6 (DIS, 2020). The USDA itself does not have regulatory authority when it comes to pet food, however they may be involved in the safety of the supply-chain when an animal is slaughtered for the purpose of human consumption and its by-products are repurposed for animal food. Once those by-products are intended for use in animal food they fall under FDA's jurisdiction, specifically referencing 21 C.F.R. § 507.28 "human food by-products held for distribution as animal food without additional manufacturing or processing by

Figure 6

Meat and Poultry-Based and Fish and Fishery Volumes by Ingredient



Note. Data retrieved from "Pet Food Production and Ingredient Analysis" by Decision Innovation Solution, 2020, pp. 69 & 71.

the human food processor must be held under conditions that will protect against contamination" (Current Good…Animals, 2021). The USDA can be involved with pet food product manufacturing on a voluntary basis through their voluntary pet food certification program outlined in 9 C.F.R. § 355, which is recommended by the FDA as a necessary measure to prevent adulteration of meat and poultry intended for raw meat foods for companion animals (CVM, 2004; Thixton, 2017). Regardless of FDA's stance on the USDA's voluntary pet food program, the FDA stated the following in the same 2004 guidance related to meat and poultry ingredients, "i) All meat- and poultry-derived ingredients should be United States Department of Agriculture (USDA)/Food Safety and Inspection Service (FSIS)-inspected and passed for human consumption" (CVM, 2004). In contradiction, in a more recent guidance document, the FDA indicated that a meat product may be diverted for use in animal food even if the "meat was produced without the benefit of USDA or equivalent state inspection" and if the facility's management determined it did not pose an animal food safety concern (CVM, 2016). While the FDA has provided some guidance related to meat and poultry-based ingredients, the problem is it is just that, guidance. The FDA uses guidance documents to describe the Agency's current thinking and the use of "should" only means a suggestion or recommendation and is not an enforceable responsibility. Therefore, even if the FDA believes a manufacturer should only use USDA-inspected meat- and poultry-based ingredients it is not a compliance requirement.

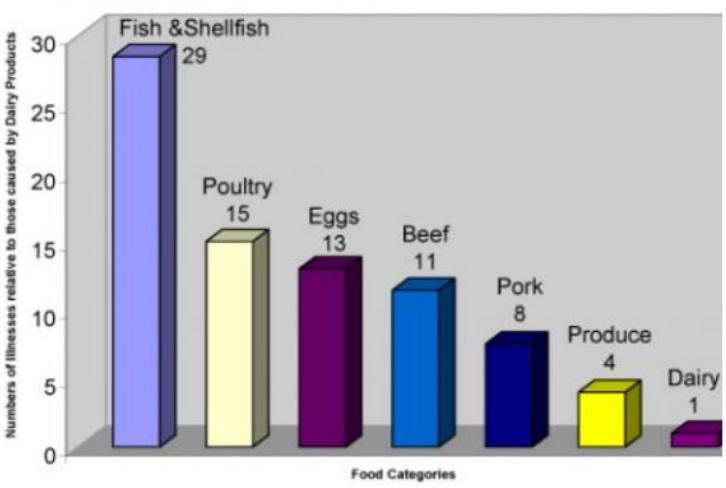
Seafood

Based on the analysis conducted by Decision Innovation Solutions, fish and fishery products accounted for 2.3% of the ingredients used in pet food and dog food specifically included ingredients such as fish broth, fish, salmon oil, whitefish, fish oil, salmon meal, fish meal, and salmon, see figure 6 for the list of ingredient volumes (2020). Utilizing and consuming

this healthy choice does not come risk-free with evidence demonstrating fish and fishery products as the frontrunner in foodborne-related illnesses and outbreaks (Iwamoto et al., 2010; Center for Science, 2008). Based on data analyzed by the Center for Science in the Public Interest fish & shellfish are the highest cause of foodborne illnesses linked to outbreaks, see figure 7 (Center for Science, 2008). Iwamoto et al. analyzed seafood-related outbreaks from 1973 to 2006 based on data reported to the Food-Borne Disease Outbreak Surveillance System, a passive system that relies on voluntary participation and reporting meaning that the numbers reported may not be an accurate representation of the number of illnesses (2010). Based on the data collected there was a total of 188 seafood-related outbreaks resulting in 4,020 illnesses, 161 hospitalizations, and 11 deaths with a majority of these outbreaks due to a bacterial agent, see figure 8 on the following page for a visual representation of the number of confirmed outbreaks from 1973 to 2006 (Iwamoto et al., 2010). While the data collected is related to outbreaks affecting the human population, the effect on the animal population should not be taken lightly. An example is the use of fish meal a seafood-based ingredient commonly used in animal feed. In AAFCO's marine section "fish meal" is defined as:

Figure 7

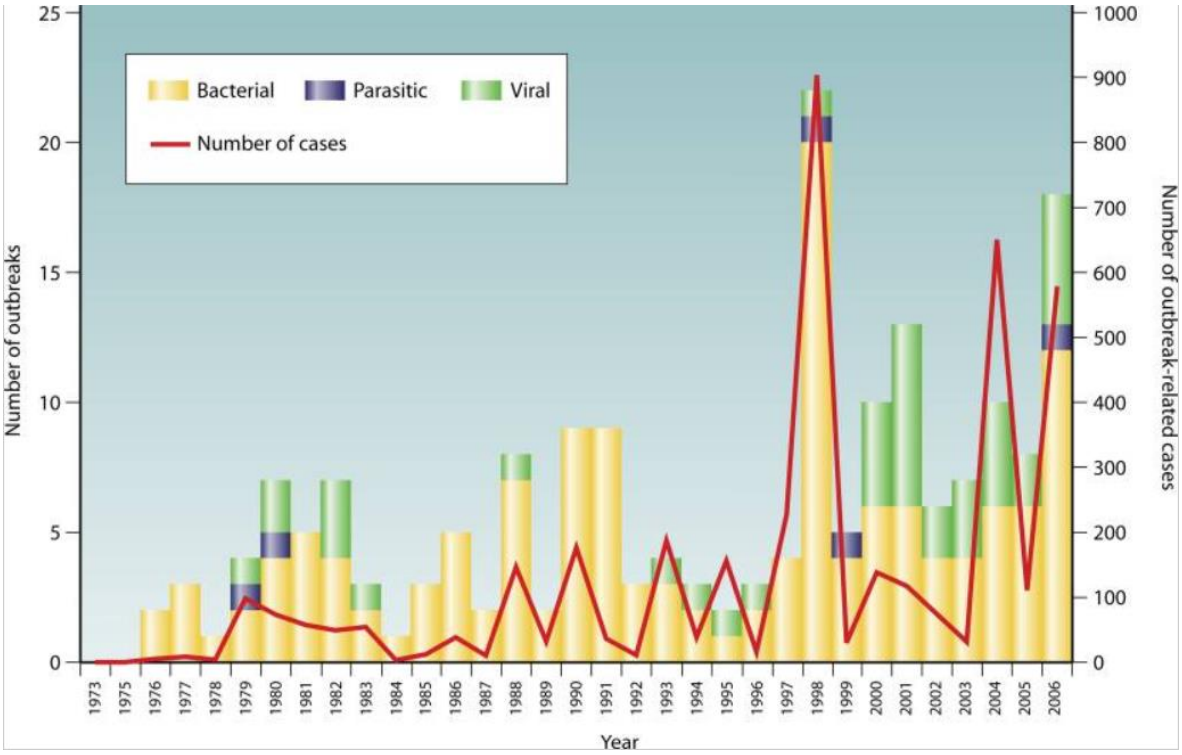
Relative number of foodborne illnesses linked to outbreaks caused by various food categories, adjusted for consumption, 1999-2006



Note. Using the yearly average illnesses linked to Dairy outbreaks as the baseline
Note. Retrieved from "Fish & Shellfish Top CSPI Outbreak List" by Center for Science in the Public Interest, 2008.

Figure 8

Number of confirmed seafood-associated outbreaks and outbreak-related cases, by year and etiology, 1973 to 2006



Note. Retrieved from "Epidemiology of seafood-associated infections in the United States" by Iwamoto et al., 2010.

> The clean, dried, ground tissue of undecomposed whole fish or fish cuttings, either or both, with or without the extraction of part of the oil. If it contains more than 3% salt (NaCl), the amount of salt must constitute a part of the product name, provided that in no case must the salt content of this product exceed 7%. […] If it bears a name descriptive of its kind, it must correspond thereto. (p. 404) (Blume [Log-in protected publication], 2021).

Fish meal alone presents the potential for contamination from pathogenic bacteria, heavy metals, and economic adulteration (Schertz, 2018). Fish meal ingredients from various countries have been implicated with *Salmonella* spp. and is currently an ingredient listed in one of FDA's import alerts, specifically Import Alert 71-04 "Detention Without Physical Examination Of Animal Feeds, Other Than Pet Treats, Due To The Presence Of *Salmonella*" (U.S. FDA, 2020

December). Import alerts are used by the FDA to prevent violative products from entering the United States and can be specific to an ingredient, a hazard, or even a country (U.S. FDA, 2019 May). Methylmercury is a high-risk hazard in fish as a result of bioaccumulation depending on the fish ingredient used to produce the fish meal, the higher up in the food chain the greater the risk (Government of Canada, 2013). The risk increases when contaminated fish meal is fed to food-producing animals as it will not only impact the health of the animal but also the health of humans who eat foods derived from the contaminated animals (Dórea, 2006). Adulteration of fish meal with melamine, as a way to artificially increase protein levels, is a possibility as the price of fish meal is dependent on the protein content (Karunasagar, 2009; World Health Organization, n.d.). In 2007 melamine-adulterated fish meal was included in a pet food recall of over 200 brands of pet food, the largest in North America, when pets fell ill and died from kidney failure (Paulman, 2008). At the time a centralized government database, similar to the Centers for Disease Control and Prevention for humans, did not exist for monitoring animal sickness and death, as such, the death toll could not be accurately quantified (2007 pet food recalls, 2007). The death toll from this gross negligence ranged from more than 100 pet deaths reported by veterinary organizations to 3,600 deaths self-reported by an online database and only 14 FDA-confirmed deaths (2007 pet food recalls, 2007). Even though fishery products make up a small portion of ingredients used in dog food, the 2007 melamine recall highlights how contamination of even the smallest ingredient in the formulation can have detrimental and costly impacts.

Fish and fishery products manufacturing is commonly associated with the seafood HACCP regulation which follows the same principles as meat and poultry in that it places responsibility on the manufacturer to assess hazards, determine critical control points, and

establish monitoring procedures (IoM, 1990). According to the FDA "the guidance, the Seafood HACCP Regulation (21 CFR 123), and the Control of Communicable Diseases regulation (21 CFR 1240) apply to all aquatic animal life, other than birds and mammals, used as food for human consumption" (CFSAN, 2020). Regulations for animal food production step-in once the product is intended for animal feed, typically in the form of fish by-products. The FDA's Hazard Analysis and Risk-based Preventive Controls for food for animals (hereinafter "PCAF") includes processing activities such as eviscerating and freezing, both of which are common to fish processing, therefore, it would stand to reason that a manufacturer processing fish and fishery products intended solely for animal food would be subject to this regulation (Current Good…Animals, 2021). The FDA's Center for Veterinary Medicine (2016) confirmed that:

> The hazard analysis and risk-based preventive controls requirements in subpart C of part 117 might not apply to certain activities in a human food facility (e.g., seafood processing subject to 21 CFR part 123). (§ 117.5) However, these facilities could still be subject to subpart C of part 507 for their animal food. If so, then the facility must follow the requirements in subpart C of part 507 for the manufacturing, processing, packing, or holding of its animal food. (p. 11)

Based on this requirement, unless the seafood processing facility is subject to certain exemptions under 507, they will be required to develop a food safety plan for the human food by-product for use as animal feed in order to identify and control any foreseeable hazards.

By-Products and Human Food By-Products

Within the first leg of regulating the pet food supply chain is a regulation pertaining to the safety of human food by-products that are commonly utilized in animal food production. Under 21 C.F.R. 507.28, and mirrored in 21 C.F.R. 117.95, human food by-products must be

held under conditions that protect against contamination such as using appropriate containers and equipment, protecting the product against trash sources, and accurately identifying the by-product (Current Good…Animals, 2021). Certain exemptions do apply in the event a human food facility is already in compliance with 21 C.F.R. 117 subpart B "Current Good Manufacturing Practice," or, an off-farm facility that conducts packaging, packing, and holding of raw agricultural commodities complies with either 21 C.F.R. 117 subpart B or the packing and holding requirements in 21 C.F.R. 112, the Produce Safety Rule (Current Good…Human Food, 2021). Some examples of by-products for use in animal food covered by this regulation include wheat middlings from the processing of flour, peels and rinds from the processing of fruits and vegetables, and human food products such as potato chips and cookies that are not acceptable as human food but are safe to use for animal food (CVM, 2016). AAFCO defines by-products by their source rather than as a collective definition, such as human food by-products, meat by-products, fish by-products, processed grain by-products, poultry by-products, and dairy food by-products (2021). Remember, the FDA accepts the listing of ingredients in the Official Publication so long as they do not pose a food safety risk (CVM, 2016). Understanding the accepted definition of an ingredient can provide manufacturers of by-products and finished pet food with necessary information in ensuring the continuity of safety throughout the supply chain.

Produce, meat and poultry, seafood, and by-products represent major sources of ingredients used in pet food processing. While regulations pertaining to these ingredients may only encompass products intended for human consumption (produce, meat and poultry, and seafood), the FDA has demonstrated through guidance that complying with these regulations is strongly recommended for products intended for animal food as it provides an added layer of assurance that the product is produced in a way to prevent adulteration and contamination.

Understanding how each is regulated is crucial knowledge for manufacturers of finished pet food products as it guides them in determining the best way to approve, monitor, and verify each of their suppliers, one of the major requirements of the PCAF regulation.

Manufacturers of Finished Pet Food Products

The next leg to ensure the safe production of pet food from farm-to-food bowl lies with the manufacturer of the finished product. When a manufacturer is evaluating the risks related to their product, they must consider the impact on the intended animal, humans that may be in contact with the feed and the intended animal, and humans through the intended animal species especially food-producing animals (Schertz, 2018). Additionally, the manufacturer must consider the risk of a hazard to the specific species, the specific class, and the diet of the intended consumer at each level of production (U.S. FDA, 2019 July). These hazard identifications would be contained within a facility's food safety plan, a requirement of the PCAF rule. The following sections will elaborate on the role the different preventive controls play in manufacturing a safe pet food product.

Supply-Chain Preventive Controls

For some products control of an ingredient-related hazard occurs prior to receipt at the manufacturing facility, with what is referred to as a "supply-chain-applied control" (CVM, 2018 June). When a hazard in a product requires a supply-chain-applied control the receiving facility is then required to implement a supply-chain program, a required written component of the facility's food safety plan (CVM, 2018 June). The supply-chain program must include the following four components: (1) use of approved suppliers, (2) determination of appropriate supplier verification activities, (3) conduct the determined supplier verification activities, and (4) documentation of the supplier verification activities (Current Good…Animals, 2021). In

determining which ingredients must be monitored through the supply-chain program, the facility must consider if a foreseeable hazard is associated with ingredient or if the hazard is controlled by the manufacturing facility (Fenton & Laborde, 2019). As defined in FDA's PCAF regulation a "hazard requiring a preventive control" means:

> A known or reasonably foreseeable hazard for which a person knowledgeable about the safe manufacturing, processing, packing, or holding of animal food would, based on the outcome of a hazard analysis […], establish one or more preventive controls to significantly minimize or prevent the hazard in an animal food and components to manage those controls […] as appropriate to the animal food, the facility, and the nature of the preventive control and its role in the facility's food safety system, 21 C.F.R. 507.3 (Current Good…Animals, 2021).

The CVM compiled a list of biological, chemical, or physical hazards associated with animal food raw materials, ingredients, and mixed ingredients based on publicly available resources and does not include all possible animal foods or hazards, see figure 9 for an excerpt from FDA's PCAF guidance (CVM, 2018 January). Manufacturers may also use sources such as one's own experience, scientific reports, global organization publications, recalls, and illness reports to identify hazards in the ingredient and determine if a supply-chain preventive control is required. Once a supply-chain preventive control is identified the facility must then determine and conduct the appropriate verification activity for each identified hazard-ingredient combination requiring the control. As explained in previous sections, different ingredients are subject to varying regulations and understanding the regulation(s) the supplier falls under can assist manufacturers in determining the most appropriate verification activity for each identified hazard-ingredient combination. For example, if a pet food manufacturer receives strawberries from a farm the

Figure 9

Excerpt depicting FDA-identified hazards associated with animal feed from Appendix E – Aid to Identifying Animal Food Hazards

TABLE 1. ANIMAL PROTEIN PRODUCTS

SUB-CATEGORY	EXAMPLE PRODUCTS	**Biological Hazards:** Pathogenic Bacteria (e.g., *Salmonella*; *L. monocytogenes*)	**Biological Hazards:** Prions (e.g., BSE)	**Biological Hazards:** Viruses or Parasites	**Chemical Hazards:** Animal Drug residue and carryover	**Chemical Hazards:** Economic Adulterants (e.g., melamine; urea)	**Chemical Hazards:** Environmental and Industrial Chemicals (e.g., dioxins; PCBs)	**Chemical Hazards:** Heavy Metals	**Chemical Hazards:** Natural Toxins (e.g., mycotoxins)	**Chemical Hazards:** Nutrient Deficiency or Toxicity	**Chemical Hazards:** Pesticides	**Physical Hazards:** Physical (e.g., metal, glass, plastic)
Blood and Serum	Animal Serum; Serum Albumin; Serum Globulin; Blood Protein; Spray Dried Animal Blood; Spray Dried Animal Blood Cells	Ref. 1	-	-	-	-	-	-	-	-	-	-

Note. Retrieved from "Hazard Analysis and Risk-Based Preventive Controls for Food for Animals: Draft Guidance for Industry" by Center for Veterinary Medicine, 2018 January.

manufacturer could utilize the supplier's compliance with FDA's produce safety rule as their verification since fruit and vegetables are associated with pesticide residues, a foreseeable hazard controlled by the supplier (CVM, 2018 January). If the produce supplier is not subject to the produce safety rule, the manufacturer may utilize other methods of verification such as third-party GAP audits and sampling and testing results to verify that pesticide residues are within acceptable limits. Fruits and vegetables are also commonly associated with pathogenic bacteria; however, supply-chain preventive controls may not be necessary depending on if the processing performed by the manufacturing facility is adequate in controlling this hazard, e.g. lethal heat treatment step. If the ingredient provided falls under human food by-products for animal feed the manufacturer may request copies of the supplier's relevant food safety records related to current good manufacturing practices if the supplier did not further manufacture or process the by-product for use in animal food (CVM, 2016). If the supplier does engage in further

manufacturing or processing of the by-product for animal feed before providing the ingredient to the manufacture than that facility must develop a food safety plan in accordance with PCAF, and the manufacture has the choice of verifying that supplier through a review of their food safety records (CVM, 2016, Current Good…Animals, 2021). While the FDA focuses on these three verification activities (audits, sampling and testing, and review of food safety records), they do include an additional option in which manufacturers may utilize, however, the FDA does not elaborate on what would constitute an acceptable other activity.

Process Preventive Controls

In addition to supply-chain applied controls, manufacturers may also utilize process preventive controls and sanitation preventive controls to control reasonably foreseeable hazards in their product and process. Process preventive controls:

> Include procedures, practices, and processes to ensure the control of parameters during operations such as heat processing, irradiating, and refrigerating animal food. Process controls must include, as appropriate to the nature of the applicable control and its role in the facility's food safety system: (i) Parameters associated with the control of the hazard; and (ii) The maximum or minimum value, or combination of values, to which any biological, chemical, or physical parameter must be controlled to significantly minimize or prevent a hazard requiring a process control, 21 C.F.R. § 507.34(c)(1) (Current Good…Animals, 2021).

Some examples of process preventive controls utilized by animal food manufacturers to control biological hazards include lethality treatments such as cooking and irradiation, time and low temperature controls such as refrigeration, product formulation controls such as acidifying, and dehydrating/drying controls such as freeze-drying (CVM, 2018 January; Fenton & Laborde,

2019). Steps such as these in the process are important as they protect the pet food product from contamination and adulteration. Animal feed is considered adulterated when contaminated with a *Salmonella* serotype that is considered pathogenic to the intended animal consumer and will not undergo any kill step (CVM, 2013; Schertz, 2018). In humans, *Salmonella* causes an estimated 1.35 million illnesses a year mostly from contaminated food but also from contact with contaminated animals and contaminated animal food (Center for Disease Control and Prevention [CDC], 2021; CDC, 2015). *Salmonella* is unique when it comes to animal food as certain serotypes can be species-specific, e.g. *Salmonella* Abortusequi present in equine feed, whereas other serotypes are universal regardless of the intended species, e.g. *Salmonella typhirium* (CVM, 2013; Schertz, 2018). In addition to pathogenic bacteria pet food could be contaminated with prions such as bovine spongiform encephalopathy, and viruses or parasites such as *Toxoplasma gondii* related to ground pork products (Guo et al., 2015, as cited in CVM, 2018 January). Bovine spongiform encephalopathy, or more commonly known as "Mad Cow Disease," is a hazard that the FDA strictly regulates to prevent its transmission in human and animal food (CVM, 2009). In 2009 the FDA published a new regulation in 21 C.F.R. 589.2001 entitled "Cattle materials prohibited in animal food or feed to prevent the transmission of bovine spongiform encephalopathy" which explicitly stated which cattle materials are prohibited, e.g. brains and spinal cords of cattle 30 months of age or older (Substances Prohibited, 2021). Manufacturers may choose to control the presence of prions through supply-chain controls.

It is important to note that pet food products can also be classified as a low-acid canned food (hereinafter "LACF") which includes products packaged in hermetically sealed containers such as pouches or trays and not just the traditional canned product (CVM, 2018 January). Pet food manufacturers are exempt from the PCAF requirements for controlling microbiological

hazards so long as they conform with the LACF requirements, found in 21 C.F.R. § 113, by subjecting their packaged product to a heat treatment step sufficient to produce commercial sterility of the finished product and destroy viable pathogenic microorganisms (CVM, 2018 January; Thixton, 2016).

Chemical hazards can occur during processing that require the presence of process preventive controls. The FDA considers nutrient deficiencies and toxicities as significant food safety concerns that warrant the use of such controls. Identifying nutrient deficiencies and toxicities as a hazard involves evaluating the facility, the type of animal food, and the intended species (CVM, 2018 January). For dogs vitamin D is an essential nutrient in their diet, however, if the dog food was contaminated with elevated levels of vitamin D it could lead to serious issues such as kidney failure and death (CVM, 2020 May). As discussed in the Introduction, of the 30 nutrient related recalls (highest number of recalls) from January 2017 to November 2020, 13 were related specifically to elevated levels of vitamin D, and of those 13 recalls 12 were specifically related to dog food products, accounting for 11% of the overall recalls (CVM [Data set], 2020). Therefore, implementing the appropriate monitoring procedures to control nutrient deficiencies and toxicities is vital in producing a safe pet food. In addition to nutrient deficiencies and toxicities, the FDA considers animal drug residue/carryover and mycotoxins as chemical hazards requiring process preventive controls (CVM, 2018 January). An example of drug residue/carryover is monensin in equine feed. Monensin is an approved drug for use in cattle, poultry, and goat feed, however, equine are extremely sensitive to the drug with only 2-3 mg/kg of their body weight needed to be fatal (Schertz, 2018). FDA's regulation in 21 C.F.R. § 558.355 clearly states that "All formulations containing monensin shall bear the following caution statement: Do not allow horses or other equines access to feed containing monensin.

Ingestion of monensin by horses has been fatal" (New Animal, 2021). Mycotoxins can develop and grow if certain susceptible ingredients are improperly stored or if the ingredients are not properly dried (CVM, 2018 January).

Finally, physical hazards are of significant concern requiring process preventive controls as they can be injurious to the intended species by causing lacerations of the gastrointestinal tract or choking in the animal. Examples of physical hazards include metal fragments, glass particles, hard plastic pieces and the condition of the animal food itself such as particle size or hardness (CVM, 2018). Common process preventive controls for physical hazards include metal detection or x-ray detection at or after packaging, inspection of packaging materials if glass is used, and the use of sieves and mesh filters throughout processing. Recent recalls due to physical hazards include Grreat's 2018 recall of their adult dog food product due to metal contamination and Muse's 2019 recall of their wet cat food product due to the potential presence of rubber pieces (CVM [Data set], 2020). Process preventive controls all in all cover a wide range of hazards and controls that could occur during the process.

Sanitation Preventive Controls

On the other hand, sanitation preventive controls are specific to the sanitary condition of the facility and processing lines and can build on the current GMPs that might already be implemented (CVM, 2018 January). Sanitation preventive controls:

> include procedures, practices, and processes to ensure that the facility is maintained in a sanitary condition adequate to significantly minimize or prevent hazards such as environmental pathogens and biological hazards due to employee handling. Sanitation controls must include, as appropriate to the facility and the animal food, procedures, practices, and processes for the: (i) Cleanliness of animal food-contact surfaces, including

> animal food-contact surfaces of utensils and equipment; and (ii) Prevention of cross-contamination from insanitary objects and from personnel to animal food, animal food-packaging material, and other animal food-contact surfaces and from raw product to processed product, 21 C.F.R. § 507.34(c)(2) (Current Good…Animals, 2021).

Within processing facilities sanitation preventive controls can be used to ensure effective cleaning and sanitizing, and, most importantly, include procedures, practices, and processes to prevent the risk of cross-contamination from sources such as insanitary objects, personnel, packaging materials, and food-contact surfaces (CVM, 2018 January).

For finished pet food products, it is the responsibility of the manufacture to identify significant hazards, such as *Salmonella* or nutrient toxicities, in the received raw materials, during processing, and in the final product, and implement the appropriate controls to prevent contamination of the finished product. While FDA provides guidance and direction to manufacturers on ways to perform these required activities, it is ultimately up to the manufacturer to ensure they are manufacturing their product in a safe and ethical manner.

Reportable Food Registry – the Responsibility of All

Even with primary producers and manufacturers playing their role in complying with regulations and conducting appropriate food safety practices, contaminated product may still find its way into the marketplace whether unintentionally or intentionally. As mentioned in the *Seafood* section, 2007 saw the largest North American pet food recall when melamine-contaminated products were consumed by pets (Paulman, 2008). At the time, a centralized surveillance system did not exist which hindered the FDA in accurately quantifying the death toll related to this recalled product (2007 pet food recalls, 2007). In September 2007, following this deadly recall, the president signed into law the Food and Drug Administration Amendments Act

of 2007 (hereinafter "FDAAA") which established a Reportable Food Registry whose purpose included reliably tracking patterns of adulterated feed and pet food products (CFSAN et al, 2010). The FDA relies on voluntary submissions from Federal, state, and local public health officials and industry submissions to identify key risk areas in order to effectively utilize FDA's limited resources to prioritize facility inspections, publish guidance documents, issue import alerts, and improve recall processes (U.S. FDA, 2016; Rumbeiha & Morrison, 2011). Industry submissions occur when a company identifies a product as causing a severe adverse health consequence or death to humans or animals (SAHCODHA) and they are then required to notify the FDA within 24 hours through the Reportable Food Registry (AAFCO, n.d.). As a result of these industry and voluntary submissions, the FDA observed a decrease in the number of primary reports for animal feed and pet food from 30 in Year 4 to 18 in Year 5 as well as a large decrease in the number of *Salmonella* related reports from 18 in Year 4 to 6 in Year 5[1] (U.S. FDA, 2016). In addition to establishing the Reportable Food Registry, the FDAAA contained provisions regarding pet food including requiring the FDA to establish ingredient and processing standards and definitions, update labeling standards, and establish an early warning surveillance and notification system (Hyman, Phelps & McNamara, P.C., 2007). In the present day, 2021, the FDA has made available a Safety Reporting Portal (Reportable Food Registry) from which manufacturers, health care professionals, researchers, public health officials, and even concerned citizens may submit a safety report to the FDA about pet food products (U.S. FDA, n.d.). While no system is perfect, surveillance from every aspect of the dog food supply chain can assist in preventing the introduction and spread of contaminated pet food products.

[1]Year 5 = September 8, 2013 – September 7, 2014; Year 4 = September 8, 2012 – September 7, 2013

Project Design and Methodology

Targeted Population

The target population for this project is consumers purchasing dog food for their pets and entities involved in the production of dog food from the raw ingredients to the finished packaged product. This information would preferably be made available to visitors on the Virginia Cooperative Extension website.

Methodology

This project was conducted by investigating available sources on dog food regulation, especially the Food Safety Modernization Act, and evaluating the information regarding regulatory oversight and the effect on dog food safety. Three fact sheets were developed to address the safety of dog food production from farm to food bowl. One fact sheet educates the consumer on dog food production (Appendix C). The second fact sheet discusses the FDA's regulation of pet food for manufacturers and suppliers (Appendices D and E). The third fact sheet focuses on the role consumers could play in enforcing a food safety culture in dog food production (RFR) (Appendix F).

Summary of Outcomes, Discussions, and Recommendations

Implications Impacts, and Recommendations

The documents are created based on information and research taken from government, scholarly, and industry sources. As demonstrated in the Review of Literature section dog food is subject to FDA regulation, however, this not an all-encompassing regulation meaning certain ingredients or practices could also be subject to other regulations or regulated under a different authority. The developed fact sheets summarize the information from multiple sources to provide

a quick and easy-to-reference format for consumers and industry professionals regarding the regulatory oversight of the ingredients, processes, and completed dog food products. These documents can assist industry professionals in manufacturing a safe dog food product in accordance with applicable regulations and provide insight to consumers on the level of controls required for the production of dog food.

It is recommended that additional educational materials be developed directed to consumers and industry professionals regarding dog food products. Other topics that could be addressed in the future include the raw dog food diet, understanding pet food labeling, manufacturing safe dog food at home, and understanding medical claims on dog food packaging.

Dissemination Plan

At this time, a dissemination plan has not been determined, however, it is the author's intention for the fact sheets to be made available to the public through the Virginia Cooperative Extension website.

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Appendices

Appendix A: Summary of Recall Cases in Calendar Year 2019

Summary

Recall Summary for Calendar Year 2019			
		Number of Recalls	Number of Pounds Recalled
Total		124	20,427,455
Recalls by Class (N=124)			
Class	I	97	19,662,158
	II	27	765,297
	III	0	
Recalls by Reason (N=124)			
Reason For Recall	STEC*	7	298,500
	Listeria monocytogenes	6	165,221
	Salmonella	3	118,830
	Undeclared Allergen	32	2,574,760
	Extraneous Material	34	15,573,818
	Processing Defect	3	32,801
	Undeclared Substance	4	76,221
	Unapproved Substance	0	
	Other**	35	1,587,304
	Recall by Species/Product (N=124)		
Species	Beef	23	695,445
	Mixed	32	618,677
	Pork	19	1,359,580
	Poultry***	37	17,126,467
	Siluriformes fish (catfish)	13	627,286

* STEC includes recalls due to Shiga toxin-producing *E. coli* (STEC). STEC organisms include *E. coli* O157:H7, *E. coli* O26, *E. coli* O45, *E. coli* O103, *E. coli* O111, *E. coli* O121, and *E. coli* O145.

**Other includes producing without inspection, failure to present for import inspection, and labeling issues, among others.

***Poultry includes egg products.

Note: Retrieved from "Summary of Recall Cases in Calendar Year 2019" by the Food Safety Inspection Service, 2020.

Appendix B: Governing Agencies of Pet Food Manufacturing and Sale

Agency, Group or Organization	Function in the U.S Pet Food Industry
U.S. Food and Drug Administration (U.S. FDA)	Federal agency. Has the main regulatory authority over the U.S. pet food industry and its suppliers. Enforces the FD&C Act and FSMA and oversees the Animal Feed Safety System. Works with AAFCO during new ingredient approval processes. Has the authority to issue a mandatory recall of a pet food product. Regulates pet food labeling.
Association of American Feed Control Officials (AAFCO)	Private, non-profit corporation with no regulatory powers. Sets standards for substantiation claims. Works with the U.S. FDA during new ingredient approval processes. Provides the industry with accepted definitions of all approved ingredients for animal feed and pet food products. Provides guidance, bills, and regulations that states may adopt as state law.
American Feed Industry Association (AFIA)	Represents the business, legislative, and regulatory interests of the U.S. animal food industry and its suppliers.
State Feed Control Officials	State agencies. Responsible for enforcing the commercial feed law within each state (except for Alaska).
Pet Food Institute (PFI)	Trade organization. Represents pet food manufacturers and has no regulatory powers.
National Research Council (NRC)	Provides recommendations on nutrient requirement standards for animal based on scientific evidence.
Environmental Protection Agency (EPA)	Federal agency that regulates the use of pesticides in raw material production as well as the discharge from processing plants.
Federal Trade Commission (FTC)	Federal agency that regulates the trade and advertising of pet food products.
United States Department of Agriculture (USDA)	Federal agency with no regulatory powers over pet food. Offers a voluntary pet food certification program but it is not acknowledged by the FDA or State Departments. Offers voluntary GAP audits to producers of fruits and vegetables.

Note: Role information was retrieved from “Canine and feline nutrition: A resource for companion animal professionals” by Case et al., 2011, “AAFCO: The people behind animal feed and pet food” by the Association of American Feed Control Officials [AAFCO], 2019, and “How is feed and pet food regulated in the united states?” by AFIA, n.d.b.

Appendix C: Dog Food Production from Farm to Food Bowl

Can be found as an attached PDF or at the following link: https://prezi.com/i/3ezocmld1ytk/

Appendix D: Regulatory Oversight of Dog Food Ingredients

Can be found as an attached PDF or at the following link: https://prezi.com/i/jo-crlphbhlo/

Appendix E: Pet Food Manufacturer Controls

Can be found as an attached PDF or at the following link: https://prezi.com/i/m2ymysoqmfby/

Appendix F: Consumers and the Reportable Food Registry

Can be found as an attached PDF or at the following link: https://prezi.com/i/dtnvnihrtryv/