# Anatomy of a Pet Food Recall: An Industry, Regulatory, and Consumer Perspective

A THESIS
SUBMITTED TO THE FACULTY OF
UNIVERSITY OF MINNESOTA
BY

Kimberly Fox

IN PARTIAL FULFILLMENT OF THE REQUIREMENTS
FOR THE DEGREE
MASTER OF SCIENCE

David Smith, PhD

June 2020

**Acknowledgements**

I am deeply appreciative for all of those who have helped make this research possible and for those who supported me in the process. I would like to thank Dr. Joellen Feirtag for introducing me to the food policy and regulatory affairs environment, being a constant source of encouragement, and ensuring I stayed safe while commuting in a record snowfall Minnesota winter. I would like to acknowledge Dr. Pedro Urriola and Dr. Jennifer van de Ligt for their continual guidance and invaluable feedback and insight throughout this project, and my advisor, Dr. David Smith, for being a guiding light towards the end. I am forever grateful to Dr. Gary Reineccius for his unwavering support and guidance throughout the last couple of years. I also wish to acknowledge Dr. Benjamin Warren from Land O'Lakes for sharing his industry knowledge and expertise and inspiring this research.

A heartfelt thank you to my family, particularly my Mom, Therese Fellner, Howard and Nancy Campbell, and my boyfriend Sam. You are the pillars that have held me up and kept me going through constant encouragement and laughter. I do not know how I would have made it through the trials and tribulations of graduate school without you.

**Abstract**

Recent, high-profile outbreaks of *Salmonellosis* infections and recalls associated with pet food and treats are indicative of an industry facing daunting challenges. Consumer demands are driving the pet food industry to formulate pet food products aimed at health and wellness that may sacrifice pet food safety, while the Food Safety Modernization Act (FSMA) requirements are putting increasing pressure on pet food manufacturers to employ comprehensive preventive measures to protect consumer and pet health. Thus, it is important to identify the next steps needed to improve collaboration among industry and regulators and the overall safety of the pet food supply chain. This study sought to identify the factors that contributed to the increase in pet food recalls between 2007-2019, providing a complete picture of the current challenges facing the pet food industry. This analysis should promote mutual understanding among the pet food industry, provide guidance for pet food manufacturers and regulatory oversight, and present data driven pet food safety information to consumers.

The objectives of this study were as follows: 1) analyze trends, patterns, and the level of supply chain complexity in published pet food product recalls from 2007-2019, 2) identify the impact that regulatory oversight and zero tolerance guideline for *Salmonella* spp. has on pet food recalls, 3) provide recommendations and implications to industry and regulators for reducing pet food recalls while still protecting human and pet health.

Pet food recall data were obtained from Food and Drug Administration (FDA) "Recalls, Market Withdrawals, and Safety Alerts," FDA "Enforcement Reports, and the FDA press releases. A thorough search of FDA recall data identified the occurrence of

health hazards in different types of pet food, quantity of pet food product recalled, product description, and notification entity involved in each pet food recall. A methodology was created in order to take into account the multiple different scenarios that were observed in the recall process.

Results show that supply chain complexity, level of regulatory oversight, magnitude of each recall based on the quantity of product recalled and market sales, and the interrelationships among notification entity, health hazard, and type of pet food are driving forces behind the overall increase in pet food recalls. Recommendations include developing and standardizing testing methods and procedures, requiring transparency into ingredient sourcing and quality to minimize large pet food recalls, utilizing advanced technologies to make the pet food supply chain safer, and having a robust environmental sanitation program. These findings allow the pet food industry and regulators to work together to make the pet food supply chain safer and reduce the total number of pet food recalls across all pet food sectors.

## Table of Contents

CHAPTER I: LITERATURE REVIEW ..... 1

1.1 INTRODUCTION ..... 1

1.2 OBJECTIVES ..... 3

1.3 PET FOOD INDUSTRY ..... 4

1.4 PET FOOD RECALL IMPACTS AND PROCESSES ..... 6

1.5 PET FOOD REGULATIONS AND GUIDELINES ..... 12

CHAPTER II: TRENDS IN CAT AND DOG FOOD PRODUCT RECALLS: 2007-2019 ..... 19

2.1 INTRODUCTION ..... 19

2.2 METHODS ..... 22

*FDA Recall Data* ..... *23*

*Nomenclature* ..... *27*

2.3 RESULTS ..... 28

*Recalls by Pet Food Products* ..... *28*

*Recalls by Health Risk* ..... *34*

*Recalls by Type of Pet Food and Contamination* ..... *41*

2.4 DISCUSSION ..... 43

CHAPTER III: REGULATORY IMPACT ON PET FOOD RECALLS ..... 48

3.1 INTRODUCTION ..... 48

3.2 METHODS ..... 51

*FDA Recall Data* ..... *51*

*Statistics* ..... *51*

*Nomenclature* ..... *52*

3.3 RESULTS ..... 52

*Regulatory Impact by Type of Pet Food* ..... *52*

*Regulatory Impact by Health Risk* ..... *55*

*Regulatory Impact by Notification Entity* ..... *62*

*Regulatory Impact of Zero-tolerance for Salmonella spp. on Pet Food Recalls* ..... *68*

3.4 DISCUSSION ..... 69

CHAPTER IV: RECOMMENDATIONS, IMPLICATIONS, AND CONCLUSIONS ... 74

4.1 INTRODUCTION ..... 74

4.2 RECOMMENDATIONS AND IMPLICATIONS ..... 76

*Microbiological Contamination in Raw Pet Food* ..... *76*

*Microbiological Contamination in Treats* ..... *82*

*Chemical Contamination in Dry and Canned Pet Food* ..... *87*

4.3 CONCLUSION ..... 91

REFERENCES ..... 93

## Table of Tables

Table 1.1 CGMP[a] and PC[b] Compliance Dates Based on Pet Food Business Size ..... 16
Table 2.1 Number of Raw and Synthesized Pet Food Recalls by Food Type, 2007-201928
Table 2.2 Annual Pet Food Sales and Amount of Pet Food Product Recalled in 2018 .... 34
Table 2.3 Total Number of Raw and Synthesized Pet Food Recalls by Health Risk, 2007-2019 ..... 35
Table 2.4 Number of Raw and Synthesized Recalls by Notification Initiating Entity and Year, 2007-2019..... 38
Table 3.1 Total and Average Number Pet Food Recalls by Food Type Before and After the PC[a] Rule was Finalized, 2010-2019 ..... 54
3.2 Total and Average Number of Pet Food Recall Events by Health Risk Before and After the PC[a] Rule was Finalized, 2010-2019 ..... 60
Table 3.3 Total and Average Number of Pet Food Recall Events by Notification Entity Before and After the PC[a] Rule was Finalized, 2010-2019 ..... 64
Table 3.4 Total Number of Surveillance and Compliance Recalls Before and After the PC[a] Rule was Finalized, 2010-2019..... 68
Table 3.5. Total and Average Number of Recalls by Pet Food Type Before and After Salmonella spp. Zero-Tolerance Guideline was Implemented, 2009-2018 ..... 69

## Table of Figures

Figure 1.1 Decision-Making Flow Chart for Initiating a Pet Food Recall (CFR, 2019).....9
Figure 2.1 Example of a "Recalls, Market Withdrawals, and Safety Alerts" Report.....24
on the FDA Reportable Food Registry Website. (FDA, 2020c). Emphasis Added.....24
Figure 2.2 Example of a "Enforcement Reports" Entry on the FDA Enforcement Reports Website. (FDA, 2020a). Emphasis added.....25
Figure 2.3 Pet Food Recall Events by Pet Food Type and Year, 2007-2019.....29
Figure 2.4 Number of Pet Food Recalls by Type of Contamination and Year, 2007-2019 .....36
Figure 2.5 Number of Pet Food Recalls by Notification Entity and Year, 2007-2019.....38
Figure 2.6 Number of Pet Food Recalls by Type of Pet Food and Health Hazard from 2007-2019.....42
Figure 3.1 Number of Pet Food Recalls by Notification Entity and Pet Food Type, 2007-2019.....54
Figure 3.2. Number of Pet Food Recalls by Notification Entity and Type of Health Hazard, 2007-2019.....61
Figure 3.3 Number of Pet Food Recalls by Inspection Type and Year, 2007-2019.....65
Figure 4.1. Number of Raw Poultry Recall Events by Type of Health Hazard and Year, 2015-2019 Note: Other includes undercooked, processing defect, without benefit of inspection, and adulteration health hazards. .....77

# Chapter I: Literature Review

## 1.1 Introduction

A recall, whether for a human food or for a pet food or treat, removes product that are deemed as hazards due to chemical, microbiological, or foreign object contamination from the marketplace and is an integral part of the United States food safety system (Enright, 2017). Highly publicized pet food recalls over the past decade have highlighted how pet food can serve as a vehicle for foodborne illnesses, as well as naturally occurring or inadvertently added toxic agents. In addition, pet food can also potentially lead to nutritional deficiencies or toxicities in pets if formulated incorrectly (Buchanan *et al.*, 2011). These contaminations can be traced back to issues involving raw materials, production, distribution, and mishandling of raw materials and complete product before consumption. Thus, ensuring the integrity of pet foods must cover the entire supply chain, from farm to fork. Failure to do so can place pet food products and businesses, along with pets and consumers, at risk for a food safety incident.

The nutritional adequacy and safety of pet foods are intertwined in the minds of consumers. Foods that are nutritionally adequate but not trusted because of safety concerns will be rejected by pet owners, as will foods that are safe but are not considered nutritionally adequate. Thus, regardless of whether the focus is on human or pet health, the ability to manufacture and distribute safe pet food products is a prerequisite for marketing a pet food product (Buchanan *et al.*, 2011). One argument in relation to the persistence of pet food recalls is that it all boils down to economics. With consumers' increasing desire for pet food products focused on health and wellness, pet food manufacturers are innovating new products to meet pet owners' insatiable demands.

However, these continued industry efforts are introducing higher risk ingredients into the pet food manufacturing plants, which makes pet food vulnerable to potential contamination (Labs, 2017). Additionally, smaller processing plants may not have the financial resources available to effectively monitor and manage microbiological contamination compared to larger processing plants (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019).

Pet food safety represents a substantial challenge over human food safety concerns because a contaminated pet food product can directly affect the pet and the consumer. The human health risk is made possible during the act of handling contaminated pet food or even when a human is licked by a pet. In effect, the U.S. Center for Disease Control and Prevention estimates that approximately 1,500 humans have been infected with *Salmonellosis* through pet food sources (Strout, Jeff; Price, 2017). This notion, combined with highly publicized pet food recalls, has led regulators to increase scrutiny over pet food safety. In 2013, the Center for Veterinary Medicine established a policy for zero-tolerance for *Salmonella* in pet food, which is more stringent than policies for human food (Phillips-Donaldson, 2015). In addition, new federal regulations through the Food Safety Modernization Act (FSMA) aim to prevent unsafe animal food from reaching the consumer through the use of science- and risk-based controls at the manufacturing level (CVM, 2019b).

Thus, the pet food industry is facing daunting challenges; consumer demands are driving the industry to formulate pet food products aimed at health and wellness that may sacrifice pet food safety, while regulatory authorities are putting increasing pressure on pet food manufacturers to employ comprehensive preventive measures to protect

consumer and pet health. Tackling these challenges requires collaboration across all aspects of the pet food supply chain to assure that production processes, regulations, food safety practices, and affordability align to protect public health (van de Ligt, 2019). However, more research is needed to identify the factors that have contributed to the overall increase in pet food recalls and the next steps needed to improve collaboration between industry and regulators and the overall safety of the pet food supply chain.

## 1.2 Objectives

The overall objective of this study was to identify the factors that contributed to the increase in pet food recalls- providing a complete picture of the current challenges facing the pet industry. This research comes at an opportune time as the pet food industry is still learning how to comply with pet food safety guidelines and regulations while still meeting consumer demands. Thus, the purposes of this research are three-fold: promote mutual understanding among the pet food industry, provide guidance for pet food manufacturers and regulatory oversight, and present data-driven pet food safety information to consumers.

Specific objectives are as follows:

1. Analyze trends, patterns, and the level of supply chain complexity in pet food product recalls from 2007-2019
2. Identify the impact regulatory oversight and zero-tolerance guideline for *Salmonella* spp. has on pet food recalls from 2007-2019
3. Provide recommendations and implications to industry and regulators for reducing pet food recalls while still protecting human and pet health

## 1.3 Pet Food Industry

Throughout history pets have played an integral role in human life, providing food, labor, companionship, and emotional support. Dogs and cats were the most popular pets in the United States households in 2019, with 63.4 million owning a dog and 42.7 million owning a cat (APPA, 2019). These pets often share meals with their human owners, go on family vacations, and are featured on holiday cards. In effect, the pet care industry is booming as Americans, especially millennials, blur the line between human child and pet.

Pet parents in the United States spent $87 billion on their pets in 2018, with Midwesterners spending the most of any region in the United States (Wall, 2019). Due to the relatively high demand for pet products, a variety of pet food products have been progressively introduced into the market (Paulelli *et al.*, 2018). Following current trends and consumer demands in the human-food industry for health and wellness, some pet food manufacturers are now formulating grain-free and grain-inclusive diets within the same product line in order to give consumers the variety they demand, while others are producing products for solution-based benefits, such as a life-stage formula, a performance supplement, or a diet designed to address a specific health issue (J. Tyler, 2020). Manufacturers are also offering pet food varieties to satisfy even the pickiest eaters, including dry, canned, semi-moist and raw. Pet treats have evolved to include freeze-dried jerky treats, dental chews, and leftover body parts from animals slaughtered for human consumption such as ears, snouts, leg bones, intestines, trotters, and other by-products (Galvão *et al.*, 2015). While commercially prepared pet foods tend to be relatively inexpensive and meet the nutritional needs of pets (Fox and Kenagy, 2015),

raw, premium and super-premium, more expensive products are driving the growth and revenue of the pet food industry.

Pet food and treat brands are now distributing their premium pet food through various mass and e-commerce channels in order to meet pet owners where they shop. As more premium and super-premium brands utilize the omnichannel approach to marketing, retailers are competing with house brands for shelf space or online position and top brands are driving their pet food products right into the hands of the consumer (Semple, 2019b). The United States cat and dog food sales in 2019 can be further broken down into: dry dog food (30%), dry cat food (13%), canned dog food (9.8%), canned cat food (12.7%), semi-moist dog food (0.65%) semi-moist cat food (12.7%), refrigerated/frozen dog food (1.7%), refrigerated/frozen cat food (0.05%), dog treats (15%), and cat treats (4%) (Semple, 2019b). While sales for dog food continue to outpace cat food sales, food for cats has grown and is projected to continue to grow at a higher rate than dog food. In 2019, cat food sales are projected to increase by 3.2 percent to $9.6 billion, while dog food sales are expected to increase by 2.5% to $19.2 billion (Semple, 2019b).

The success of the pet food industry is dependent on how regulatory oversight, consumer demands, and manufacturers interplay. Pet food safety is a function of direct regulation, exposure to legal liability, and the market response of companies to protect their brands in the event of a pet food product recall (Fox and Kenagy, 2015). Thus, the pet food industry's biggest threat to profitability is when a pet food manufacturer or company must initiate a recall to remove contaminated pet food products from the marketplace.

## 1.4 Pet Food Recall Impacts and Processes

The worst thing that can happen to the pet food industry is the loss of consumer confidence due to recalls or foodborne disease outbreaks (Ostroff, 2018). A 2018 survey by a market research firm revealed approximately 50 percent of dog and cat owners agreed that fear of pet food contamination and product safety was a key consideration in what pet foods they buy, while more than 60 percent of pet parents agreed that they are concerned about the safety of the pet food, treats, and chews they purchase (Packaged Facts, 2019). Additionally, in a Harris Interactive Poll, 55 percent of consumers said they would switch brands temporarily during a recall, 15 percent said they would never purchase the recalled product again, and 21 percent said they would avoid purchasing any brand made by the manufacturer of the recalled product (Tyco Integrated Security, 2012).

While pet food recalls are most imperatively a public health issue, they also have substantial economic issues as well (Ostroff, 2018). The direct costs of a recall include notification (to regulatory bodies, the downstream supply chain, and consumers), customer reimbursement, product retrieval, storage and destruction, business interruption, investigation of the root cause, and implementing corrective actions to prevent reoccurrence. There are also indirect costs, including litigation costs and the costs to the company's market value and brand reputation (Tyco Integrated Security, 2012).

In 2012, the Food Marketing Institute and the Grocery Manufacturers Association estimated the average cost of a recall in the United States was $10 million in direct costs. In another survey conducted by the Grocery Manufacturers Association, 18 percent of multi-national corporations indicated they have been involved in recalls with estimate costs between $30 million and $99 million each. Another 5 percent said they had been

involved in recalls that cost more than $100 million (Ostroff, 2018). In 2019, the U.S. Food and Drug Administration (FDA) participated in 46 preventive controls recall events for animal food and 4 recall events attributed to imported finished animal food (CVM, 2019b). Using the 2012 recall estimate, the animal food industry spent more than $500 million dollars in direct costs alone. Ultimately, every recall that is prevented, whether from a standpoint of consumers or industry, is money saved. For industry, this is money that could be invested in product innovation, facility upgrades, marketing, or other profit-generating components of the company. For consumers, there are billions of dollars in veterinary and healthcare costs that could be allocated and used other ways, not to mention the irreparable loss of a human or pet (Ostroff, 2018).

A recall is a method of removing or correcting consumer products that are in violation of laws administered by the FDA (Rumbeiha and Morrison, 2011). A recall may be initiated one of three ways: by the manufacturer, by the request of the FDA, or by the FDA agency itself (Fox and Kenagy, 2015). A firm-initiated recall can occur when the manufacturer or pet food company decides of its own volition to remove a distributed product from the marketplace (CFR, 2019). In this circumstance, the removal will be considered a recall only if the FDA regards the violation as subject to legal action (Figure 1.1). A firm-initiated recall can also occur if the FDA has determined that the product in question violates the law, but the FDA has not specifically requested a recall (CFR, 2019). This often occurs when the FDA conducts routine or random microbiological or analytical testing on a specific pet food product and, if adulteration is confirmed, notifies the firm asking them to initiate a recall (Rumbeiha and Morrison, 2011). An FDA-initiated recall occurs when the following determinations have been made: the pet food

product that has been distributed presents a risk of illness, injury or blatant consumer deception, the manufacturer refuses to initiate a recall for the product, and the action of the FDA is necessary to protect public health and welfare (CFR, 2019). In this circumstance, the FDA notifies the manufacturer of this determination and the need to immediately remove the product from the marketplace. Given the significant adverse publicity a mandatory recall would generate, the high costs associated with litigation, and the need to maintain a positive brand image in the public, this is an uncommon occurrence and the manufacturer usually voluntarily recalls the potentially tainted pet food product (Fox and Kenagy, 2015).

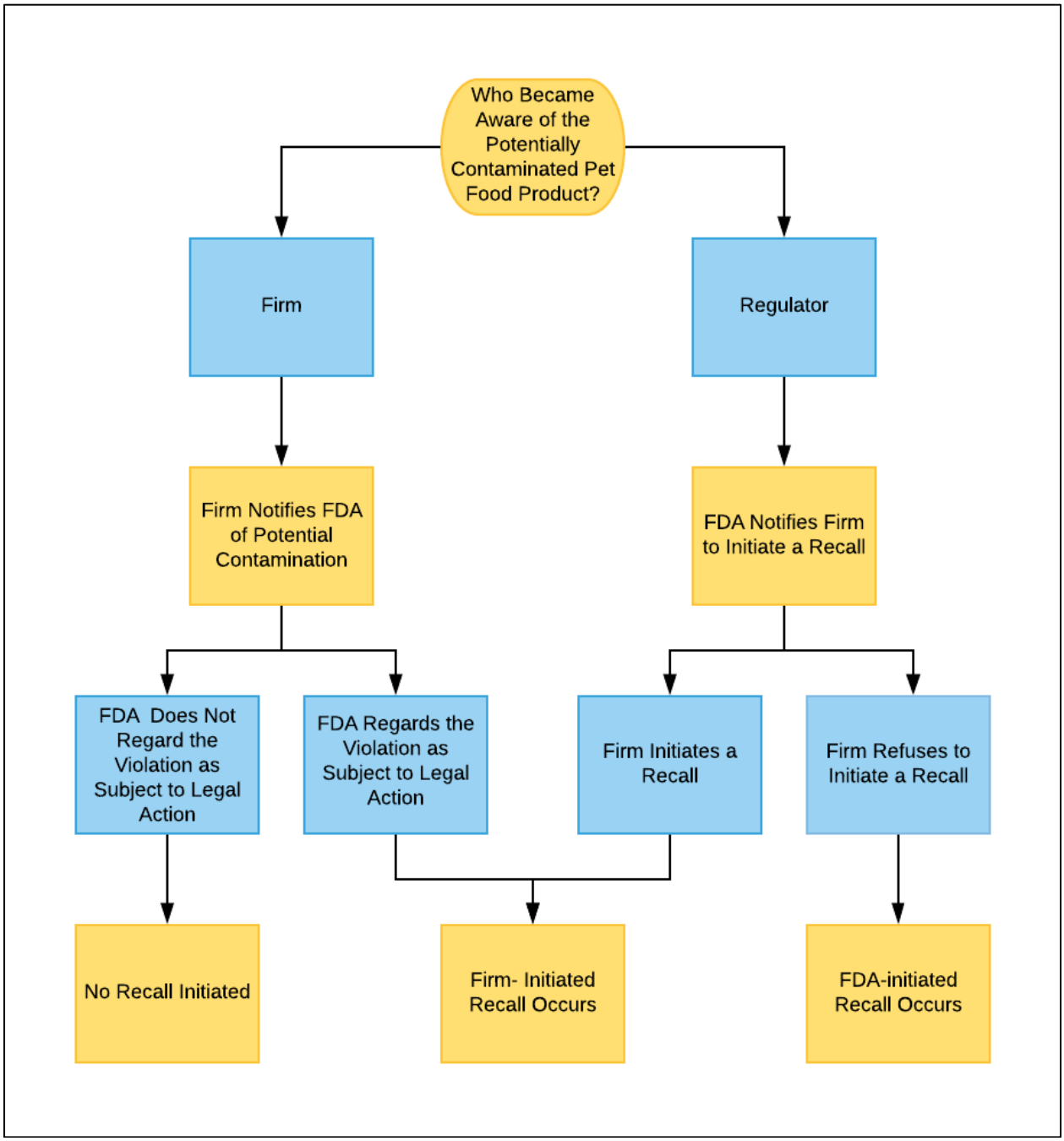



**Figure 1.1 Decision-Making Flow Chart for Initiating a Pet Food Recall** (CFR, 2019)

In the event of a firm-initiated recall, the recall process begins with collection of data needed to assess the situation. The firm submits information including the product name and description of type of pet food product involved, its intended use, and proposed strategy for conducting the recall. Details regarding the site of production, the dates of

production, volume of distribution, names and locations of distributors, and applicable lots are also essential (Dzanis, 2008). Information regarding the reason for product removal and potential health risk the product poses are submitted as well. The firm must submit the report to the FDA within 24 hours after determining that there is reasonable potential that the use or exposure to the pet food can cause serious adverse health effects to humans or pets (Rumbeiha and Morrison, 2011). Following consumer complaints to the FDA or notification by the manufacturer, the FDA collects additional information by interviewing the complainant(s) and collecting and analyzing pet food samples (Rumbeiha and Morrison, 2011). The FDA reviews the information submitted and any additional data collected to conduct a Health Hazard Evaluation, which forms the basis for classification of the recall (Dzanis, 2008).

The FDA categorizes recalls into three classes based on the severity of the health hazard:

Class I recalls: include defective products or dangerous foods that are likely to cause serious health problems (Evanson *et al.*, 2019).

Class II recalls: include foods or products that present only a slight risk of serious health effects or could potentially cause a temporary health problem.

Class III recalls: pertain to recalls that violate FDA manufacturing laws or labeling requirements, but are unlikely to cause any adverse health effects.

The FDA prescribes a "depth of recall" strategy based on the recall classification and other factors such as the extent and pattern of distribution, the amount of product remaining unused in the marketplace and ease of identification. A contamination in which the health consequences are remote may require a recall only at the wholesale or

retail level whereas if the health consequences are likely to cause serious adverse health effects, a more extensive recall at the consumer level is indicated (Dzanis, 2008).

The FDA oversees all steps of the recall process, including contact with consumers of the violative product, the handling and destruction of the product, and providing guidance on appropriate issuance of press releases and recall notifications. Throughout the recall process, FDA conducts investigations, periodic audits, and laboratory analyses to determine the nature and root cause of the contamination, and what steps may need to be taken to prevent its recurrence (Dzanis, 2008). The manufacturer must also submit periodic recall status report updates so the FDA can assess the progress of the recall. The recall status report includes documentation of initial recall notification to the recipients, number of recipients who responded and did not respond to the recall notification, and quantity of products returned or corrected by the recipients (CFR, 2019).

All recalls monitored by the FDA are recorded on the FDA "Enforcement Reports" website once the recall has been classified according the level of hazard (CFR, 2019). The FDA addresses urgent situations, such as a nationwide distribution of a class I recall, by issuing a public warning through a nationwide or regionally targeted press release (Fox and Kenagy, 2015). If state regulatory agencies are also involved, the FDA coordinates efforts to maximize available resources (Dzanis, 2008). The combination of the FDA press releases and "Enforcement Reports" often provides a complete picture of pet food products recalled in the United States.

The FDA terminates the recall when it is satisfied that all reasonable efforts have been made to remove the product in accordance with the depth of recall strategy, and the product has been removed and properly disposed of (Rumbeiha and Morrison, 2011).

## 1.5 Pet Food Regulations and Guidelines

Pet food is among the most highly regulated of all U.S. products (Enright, 2017). At the federal level, the Food and Drug Administration (FDA) is the primary regulatory agency responsible for the safety of animal feed (CVM, 2019c). Animal feed is comprised of complete and balanced pet foods, treats, edible chews, dietary supplements, and ingredients intended to be added to pet foods. The FDA manages animal feeds in interstate commerce under the Animal Feed Safety System (AFSS), which is managed by the Center for Veterinary Medicine (CVM). The AFSS is responsible for all regulatory aspects of animal food safety, including performing inspections and investigations, taking enforcement actions to remove unsafe animal food from the marketplace, and partnering with other government agencies regarding feed safety (CVM, 2019c). In addition to FDA regulations, pet food manufacturers must adhere to federal rules and regulations set by the Federal Trade Commission, which is responsible for regulating pet food labeling and advertising claims (Enright, 2017). The United States Department of Agriculture (USDA) regulates meat quality and determines which animals can be used for human or animal consumption (Enright, 2017). On the state level, individual states enforce pet food regulations through the state Department of Agriculture (Mehlenbacher *et al.*, 2012). State feed officials help the FDA by inspecting animal food manufacturers and enforcing state and federal laws (CVM, 2019c). The state feed control officials partner with the Association of American Feed Officials (AAFCO) to establish a uniform standard on which 49 of the 50 states base their individual feed laws and regulations. These uniform guidelines address manufacturing, distributing, labeling, and selling of animal foods. Given the number of agencies sharing regulatory authority over pet food, the focus of this

review is on FDA policy guidelines and regulatory reforms that drastically changed how the pet food industry manufactures and produces pet food products.

Prior to 2007, pet food recalls were limited to one single manufacturer and involved a "quickly identified and understood contaminant" (Dzanis, 2008). Thus, the extensive recall of more than 5300 different types of pet food products manufactured and sold under 150 different brand names in 2007 was unprecedented. The recalls resulted from intentionally adulterated wheat gluten and other vegetable protein ingredients in which melamine was added to falsely increase the protein content (Dzanis, 2008). While this recall only affected 1% of pet food products produced in the United States, the FDA and pet food industry became completely inundated as the recall unfolded, with the FDA logging over 18,000 calls total from worried consumers (Fox and Kenagy, 2015).

In response to this major pet food recall, "The Food and Drug Administration Amendments Act (FDAAA)" was passed by the legislature and signed by the president in 2007. Under the FDAAA, the FDA was required to establish a "Reportable Food Registry," implement an early warning and detection program for potentially contaminated pet food products, and improve coordination efforts with the State Departments of Agriculture (Dzanis, 2008).

A reportable pet food product is considered any animal food that has been distributed to the marketplace and is likely to lead to illness or injury to humans or animals. Information regarding adulterated or misbranded pet food comes from a variety of sources, including pet food manufacturers, practicing veterinarians, federal and state health officials, and consumers. The "Reportable Food Registry" was developed in 2007 to enable the FDA to track these reports (CVM, 2019c). A Safety Reporting Portal was

developed to allow consumers to report any adverse events associated with pet food safety to the registry. The Integrated Food Safety System was developed in 2009 to allow states and the federal government to share information regarding contaminated pet food products. This system enables food safety professionals from federal, state, and local governments to coordinate efforts in pet food, epidemiology, laboratory testing, animal health, and public health (CVM, 2019c) . The Pet Event Tracking Network (PETNet) was launched in 2011 to provide state and regulatory agencies that have jurisdiction over pet food products a vehicle to share and disseminate confidential information. This enables state regulators, who are in the best position to act quickly, to protect the health of pets and pet owners as information becomes available to the FDA (CVM, 2019c).

The recalls for pet food and the potential human health risk led Congress to establish legislation to help FDA create regulations to help pet food manufacturers identify hazards surrounding pet food (Strout, Jeff; Price, 2017). The Animal Feed Safety System Team reviewed the U.S. feed safety system and found that the system lacked baseline requirements for producing safe animal food, including Current Good Manufacturing Practice (CGMP) and Preventive Control requirements (CVM, 2019c). CGMP's are up-to-date steps that help ensure foods are produce in safe environments. Thus, the regulatory landscape drastically changed for pet food manufacturers when Congress passed the FDA Food Safety Modernization Act (FSMA), which was signed into law by President Obama on January 4, 2011.

The FSMA was the most sweeping reform in the United States food safety laws since the Federal Food, Drug, and Cosmetic Act (FD&C Act) of 1938. Under the FD&C Act, the FDA was responsible for ensuring that pet foods were unadulterated, wholesome and

safe to eat, were produced under sanitary conditions, contained no harmful substances, and were accurately labeled (Mehlenbacher *et al.*, 2012). The FSMA seeks to strengthen animal food safety regulation by amending the FD&C Act to improve preventive controls for animal food, controls over imported food, inspection and compliance initiatives, and sanitary transportation measures. (CVM, 2019b). The ultimate goal of the preventive controls rule for animal food is to "build a food safety system for the future that makes modern science- and risk-based preventive controls the norm across all sectors of the animal food system (Strout, Jeff; Price, 2017)."

The Preventive controls rule stipulates that a production facility that produces, processes, packs, or holds pet food must have Current Good Manufacturing Practices (CGMPs) established. A production facility must also have a robust food safety system that includes hazard-analysis and risk-based preventive controls as well as a written food safety plan. The food safety plan must include oversight and management of preventive controls (monitoring, corrective actions, verifications), a recall plan, and, if applicable, a supply chain program. For animal food, FDA delayed the start of routine inspection of the preventive controls requirements one year beyond the compliance for each business size (see Table 1). The preventive controls rule for animal food aims to recall unsafe marketed animal food at the manufacturing level and thus prevent it from ever reaching the consumer (CVM, 2019b).

Pet food products imported into the United States are required to meet the same laws and regulations as domestic pet food products. The Foreign Supplier Verification Program (FSVP) rule of the FSMA requires that importers verify their suppliers are producing pet food using processes and procedures that offer the same level of public

health protection as the Preventive Controls requirements in the CGMP and Preventive Controls rules for animal food.

**Table 1.1 Current Good Manufacturing Processes and Preventive Controls Compliance Dates Based on Pet Food Business Size**

| Business Size | CGMP[a] Compliance Date | PC[b] Compliance Date |
|---|---|---|
| Business other than small and very small | September 19, 2016 | September 18, 2017 |
| Small Business (fewer than 500 full-time equivalent employees) | September 18, 2017 | September 17, 2018 |
| Very Small Business (less than $2,500,000 per year during the 3-year period preceding the applicable calendar year) | September 17, 2018 | September 17, 2019 |

Prior to the FSMA, pet food manufacturers were only inspected for adulteration, misbranding and, when applicable, Bovine Spongiform Encephalopathy (BSE) requirements for pet food manufacturers that use protein derived mammalian tissues. Although FDA and/or state Departments of Agriculture performed routine inspections every five or more years and conducted random testing of pet food retail products, investigations were mostly prompted after complaints had been received from consumers or veterinarians (CVM, 2019b). Under FSMA, inspection is to educate first then regulate. Historically, 80 percent of animal food inspections were conducted by states on FDA's behalf. As of 2019, 32 states are doing these inspections. The FDA is expected to inspect all high-risk domestic food facilities within 5 years of the FSMA implementation and every three years thereafter. High-risk pet foods are defined as those that are most commonly recalled or are produced in a way that makes them more likely to contain harmful bacteria. The FSMA also mandated, within one year of enactment, the FDA to inspect at least 600 foreign facilities and double those inspections every year for the next

five years (Fox and Kenagy, 2015). Additionally, FDA now has access to food safety plan implementation records that the manufacturers are required to document and maintain. The FDA-track: Food Safety Dashboard tracks outcomes for three FSMA rules in the areas of inspections and recalls: "CGMP, Hazard Analysis, and Risk-based Preventive Controls" for animal food and import food safety.

Laboratory accreditation was mandated by the FSMA in order to ensure the safety of the U.S. food supply, protect public health, and provide consistent quality in laboratory testing and analytical data. The laboratory accreditation program, once established, will require that testing of food in certain circumstances be conducted by laboratories that voluntarily become accredited under the program (FDA, 2020b).

The Sanitary Transportation rule applies to shippers, receivers, and carriers that transport food directly into or within the United States. This rule aims to ensure the design and maintenance of transportation equipment used to transport pet food products does not compromise pet food safety. This includes adequate temperature controls, cross-contamination measures, and training of carrier personnel (CVM, 2019b).

Along with the development and implementation of FSMA, FDA also issued a compliance policy guide for *Salmonella* spp. in pet food in 2013 due to human outbreaks of salmonellosis associated with *Salmonella*-contaminated pet foods (CVM, 2013). Under the FD&C Act, FDA considers pet food contaminated with *Salmonella* spp. to be adulterated if it will not subsequently undergo a commercial heat step or other commercial process to kill *Salmonella* spp. Thus, FDA believes regulatory action is warranted in cases involving pet food contaminated with any *Salmonella* spp. serotype due to the high likelihood of direct human contact with pet food. The term *pet food*

includes dog and cat food, raw meat and raw poultry formulations for pets, pet treats and chews, and vitamins, minerals, and other nutritional supplements intended for dogs or cats (CVM, 2013).

New regulations and policies are drastically changing the animal food approach to safety. In addition, consumer demands, regulatory requirements and pet food safety go hand-in-hand. Thus, the next chapter will explore how changes in regulations, consumer demands, and the pet food industry have affected the number of pet food recalls.

# Chapter II: Trends in Cat and Dog Food Product Recalls: 2007-2019

## 2.1 Introduction

A pet food company can either manufacture it themselves or choose a co-packer who will either use a private label or manufacture the food to the specifications of the brand. Pet food companies tend to outsource pet food production to another entity, rather than building their own plant, for a multitude of reasons, including cost-saving measures, increased scalability, and facility certifications. A contract manufacturer (co-packer) is a company that manufactures and packages foods for pet food companies. The contract manufacturer works under a contract with the hiring pet food company to manufacture the pet food products as though the pet food company was manufacturing the products themselves. Thus, co-packers often manufacture several different brands, for several different companies at once. This becomes problematic when an ingredient or manufacturing plant becomes contaminated because either the same contaminated ingredient is used to manufacture multiple pet food products for different brands or cross-contamination occurs between the pet food products and the manufacturing plant.

For example, Sunshine Mills Inc., a co-packer or contract manufacturer, produced dry dog food products under different brand names for various pet food companies, including Nutrisca, Natural Life Pet Products, Sunshine Mills, Inc., ANF, Inc., Lidl, Kroger, Elm Pet Foods, and Ahold Delhaize. In 2018, the FDA issued a warning to consumers about several dog food recalls after receiving consumer complaints that dog's eating the dry pet food experienced vitamin D toxicity. Testing found that samples of the dog food contained as much as 70 times the intended amount of vitamin D. Sunshine Mills Inc. was identified as the common contract manufacturer that produced all of the

recalled dry dog food products that were marketed under different brand names (Entis, 2019). The chemical contamination was the result of a formulation error and ended up affecting 11 different brands and resulted in 8 FDA recalls. This example exemplifies the level of supply chain complexity that can occur within the pet food industry, and how a single source of contamination can escalate the number of pet food recalls.

Despite the considerable increase in the total number of pet food recalls over the past decade, the Center for Veterinary Medicine maintains that pet food safety has been steadily improving (Maberry, 2016). A 2002 to 2006 Center for Veterinary Medicine study indicated that the prevalence of *Salmonella* spp. contamination in commercial pet food was 13 percent, while a second study conducted between 2010-2012 indicated only 1.7 percent of samples contained *Salmonella* spp. Yet, the prevalence of *Salmonella* spp. and *Listeria monocytogenes* contamination in the 2010-2012 study for raw pet food was 7.6 percent and 16.3 percent. The results of this study suggested that raw pet food is more likely to be contaminated with *Listeria* or *Salmonella* spp. versus commercial pet food and exposure to and handling of raw pet food makes pet owners more susceptible to contracting foodborne illnesses (CVM, 2018c).

Dry and canned pet foods are thought to be safer for pets today than ever before for the following reasons: pet foods use multiple ingredients, thereby reducing the potential of any one ingredient to cause harm; manufacturing techniques that involve extrusion and retorting produce high heat levels that destroy pathogens and heat-sensitive toxins; improvements in how raw materials and finished pet foods are stored reduces the risk of contamination from moisture; and advanced analytical techniques are utilized to verify the ingredients and final products are free of contaminants. (Fox and Kenagy,

2015). Despite these advancements, if a contaminant is present in the pet food, there is an increased risk of adverse effects for pets since this single bag of food from a single brand/lot will likely be their primary source of nutrition until the bag is empty.

The 2019 Food Safety and Inspection progress report on *Salmonella* testing of raw meat and poultry products indicated the *Salmonella* spp. prevalence was between 10.0-10.7 percent for raw chicken, 8.1-12.6 percent for raw turkey, 1.1-2.6 percent for raw beef, and 14.6-15.7 percent for raw pork (FSIS, 2019). A study conducted in 2018 on raw pet food also identified *Listeria monocytogenes* in 19 products (54%), *Listeria* spp. species in 15 products (43%), Escherichia *coli* O157:H7 in 8 products (23%), and *Salmonella* spp. in 7 products (20%) (van Bree *et al.*, 2018).

Pig ears contaminated with *Salmonella* spp. have consistently been a problem in the United States pet food industry beginning in 1999 and is still ongoing today. In a study conducted from 1999 to 2000 in the U.S., strains of *Salmonella* spp. were isolated from 65 (41 percent) of 158 pig ears and other pet treats obtained from pet retail stores. Of these, 8 (31 percent) were domestic and 57 (43 percent) were imported. In another study conducted in the European Union (EU), 25 of 102 (24.5 percent) pig ear treats samples contained *Salmonella* spp. despite EU regulations which require an absence of *Salmonella* spp. in 25g in both domestic and imported treats. However, samples of EU origin were consistently negative for Salmonella spp. while all positive samples were sourced from Brazil (Adley *et al.*, 2011).

While stricter regulatory oversight has shed a spotlight on pet food safety issues that might have otherwise gone unnoticed, there is clearly still an opportunity to improve pet food safety across all sectors (Packaged Facts, 2019). As pet food manufacturers

strive to meet consumer demands for wholesome pet food, the risk for ingredient- and manufacturing-related chemical and microbiological contamination increases. Furthermore, trust between the consumer and manufacturer, and the knowledge that a pet owner can believe what they see on the shelves, is paramount. Given that consumers lose trust in a manufacturer when a pet food recall does occur as well as the health risks for pets and consumers, there is a fundamental need to understand the factors that have contributed to the overall increase in pet food recalls. The primary objective of this first chapter is to analyze trends, patterns, and the level of supply chain complexity in pet food product recalls from 2007-2019. Specifically, trends are identified by types of pet food products being recalled, the consumer, regulatory body, or manufacturer who initiated the recall, the health hazard posed by the recalled products, and the interrelationship between health hazard and type of pet food. The level of supply chain complexity for each recall event is evaluated based on the number of FDA recalls for each contract manufacturer, the quantity of product recalled, and the number of brands affected. Identification of trends and patterns may provide guidance for pet food manufacturers food safety processes and targets for regulatory oversight. These insights could potentially lead to a reduction in the total number of pet food recalls and manufacturer recall costs, improve the overall quality and safety of the pet food supply chain, and result in fewer human and pet illnesses and foodborne outbreaks.

## 2.2 Methods

The period chosen for this analysis, 2007-2019, was a pivotal period regarding pet food recalls in the United States. During this time, there were several highly publicized recalls and foodborne illness outbreaks linked to contaminated pet food products, notably

melamine in dry pet food, canned pet food, and treats (2007), *Salmonella* enterica in dry pet food (2008), excess vitamin D in dry and canned pet food (2018 and 2019), and multi-drug resistant *Salmonella* in pig ear treats (2019).

According the Association of American Feed Control Officials, *pet food* means commercial feed prepared and distributed for consumption by dogs or cats (AAFCO, 2012). Thus, for the purpose of this paper, the term *pet* will only refer to dogs and cats. The term *pet food* was used to mean food for pets and includes complete diets, treats, and chews for pets.

***FDA Recall Data***

Data for the pet food recalls came from two different sources. The FDA class I recall data from 2007 to 2019 were available from the FDA website for "Recalls, Market Withdrawals, and Safety Alerts (FDA, 2020c)." Data for class II and class III recalls from 2012 to 2019 were collected from the FDA website for "Enforcement Reports (FDA, 2020a)." The "Enforcement Reports" includes the recall initiation and termination dates, a description of the product(s) recalled, the reason for the recall and health hazard involved, quantity of product(s) recalled, recall classification, and the distribution of the contaminated product (FDA, 2020a). While the "Recalls, Market Withdrawals, and Safety Alerts" does not include the recall initiation and termination dates, quantity of product recalled, or the recall classification, it includes additional information including the date of the FDA recall announcement and information on how the health hazard was discovered (FDA, 2020c). Examples of a "Recalls, Market Withdrawals, and Safety Alerts" submission and the corresponding entry in the FDA "Enforcement Reports" are presented in Figure 2.1 and Figure 2.2.

## Summary

| | |
|---|---|
| **Company Announcement Date:** | September 20, 2019 |
| **FDA Publish Date:** | September 24, 2019 |
| **Product Type:** | Animal & Veterinary<br>Animal Feed |
| **Reason for Announcement:** | Salmonella contamination |
| **Company Name:** | TDBBS LLC |
| **Brand Name:** | TDBBS |
| **Product Description:** | Pig ear pet treat |

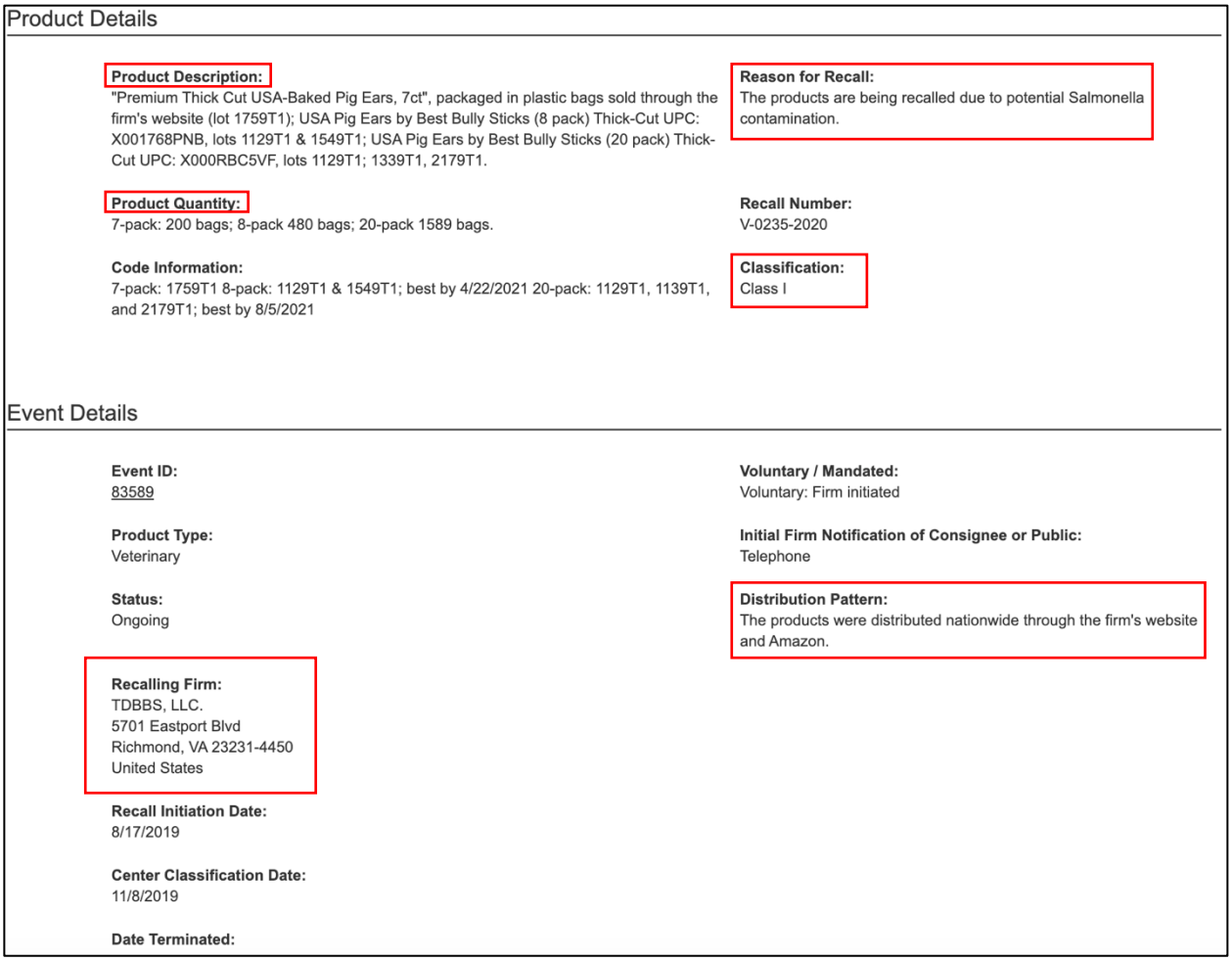
*TDBBS provided the following information about specific products recalled:*

This recall is the result of routine sampling conducted by the Michigan Department of Agriculture & Rural Development. The sample bag tested positive for *Salmonella*. *Salmonella* can affect animals eating the products, and there is risk to humans from handling contaminated pet products, especially if they have not thoroughly washed their hands after having contact with the products or surfaces exposed to these products.

This product was shipped to customers between April 22, 2019, and August 13, 2019. Customers should **dispose** of any USA Thick Pig Ear 8 Pack and USA Thick Pig Ear 20 Pack from these shipments.

| TDBBS, LLC USA Thick Pig Ear 8 Pack | TDBBS, LLC USA Thick Pig Ear 20 Pack |
|---|---|
| UPC: X001768PNB | UPC: X000RBC5VF |
| Best By Date: 4/22/2021 Lot Code: 1129T1 | Best By Date: 4/22/2021 Lot Code: 1129T1 |
| Best By Date: 6/06/2021 Lot Code: 1549T1 | Best By Date: 5/13/2021 Lot Code: 1339T1 |
| | Best By Date: 8/05/2021 Lot Code: 2179T1 |

**Figure 2.1 Example of a "Recalls, Market Withdrawals, and Safety Alerts" Report on the FDA Reportable Food Registry Website.** (FDA, 2020c). Emphasis Added.



Product Details

**Product Description:**
"Premium Thick Cut USA-Baked Pig Ears, 7ct", packaged in plastic bags sold through the firm's website (lot 1759T1); USA Pig Ears by Best Bully Sticks (8 pack) Thick-Cut UPC: X001768PNB, lots 1129T1 & 1549T1; USA Pig Ears by Best Bully Sticks (20 pack) Thick-Cut UPC: X000RBC5VF, lots 1129T1; 1339T1, 2179T1.

**Reason for Recall:**
The products are being recalled due to potential Salmonella contamination.

**Product Quantity:**
7-pack: 200 bags; 8-pack 480 bags; 20-pack 1589 bags.

**Recall Number:**
V-0235-2020

**Code Information:**
7-pack: 1759T1 8-pack: 1129T1 & 1549T1; best by 4/22/2021 20-pack: 1129T1, 1139T1, and 2179T1; best by 8/5/2021

**Classification:**
Class I

Event Details

**Event ID:**
83589

**Voluntary / Mandated:**
Voluntary: Firm initiated

**Product Type:**
Veterinary

**Initial Firm Notification of Consignee or Public:**
Telephone

**Status:**
Ongoing

**Distribution Pattern:**
The products were distributed nationwide through the firm's website and Amazon.

**Recalling Firm:**
TDBBS, LLC.
5701 Eastport Blvd
Richmond, VA 23231-4450
United States

**Recall Initiation Date:**
8/17/2019

**Center Classification Date:**
11/8/2019

**Date Terminated:**

**Figure 2.2 Example of a "Enforcement Reports" Entry on the FDA Enforcement Reports Website.** (FDA, 2020a). Emphasis added.

For each recall entry, the following information was recorded:

- Date of Recall
- Brand Name
- Manufacturer Name
- Type of Contamination
- Type of Pet Food
- Product Description
- Reporting Entity
- Class of Recall
- Length of Recall
- Quantity of Product Recalled

There were 6 different scenarios that were observed when a pet food manufacturer or company initiated a recall:

- Single manufacturer produced the product, 1 brand was impacted, 1 product was recalled, 1 recall was issued
- Single manufacturer produced the product, 1 brand was impacted, 1 product was recalled, 1 or more recalls were issued
- Single manufacturer produced the product, 1 brand was impacted, 1 or more products were recalled, 1 recall was issued
- Single manufacturer produced the product, 1 or more brands were impacted, 1 or more products were recalled, 1 or more recalls were issued
- One or more manufacturers produced the product, 1 or more brands were impacted, 1 or more products recalled, 1 or more recalls were issued (each brand issued own recall)

A methodology was created to take into account the multiple different scenarios that were observed in the recall process. A spreadsheet was created to record the FDA pet food recall data. Each row in the database represented a recall involving a contamination event in a pet food or treat. The raw data collection represents the data in which it was presented in the "Enforcement Reports" and "Recalls, Market Withdrawals, and Safety Alerts." Thus, all the scenarios above were counted as one recall, regardless of the number of brands or products that were included in each recall submission. The synthesized data specifically addressed the situations where a manufacturer issued an extended recall(s), a contract manufacturer produced multiple brands of pet food for multiple different companies, or multiple products were produced by different manufacturers and the products became cross-contaminated in the supply-chain. Thus, in a recall event where multiple brands were recalled due to a common contract manufacturer, and multiple recalls were issued by the different brands, the recalls from all the various brands were condensed in the synthesized recall data to represent one recall total. If a single manufacturer issued one or more extended recalls after the initial

recall, then the initial recall and the extended recalls were condensed to represent one recall in the synthesized recall data. Lastly, if multiple pet food products produced by different manufacturers became contaminated due to cross-contamination within the supply chain, and each manufacturer issued a recall for their specific products, the synthesized data would represent 1 recall for all the manufacturers and products combined. The synthesized methodology provided insight into the level of complexity within the pet food supply chain, ensured that the number of recalls for each type of pet food and health hazard weren't overestimated, and allows the reader to visually identify what types of pet food products or health hazard had multiple recalls from a single source of contamination in any given year.

For example, the Sunshine Mill's Inc., recall that was referred to in the introduction involved 11 different brands and resulted in 8 FDA recalls. Natural Life Pet Products, ANF, Inc., Elm Pet Foods, Kroger Company, and Sunshine Mill's Inc. all issued recalls for their dry dog food products due to the potential to be contaminated with excess Vitamin D. Since Sunshine Mill's Inc. was linked to all of these recalls, the synthesized data represented 1 recall for all of the companies and their respective products involved. In contrast, the recalls issued by each company were posted separately on the FDA website, and thus the raw data represented 8 FDA recalls.

***Nomenclature***

For finished dog and cat food products, the food categories were by physical consistency (dry, canned, semi-moist, and raw). For the purposes of this research, dry foods contained less than 11 percent water, semi-moist foods between 25 and 35 percent, and canned food between 60 and 87 percent water (Paulelli *et al.*, 2018). The term *treats*

included dental chews and bone-like treats, animal appendages, soft chews, crunchy treats, animal bones & hooves, freeze-dried and jerky treats, and rawhide bones. The term *raw* referred to uncooked frozen and freeze-dried meat and poultry products.

## 2.3 Results

### *Recalls by Pet Food Products*

Five main pet food types were defined to categorize pet food recall events: Dry, Canned, Raw, Semi-moist, and Treats. These types were based on food categorization systems common in animal science and food science literature. Table 2.1 lists the frequency of pet food recall events from 2007-2019. The differences between the raw and synthesized data were used in order to evaluate the level of supply chain complexity for each pet food category. The raw data represents the total number of recalls whereas the synthesized data accounts for different brand names that were recalled due to a common contract manufacturer and extended recalls. Thus, the dry and canned food had more complex supply chains since the percentage difference between the raw and synthesized data was greater compared to the other pet food product categories. However, the most frequent pet food products recalled overall were treats and raw pet food.

**Table 2.1 Number of Raw and Synthesized Pet Food Recalls by Food Type, 2007-2019**

| Pet Food Type | Raw Data Recall Frequency | Synthesized Data Recall Frequency | Percent Difference (%) |
|---|---|---|---|
| Dry | 69[a] | 28 | 59 |
| Canned | 38[c] | 20 | 47 |
| Raw | 75[b] | 60 | 20 |
| Semi-Moist | 1 | 1 | 0 |
| Treats | 88[abc] | 53 | 40 |

[a] Four recall events involved dry and treat pet food products
[b] One recall event involved raw and treat pet food products
[c] Two recall events involved canned and treat pet food products
Note: Raw data represents how the recalls were presented in the FDA "Enforcement Reports" and "Recalls, Market Withdrawals, and Safety Alerts." Synthesized data

combines the recalls that were an extension of a previous recall, attributed to the same contract manufacturer, or due to cross-contamination within the supply-chain.

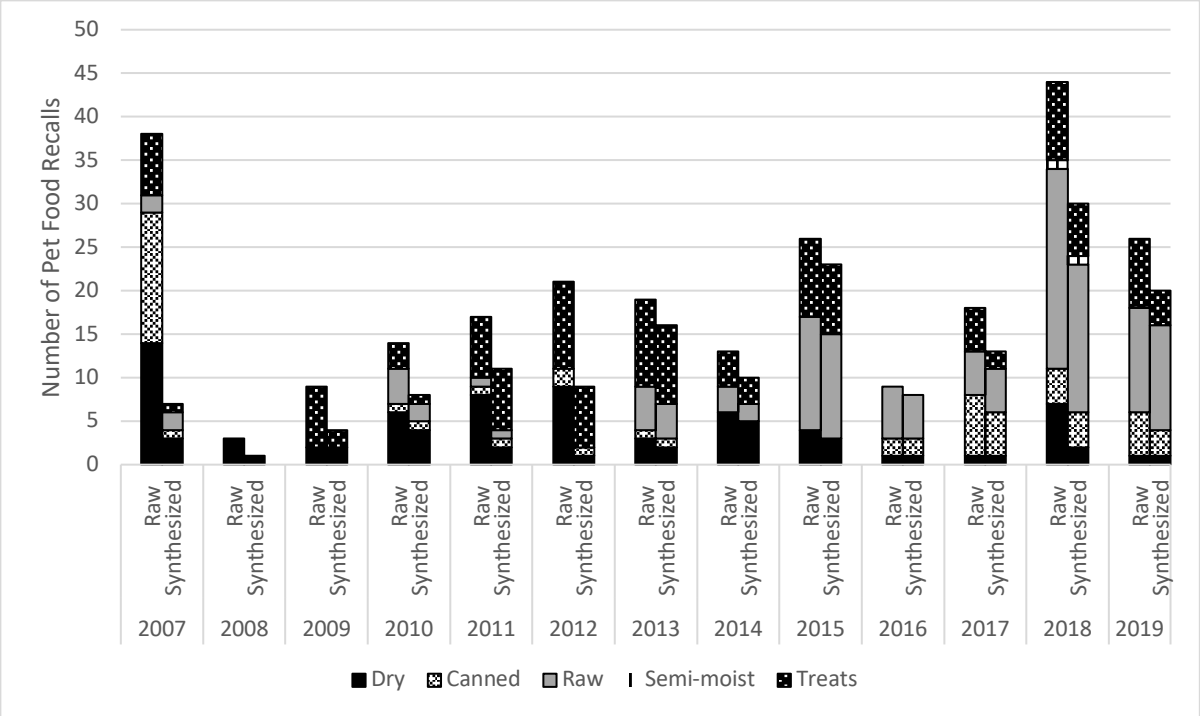



**Figure 2.3 Pet Food Recall Events by Pet Food Type and Year, 2007-2019**

The pet food types were plotted over time to gain further insight into the general increase in the number of pet food recalls and identify the level of supply chain complexity by pet food type (Figure 2.3). The first discernable recall occurred in March 2007 when Menu Foods, Inc. announced it was recalling over 90 brands of adulterated cat and dog food, and eleven other manufacturers subsequently announced their own pet food recalls (Fox and Kenagy, 2015). One of the most paramount factors in this recall was the large involvement of multiple major pet food manufacturers. These manufacturers made up approximately 98 percent of the pet food manufactured and sold in the United States and therefore the size of this recall was unprecedented (PFI, 2020). The decrease between the raw and synthesized data in 2007 illustrated that the recall

impacted multiple pet food product categories, specifically dry, canned, and treat products.

In the same year, dry dog food produced at a single manufacturing plant in Pennsylvania was identified as the source of a multistate outbreak of *Salmonella* enterica serotype Schwarzengrund. While the first two recalls for this outbreak were undetectable in 2007 due to the large recall for melamine contaminated dry pet products, the recalls for dry products in 2008 were exclusively due to this outbreak (CDC, 2008b). While the synthesized and raw data recalls in 2007 only included two different dry food products and 1 brand, the recalls in 2008 consisted of 46 different dry products and 10 different brands.

Recalls in 2009 for pet treats were greatly attributed to peanut products that were adulterated with *Salmonella* serotype Typhimurium. The peanut butter and peanut paste were produced by a single manufacturing facility in Texas and were used in 18 different types of pet treat products, contaminated 5 different brands, and resulted in 5 FDA recalls. (CDC, 2008a).

Aflatoxin levels that exceeded FDA's action levels were detected in 7 brands of dry dog food in 2011. A single supplier and manufacturer were linked to the contaminated dry dog food products. The drop between the raw and synthesized data for dry pet food in 2011 supported the high-level of supply chain complexity that was observed as the recall unfolded. A total of 6 FDA recalls were initiated and 18 different products were affected.

In 2012, epidemiologic, laboratory, and regulatory investigations linked dry dog food to the *Salmonella* Infantis outbreak. The source of this outbreak was a single production facility in South Carolina and resulted in recalling 47 different types of dry dog food and

impacting 14 different brands (CDC, 2012). The complexity of this recall was further represented by the sharp decline in dry dog food recalls in 2012 between the raw and synthesized data.

The combination of two major recalls in 2013 for pet treat products contaminated with *Salmonella* resulted in a slight decrease in pet treat recalls between the raw and synthesized data. While these were two unrelated events, each recall was associated with a single manufacturing facility, and resulted in recalling over 55 different pet treat products and affecting over 5 different brands.

In December 2018, nine dog food companies recalled dry pet products due to elevated levels of vitamin D (CVM, 2018a). This recall was linked to a common contract manufacturer and resulted in 7 FDA recalls and affected 9 different types of dry products and 11 different brands. This recall was identified by the decrease in dry pet products between the raw and synthesized data in 2018. Subsequently, 33 varieties of canned dog food products were recalled in 2019 due to elevated levels of Vitamin D (CVM, 2019a). This recall resulted in 3 FDA recalls and affected 2 different brands and was represented by the distinct decline in canned products between the raw and synthesized data in 2019.

The recalls for raw pet food remained relatively low until a large uptick in 2015. While there were 13 raw data and 12 synthesized recalls in 2015 for raw pet food, the event appears to be dispersed and not a systemic issue because all of these recalls were unrelated events and the majority of companies only issued one recall. This trend was illustrated by the minimal difference between raw and synthesized data in 2015. In comparison, there was a significant uptick in the number of recalls for raw pet food in 2018, as well as a noticeable decline between the raw and synthesized data. This decline was caused by the

cumulation of three unrelated recall events. Between 2018-2019, raw pet food products manufactured in Minnesota were linked to the outbreak strain of multi-drug resistant *Salmonella* spp. that was present in live turkeys and in many types of turkey products (CDC, 2019). While the outbreak was primarily linked to raw ground turkey in human food, the outbreak spilled over into the raw pet food supply chain when two children became sick from raw turkey pet food. In total, this recall event was linked to 2 different brands, 2 different raw pet food products, and resulted in 2 FDA recalls. The largest raw pet food recall in history occurred in 2018 when a raw pet food company had to recall over 1 million pounds of raw cat food due to the potential for *Listeria* spp. contamination. The contamination was linked to a single manufacturing facility and the recall included 1 brand, 6 products, and 3 FDA recalls. Lastly, another raw pet food manufacturer recalled their entire product line due to the potential for *Listeria* spp. contamination. The contamination was localized to a single manufacturing facility of this other manufacturer and impacted 3 brands and 26 products.

The difference between the raw and synthesized data for pet treats in 2019 was associated with the multidrug-resistant *Salmonellosis* infections linked to contact with pig ear dog treats. This outbreak involved multiple manufacturers and resulted in six dog treat recalls and affected four different brands in 2019.

The overall trends highlight the outlier recall events with complex supply chains in concurrence with a large quantity of pet food products. However, there were instances where a recall that affected multiple products and brands and recalled substantial quantities of pet food products was not discernable in Figure 2.3. In 2013, 30 varieties of dry pet food products were recalled due to the potential to be contaminated with

*Salmonella*. The products were made during a 10-day window at a single manufacturing site, and all brands and products were included in 1 FDA recall. In a similar scenario, 22 varieties of canned dog food were recalled in 2016 due to deficient levels of vitamins and minerals. This recall impacted 2 brands and all brands and products were included in 1 FDA recall. In both scenarios, the level of supply chain complexity in conjunction with more than $3 million pounds of pet food recalled posed a substantial threat to pet health despite having only one recall issued. Another significant event occurred in 2018 when over 20 million pounds of canned dog food were recalled due to pentobarbital contamination. The chemical contamination impacted 18 different canned products from 3 different brands were represented by one FDA recall.

While plotting the type of pet food against the number of recalls allowed for clear identification of the most frequent type of pet food recalls, the graph did not take into account the annual sales or the amount of product recalled according to the type of pet food. Table 2.2 presents the market sales data and the quantity of pet food product recalled by pet food type in 2018. While raw pet food had the most recalls in 2018, more quantities of dry and canned pet food were recalled. However, one large recall of 3,902,122 pounds accounted for the majority of dry pet food recalled in 2018. This trend was similar to the canned food recalls, where two recalls of 20,298,494 pounds and 23,681,364 pounds accounted for the majority of canned pet food recalled. In comparison, the median amount of raw pet food recalled suggested each raw food recall involved a smaller amount of product. Additionally, the dry pet food sales were more than 25 times higher compared to the raw and refrigerated pet food, while the canned pet food sales were approximately 13 times higher than the raw and refrigerated pet food

sales. While treats had the least number of pounds recalled, the average weight of a bag of pet treats was approximately 4.5 ounces compared to 17 ½ pound bag of dry dog food. Treats are also not a main component of a pet's diet, which may have accounted for the lower number of market sales for pet treats.

**Table 2.2 Annual Pet Food Sales and Amount of Pet Food Product Recalled in 2018**

| Type of Pet Food | Market Sales (million)[a] | Pet Food Recalled (lbs) | Median Pet Food Recalled (lbs) | Number of Synthesized Data Recalls |
|---|---|---|---|---|
| Dry | 7,727 | 3,925,231 | 1,962,616 | 3 |
| Canned | 3,992 | 45,138,781 | 20,298,494 | 4 |
| Raw and Refrigerated | 306 | 1,560,489 | 8,054 | 17 |
| Treats | 3,406 | 39,841 | 937 | 6 |

[a]US multi-outlet (52 weeks starting Aug 11, 2018) includes grocery, mass market, military, select clubs and dollar retailers (Semple, 2019b).

***Recalls by Health Hazard***

Recalls are initiated when a pet food product has the potential to be contaminated with a microbiological, biological, or physical hazard and poses serious adverse health effects to pets and/or human health. These health hazards were categorized into 3 main groups: chemical contamination, microbiological contamination, and foreign material contamination. Contamination from chemical or microbiological hazards can occur at any stage in the pet food supply chain- harvest, manufacture, storage, or transportation. Additionally, environmental, agricultural, industrial, or other sources can contaminate animal food and food ingredients (CVM, 2019c). There were 4 main types of chemical contaminations that were observed: "Naturally occurring" contaminants in the natural environment contaminated raw ingredients used in pet food; Vitamins or minerals became hazardous due to errors in product formulation; Toxic chemicals or drug residues were unintentionally added to pet foods; and pet food products were intentionally

contaminated for economically motivated reasons. Microbiological contamination included *Salmonella* spp. (a bacterium that may cause nausea, vomiting, abdominal cramps and fever) and *Listeria* spp. (a bacterium that may cause vomiting, nausea, persistent fever, muscles aches, and a stiff neck). Foreign material contamination occurred when plastic fragments, metal shavings, or other foreign materials were inadvertently added to pet food products.

*Salmonella* spp. contamination was the leading cause of pet food recall events between 2007 and 2019 (Table 2.3). The second leading cause was chemical contamination. Microbiological contamination, specifically *Salmonella* and *Listeria*, accounted for 66 percent (75 percent synthesized) of all recall events between 2007-2019 while chemical contamination had the largest difference between the raw and synthesized data. The recalls for chemical contamination can be further broken down into: 37% of raw data recalls (52% of synthesized recalls) were due to excess or deficient vitamins and minerals, 17% of raw data recalls (22% synthesized recalls) were for "naturally occurring" chemical hazards, 12% of raw data recalls (22% synthesized recalls) were for toxic chemicals or drug residues in pet food, and 46% of raw data recalls (4% synthesized recalls) were for the economically motivated melamine contamination in pet food.

**Table 2.3 Total Number of Raw and Synthesized Pet Food Recalls by Health Hazard, 2007-2019**

| Health Hazard Type | Raw Data Recall Frequency | Synthesized Data Recall Frequency | Percent Difference (%) |
|---|---|---|---|
| Chemical | 88 | 37 | 58 |
| Microbiological (Total) | 144 | 94 | 35 |
| *Salmonella* spp. | 145 | 94 | 35 |
| *Listeria* spp. | 39 | 32 | 2 |
| Foreign Material | 8 | 5 | 38 |

Note: Raw data represents how the recalls were presented in the FDA "Enforcement Reports" and "Recalls, Market Withdrawals, and Safety Alerts." Synthesized data

combines the recalls that were an extension of a previous recall, attributed to the same contract manufacturer, or due to cross-contamination within the supply-chain.

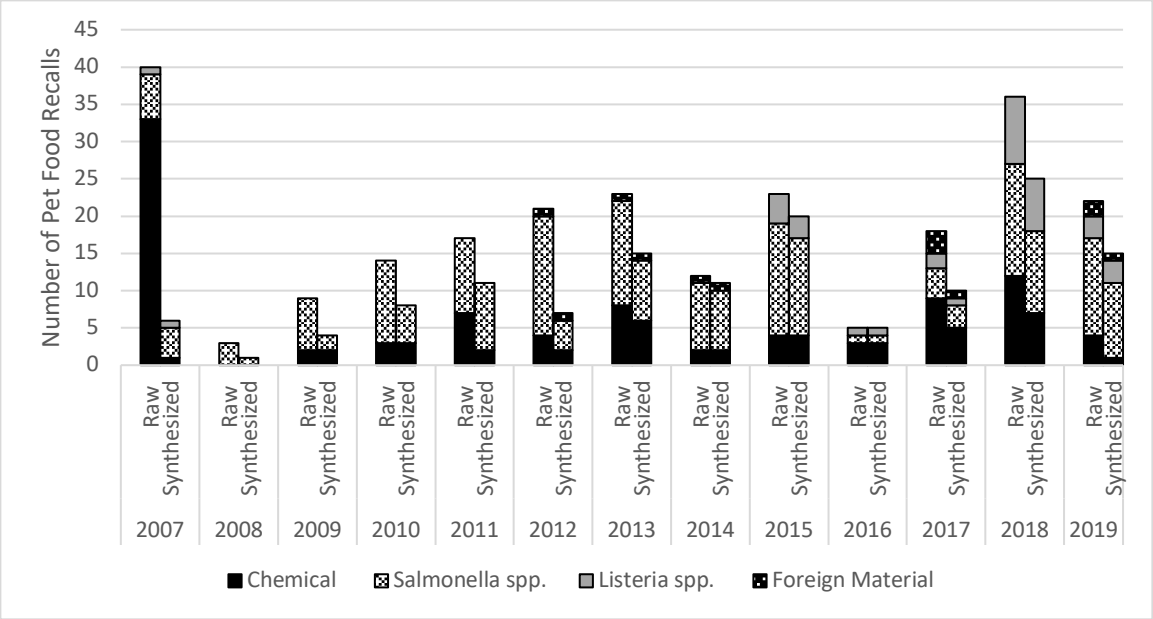



**Figure 2.4 Number of Pet Food Recalls by Type of Contamination and Year, 2007-2019**

The distinct differences between the raw and synthesized data illustrated how a contamination from a single supplier, manufacturer, or distributor can decimate the entire pet food supply chain (Figure 2.4). The types of contamination for the major recalls identified were either ingredient-driven or caused by supply-chain or environmental contamination. The ingredient-driven recalls included the chemical melamine contamination in 2007, *Salmonella* Typhimurium contamination in 2009, aflatoxin chemical contamination in 2011, and chemical elevated levels of vitamin D contamination recalls in 2018 and 2019. These ingredient-driven recalls were recognizable based on the sharp decline between the raw and synthesized data for each of these events. The recalls due to environmental contamination pertained to the *Salmonella* enterica serotype Schwarzengrund outbreak in 2007 and 2008, the *Salmonella* Infantis outbreak in 2012, *Salmonella* spp. in 2013, and the *Listeria* spp. contamination recall in 2018. The two outbreaks of multi-drug resistant *Salmonella* in 2018 and 2019 occurred

within the supply chain before it reached consumers. The trends between the raw and synthesized data for *Salmonella* spp. coincided with the pet food product trends found in Figure 2.3. In addition, Figure 2.4 was able to exhibit the *Salmonella* enterica serotype Schwarzengrund recalls in 2007 since the recalls were no longer overlapped with the chemical melamine contamination. In contrast to chemical and *Salmonella* spp. recalls that appeared to be mostly attributable to complex supply chains and outlier events, the number of *Listeria* spp. recalls appeared to increase steadily throughout the decade.

***Recalls by Notification Entity***

Notification of a potential health hazard in pet food was observed one of four ways: by a consumer complaint, the manufacturer, the State Department of Agriculture or the FDA. The consumer notified regulatory authorities through the Safety Reporting Portal or by calling the State's FDA Consumer Complaint Coordinators. The state Department of Agriculture and FDA identified potential health hazards during routine and non-routine inspections or by randomly testing pet food products from retail stores. Notifications by the company specifically pertained to recall events where the company detected a potential health hazard by themselves, without any external prompts, through their quality assurance program.

Consumers and State Department of Agriculture initiated the most recalls as observed by the greatest frequency of recalls between 2007 and 2019 (Table 2.4). However, the synthesized data suggested that the State Department of Agriculture identified the most recalls overall since there was a 28 percent decrease between the raw and synthesized data for the State Department of Agriculture compared to a 65 percent decrease for consumer complaints. Therefore, it appears that the recall investigations that

were initially identified by a consumer complaint where those that had a higher level of supply chain complexity because it involved multiple events. The manufacturer detected the health risk using their internal quality systems in only 8 percent of raw data recalls (28% synthesized).

**Table 2.4 Number of Raw and Synthesized Recalls by Notification Initiating Entity and Year, 2007-2019**

| Reporting Entity | Raw Data Frequency[a] | Synthesized Data Frequency[b] | Percent Difference (%) |
|---|---|---|---|
| Consumer Complaint | 85 | 30 | 65 |
| FDA[c] | 36 | 21 | 42 |
| Manufacturer | 18 | 13 | 28 |
| State | 82 | 52 | 37 |

[a] Notification entity information was not available for 38 recalls
[b] Notification entity information was not available for 32 recalls
[c] Food and Drug Administration
Note: Raw data represents how the recalls were presented in the FDA "Enforcement Reports" and "Recalls, Market Withdrawals, and Safety Alerts." Synthesized data combines the recalls that were an extension of a previous recall, attributed to the same contract manufacturer, or due to cross-contamination within the supply-chain.

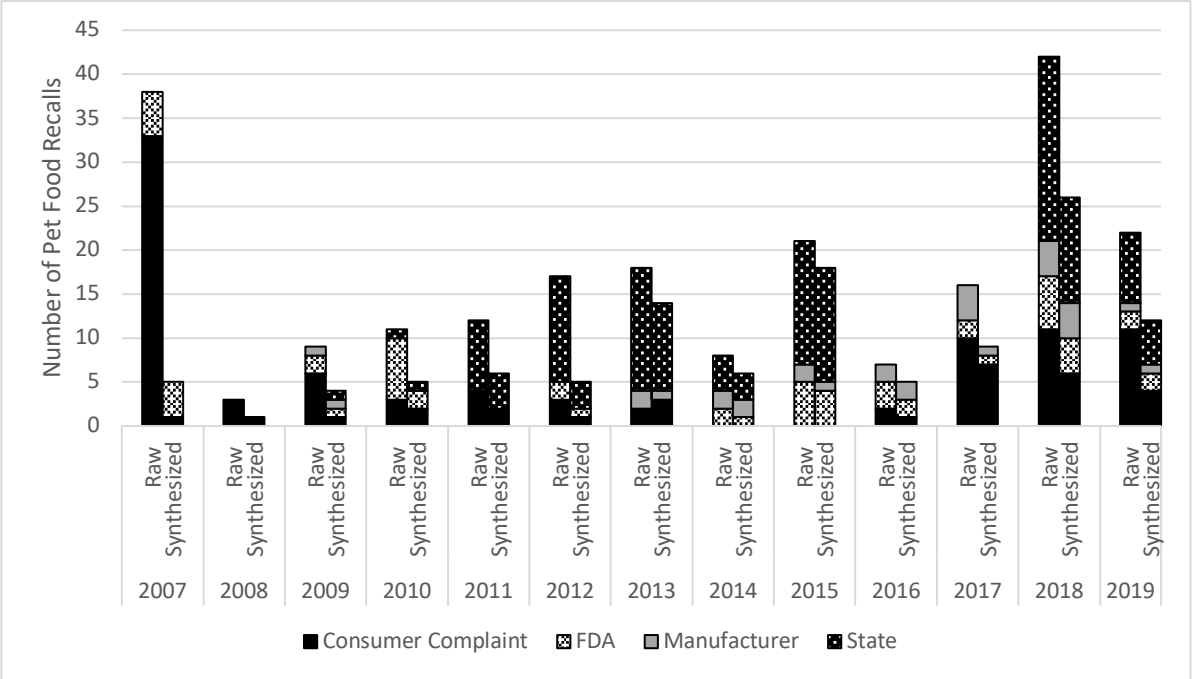



**Figure 2.5 Number of Pet Food Recalls by Notification Entity and Year, 2007-2019**

Consumer complaint-related FDA investigations were most prevalent in 2007, 2017, 2018, and 2019. The large amount of consumer complaints in 2007 was related to the Menu Foods recall for melamine-contaminated pet food. The extreme drop between the raw and synthesized data for consumer complaints in 2007 supported the extensive supply-chain complexity that was involved with this recall and coincided with prior observations of recall structures inferred from other data types (Figure 2.3 and Figure 2.4). In comparison, the consumer complaint-initiated FDA investigations in 2017 remained unchanged between the raw and synthesized data. In addition, no major outbreaks or recalls were identified during this time period. This suggested that the recalls identified by consumer complaints in 2017 were unrelated and thus had a low level of supply chain complexity. The increase in the number of consumer complaint-related recalls in 2018 were linked to the elevated levels of Vitamin D contamination in dry pet food, multi-drug resistant *Salmonella* spp. outbreak in raw pet food, and the pentobarbital contamination in canned pet food. In 2019, the consumer complaint-initiated FDA investigations were linked to multi-drug resistant *Salmonella* spp. outbreak related to pig ears and elevated levels of Vitamin D contamination in canned pet food. The decline between the raw and synthesized data in 2019 for consumer complaints supported the level of supply chain complexity involved in both of these recall events. While there weren't as many consumer complaints in 2008 and 2009 compared to other years, two significant recalls were associated with this time period, specifically the multistate outbreak of *Salmonella* enterica serotype Schwarzengrund in dry dog food and *Salmonella* serotype Typhimurium that pertained to peanut products in pet treats. Additionally, all of the consumer complaint-related FDA investigations were due to

human or pet illnesses and in some cases, deaths. Thus, differences between the raw and synthesized data for consumer complaints not only reflected the level of supply-chain complexity but also the magnitude in which consumers were negatively affected by the recall.

In contrast to the consumer complaint-related recalls that appeared to be mostly related to complex supply chains and outlier events, the number of recalls related to the State Department of Agriculture increased steadily beginning in 2011. The substantial decline between the raw and synthesized data in regard to State Department of Agriculture-related recalls were greatest in 2011, 2012, 2018, and 2019. The recalls in 2011 and 2012 were associated with the aflatoxin and *Salmonella* contamination in dry pet food. In 2011, Louisiana State Agriculture regulators performed a routine testing and detected elevated levels of aflatoxin in dry dog food. Subsequently, in 2012, Michigan officials detected *Salmonella* Infantis in an unopened retail bag of dry dog food during routine testing. The overall pattern between the raw and synthesized data in 2011 and 2012 corresponded with the trends observed in Figure 2.3 and Figure 2.4. Additionally, the high level of State Department of Agriculture involvement in 2018 and 2019 coincided with the increase in the number of raw food recalls, specifically *Salmonella* spp. and *Listeria* spp. in Figure 2.4. The large amount of State Department of Agriculture recalls in 2019 were attributed to multiple unrelated recall events, and specifically pertained to raw pet food and treats.

While the slight difference between the raw and synthesized data in 2013 suggested a low level of supply chain complexity, there was still a high-level of state Department of Agriculture recall involvement. These recalls were linked to *Salmonella*

contamination in pet treat products. A pet treat retail sample tested positive for *Salmonella* by the Colorado Department of Agriculture in 2013. Additional inspections by the FDA found all finished pet food products at the firm, as well as 48 out of 78 environmental samples collected during the inspection, contained *Salmonella*. In an unrelated recall, sampling conducted by the Michigan Department of Agriculture and the Georgia Department of Agriculture confirmed *Salmonella* in a cat pet treat in 2013.

While the level of FDA involvement in identifying recalls remained relatively steady throughout the decade, the company-initiated recalls remained relatively low and sporadic. Additionally, there was very little variation between the raw and synthesized data in regard to company-initiated recalls. This suggested company-initiated recalls had a lower level of supply chain complexity. However, this did not represent the overall severity and size of the recall. For instance, the recall regarding incorrect levels of vitamins and minerals in 2016 was discovered through a company's own testing. While the recall was limited to 2 brands and 1 FDA recall, the products were produced by a pet food company that sold 20 percent of the pet food in the United States, and thus the recall affected 22 different types of canned dog food products and resulted in recalling 4,670,962 million pounds of canned dog food.

***Recalls by Type of Pet Food and Contamination***

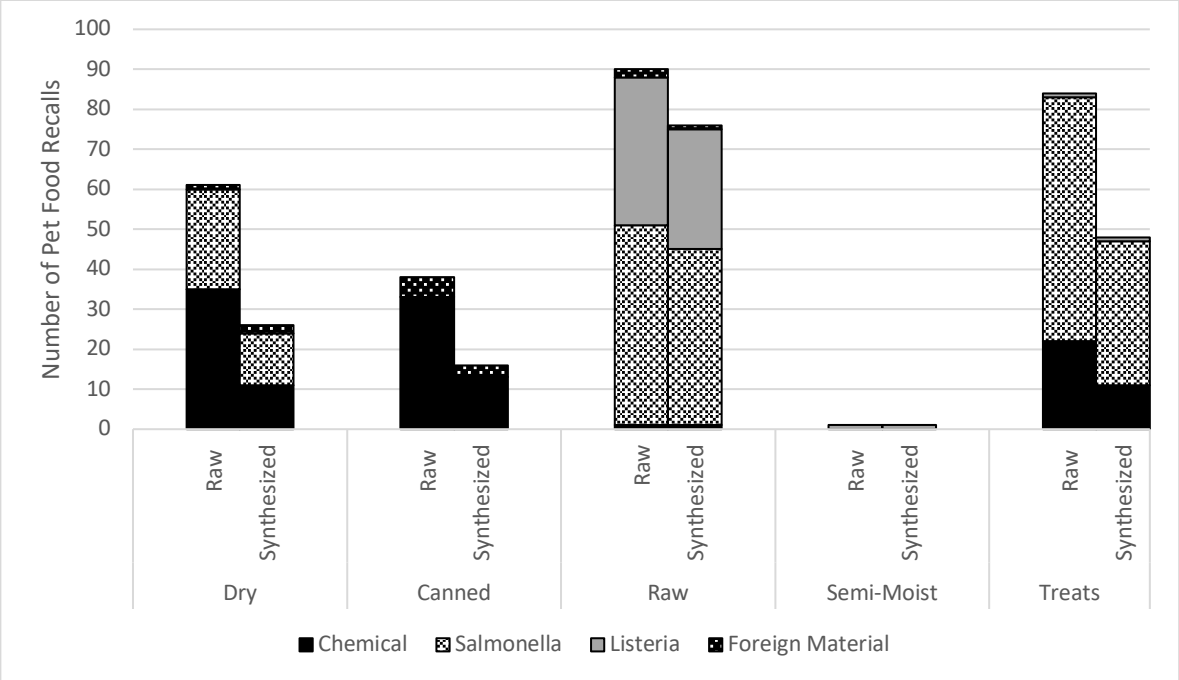



**Figure 2.6 Number of Pet Food Recalls by Type of Pet Food and Health Hazard from 2007-2019**

The relationships between pet food categories and health hazard were examined in order to determine the types of contamination associated with each pet food category from 2007-2019. For each of these pet food categories in Figure 2.6, except for canned products, the potential for *Salmonella* contamination was the number one reason products were recalled, accounting for 47 to 100 percent of product recalls in each category. The next most frequent reason was the potential for chemical contamination in dry and treat products, and *Listeria* spp. contamination in raw pet food products. Canned pet food products were highly associated with chemical contamination, which accounted for 80 percent of the recalls.

Chemical contamination showed a considerable reduction in the number of recalls between the raw and synthesized data for dry, canned, and treat categories. *Salmonella* contamination for dry and treat categories also showed a sharp decline between the raw and synthesized data, while the recalls for raw pet food remained largely unchanged. The

amount of dry pet food recalls for each type of health hazard were consistent with the outbreaks and large recalls previously discussed, specifically chemical melamine contamination in 2007, *Salmonella* enterica serotype Schwarzengrund outbreak in 2007 and 2008 ,the *Salmonella* Infantis outbreak in 2012, and chemical elevated levels of vitamin D contamination recalls in 2018 and 2019. The level of recalls for treats and *Salmonella* contamination were congruous with the *Salmonella* serotype Typhimurium outbreak in 2009 and the multi-drug resistant *Salmonella* outbreak in 2019.

While recalls linked to raw pet food were associated with lower quantities of product, this category had the highest number of recalls between 2007-2019. Once again, the raw pet food sales were considerably lower compared to the other pet food categories (see Table 2.2). Thus, while there were a higher number of raw pet food recalls overall, the potential health risk these recalls had on pets and consumers was much lower compared to dry, canned, and treat products.

## 2.4 Discussion

Previous studies have discussed raw pet food in terms of bacterial contamination, risk of foodborne illness, nutritional inadequacy, and the motivations for consumers to feed their pet a raw food diet (Mehlenbacher *et al.*, 2012). The presence and survival of *Salmonella* spp. has been investigated in pet treats, specifically pig ear treats, in the United States and other countries (Adley *et al.*, 2011). The prevalence and concentration of *Salmonella* spp., production process parameters, bacterial ecology and pet and human exposure to *Salmonella* spp. has been studied in dry and canned pet food (Lambertini *et al.*, 2016). However, very little research has been conducted regarding what factors have contributed to the overall increase in pet food recalls. Therefore, the objective of this

chapter was to determine the overall trends and level of supply chain complexity in pet food recalls among 2007-2019.

Four factors were considered when evaluating the general increase in pet food recalls from 2007-2012: 1) level of supply chain complexity; 2) magnitude of each recall based on the quantity of product recalled and market sales; 3) interrelationships between type of pet foods with the type of health hazard, and 4) notification entity and type of pet food; trends and patterns in pet food recalls over the past decade. By considering these factors, we propose that these are the potential driving forces behind the overall increase in pet food recalls.

The trends illustrated how contamination from a single supplier, manufacturer, or distributor can affect multiple brands and increase the number of pet food recalls. In total, there were 260 raw data and 171 synthesized data recalls from 2007-2019. This suggested that 34 percent of the pet food recalls involved more than one recall and/or complex supply chains. Thus, while using a co-packer increases the level of supply chain complexity and the number of pet food recalls, it also provides an opportunity to improve pet food safety and substantially reduce the number of pet food recalls since products from different brands are produced in the same manufacturing facility. In effect, one manufacturing facility needs to comply with FSMA regulations and implement a robust supply chain program compared to multiple manufacturing facilities for multiple different brands.

However, supply chain complexity wasn't the only factor that caused an increase in pet food recalls over the past decade. The quantity of pet food products recalled and level of supply chain complexity became a benchmark to evaluate the impact dry,

canned, raw, and treat pet food had on recalls. While treats and raw pet food had more recalls overall, dry and canned food products recalled the highest amount of pet food per recall event. Additionally, treats and raw pet food had a lower level of supply chain complexity. This suggested that treats and raw pet foods had smaller, more frequent recalls that together added up to a large amount of recalls whereas dry and canned pet foods had less frequent recalls that were substantially larger. Still, the quantity of treats and raw food recalled combined were noncomparable to even one dry or canned pet food recall. This was primarily because the outlier recalls for dry and canned pet food were manufactured by top brands in the pet food industry.

The major pet food recalls identified were able to be categorized into ingredient-driven or caused by supply-chain or environmental contamination. The ingredient-driven recalls were mostly associated with dry pet food, canned pet food, and chemical contamination. In addition, dry pet food had 35 raw data recalls total for chemical contamination, followed by 33 raw data recalls for canned pet food. This suggested that high-risk ingredients, such as vitamins and minerals, may require more preventive controls and additional regulatory oversight in order to protect the pet food industry from recalls and pets from potential health risks. Recalls relating to environmental contamination were associated with *Salmonella* spp. and *Listeria* spp. While the potential for *Salmonella* spp. contamination was the most frequent reason dry food products were recalled, the trends for microbiological contaminations in dry dog food changed overtime. Between 2008-2013, there were 3 major recalls related to dry dog food and environmental contamination with *Salmonella* spp. A notable shift occurred after this time frame that suggested dry pet food manufacturers developed and implemented

appropriate food safety systems that prevented the growth of *Salmonella* spp. and *Listeria* spp. in their manufacturing plants. The multi-drug resistant *Salmonella* spp. outbreak linked to pig ears was tied to supply-chain contamination. While investigations into some of the pig ears originated in Argentina and Brazil, pig ears sold in bulk bins became commingled with multiple sources, which prevented investigators from distinguishing the products. While there was only one occurrence of contamination within the pet food supply chain, this example exemplifies the importance of having traceability systems in place and how one contaminated pet treat can cause multiple recalls.

The outlier recalls were primarily identified by consumer complaints or state Department of Agriculture. Consumer complaint-initiated FDA investigations were linked to complex supply chains and notification of pet and human illnesses. While this did not explain the increase in pet food recalls, it did highlight the magnitude in which consumers and their pets are negatively affected by pet food recalls. The health hazards identified by State of Departments of Agriculture started steadily increasing in 2011 and continued to have a high-level of involvement. Specifically, the high level of State Department of Agriculture involvement in 2018 and 2019 was linked with raw pet food and treats. Since the FDA concentrates on high-risk categories, raw pet food may have been targeted since pet owners have an increased risk of contracting foodborne illnesses when handling or being exposed to raw pet food. Treats may have been targeted due to the recent outbreak of multi-drug resistant *Salmonella* spp. in pig ears.

A pet food recall can be a company-defining event; the company has to maintain consumer trust and brand image despite having to pull millions of pounds of pet food from marketplace shelves and spending millions of dollars on direct and indirect costs.

Additionally, dramatic changes in the types of pet food in the market today, driven by consumer demand, have resulted in a shift in food safety and regulatory concerns. Furthermore, the FSMA changed the approach pet food companies must take to address food safety concerns by requiring companies to identify and mitigate food safety risks and put focus on the entire supply chain (White *et al.*, 2018). Yet, despite these advancements, dry and canned pet food products are still facing challenges with chemical contamination, while treats and raw pet food continue to be vulnerable to microbiological contamination. Therefore, further investigation needs to be conducted on the impact regulatory oversight has on pet food recalls as well as what methods can be employed to reduce the number of pet food recalls associated with different types of pet food products.

# Chapter III: Regulatory Impact on Pet Food Recalls

## 3.1 Introduction

The primary purpose of regulatory oversight is to determine whether pet food facilities and pet food products comply with federal and state regulations. Historically, FDA's oversight on pet food manufacturing has been limited. While pet food manufacturers have always been required to market safe products under the Federal Food, Drug, and Cosmetic Act of 1938, the Food Safety Modernization Act (FSMA) shifted the emphasis on food safety from correction to prevention of foodborne illness. Thus, FSMA provides a much-needed regulatory framework for a preventive approach to pet food safety.

Today's pet food safety programs must be prevention-based and employ practices such as applying advanced technologies, adhering to strict testing protocols, practicing zero-tolerance for *Salmonella* and continuous monitoring throughout the manufacturing process (Enright, 2017). The hazard analysis and risk-based preventive controls require each pet food manufacturer to identify known or foreseeable hazards (physical, chemical and biological) associated with the type of pet food products they produce, address the probability of a hazard occurring in a specific type of pet food, evaluate the severity of its effect on animal and human health should exposure to the hazard occur, and implement appropriate controls to mitigate them if a preventive control is needed (Enright, 2017; Evanson *et al.*, 2019). The level of severity of the illness or injury if the hazard were to occur is evaluated based on the susceptibility of the pet to the illness or injury (i.e. dogs are more susceptible to aflatoxin than most other species), susceptibility of humans to the illness or injury (i.e. individuals may be more susceptible to certain foodborne illnesses

from handling pathogen contaminated pet food), potential magnitude of the illness or injury (i.e. how long a pet may be sick), and possible secondary illnesses from the hazard (i.e. kidney damage) (FDA, 2016). Facilities must also monitor their preventive controls, conduct verification activities to ensure the preventive controls are effective, take appropriate corrective actions and maintain records documenting these actions.

State and FDA regulators routinely inspect pet food manufacturing facilities to analyze pet food hazards, take environmental and food samples, ensure appropriate documentation is in place, and a food safety plan is written and followed (Enright, 2017). Since not all pet food hazards carry the same risk for adverse consequences to animal or human health, the FDA uses risk-based decision-making approaches to determine which animal food hazards to focus on for inspections or enforcement and directs its regulatory resources to the pet food hazards that are a risk to animal and public health (CVM, 2019c).

Despite the innovations in regulations, there have been instances where the implementation of pet food safety plans and the Preventive Control (PC) requirements proved to be ineffective at preventing contaminated pet food from entering the marketplace and reducing pet food recalls. In 2018 and 2019, toxic levels of vitamin D in Sunshine Mill's dry pet foods and Hill's Pet Nutrition canned pet foods could have been prevented had both companies followed their own food safety plans. In the case of Sunshine Mill's recall, an ordering error by a Sunshine Mill's employee caused the wrong Vitamin D ingredient to be shipped to the company, while a manufacturing error on the part of Hill's Pet Nutrition's Vitamin Premix supplier was the cause of excessive levels of vitamin D in their canned pet food. Although the sources of elevated vitamin D

were different in these two situations, the course of events were similar: Both of these manufacturers received an ingredient that was substantially higher in Vitamin D than specified; Both had written food safety procedures in place for receiving raw ingredients, and these procedures mandated testing for vitamin D concentration. Neither manufacturer carried out laboratory analysis mandated in their written food safety plan; and had both manufacturers followed their written procedures, the incorrect vitamin D ingredient concentration would have been detected (Entis, 2019). Therefore, both manufacturers could have saved millions of dollars on both direct and indirect costs related to having to recall the affected pet food products.

Routine preventive control inspections of larger pet food facilities under FSMA regulations began in October 2018. During FDA's 2019 fiscal year (FY19), starting at the same time, pet food businesses of all sizes were subject to routine current good manufacturing practice (CGMP) inspections under FSMA. CGMPs had the largest number of animal feed and pet food inspections in FY19, at 516, with 96 percent conducted by states. Only 15 percent of CGMP inspections in FY19 returned violations. However, while only 167 Preventive Control (PC) inspections were conducted for large animal feed and pet food businesses, 20 percent returned violations (Phillips-Donaldson, 2018).

The year 2015 was used as a benchmark to evaluate the cultural shift in enforcement actions since this is when the PC Rule for animal food was finalized. Other factors played a role in the number of pet food recalls during this period as well: accredited 3rd party certification, food supplier verification programs for animals, sanitation transportation for animal food rule, new intervention technologies to reduce

food contamination, and increased attention to imported pet food. In addition, changes in consumer behavior, pet food marketing strategies, and changes in pet food supply chains and distribution during this time period mostly likely had an impact as well. Therefore, identifying a direct causation between the preventive controls rule and number of pet food recalls is difficult. While it is too early and complex to evaluate the overall impact the new preventive control requirements have on pet food recalls, it is possible to determine whether the average number of recalls decreased after the PC rule was finalized in 2015. The primary objective of this chapter is to identify the overall trends in recalls before and after the PC rule was finalized and identify the impact regulatory oversight and zero tolerance guidelines for *Salmonella* spp. has on pet food recalls. The average number of annual recalls between 2010-2014 and 2015-2019 were compared by type of pet food, health hazard, and notification entity. The impact regulatory oversight has had on pet food recalls is evaluated by identifying what type of notification entity is most associated with different types of pet food products and health hazards. Pet food recalls are also further classified as "Surveillance" and "Compliance" testing based on how the regulatory agency identified the health hazards. Finally, the impact zero-tolerance for *Salmonella* guidelines set forth by the FDA has on pet food recalls is evaluated by comparing the total and average number of pet food recalls for *Salmonella* from 2009-2013 with 2014-2018 by pet food type.

## 3.2 Methods

### *FDA Recall Data*

Data collection was performed in accordance with the methods section 2.2 in Chapter 2.

### *Statistics*

All data analysis was performed using descriptive statistics on the raw data in this chapter. The mean number of recalls between 2010-2014 and 2015-2019 by types of pet food, notification entity, and health hazard were compared by using a two-tailed paired t-test. The level of significance was set at 0.05. Statistical analyses were performed using Microsoft Excel 2020 software.

***Nomenclature***

For the purposes of this chapter, the term *data* exclusively refers to raw data recalls as supply chain complexity was not assessed in this chapter.

## 3.3 Results

***Regulatory Impact by Type of Pet Food***

The number of pet food recalls for dry, canned, and raw pet food and treats were analyzed before and after the PC rule was implemented. Data revealed a statistically significant increase in the total number of recalls for raw pet food between 2010-2014 and 2015-2019 (Table 3.1). Specifically, the average number of raw food recalls increased by 6 times the amount when comparing these two time periods.

The type of pet treats recalled during these time periods included dental chews and bone-like treats, animal appendages, soft chews, crunchy treats, animal bones & hooves, and freeze-dried and jerky treats. Since a wide variety of treats were recalled, there was no indication that a specific type of pet treat was associated with the large amount of recalls. This also suggested that the preventive controls rule did not have a positive effect on reducing the number of recalls for a particular type of pet treat. Alternatively, the Foreign Supplier Verification Program or the Sanitation Transportation

for Animal Food Rule may be more effective at reducing the number of pet food recalls related to treats.

The compliance date for the preventive controls rule for large pet food manufacturers, including Nestle Purina, J.M. Smucker, Mars Petcare, Hill's Pet Nutrition, Diamond Pet Foods, Blue Buffalo, Sunshine Mills, and Proctor and Gamble, was implemented in 2016. All of these pet food companies produce dry and/or canned pet foods and all had recalls during the 2010-2019 period. Specifically, these companies accounted for 40 percent of the canned pet food and 81 percent of dry pet food recalls between 2010-2014, and 67 percent of the canned pet food and 60 percent of the dry pet food recalls between 2015-2019. This observation indicates that the number of pet food recalls for major canned pet food manufacturers increased by 27 percent, while the recalls related to major dry pet food manufacturers decreased by 14 percent. While it is likely that the preventive controls rule played some role in the decline in the number of dry pet food recalls, the decrease was not significant. Overall, the average number of recalls decreased by 50 percent for dry pet food and increased by 75 percent for canned pet food between the two periods. Additionally, this data indicated the preventive controls rule, as well as the implementation of FSMA, has not been effective at reducing the number of pet food recalls for canned pet food.

**Table 3.1 Total and Average Number Pet Food Recalls by Food Type Before and After the PC[a] Rule was Finalized, 2010-2019**

| Type of Pet Food | Range of Years | | | |
|---|---|---|---|---|
| | 2010-2014 | | 2015-2019 | |
| | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] |
| Dry | 32 | 6 (2.3) | 18 | 3 (2.7) |
| Canned | 5 | 1(0.71) | 18 | 4 (2.7) |
| Raw | 13 | 2 (2.1) | 60 | 12 (7.2) |
| Treats | 34 | 7 (3.3) | 36 | 7 (4.6) |

[a] Preventive Control
[b] Standard Deviation
P value: Differences across the means by pet food type between 2010-2014 and 2015-2019 had P-values ≥0.05, except for raw pet food (P = 0.02).

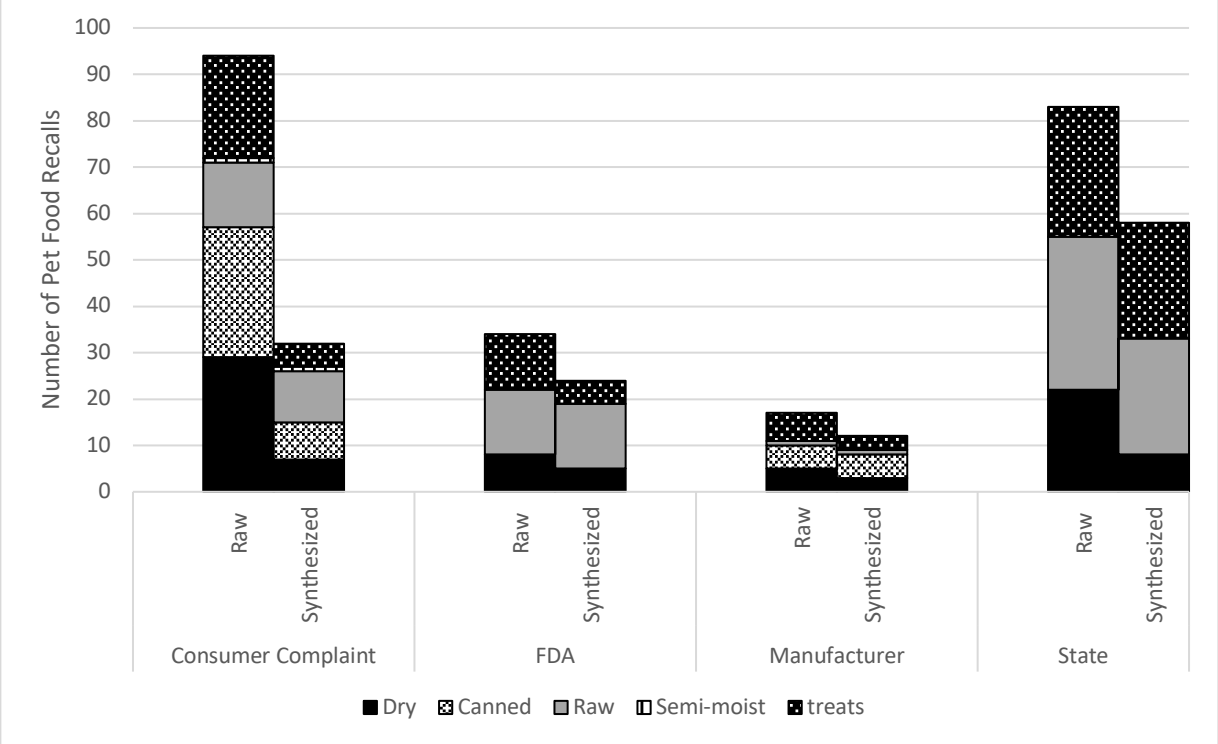



**Figure 3.1 Number of Pet Food Recalls by Notification Entity and Pet Food Type, 2007-2019**

The relationships between notification entity and type of pet food were examined in order to determine the types of notification entity associated with each pet food category from 2007-2019. Consumer complaint and State Department of Agriculture-

related recalls were both highly associated with dry and raw pet food and treats. The number of dry pet food and treat recalls were comparable for both of these entities, with 31 percent and 23 percent of consumer-related recalls and 27 percent and 31 percent of State Department of Agriculture related recalls. However, the difference in distribution of raw pet food products between these two entities was substantial. Specifically, raw pet food recalls associated with consumer complaints accounted for 15 percent of the recalls, while 41 percent of raw pet food recalls were related to the State Department of Agriculture. The FDA-related recalls were linked to dry and raw pet food and treats, with raw pet food accounting for 41 percent of the FDA-related recalls followed by treats with 35 percent and dry pet food with 24 percent. This suggested that the FDA and State Department of Agriculture allocated their resources toward identifying health risks in raw and dry pet food and treats. Canned pet food was initially identified by consumers or by the manufacturer, with 85 percent of canned pet food recalls related to consumer complaints. Overall, manufacturer-related recalls were the least associated with all types of pet food.

***Regulatory Impact by Health Hazard***

Nutrient deficiencies or toxicities were prevalent in the pet food recall data collected from the FDA Enforcement Reports and Reportable Food Registry. The Association of American Feed Control Officials (AAFCO) Dog and Cat Food Nutrient Profiles were designed to establish minimum and maximum nutrient concentrations for dog and cat foods. These concentrations were established based on previous research and continue to be reassessed as new research is presented. The minimum concentration for Vitamin D in dog food is 500 IU/kg, while the maximum is 3,000 IU/kg (AAFCO, 2014).

Thiamine has no established maximum for dog pet food but has a minimum of 2.25 mg/kg. In regard to cat food, the minimum amount of recommended of Vitamin D is 280 IU/kg, while the maximum is 30,080 IU/kg (AAFCO, 2014). Similar to dog food, there is no maximum for thiamine concentration in cat food, while the minimum concentration is 5.6 mg/kg. According to the formula guidelines set forth by AAFCO pet foods marketed as "complete and balanced" must either meet one of AAFCO's dog or cat food nutrient profiles or pass a feeding trial using AAFCO procedures. In order to be "formulated to meet AAFO nutrient profiles," the pet food only needs to meet those specific nutrient requirements at the time of formulation. There is no requirement in place that nutrient profiles must be met post-production. Thus, pet food companies and manufacturers must assume a greater responsibility to ensure a pet food is truly "complete and balance."

Many nutrient deficiency or toxicity hazards occurred due to incorrect levels of nutrients in incoming raw materials or ingredients, incorrect nutrient recipe or formulation, errors in manufacturing, or a combination of these. Preventive controls for this type of chemical hazard could include ensuring the pet food manufacturing equipment is capable of producing a homogenous mixture, understanding of the ingredient nutrient content bioavailability as well as interactions with other dietary components (White *et al.*, 2018), and analyzing the nutrient pre-mix to ensure it meets the company's specifications (FDA, 2018). Additionally, elevated levels of beef thyroid hormone were observed in 18 percent of all pet food recalls. Pet food manufactured with thyroid gland tissue obtained from beef slaughter establishments could be the potential source of thyroid tissue that caused elevated levels of thyroid hormone in the pet food.

Therefore, pet food and treat manufacturers should determine whether their beef supplier uses thyroid tissue in their product (FDA, 2018).

Pet food recalls pertaining to "naturally occurring" and drug residue chemical contaminations occurred less frequently compared to nutrient deficiencies or toxicities over the past decade. The FDA control limit for raw mycotoxins in grains is 20 ppb while there are no established limits for safe levels of pentobarbital in pet food. Elevated levels of aflatoxin in dry dog food was the only type of "naturally occurring" chemical hazard identified in the pet food recall data. Preventive controls for "naturally occurring" chemical hazards include proper drying and maintaining appropriate storage conditions, especially moisture, to prevent the growth of mold and production of mycotoxins in storage (FDA, 2016). Additionally, a preventive control for laboratory analysis or on-site rapid testing method for aflatoxin in high-risk ingredients, such as corn, may be needed depending on the weather conditions and year. Pentobarbital contamination was the primary drug-residue chemical hazard identified in the pet food recall data. Pentobarbital is a component of euthanasia solutions that are used to humanely kill animals however, pentobarbital is not used in the slaughter of animals for human or animal consumption (FDA, 2018). Pentobarbital was introduced into the pet food through a combination of ingredient containing residues (ingredient-related chemical hazard) and drug carryover and cross- contamination (process-related chemical hazard) during manufacturing. Preventive controls include preventing the accidental addition of animal drugs to the wrong animal and proper equipment cleanout procedures throughout manufacturing (FDA, 2018).

Pet food recalls associated with *Salmonella* spp. and *Listeria* spp. health hazards were primarily ingredient-related or caused by environmental contamination. The prevalence of environmental pathogens in the manufacturing environment can be influenced by the raw materials used in the process, the type of process, and the hygienic practices applied to keep the processing area clean and sanitized. For instance, a manufacturing plant that produces, processes, packs, and holds raw pet food may have cold, moist conditions that are conducive to the development of a niche where *Listeria monocytogenes* can become established and contaminate animal food-contact surface and finished pet food (FDA, 2018). The Preventive Control rule stipulates that sanitation controls include procedures, practices, and processes to ensure that the manufacturing plant is maintained in a sanitary condition adequate to significantly minimize or prevent environmental pathogens. This includes environmental monitoring for pathogens such as *Salmonella* spp. and *Listeria* spp. by collecting and testing environmental samples (FDA, 2018). In addition to environmental and surface contamination problems, strains of *Salmonella* may contaminate internal tissues and this may vary by type of *Salmonella* and food animal species (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019). Preventive controls for ingredient-related microbiological contaminations may include employing the use of lethality treatments to eliminate or reduce pathogens in the pet food product, such as thermal processing, high pressure processing, or irradiation (FDA, 2018).

Foreign material recalls were the least prevalent type of health hazard identified in the pet food recall data. Foreign material contamination occurred when plastic fragments and metal shavings were inadvertently added to pet food products or the final pet food

product did not meet specification requirements. Metal-to-metal contact during pet food processing can cause metal fragments to break off during mechanical cutting and blending operations. Preventive controls for a metal foreign material hazard include physical separation techniques (i.e. magnets, sieves, or screens), electronic or x-ray metal detection devices, and by regularly visually inspecting at-risk equipment for signs of wear and tear. Cracked and broken plastic tools and equipment (i.e. scoops, screens, sieves) can cause hard plastic fragments to be introduced into pet food at any time during processing. Preventive controls that can be implemented to significantly minimize or prevent hard plastics in pet food include visually inspection pet food and using physical separation techniques. Incorrect physical, mechanical, and other characteristics of pet food (i.e. particles size, hardness, surface roughness, digestibility) can cause illness or injury in pets. Preventive controls for achieving a desired particle size could include using a screen during the manufacturing process (FDA, 2018).

The different types of health hazards before and after the PC rule was finalized were compared in Table 3.2. Data revealed a statistically significant increase between 2010-2014 and 2015-2019 for *Listeria* spp. contamination, while health hazards from *Salmonella* spp., chemical contamination, and foreign material continued to trend upward. The number of pet food recalls related to *Salmonella* contamination increased by 13 percent between the two time periods while chemical contamination increased by 25 percent. However, *Salmonella* spp. had the highest total and average number of recalls per year for both time periods. The average and total number of pet food recalls for chemical contamination were consistent with the number of recalls for canned and dry pet food in Table 3.1. While *Listeria* spp. showed the largest increase in the number of

pet food recalls, the FDA and state Department of Health did not start testing for *Listeria* spp. until 2015. The average number of recalls per year for foreign material contamination remained consistent between 2010-2014 and 2015-2019. Overall, despite the implementation of preventive controls to reduce the likelihood of contamination, the average and total number of recalls by health hazard continued to increase after the Preventive Control rule was implemented in 2015.

**Table 3.2 Total and Average Number of Pet Food Recall Events by Health Hazard Before and After the PC[a] Rule was Finalized, 2010-2019**

| Type of Health Hazard | Range of Years | | | |
|---|---|---|---|---|
| | 2010-2014 | | 2015-2019 | |
| | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] |
| Chemical | 24 | 5 (2.6) | 32 | 6 (3.9) |
| *Salmonella* spp. | 60 | 12 (2.9) | 68[c] | 13 (8.6) |
| *Listeria* spp. | 0 | 0 (0) | 39[c] | 8 (5.6) |
| Foreign Material | 3 | 1(0.55) | 5 | 1 (1.4) |

[a] Preventive Control
[b] Standard Deviation
[c] Twenty pet food recalls involved both *Salmonella* spp. and *Listeria* spp. contamination
P value: Differences across the means by type of health hazard between 2010-2014 and 2015-2019 had P-values ≥0.05, except for *Listeria* spp. (P = 0.036).

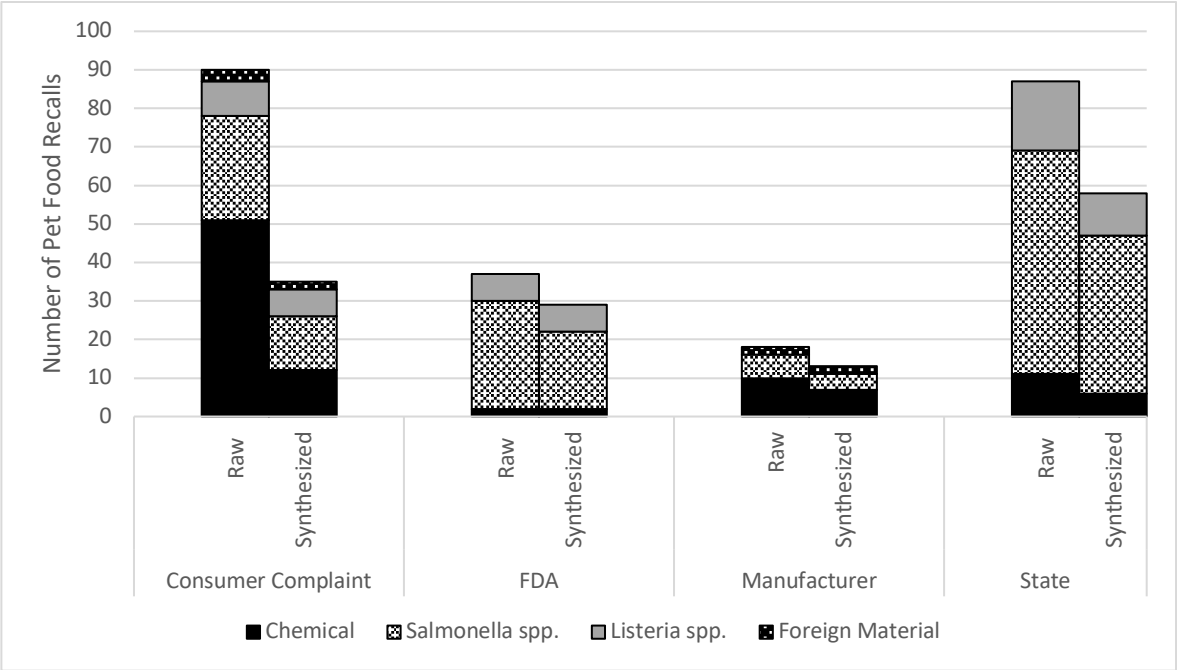



**Figure 3.2. Number of Pet Food Recalls by Notification Entity and Type of Health Hazard, 2007-2019**

The relationships between notification entity and type of health hazard were examined in order to determine what types of notification entity were most associated with different types of health hazards from 2007-2019 (Figure 3.2).

In regard to the pet food recalls linked to *Salmonella* spp. health hazard, 40 percent were related to the State Department of Agriculture, 19 percent were related to the FDA, 19 percent were identified by consumer complaints, and only 4 percent were identified by the manufacturer through their quality assurance program. The breakdown of the pet food recalls linked to *Listeria* spp. health hazard was comparable with 46 percent of recalls related to the State Department of Agriculture, 18 percent related to the FDA, 25 percent were identified by consumer complaints, and none were identified by the manufacturer. Therefore, the FDA and State Department of Agriculture identified 59 percent of the recalls related to *Salmonella* spp. and 64 percent related to *Listeria* spp.. This suggested that the FDA and State Department of Agriculture concentrated their

resources on testing for *Salmonella* spp. and *Listeria* spp. in pet food. The number of FDA and State Department of Agriculture recalls linked to dry and raw pet food and treats in Figure 3.1 was consistent with the number of FDA and State Department of Agriculture recalls related to *Salmonella* spp., *Listeria* spp., and chemical contamination in Figure 3.2. Together, this suggested that the FDA and State Department of Agriculture primarily allocated their resources towards testing dry and raw pet food and treats for microbiological contamination.

While consumers initially notified the FDA regarding a potential health risk, it was the FDA's responsibility to follow-up on the complaint by contacting the manufacturer and conducting facility investigations. Therefore, the FDA's high involvement in pet food recalls was overshadowed by the high number of recalls related to consumer complaints. Consumer's identified 58 percent of pet food recalls related to chemical contamination and 19 percent related to *Salmonella* spp. contamination. Additionally, since consumer complaints stemmed from observing illnesses in humans or pets, a substantially larger number of pets became ill from chemical contamination in pet food compared to humans who became infected with *Salmonellosis* from pet food.

The number of manufacturer-related recalls corroborated with dry, canned, raw, and treat recalls in this same notification entity in Figure 3.1. Once again, the manufacturer-related recalls were least associated with initially identifying a health hazard, accounting for only 8 percent of pet food recalls.

### *Regulatory Impact by Notification Entity*

A comparison of the pet food recall data by notification entity before and after the PC rule was finalized is presented in Table 3.3. The number of FDA-related recalls

increased by 39 percent while the State Department of Agriculture-related recalls only increased by 9 percent between 2010-2014 and 2015-2019. This suggested that the FDA and State Department of Agriculture increased regulatory oversight and identified more health hazards in pet food products after the PC rule was finalized. Additionally, the larger increase in FDA-related recalls suggested the PC rule had a greater impact on FDA regulatory oversight. While the FDA had a larger increase in the number of pet food recalls identified during the two time periods, the State Department of Agriculture identified over twice as many recalls.

The number of consumer complaint-initiated FDA investigations increased by 65 percent and the number of total recalls increased close to 3-fold. The total number of recalls related to consumer complaints were consistent with the total number of recalls related to chemical contamination in Table 3.2 and the combination of dry and canned pet food products in Table 3.1. Together, the increase in the total and average number of recalls for consumer complaint-related FDA investigations, dry and canned pet food products, and chemical contamination represented the major recalls that occurred between 2015-2019, specifically the Sunshine Mill's and Hill's Pet Nutrition recalls referred to in this Chapter's introduction. This trend was also consistent with high number of dry and canned foods related to consumer complaints in Figure 3.1 and the low number of chemical contaminations identified by the FDA and State Department of Agriculture in Figure 3.2. This suggested the implementation of the PC rule was not effective at reducing the number of recalls related to consumer complaints since the PC compliance date for large companies was in 2016 and the consumer complaint-related recalls were associated with large pet food manufacturers.

The manufacturer-related recalls increased by 69 percent between 2010-2014 and 2015- 2019. This suggested that the PC rule had a positive effect on manufacturers reviewing their quality control processes and performing routine self-audits. While the total and average number of manufacturer-related recalls had the lowest frequency of occurrence in both time periods, the average and total number of recalls became comparable to the FDA-related recalls during the 2015-2019 time period. This further supported the notion that pet food manufacturers are implementing and maintaining food safety plans.

**Table 3.3 Total and Average Number of Pet Food Recall Events by Notification Entity Before and After the PC[a] Rule was Finalized, 2010-2019**

| Notification Entity | Range of Years | | | |
|---|---|---|---|---|
| | 2010-2014 | | 2015-2019 | |
| | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] | Total Number of Recalls | Average Number of Recalls (per year) (SD)[b] |
| Consumer Complaint | 12 | 2 (1.5) | 34 | 7 (5.4) |
| FDA | 11 | 2 (2.9) | 18 | 4 (1.8) |
| Manufacturer | 4 | 1 (1.1) | 13 | 3 (1.3) |
| State | 39 | 8 (5.4) | 43 | 9 (9.1) |

[a] Preventive Control
[b] Standard Deviation
P value: Differences across the means by notification entity between 2010-2014 and 2015-2019 had P-values ≥0.05.

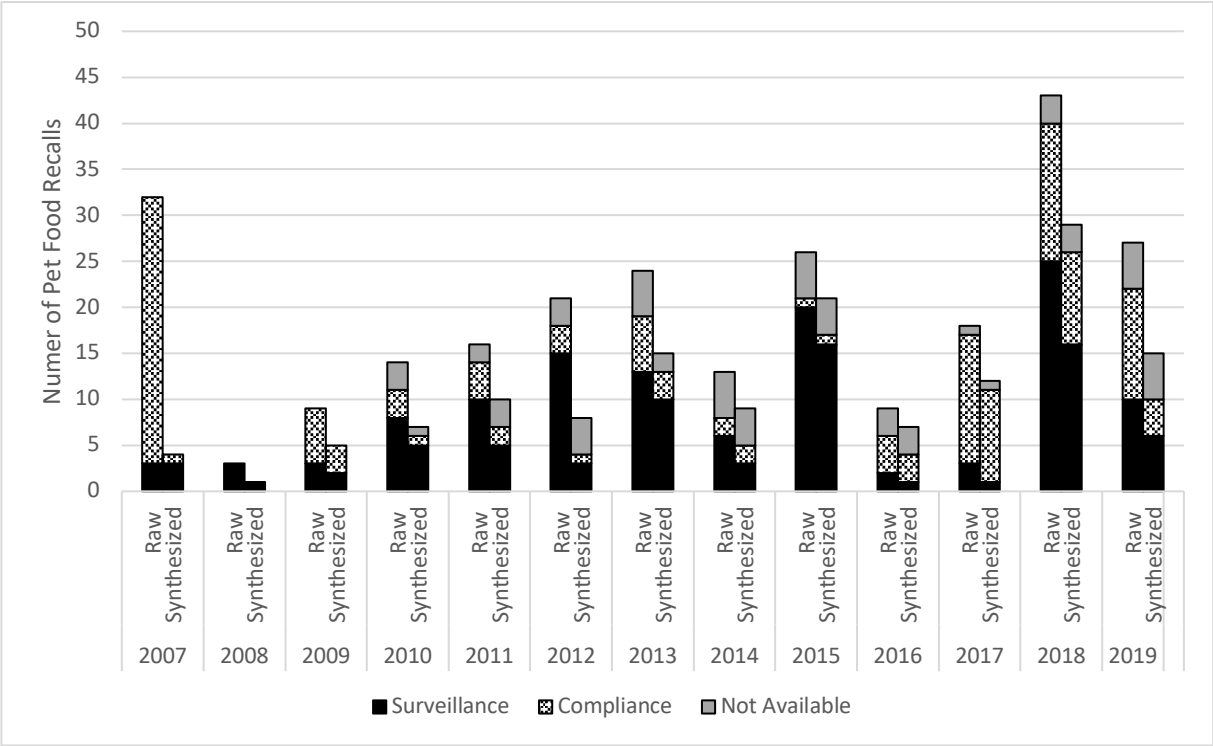



**Figure 3.3 Number of Pet Food Recalls by Inspection Type and Year, 2007-2019**

Surveillance inspections determine whether the pet food manufacturing operation is adequately controlled, while compliance inspections are used to document observations that could support enforcement actions against the manufacturer (CVM, 2019c). Thus, the FDA and State Department of Agriculture- related recalls were categorized into two main inspection categories: Surveillance and Compliance. Surveillance testing refers to testing that was conducted during regularly scheduled inspections and random retail testing while compliance testing refers to instances when a consumer-complaint or manufacturer identified a potential contamination and notified the proper regulatory authorities. The type of regulatory testing was plotted over for time in Figure 3.3 to determine the amount of pet food recalls related to surveillance and compliance testing and compare the number of recalls related to surveillance and compliance routing testing before and after the PC rule was finalized. Overall, more surveillance testing was

conducted compared to compliance testing among 2007-2019. Pet food recalls initiated by surveillance testing occurred 51 percent of the time, while recalls related to compliance occurred 35 percent of the time. This suggested that the FDA and State Department of Agriculture identified more health hazards compared to manufacturers and consumers.

Using the year ranges before and after the PC rule was finalized, the recalls that resulted from surveillance testing and inspections increased by 30 percent between 2010-2014 and 2015-2019, while recalls related to compliance testing and inspections increased by 61 percent. This suggested consumer-complaints and manufacturer-related pet food recalls increased twice as much compared to FDA and State Department of Agriculture-related recalls since the PC rule was finalized. However, there were still more surveillance recalls during both of these time periods compared to compliance recalls. In total, 49 surveillance inspections and tests resulted in a recall between 2010-2014, compared to 14 compliance inspections and tests during this same time period. Additionally, 70 surveillance inspections and tests resulted in a recall between 2015-2019, compared to 36 compliance inspection and tests. Overall, surveillance testing conducted by the FDA and State Department of Agriculture detected the most potential health hazards in pet food.

The relationships between type of inspection and type of pet food were examined in order to determine what types of inspections were most associated with different types of pet foods before and after the PC rule was finalized. In regard to type of pet food recalls linked to routine surveillance between 2010-2014, 53 percent were related to dry pet food, 0 percent were related to canned pet food, 10 percent were related to raw pet

food, and 37 percent were related to treats. The breakdown of type of pet food recalls linked to surveillance testing during 2015-2019 was substantially different, with 3 percent related to dry pet food, 0 percent related to canned pet food, 66 percent related to raw pet food, and 31 percent related to treats. Most notably, dry and raw pet food had the largest differences in the number of surveillance recalls between the two time periods. Indeed, the number of dry pet food recalls associated with surveillance testing decreased by 93 percent, while the raw pet food recalls associated with surveillance testing increased by 88 percent. These results were consistent with the notion that the FDA and State Department of Agriculture view dry pet food as lower risk. Thus, the high concentration of surveillance testing on raw pet food and treats between 2015-2019 suggested the FDA and State Department of Agriculture allocated more resources towards testing these pet food categories compared to dry and canned pet food, and thus viewed raw pet food and as higher risk. Additionally, pet food recalls related to raw pet food were precautionary, resulting from surveillance samples, not pets or humans getting sick from foodborne illnesses.

All of the pet food categories experienced an increase in the number compliance testing recalls between 2010-2014 and 2015-2019 and ranged from a 75 to 88 percent increase in each pet food category. This trend coincided with the increase in consumer complaint and manufacturer-related recalls in Table 3.3. The number of recalls related to surveillance and compliance testing for treats remained relatively unchanged between 2010-2014 and 2015-2019. This trend coincided with the number of annual pet treat recalls in Table 3.1.

**Table 3.4 Total Number of Surveillance and Compliance Recalls Before and After the PC[a] Rule was Finalized, 2010-2019**

| Type of Pet Food | Range of Years | | | |
|---|---|---|---|---|
| | 2010-2014 | | 2015-2019 | |
| | Number of Surveillance Recalls | Number of Compliance Recalls | Number of Surveillance Recalls | Number of Compliance Recalls |
| Dry | 28 | 5 | 2 | 9 |
| Canned | 0 | 2 | 0 | 15 |
| Raw | 5 | 3 | 39 | 13 |
| Treats | 19 | 7 | 18 | 9 |

[a]Preventive Control

***Regulatory Impact of Zero-tolerance for Salmonella spp. on Pet Food Recalls***

While comparing the type of health hazard against the number of recalls before and after the PC rule was finalized in Table 3.2 illustrated the number of recalls related to *Salmonella* spp. contamination remained relatively unchanged, the table did not take into account the impact the zero-tolerance compliance guideline for *Salmonella* spp. in pet food had on pet food recalls when it was implemented in 2013. Therefore, the impact zero-tolerance for *Salmonella* spp. guidelines set forth by the FDA has had on pet food recalls is evaluated by comparing the total and average number of pet food recalls for *Salmonella* from 2009-2013 and 2014-2018 by pet food type in Table 3.3. The total and average number of recalls for all types of pet foods, except for raw pet food, decreased between the two time periods. This suggested the zero-tolerance guideline for *Salmonella* did not cause an increase in the number of pet food recalls for these pet food types. In contrast, the total number of raw pet food recalls increased by 79 percent, while the average number of raw pet recalls per year increased by 71 percent before and after the zero-tolerance *Salmonella* guideline was implemented. In addition, Figure 3.1 illustrated the FDA and State Department of Agriculture identified 64 percent of raw pet food recalls and Table 3.4 showed an increase in the number of recalls due to surveillance

inspections for raw pet food. Together, these observations suggest that increased regulatory oversight on raw pet and the zero-tolerance compliance guideline for *Salmonella* contributed completely or partially to the overall increase in pet food recalls for raw pet food.

**Table 3.5. Total and Average Number of Recalls by Pet Food Type Before and After Salmonella spp. Zero-Tolerance Guideline was Implemented, 2009-2018**

| Type of Pet Food | Range of Years | | | |
|---|---|---|---|---|
| | 2009-2013 | | 2014-2018 | |
| | Total Number of Recalls for *Salmonella* spp. | Average Number of Recalls for *Salmonella* spp. (per year) | Total Number of Recalls for *Salmonella* spp. | Average Number of Recalls for *Salmonella* spp. (per year) |
| Dry | 17 | 3 | 7 | 1 |
| Canned | 0 | 0 | 0 | 0 |
| Raw | 9 | 2 | 33 | 7 |
| Treats | 29 | 6 | 20 | 4 |

## 3.4 Discussion

Four factors were considered when evaluating the regulatory impact on the general increase in pet food recalls over the past decade: 1) overall trends in pet food recalls before and after the Preventive Control rule was finalized 2) interrelationships between notification entity and type of pet foods and type of health hazard 3 ) the level of regulatory oversight using surveillance and compliance inspections and 4) the implementation of the *Salmonella* spp. zero-tolerance compliance guideline. By considering these factors, we propose that the level of regulatory oversight is a potential driving force behind the overall increase in pet food recalls.

The pet food recalls related to the FDA and State Department of Agriculture were highly associated with *Salmonella* spp. in dry pet food and treats, and *Salmonella* spp. and *Listeria* spp. in raw pet food. However, the time period when the FDA and State

Department of Agriculture allocated their resources towards identifying *Salmonella* spp. health hazards in dry and raw pet food need to be considered. The results illustrated the number of dry pet food recalls decreased overtime while the number of raw pet food recalls increased overtime. Additionally, the number of dry pet food recalls related to surveillance inspections decreased overtime, while the number of raw pet food recalls related to surveillance inspections increased substantially after the PC rule was implemented. The combination of these three analyses suggested the FDA and State Department of Agriculture shifted their surveillance testing from dry pet food to raw pet food between 2010-2014 and 2015-2019. Furthermore, the type of pet food associated with the recalls due to *Salmonella* spp. changed during these two time periods as well. During the 2010-2014 time period, the recalls related to *Salmonella* spp. were associated with dry pet food and treats. In contrast, raw pet food and treats were highly associated with recalls related to *Salmonella* spp. among 2014-2018. Thus, although the recalls remained relatively consistent, the source of the *Salmonella* contamination changed. Additionally, dry pet food recalls were highly associated with consumer complaints and *Salmonella* spp. contamination during the 2010-2014 time period before the PC rule was implemented, while raw pet food recalls in combination with consumer complaints and *Salmonella* spp. were predominant among 2015-2019 after the PC rule was implemented.

Together, the overall decrease in dry pet food recalls before and after the PC rule was finalized was associated with the decrease in regulatory testing and decrease in *Salmonella* spp. recalls related to consumer complaints. Thus, the overall decrease in dry pet food recalls for *Salmonella* spp. may be due to decreased regulatory oversight or the implementation of preventive controls or a combination of both. Furthermore, since

consumer complaints are independent of any regulatory authority, the risk for *Salmonella* spp. in dry food has decreased since the PC rule was finalized, while *Salmonella* spp. contamination in raw pet food remains a large issue for the raw pet food industry. The substantial increase in the number of raw pet food recalls after the zero-tolerance compliance guideline for *Salmonella* spp. was implemented combined with the increased regulatory oversight surveillance inspections and increased consumer complaint-related FDA investigations contributed to the overall increase in the number of raw pet food recalls.

The combination of the relatively high amount of treat recalls linked to surveillance testing in 2010-2014 and 2015-2019, the high association between FDA and State Department of Agriculture and pet treat recalls, and the relatively consistent number of recalls before and after zero-tolerance guidelines for *Salmonella* spp. were implemented and the PC rule was finalized suggested the FDA and State Department of Agriculture view treats as a high-risk pet food vulnerable to potential contamination and the PC rule was not effective at decreasing the overall number of pet food recalls related to treats. The high level of regulatory oversight on pet treats by routine surveillance inspections combined with pet treat products vulnerable to *Salmonella* spp. contamination most likely contributed to the high number of pet food recalls related to treats.

The FDA and State Department of Agriculture- related recalls along with routine surveillance inspections were not associated with canned pet food. Rather, the FDA became involved in canned pet food recalls through compliance inspections. Since regulatory authorities focus on *Salmonella* spp. and *Listeria* spp. health hazards, and

canned pet food recalls were not associated with either of these health hazards, it is probable that FDA and the state Department of Agriculture view canned pet food as very low risk and do not allocate as many of their resources towards this type of pet food.

Chemical contamination was highly associated with large canned and dry pet food manufacturers, consumer complaint-related FDA investigations, and compliance inspections. This suggested that there is little regulatory oversight on chemical contaminations in pet food and the FDA and State Department of Agriculture take a reactive approach rather than proactive with this type of health hazard. Thus, regulatory oversight did not contribute to the overall increase in the number of canned pet food recalls. Additionally, the number of dry pet food recalls related to chemical contamination before and after the PC rule was implemented was comparable, with 13 total recalls among 2010-2014 and 11 total recalls among 2015-2019. While chemical contaminations do not pose a direct threat to consumers, it is evident they are still suffering the repercussions.

The low number of consumer complaint-related FDA investigations for raw pet food suggested the high-level of regulatory oversight had a positive effect on preventing pet food contaminated with *Salmonella* spp. and *Listeria* spp. from reaching consumers. Yet, it is important to recognize that the vast majority of the recalls for *Salmonella* spp. were preventive in nature, meaning *Salmonella* spp. *could* cause a human or pet to get sick. This is an unsustainable solution because pet food companies and manufacturers are spending millions of dollars on recalls that *might* cause a human or pet harm. Still, an outbreak of *Salmonella* infections associated with their product would be even more costly. For instance, lack of surveillance testing for chemical contaminations in dry and

canned pet food mostly likely contributed to thousands of pets becoming ill and dying, costing the companies legal fees and loss of brand reputation. The next chapter will discuss steps that can be taken to reduce the number of pet food recalls while also protecting pet and human health.

# Chapter IV: Recommendations, Implications, and Conclusions

## 4.1 Introduction

The regulatory environment over the past decade has brought U.S. pet food processing standards in line with human food manufacturing, increasing pressure on pet food manufacturers to ensure that their processes and products stay competitive (Semple, 2019b). While pet food is manufactured and regulated differently from human food, the same food safety principles apply to both industries. Equipment design and construction have aligned to follow requirements set forth for human-grade production and much of the equipment now used in the production of pet food is cross-functional in human food facilities. Dry pet food is produced using an extruder and these same, or slightly modified, extruders are also used to make human food. Most of the downstream equipment is also the same, including coolers, ovens, coaters, and packaging equipment. Canned pet food is produced using equipment that could be used to make canned meat products intended for human consumption. Having a hygienically safe manufacturing environment includes adequate maintenance of equipment and utensils used within processing areas and the use of suitable chemicals within and around the manufacturing plant (Labs, 2017). In addition to manufacturing plant and design similarities, cross-contamination between these two supply chains can also occur. This was exemplified when the multistate, multi-drug resistant *Salmonella* Reading transmission was linked to raw ground turkey products that contaminated human and raw pet food supply chains. Thus, the heightened focus on pet food under FSMA has arisen from the law's intention to bring all food products consumed in the United States, whether by humans or by

animals, under the same safety and quality standards and practices (Phillips-Donaldson, 2015).

The safety of human meat and poultry products was sparked in the 20th century when Upton Sinclair wrote his famous novel, *The Jungle*, which characterized the harsh working conditions of the meatpacking industry and eventually spurred calls for stricter government oversight of the industry. The Federal Meat Inspection Act in 1906 and the Poultry Products Inspection Act in 1957 were created to assure that meat food products distributed to consumers were wholesome and unadulterated. Today, the U.S. Department of Agriculture, Food Safety and Inspection Service (FSIS) is responsible for protecting consumers from risks associated with contaminated meat and poultry products and the consequences of foodborne illness. FSIS maintains a zero-tolerance policy for pathogens the agency considers adulterants and therefore tests for the pathogens in the relevant products to enforce the zero-tolerance standard. However, in contrast to pet food, *Salmonella* is not considered an adulterant in a raw food product and therefore there is no zero-tolerance guideline for *Salmonella*. Rather, FSIS uses performance standards to help drive reductions in *Salmonella* contamination and then manufacturing plants work to meet this standard. In addition, research based on monitoring the prevalence of *Salmonella* in various production systems has helped reduce the occurrence of *Salmonella* contamination of raw meat and poultry over the past decade (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells 2019). FSIS based this regulation on the claim that cooking practices will generally destroy the pathogen and that proper handling is sufficient to prevent cross-contamination. However, a raw food product that is

contaminated with *Salmonella* and linked to a foodborne illness outbreak is considered adulterated and therefore a recall of the contaminated products is warranted.

The synchronicity between dry and canned food and human food processing may explain how these pet food manufacturers have been effective at reducing the amount of *Salmonella* contamination in its pet food and processing plants that was identified in the pet food recall data in Chapter 2 and Chapter 3. In addition, the successful adaptation of human food processing equipment to pet food processing exemplifies how the pet food industry and regulatory authorities can improve pet food safety by following human food manufacturing principles. Yet, pet food is not subject to the same regulations as food intended for humans. Thus, this chapter aims to explore how the raw pet food industry can adopt, adapt, and implement USDA regulations and human food preventive controls to reduce the number of pet food recalls while still protecting pets and public health. In addition, recommendations are made for all pet food types based on the factors that were identified in Chapter 2 and Chapter 3 that have contributed to the overall increase in pet food recalls. These include the level of supply chain complexity, the level and focus of regulatory oversight, and overall trends and patterns in pet food recalls between 2007-2019. Together, consumer demands, regulatory oversight, and pet food manufacturers, are considered when providing practical and sustainable recommendations to reduce the number of pet food recalls.

## 4.2 Recommendations and Implications

### *Microbiological Contamination in Raw Pet Food*

Approximately 33 percent of all food-related salmonellosis cases were linked with meat products regulated by FSIS. Of those, poultry represented approximately 58 percent

of the cases, with 85 percent associated with chicken (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019). Thus, FSIS raw poultry recalls were used as a control group against raw pet food recalls. The distribution and identification of health hazards for raw poultry provided insight into how the overall trends of raw pet food recalls might change if USDA regulations for *Salmonella* were harmonized with FDA pet food regulations. The primary sources of health hazards for raw poultry from 2015-2019 can be broken down into misbranding (26%), undeclared allergen (24%), and foreign material (13%). In contrast, *Listeria* spp. accounted for 7 percent of recalls from 2015-2019, while *Salmonella* spp. accounted for 2 percent of recalls. Thus, while raw pet food manufacturers are struggling with microbiological contamination, human food manufacturers are contending with misbranding, undeclared allergen, and foreign material contaminations.

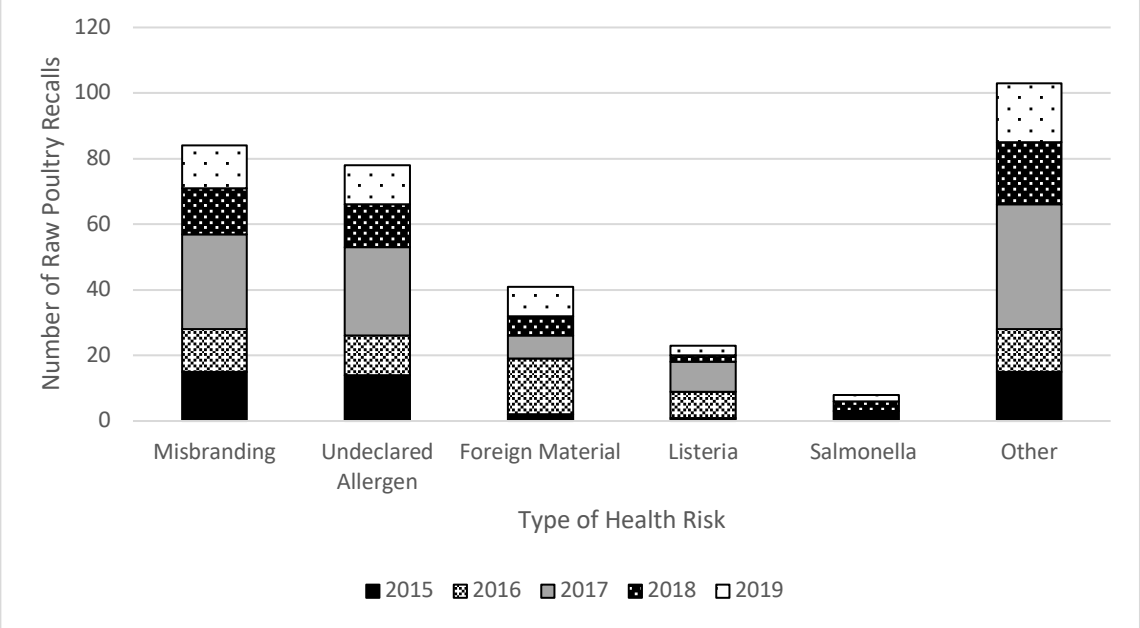



**Figure 4.1. Number of Raw Poultry Recall Events by Type of Health Hazard and Year, 2015-2019** Note: Other includes undercooked, processing defect, without benefit of inspection, and adulteration health hazards.

Still, the occurrence of high-profile outbreaks, such as the multistate, multidrug-resistant *Salmonella* Reading transmission linked to raw ground turkey products, reinforces the demand for new strategies to control *Salmonella* in raw meat and poultry. A policy brief published in 2019 by the Center For Animal Health and Food Safety at the University of Minnesota provided possible alternatives to a zero-tolerance policy for *Salmonella* on raw meat and poultry, including requiring the use of high pressure processing and developing enforceable performance standards based on levels of *Salmonella* contamination associated with illness rather than the qualitative presence or absence of *Salmonella* (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019). These alternatives to zero tolerance for *Salmonella* have the potential to be effective at controlling the presence of *Salmonella* in raw pet food as well.

As consumer demand for raw pet food continues to grow, pet food manufacturers are beginning to utilize High-Pressure Processing (HPP) to pasteurize their food products and comply with food safety regulations (Phillips-Donaldson, 2017). HPP is a cold pasteurization technique that eliminates pathogens by creating high pressure uniformly around a pet food container that is sealed in a tank of water. Under this high pressure, disease-causing microorganisms and food-spoiling enzymes are deactivated (Semple, 2019a). The pressures used in HPP causes few physical changes to the ingredients since the high pressure does not affect covalent bonds (Phillips-Donaldson, 2017). Additionally, HPP can be an effective tool to either cold pasteurize ingredients prior to processing or finished products in their final packaging (Semple, 2019a). However, there are some hindrances that may be currently preventing some raw pet food manufacturers from implementing this technique. One of these challenges is the lack of published

scientific data on the precise combinations of pressure and time needed to neutralize pathogens, such as *Salmonella* and *Listeria*. Adequately pasteurizing pet food products using HPP requires set parameters specific to each pet food product based on its ingredients or formula (Phillips-Donaldson, 2017). Another drawback is the significant added costs to the pet food manufacturer with HPP, which are ultimately passed along to the consumer. The cost for HPP, as well as the volume being produced, can be prohibitive to warrant having in-house HPP capabilities. An annual volume of 3 to 4 million pounds per year is typically needed to justify the expense of an in-house system. For raw pet food processors that do not have in-house HPP system, HPP tolling services are available (Semple, 2019a). However, this increases the supply chain complexity of the raw pet food product, and thus, increases risk of contamination and larger pet food recalls as identified with large pet food manufacturers in chapter 2. Additionally, while some raw pet food companies have implemented HPP as a way to eliminate bacterial pathogens, these companies were still prevalent in the pet food recall data. For example, a pet food manufacturer implemented HPP in 2015, however recalled 23,000 pounds of raw pet food between 2018 and 2019 due to *Salmonella* spp. contamination. When the FDA inspected the pet food facility in 2018, they found CGMP violations including inadequate sanitation of contact surfaces, equipment, and utensils, as well as inappropriate storage of finished products. They also observed employees were improperly trained and educated (Tyler, 2020). Thus, HPP is only effective at eliminating pathogens and reducing raw pet food recalls when effective CGMPs and preventive controls are in place. Ultimately, HPP is an avenue raw pet food manufacturers can explore in order to currently meet the zero tolerance guidelines set forth by the FDA or

reduce the occurrence of *Salmonella* in raw pet food if the zero tolerance policy for *Salmonella* spp. was lifted.

While most regulatory efforts have focused on reducing the overall prevalence of *Salmonella* spp., very little epidemiological investigations have been conducted to estimate the impact on animal and public health by reducing the concentration of *Salmonella* in positive lots of raw pet food. Methods that quantify levels of *Salmonella* on raw meat and poultry can help identify the risk of human and pet illness at different levels of exposure. Disease transmission models based on pet food outbreaks and dose-response models (estimates the relationship between the probability of illness and the ingested *Salmonella* dose in a food product) are needed to improve our understanding of the relationship between levels of contamination in raw meat and poultry products and the risk of illnesses in pets and consumers exposed to the products (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019). Thus, to provide risk modelers with quantitative, cost-effective methods that can also enumerate low levels of *Salmonella* are needed. Quantitative Polymerase Chain Reaction (qPCR) provides an alternative to existing standard culture methods as it enables reliable detection and quantification of bacterial pathogens. However, the pathogen's phenotypic and biochemical features must be confirmed from bacterial isolates (Kralik and Ricchi, 2017). Additionally, FDA and State Department of Agriculture regulators would need to have the resources to adopt quantitative microbiological testing when performing surveillance and compliance testing in order to determine if the pet food is adulterated.

Changes in consumer behavior and practices when handling raw poultry and meat products is also considered since FSMA compliance is a recognition that pet food has to

be manufactured as though human consumption is a possibility. A previous study characterized the raw pet food label information in the Minneapolis/St. Paul area and found 27 percent (11 total brands) of raw pet food brands stated that raw meat can contain harmful bacteria and cause illness in humans and pets if the raw pet food was mishandled. Additionally, labels on 55 percent of raw pet food brands recommended washing all surfaces, utensils, and food bowls that come in contact with raw meat with hot, soapy water, but did not explain why cleaning was recommended (Mehlenbacher *et al.*, 2012). A research study that evaluated consumer handling practices of raw ground turkey in a restaurant and home setting showed the mean risk of contracting a foodborne illness after eating in a restaurant was 10 times lower for consumers than one predicted at home due to differences in cooking. (Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, 2019). An observation study on chicken preparation found that 64 percent of meal preparers did not wash their hands before starting to prepare a meal and 38 percent did not wash their hands after touching raw chicken (Feng, Bruhn and Marx, 2016). Together, there is a lack of communication to consumers regarding the potential foodborne illness from raw meat and proper handling of raw meat.

Currently, most food safety education is delivered through reading materials. In 2005, the FDA released a guideline for industry regarding the manufacturing and labelling of raw pet food. The document 'Manufacture and Labeling of Raw Meat Foods for Companion and Captive Non-companion Carnivores and Omnivores' suggests that the cautionary statement required by the USDA on the labels of raw meat intended for human consumption be provided on labels of raw meat diets for pets (Mehlenbacher *et al.*, 2012). However, previous research suggests this precautionary statement is an ineffective

mode of communicating potential foodborne illness from raw meat and proper handling of raw meat. A previous study showed that the difference between using graphic images and just text warning on cognitive processing is significant. Participants who saw a visual warning label reported a much higher level of cognitive processing of the label than the text-only group. Thus, the use of graphic images could increase understanding and retention of important food safety messages. Additional research in this area, specifically related to food safety, would be useful for consumers and pet food manufacturers (Yiannas, 2015). Alternatively, Positive Deviance (PD) in food safety education allows participants to discuss their food handling behaviors and decide to try recommended practices modeled by people like themselves. In previous research, the PD group demonstrated improved knowledge compared to standard reading intervention. More importantly, the interaction with participants and practice of recommended behavior influenced future behavior. Future research efforts need to include larger sample sizes and use of a randomized sampling process in order to generalize findings for a larger population (Feng, Bruhn and Marx, 2016).

### *Microbiological Contamination in Treats*

The results from chapter 2 and chapter 3 indicated there are large opportunities for improvement in preventing *Salmonella* spp. contamination in pet treats. Additionally, there were a multitude of different sources of contamination that were linked to recalls related to pet treats, including poorly maintained manufacturing facilities, lack of supply chain controls, and lack of or improperly performed kill steps. Furthermore, these types of contaminations were linked to multiple different types of pet treats. Thus, the manufacturing and supply chain issues related to pet treats are vast and complex.

Continued pet food industry efforts to innovate with new products are bringing in high-risk ingredients that are susceptible to microbiological contamination. Therefore, these ingredients are challenging the boundaries of process limits and good manufacturing practices required to appropriately manage the pet food safety risk involved and bring a higher level of risk to the manufacturing plant. Pet food and treats include animal-based products that are at a high-risk for microbial contamination, specifically *Salmonella* spp. Due to these risks, pet treat manufacturers must pay particular attention to the hygienic design of the equipment and avoid cleaning solutions that contain water (Labs, 2017). Additionally, in order to comply with FSMA and control contamination, the manufacturing plant needs to have hygienic zoning, raw and ready-to-eat separations, and stainless-steel construction materials (e.g. walls, electrical conduit, HVAC hoods/ductwork, floor drains). Therefore, there are a multitude of root causes for improper sanitation in a pet food manufacturing facility. It could be due to improperly trained employees, the incorrect procedure, or frequency; it is also possible the equipment was not built with hygienic design in mind, the incorrect chemical is being utilized, or it's not being used in the correct manner. Thus, getting to the root cause of the problem is the best way for pet food manufacturers to prevent contamination. Additionally, having a robust environmental monitoring program can help identify if there is a problem with the sanitation program before a positive *Salmonella* spp. result. This includes plotting microbiological data and observations over time to identify potential issues before they escalate into a real problem. Another approach is trending preoperational observations by listing sites and calculating how many unsatisfactory results occur each month. This would not only provide information on equipment that is harder to clean but also

sanitation employees who might be struggling to clean the equipment effectively (White, 2020). Pet treat manufacturers must consider how sanitation can be achieved, what capital requirements are needed, and what actions should be prioritized. Thus, pet treat manufacturers would greatly benefit from specialized guidance from facility engineers who are familiar with FSMA, perform gap analyses, and can create action plans to mitigate risks while minimizing expenses to bring a plant up to compliance (Labs, 2017).

The occurrence of supply chain outbreaks, such as the multistate, multidrug-resistant *Salmonella* spp. transmission linked to pig ear treats, reinforces the demand to implement appropriate supply chain controls. Under the Foreign Supplier Verification Program (FSVP) rule of FSMA, importers must verify that their foreign suppliers of food for animal consumption are producing food using processes and procedures that offer the same level of public health protection as the preventive control and CGMP requirements for animal food (CVM, 2019b). An import alert dating all the way back to 2003 related to foreign firms exporting pig ears to the United States was updated in 2019 to include three foreign firms in Argentina, Colombia, and Brazil that presented pig ears for import that tested positive for *Salmonella* spp. (Phillips-Donaldson, 2018). Import alert 72-03 stipulates importers must provide results of private laboratory analysis of a representative sample of the shipment in order to verify compliance that the pig ear products do not contain *Salmonella* spp. However, the FSVP regulations were found to be the least applicable and least understood in Fiscal Year 2019 (FY19). While there were only 20 FSVP inspections for animal feed and pet food facilities in 2019, they returned 40 percent of the violations. The most common citations resulted from failure to establish an FSVP when required, failure to document suppliers' approval, and failure to establish or follow

written procedures for ensuring appropriate supplier verification activities (Phillips-Donaldson, 2018). This reinforces the need for clarification from the FDA on the FSVP rule as well as more FSVP inspections.

Bulk bins are of particular health importance as there is no guarantee that the pet treat products found in these bins are from the same manufacturer. This compromises the ability of the FDA and State Department of Agriculture to conduct a thorough recall or product traceback, as information on the brand, country of origin, lot number, and whether or not the product has been irradiated is not readily available as it would be in a labelled packaged product. This scenario was witnessed with the multi-drug resistant *Salmonella* outbreak in pig ears in 2019 and contributed to the overall increase and complexity of the recall. Thus, pet food manufacturers who sell their pet treat product by use of bulk bins are exposing themselves to a potential recall despite having appropriate preventive controls in place at their facility. Bulk bins are also a source of foodborne illness for customers, especially children, who physically handle the product since there is no packaging to prevent direct contact with the potentially contaminated pet treat product. One major North American pet store chain has attempted to reduce cross-contamination and possible human infection by no longer selling individual, unwrapped pig ears at their checkout stations. Rather, the pig ears are pre-wrapped in cellophane and have signs advising customers to wash their hands after handling the product (Finley, 2012). Other pet stores should consider following this practice as an alternative to bulk bins and pet food manufacturers should not allow their pet treat products to be sold in bulk bins.

In 2001, the FDA approved the use of irradiation of animal feeds to include pet treats and chews. The purpose of irradiation of pet treats is for microbial disinfection, control or elimination. Under FDA regulations, ionizing radiation can be from x-rays generated from machine sources or gamma rays emitted during radioactive decay of radionuclides to break apart the bacteria. In either case, the pet food does not come in direct contact with radioactive material nor is there a chemically synthetic step in the process. While irradiation is not a substitute for other appropriate sanitation measures, it provides manufacturers another approach to combat potential microbial contamination (Dzanis, 2009). However, there are some drawbacks to utilizing irradiation as a control measure for microbial pathogens. To date, there is a lack of published studies on the effects of irradiation on *Salmonella* contamination in pet treats, including pig ears. Thus, further studies need to be conducted on the effects of irradiation on *Salmonella* spp. in pet treat products including animal part pet treats. Additionally, the FDA allows pet treats to be irradiated up to 50 kGy. However, there are currently no validated testing methods to determine the dose of radiation that was used to ensure the pet treat product was properly irradiated. For instance, from 2007-2015 the FDA received approximately 5,200 complaints of illnesses associated with the consumption of chicken, duck, sweet potato jerky treats, many of which involved products imported from China. To date, testing for contaminants in the jerky treats has not revealed a root cause for the reported symptoms in pets. FDA's product-based testing targets the main ingredients (e.g. chicken, duck, sweet potatoes), and considers other information on the product label (e.g. irradiation) (CVM, 2018b). Thus, the FDA has no method of identifying if high levels of irradiation is the cause of the illnesses. In another scenario, the pig ear multi-resistant *Salmonella*

spp. outbreak discussed in Chapter 2 may have been due to ineffective pig ear product irradiation. Once again, the FDA had no way of identifying if the pet treat product was properly irradiated. Laboratory analysis would have enabled the FDA to identify if insufficient irradiation was the root cause of the outbreak and subsequently conduct traceback investigations to the original source. Thus, new technologies that are cost-effective and allow for quantitative analysis of irradiation in pet food are greatly needed. Furthermore, there is currently a strong consumer demand health and wellness concerns and more pet owners are turning to functional treats for health conditions. However, previous studies have shown that irradiation decreases the nutritional content of foods and alters the chemical structure, including creating carcinogens. Thus, it is a struggle between what consumers want and what the pet treat industry can realistically provide.

### *Chemical Contamination in Dry and Canned Pet Food*

There is a perception that designer pet food manufacturers have more problems with health hazards than the large pet food companies. While previous studies have shown that larger companies have more resources, and thus lower levels of contamination (Sampedro *et al.*, 2019), the pet food recall data exposed the issues large pet food companies are experiencing with chemical contamination and consumer complaints.

The high level of recalls for chemical contamination in pet food is indicative of an industry that is moving away from long-term feeding studies that involve testing on pets before the pet food is distributed and landing on store shelves. Raw materials should be tested for purity and composition to allow manufacturers to fine tune their recipes' parameters based on the ingredients' parameters (Labs, 2017). A key component to identifying potential issues and ensuring pet food product safety is testing the vitamin

premix or raw ingredient upon receipt, ensuring the supplier provides a Certificate of Analysis (COA), and having regulatory oversight. While this may seem straightforward, variabilities in state requirements for laboratory testing methods and method availability often leads to unreliable and inconsistent results. For instance, the Association of Official Analytic Chemists International (AOACI) is responsible for establishing official, legally defensible analytic methods in the United States. Some states require pet food manufacturers to utilize AOACI approved methods when performing laboratory analysis, while others do not. Furthermore, this inconsistency is exacerbated when different methods have different levels of sensitivity, selectivity, and precision.

For example, pet food has a very complex matrix that requires a comprehensive sample preparation to avoid interferences with chemical formulas and structures similar to those of Vitamin D (Huang and Winters, 2011). AOAC method 982.29 is a High-Performance Liquid Chromatography (HPLC) method that involves saponification and extraction steps followed by HPLC normal phase column and UV detection. This method is labor intensive, requires a skilled technician and extreme attention to detail. Thus, the quality of results is directly proportional to the experience of the analyst. Additionally, pet foods include ingredients from animal meats that introduce Vitamin $D_3$, as well as its isomers. As a result, a longer elution time is necessary to separate the interfering isomers. Since this method is expensive, laboratories tend to process as few samples as possible even though it decreases the precision of the means (Byrdwell *et al.*, 2008). In recent years, many laboratories have started using Mass Spectrometry (MS) detection instead of UV to provide greater specificity in identifying vitamin D and reduce the need to separate vitamin $D_2$ and vitamin $D_3$. (Byrdwell *et al.*, 2008). A previous study that used Ultra-

Performance Liquid Chromatography (UPLC)/MS/MS to measure vitamin D showed a robust method that decreased chromatographic separation run time, while equal or better separation efficiency was achieved for complex food matrices. Additionally, vitamin $D_2$ and vitamin $D_3$ were separated from their corresponding vitamins (Huang and Winters, 2011). Unfortunately, the initial saponification and extraction steps were still necessary. New technologies that are cost-effective and allow for direct analysis of nutrients with little, if any, sample preparation are greatly needed. Additionally, the FSMA laboratory accreditation program should require all accredited laboratories to compare results and have them all be within a small percentage to help produce consistently reliable and valid test results across all laboratories.

Hill's pet nutrition has circumvented this barrier by implementing a procedure where incoming vitamin premixes undergo three levels of vitamin D testing prior to inclusion in the final product. One test is done by the supplier, another by Hill's Pet Nutrition, and a third test is performed by an independent third party. Thus, the bulk of their quality control measures are in the initial, raw ingredient phases (Taurine, 2019). While this meets the FSMA regulations and greatly reduces the risk of excess Vitamin D contaminating pet food, it is a costly solution. However, not as costly as wasting a 10,000 pounds batch of pet food or recalling over 20,000 pounds of canned pet food due to excess Vitamin D contamination. However, not all pet food companies have the resources available to implement such a robust testing program for nutrient toxicities in pet food. Additionally, co-packers for Hill's Pet Nutrition are required to use supplier's approved by Hill's or perform additional testing to prove compliance (Taurine, 2019). By implementing requirements for co-packers to use their suppliers, Hill's Pet Nutrition is

making the global pet food supply chain safer. Thus, other pet food manufacturers should follow suit by auditing their co-packer's vendors and demanding more transparency into ingredient sourcing and quality. In comparison, Sunshine Mill's corrective actions for Vitamin D toxicity in dry pet food included requiring a COA with all incoming shipments, random laboratory testing for all incoming lots at least quarterly to ensure specifications match those in the COA, and randomly testing finished pet food for vitamin levels (FDA, 2019). Thus, while both manufacturers encountered similar course of events that led to excessive levels of Vitamin D in their finished pet food products, their corrective actions were drastically different. This comparison exemplifies the differences in how different pet food manufacturers perceive and evaluate risk, and the need for regulatory oversight to intervene by educating first then regulating.

An alternative preventive control to analytical testing is implementing additional process controls to prevent human error. Currently, quality control is performed manually. If the formulation process was digitized, then employees would be eliminated. When employees are eliminated, then the cost and risk are eliminated as well. When the risk is eliminated, then chance of error is eliminated. When there is no error involved, there is no need to hold a product before laboratory test results are received. And when a company doesn't need to hold a product, then it can be shipped out faster. Thus, the more centralized and simplified the process is, the more efficient and safer a process becomes (Beaton, 2019).

Widely dispersed, inexpensive, and easy-to-use technologies can be powerful tools for advancing pet food safety. While their proliferation can be extremely beneficial, it presents big challenges. These include how to stay current on large, rapidly growing set

of technologies; how to perform cost-benefit analyses quickly and effectively; how to manage a large body of data and extract useful information from it; and how to allocate scarce resources in selecting the technologies to adopt (Buchanan *et al.*, 2011).

While implementing new receiving and testing procedures, integrating COA requirements, and digitalizing processes are solutions for pet food manufacturers to prevent chemical contamination and pet food recalls, these solutions do not address the lack of regulatory oversight on chemical contamination in pet food. FDA continues to manage its inspectional resources using a risk-based approach to meet FSMA inspection frequency. Thus, regulators inspect those facilities producing, holding, or distributing high-risk pet foods more frequently than those producing, holding, or distributing lower-high risk pet foods (Ferguson, 2019). The combination of the results in Chapter 2 and Chapter 3 illustrated that large pet food manufacturers recall substantially more product when a recall does occur compared to designer pet food manufacturers and regulators allocate their resources towards raw pet food products and treats because of their high-risk for microbiological contamination. Arguably, although large pet food manufacturers produce lower risk pet food products for microbiological contamination, the quantity of product recalled when a recall does occur should be factored into their risk-based analysis. Additionally, the results in Chapter 2 and Chapter 3 highlight that chemical contamination in pet food is a much more pervasive problem than originally thought.

## 4.3 Conclusion

Pet food has been regulated for years at the state and federal levels for labeling and adulteration, but the FSMA is the first time there has been a comprehensive oversight on the preventive side. Thus, the general increase in pet food recalls is representative of

an industry that is still learning on how to comply with these new regulations while continuing to meet consumer demands. Furthermore, many of the recommendations presented in this chapter are universal across all pet food types. These include developing and standardizing testing methods and procedures, demanding transparency into ingredient sourcing and quality to minimize large pet food recalls, utilizing advanced technologies to make the pet food supply chain safer, and employing comprehensive preventive measures to help prevent raw ingredient contamination. These similarities allow the pet food industry and regulators to work together to make the pet food supply chain safer and reduce the total number of pet food recalls across all pet food sectors.

# References


AAFCO (2012) *The Business of Pet Food*, *Association of American Feed Control Officials*. Available at: https://petfood.aafco.org/Starting-a-Pet-Food-Business (Accessed: 3 March 2020).

AAFCO (2014) *AAFCO Methods for Substantiating Nutritional Adequacy of Dog and Cat Foods*, *Association of American Feed Control Officials*. Available at: https://www.aafco.org/Portals/0/SiteContent/Regulatory/Committees/Pet-Food/Reports/Pet_Food_Report_2013_Midyear-Proposed_Revisions_to_AAFCO_Nutrient_Profiles.pdf (Accessed: 20 April 2020).

Adley, C. *et al.* (2011) 'Prevalence of Salmonella in pig ear pet treats', *Food Research International*. Elsevier Ltd, 44(1), pp. 193–197. doi: 10.1016/j.foodres.2010.10.041.

APPA (2019) *Pet Industry Market Size & Ownership Statistics*, *American Pet Products Association*. Available at: https://www.americanpetproducts.org/press_industrytrends.asp (Accessed: 1 March 2019).

Beaton, L. (2019) *Transparency: A complex issue for the pet food industry*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/articles/8572-transparency-a-complex-issue-for-the-pet-food-industry?v=preview (Accessed: 26 November 2019).

van Bree, F. P. J. *et al.* (2018) 'Zoonotic bacteria and parasites found in raw meat-based diets for cats and dogs', *The Veterinary record*, 182(2), p. 50. doi: 10.1136/vr.104535.

Buchanan, R. L. *et al.* (2011) 'Pet food safety: a shared concern', *British Journal of Nutrition*, 106(S1), pp. S78–S84. doi: 10.1017/s0007114511005034.

Byrdwell, W. C. *et al.* (2008) 'Analyzing vitamin D in foods and supplements: Methodologic challenges', *American Journal of Clinical Nutrition*, 88(2), pp. 554–557. doi: 10.1093/ajcn/88.2.554s.

CDC (2008a) *Investigation Information for Outbreak of Salmonella Typhimurium Infections, 2008–2009 | Salmonella CDC*, *Center for Disease Control*. Available at: https://www.cdc.gov/salmonella/2009/peanut-butter-2008-2009.html (Accessed: 23 February 2020).

CDC (2008b) *Multistate Outbreak of Human Salmonella Infections Caused by Contaminated Dry Dog Food --- United States, 2006--2007*, *Center for Disease Control*. Available at: https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5719a4.htm (Accessed: 23 February 2020).

CDC (2012) *CDC - Salmonella Infantis Infections Linked to Dry Dog Food - Salmonella*, *Center for Disease Control*. Available at: https://www.cdc.gov/salmonella/dog-food-05-12/index.html (Accessed: 24 February 2020).

CDC (2019) *Outbreak of Multidrug-Resistant Salmonella Infections Linked to Raw Turkey Products*. Available at: https://www.cdc.gov/salmonella/reading-07-18/index.html.

CFR (2019) *CFR: Code of Federal Regulations Title 21*, *Code of Federal Regulation*. Available at:

https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfcfr/CFRSearch.cfm?CFRPart=7 (Accessed: 6 March 2020).

CVM (2013) *Guidance for FDA Staff Compliance Policy Guide Sec. 690.800 Salmonella in Food for Animals*.

CVM (2018a) *FDA Alerts Pet Owners about Potentially Toxic Levels of Vitamin D in Several Dry Pet Foods | FDA*, *Center for Veterinary Medicine*. Available at: https://www.fda.gov/animal-veterinary/news-events/fda-alerts-pet-owners-about-potentially-toxic-levels-vitamin-d-several-dry-pet-foods (Accessed: 25 February 2020).

CVM (2018b) *FDA Investigates Animal Illnesses Linked to Jerky Pet Treats | FDA*, *Center for Veterinary Medicine*. Available at: https://www.fda.gov/animal-veterinary/news-events/fda-investigates-animal-illnesses-linked-jerky-pet-treats (Accessed: 23 February 2020).

CVM (2018c) *Get the Facts! Raw Pet Food Diets can be Dangerous to You and Your Pet | FDA*, *Center for Veterinary Medicine*. Available at: https://www.fda.gov/animal-veterinary/animal-health-literacy/get-facts-raw-pet-food-diets-can-be-dangerous-you-and-your-pet (Accessed: 29 February 2020).

CVM (2019a) *FDA Alerts Pet Owners and Veterinarians About Potentially Toxic Levels of Vitamin D in 33 Varieties of Hill's Canned Dog Food in Expanded Recall | FDA*, *Center for Veterinary Medicine*. Available at: https://www.fda.gov/animal-veterinary/news-events/fda-alerts-pet-owners-and-veterinarians-about-potentially-toxic-levels-vitamin-d-33-varieties-hills (Accessed: 25 February 2020).

CVM (2019b) *FDA Launches the FDA-TRACK: Food Safety Dashboard to Track FSMA Progress*, *Center for Veterinary Medicine*. Available at: https://www.fda.gov/about-fda/fda-track-agency-wide-program-performance/fda-track-whats-new (Accessed: 29 November 2019).

CVM (2019c) *Overview of FDA's Animal Feed Safety System (AFSS) | Enhanced Reader*, *Center for Veterinary Medicine*. Available at: moz-extension://a7cbcd3c-df23-4510-96a9-7c4992fcfa85/enhanced-reader.html?openApp&pdf=https%3A%2F%2Fwww.fda.gov%2Fmedia%2F81751%2Fdownload (Accessed: 29 February 2020).

Dzanis, D. A. (2008) 'Anatomy of a Recall', *Topics in Companion Animal Medicine*, 23(3), pp. 133–136. doi: 10.1053/j.tcam.2008.04.005.

Dzanis, D. A. (2009) *Is irradiation of petfoods natural?*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/articles/57-is-irradiation-of-petfoods-natural (Accessed: 24 April 2020).

Enright, C. P. D. (2017) *Pet Food and Treat Safety: It's Time for Facts, Not Fearmongering - Food Safety Magazine*, *FoodSafety Magazine*. Available at: https://www.foodsafetymagazine.com/magazine-archive1/octobernovember-2017/pet-food-and-treat-safety-ite28099s-time-for-facts-not-fearmongering/ (Accessed: 23 February 2020).

Entis, P. (2019) *Lax testing practices resulted in Vitamin D overdoses in Hill's and Sunshine Mills pet food*, *FoodSafety News*. Available at: https://www.foodsafetynews.com/tag/sunshine-mills/ (Accessed: 8 March 2020).

Evanson, J. F. *et al.* (2019) 'Methodology for Creating an Information Tool for Animal Food Facilities', *Journal of Agricultural and Food Information*. Routledge, 20(3), pp. 220–236. doi: 10.1080/10496505.2019.1618314.

FDA (2016) ‘Hazard Analysis and Risk-Based Preventive Controls for Human Food : Guidance for Industry’, 3(January 2018), pp. 1–185. Available at: http://www.fda.gov/Food/GuidanceRegulation/FSMA/ucm459719.htm.

FDA (2018) *Hazard Analysis and Risk-Based Preventive Controls for Food for Animals*, *U.S. Department of Health and Human Services*.

FDA (2019) *Sunshine Mill’s Inc*, *Food and Drug Administration*. Available at: https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/sunshine-mills-inc-576411-06252019 (Accessed: 22 April 2019).

FDA (2020a) *FDA Enforcement Reports*, *Food and Drug Administration*. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts/enforcement-reports (Accessed: 6 March 2020).

FDA (2020b) *FSMA Proposed Rule on Laboratory Accreditation*, *Food and Drug Administration*. Available at: https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-proposed-rule-laboratory-accreditation (Accessed: 11 March 2019).

FDA (2020c) *Recalls, Market Withdrawals, & Safety Alerts*, *Food and Drug Administration*. Available at: https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts (Accessed: 6 March 2020).

Feng, Y., Bruhn, C. and Marx, D. (2016) ‘Evaluation of different food safety education interventions’, *British Food Journal*, 118(4), pp. 762–776. doi: 10.1108/BFJ-10-2015-0372.

Ferguson, B. (2019) *What Industry and FDA Are Thinking about FSMA Implementation – Part 2*, *FoodSafety Magazine*. Available at: https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2019/what-industry-and-fda-are-thinking-about-fsma-implementation-part-2/ (Accessed: 22 April 2019).

Finley (2012) *Salmonella In Commercially Available Pig Ear Treats and Raw Food Diets: Prevalence Survey & Canine Feeding Trials*, *Journal of Drugs in Dermatology*. Available at: http://scholar.google.com/scholar?hl=en&btnG=Search&q=intitle:Early+steps+in+analysis#1.

Fox, M. A. and Kenagy, R. (2015) ‘Commercial pet food recalls: Incentives to improve pet food safety’, *Contemporary Readings in Law and Social Justice*, 7(2), pp. 17–39.

FSIS (2019) *Quarterly Sampling Reports on Salmonella*, *Food Safety and Inspection Service*. Available at: https://www.fsis.usda.gov/wps/portal/fsis/topics/data-collection-and-reports/microbiology/quarterly-reports-salmonella/quarterly-progress-reports (Accessed: 4 March 2020).

Galvão, J. A. *et al.* (2015) ‘Quality and Safety of Pet Treats: Assessment of the Microbial Safety and Quality of Pet Treats’, *Journal of Food Processing and Preservation*, 39(6), pp. 1201–1205. doi: 10.1111/jfpp.12336.

Hedberg, Craig; Bender, Jeff; Sampedro, Fernando; Wells, S. (2019) *Potential Impacts of a Zero Tolerance Policy for Salmonella on Raw Meat and Poultry*.

Huang, M. and Winters, D. (2011) ‘Application of ultra-performance liquid chromatography/tandemmass spectrometry for the measurement of vitamin D in foods and nutritional supplements’, *Journal of AOAC International*, 94(1), pp. 211–223.

J. Tyler, J. S. (2020) *Top 5 trends seen at Global Pet Expo 2020*, *Pet Food*

*Processing*. Available at: https://www.petfoodprocessing.net/articles/13659-top-5-trends-seen-at-global-pet-expo-2020.

Kralik, P. and Ricchi, M. (2017) 'A basic guide to real time PCR in microbial diagnostics: Definitions, parameters, and everything', *Frontiers in Microbiology*, 8(FEB). doi: 10.3389/fmicb.2017.00108.

Labs, W. (2017) *Complying with FSMA for pet food manufacturing*. Available at: https://www.foodengineeringmag.com/articles/98498-complying-with-fsma-for-pet-food-manufacturing (Accessed: 30 March 2020).

Lambertini, E. *et al.* (2016) 'Quantitative assessment of human and pet exposure to Salmonella associated with dry pet foods', *International Journal of Food Microbiology*. Elsevier B.V., 216, pp. 79–90. doi: 10.1016/j.ijfoodmicro.2015.09.005.

van de Ligt, J. (2019) *The Changing Face of Leadership in the Food and Beverage Industry*, *FoodSafetyTech*. Available at: https://foodsafetytech.com/column/the-changing-face-of-leadership-in-the-food-and-beverage-industry/ (Accessed: 28 March 2020).

Maberry, T. (2016) *FSM Scoop: Pet Food Safety - Food Safety Magazine*, *FoodSafety Magazine*. Available at: https://www.foodsafetymagazine.com/enewsletter/fsm-scoop-pet-food-safety/ (Accessed: 23 February 2020).

Mehlenbacher, S. *et al.* (2012) 'Availability, Brands, Labelling and Salmonella Contamination of Raw Pet Food in the Minneapolis/St. Paul Area', *Zoonoses and Public Health*, 59(7), pp. 513–520. doi: 10.1111/j.1863-2378.2012.01491.x.

Ostroff, S. M. D. (2018) *The Cost of Foodborne Illness, Product Recalls Make the Case for Food Safety Investments*, *Food Safety Magazine*. Available at: https://www.foodsafetymagazine.com/magazine-archive1/junejuly-2018/the-costs-of-foodborne-illness-product-recalls-make-the-case-for-food-safety-investments/ (Accessed: 1 March 2020).

Packaged Facts (2019) *Recalls Have 60% of Pet Parents Concerned About the Safety of Dog and Cat Food, reports Packaged Facts*, *PR Newswire*. Available at: https://www.prnewswire.com/news-releases/recalls-have-60-of-pet-parents-concerned-about-the-safety-of-dog-and-cat-food-reports-packaged-facts-300790672.html (Accessed: 1 March 2020).

Paulelli, A. C. C. *et al.* (2018) 'Risk assessment of 22 chemical elements in dry and canned pet foods', *Journel of Consumer Protection and Food Safety*, 13(4), pp. 359–365. doi: 10.1007/s00003-018-1178-5.

PFI (2020) *About Pet Food Institute*, *Pet Food Institute*. Available at: https://www.petfoodinstitute.org/about-pfi/ (Accessed: 15 March 2020).

Phillips-Donaldson, D. (2015) *All eyes on pet food safety as FSMA rule takes effect*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/blogs/7-adventures-in-pet-food/post/5313-all-eyes-on-pet-food-safety-as-fsma-rule-takes-effect (Accessed: 30 March 2020).

Phillips-Donaldson, D. (2017) *High pressure processing: more raw pet food research needed*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/articles/6336-high-pressure-processing-more-raw-pet-food-research-needed (Accessed: 15 April 2020).

Phillips-Donaldson, D. (2018) *FDA reports on pig ear recalls, FSMA pet food*

*compliance*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/articles/8558-fda-reports-on-pig-ear-recalls-fsma-pet-food-compliance (Accessed: 30 April 2020).

Rumbeiha, W. and Morrison, J. (2011) 'A Review of Class I and Class II Pet Food Recalls Involving Chemical Contaminants from 1996 to 2008', *Journal of Medical Toxicology*, 7(1), pp. 60–66. doi: 10.1007/s13181-010-0123-5.

Sampedro, F. *et al.* (2019) 'Developing a risk management framework to improve public health outcomes by enumerating Salmonella in ground Turkey', *Epidemiology and Infection*, 147. doi: 10.1017/S095026881800328X.

Semple, J. (2019a) *3 Key considerdations for producing raw, minimally cooked pet products*, *Pet Food Processing*. Available at: https://www.petfoodprocessing.net/artciles/13554-key-considerations-for-producing-raw-minimally-cooked-pet-products.

Semple, J. (2019b) *State of US pet food and treat indsutry, 2019*, *Pet Food Processing*. Available at: https://www.petfoodprocessing.net/articles/13528-state-of-the-us-pet-food-and-treat-industry-2019 (Accessed: 3 March 2019).

Strout, Jeff; Price, N. (2017) *Go Feed the Animals - Food Safety Magazine*, *FoodSafety Magazine*. Available at: https://www.foodsafetymagazine.com/magazine-archive1/aprilmay-2017/go-feed-the-animals/ (Accessed: 23 February 2020).

Taurine (2019) *Pet food company visits: Hills Pet Food, Topeka, Kansas*, *Taurine DCM*. Available at: https://dcmdogfood.com/pet-food-company-visits-hills-pet-food-topeka-kansas/ (Accessed: 20 April 2020).

Tyco Integrated Security (2012) *Recall: The Food Industry's Biggest Threat to Profitability*, *FoodSafety Magazine*. Available at: https://www.foodsafetymagazine.com/signature-series/recall-the-food-industrys-biggest-threat-to-profitability/ (Accessed: 1 March 2020).

Tyler, J. (2020) *Bravo Packing issued FDA warning letter for FD&C violations*, *Pet Food Processing*. Available at: https://www.petfoodprocessing.net/articles/13726-bravo-packing-issued-fda-warning-letter-for-fdc-violations (Accessed: 23 April 2020).

Wall, T. (2019) *US pet spending grew at double rate of household income | PetfoodIndustry.com*, *Pet Food Industry*. Available at: https://www.petfoodindustry.com/articles/8685-us-pet-spending-grew-at-double-rate-of-household-income (Accessed: 23 February 2020).

White, B. L. *et al.* (2018) *Changes in the Food Safety Landscape of Pet Foods in the United States*, *Food and Feed Safety Systems and Analysis*. Elsevier Inc. doi: 10.1016/B978-0-12-811835-1.00001-4.

White, W. (2020) 'Getting Sanitation out of the Reclean/Retest Rut', *FoodSafety Magazine*, pp. 24–27.

Yiannas, F. (2015) *Food Safety = Behavior*. New York: Springer Science Business Media. doi: 10.1007/978-1-4939-2489-9_28.