Master of Public Health

Integrative Learning Experience Report

Evaluation of recalls of FSIS-regulated food products: January 1994 through August 2018

by

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submitted in partial fulfillment of the requirements for the degree

MASTER OF PUBLIC HEALTH

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Manhattan, Kansas
March 2019

Acknowledgements

Special thank you to all of those who assisted in making this experience one that will never be forgotten.

Summary/Abstract

The primary focus of this integrated learning experience project was to evaluate and analyze recalls of FSIS-regulated food products that occurred between January 1994 and August 2018. This evaluation of the data recorded from these recalls is a trend analysis. This analysis characterized the recalls of FSIS-regulated food products in several ways including by: pounds of product recalled, severity of potential health risk (i.e., recall class), facility size, the type of meat product involved, the method by which the recall was initiated, and the reason for the recall. The analysis further evaluated pathogen-related recalls in more depth, particularly those related to shiga toxin-producing *Escherichia coli* (STEC).

During the 24 years and 8 months encompassed by the trend analysis time period (January 1994 through August 2018), there were a total of 1,810 recalls of FSIS-regulated food products. Because the final year of data is an incomplete year, the calendar years of 1994 through 2017 were used to calculate calendar year averages. During the 1994 through 2017 calendar years, there were 1,737 recalls in total with an average of 73 recalls per year. More than 774 million pounds of food products were recalled during the entire study period with 771.3 million pounds of food products recalled from 1994 through 2017 which was used to calculate the average of 32.1 million pounds recalled per calendar year. During the 1994-2017 calendar years, there was an average of 444,070 pounds of food products per recall, with the least number of pounds recalled being 0 pounds and the largest number of pounds recalled in a single recall being 143.4 million pounds. For the entire study period Class I recalls comprised 71% of the total number of recalls whereas Class II represented 21%, and Class III represented 8%. Of the 1,810 recalls, 692 were due to presence of a pathogen, with 21% of those being associated with STEC. Starting in 2004, data regarding the size of a facility (as per HACCP regulations) was

documented. Of the 1,052 recalls with specified HACCP facility sizes, 54% were small, 30% were very small, and 16% were large facilities. During the study period, the top 3 reasons for initiation of a recall were the presence of (1) an undeclared allergen, (2) *Listeria monocytogenes*, and (3) *Escherichia coli* O157:H7.

A total of 264 recalls of FSIS-regulated food products involved STEC. On average, 15% of all recalls of FSIS-regulated food products were associated with STEC for each calendar year from 1994 through 2017. Sixty-one (23%) of the STEC recalls were associated with an illness or outbreak while 203 (77%) of the STEC recalls were not. Of the total number of recalls associated with illness or outbreak (95), 61 of them were associated with STEC (64.2%). Of those recalls associated with STEC for which a HACCP facility size was recorded, from January 2004 through August 2018, 55% were attributed to small facilities, 28% to very small facilities, and 17% to large facilities. From 1994-2010 all recalls attributed to STEC were associated with O157:H7 as that was the only STEC that had been declared an adulterant. In January of 2010, the FSIS begin to more specifically identify those previously categorized as non-O157:H7 by the six serotypes laid out in the new directive. The serotypes that were included in the new directive for serotyping *Escherichia coli* were O26, O45, O103, O111, O121, and O145. However, they were not formally recognized as adulterants until the directive went into effect in June 4, 2012. The breakdown of post-2010 recalls due to STEC, was O157:H7 70%, O26 7%, O45 3%, O103 8%, O111 1%, O121 4%, and O145 3% with the remaining 3% associated with non-O157:H7 and O157: non-motile.

Subject Keywords: Food Safety, *Escherichia coli*, Shiga toxin-producing *Escherichia coli*, O157:H7, O26, O45, O103, O111, O121, O145, Food Recalls, FSIS, USDA

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Chapter 1. Literature Review

Every year, millions of pounds of meat are voluntarily recalled by producers and manufacturers because of an array of reasons including mislabeling as well as presence of undeclared allergens, foreign materials, and biological contaminants (Beier & Pillai, 2007; Dodd & Powell, 2009; Gorton & Stasiewicz, 2017). According to the Federal Meat Inspection Act (FMIA) (2016), meat food products of cattle, sheep, swine, goats, horses, mules, or other equines are monitored by the Food Safety and Inspection Service (FSIS), a branch of the United States Department of Agriculture (USDA). These regulations allow the FSIS to hold all the meat production facilities, which are USDA inspected, accountable to the gold standard of practice, to strive to ensure the safest and most superior quality food supply in the world.

The Federal Meat Inspection Act was updated in 1994 in response to a major outbreak of *E. coli* O157:H7. The FSIS administrator at that time, Michael R. Taylor, decided to play a more active role in food safety through scientific rather than strictly organoleptic means as well as to become more proactive regarding management of pathogens (FSIS, 2014; Bottemiller, 2011). Their first initiative was to declare *E. coli* O157:H7 to be an adulterant in "all raw beef products, including ground beef, other non-intact beef products, and intact beef products" (FSIS, 2013a; Pathogen reduction; hazard analysis and critical control point (HACCP) systems, 1996). Title 21 of the United States Code, chapter 12, subchapter I, section 601.2 (FMIA, 2016) states:

> The term ''adulterated'' shall apply to any carcass, part thereof, meat or meat food product under one or more of the following circumstances: (1) if it bears or contains any poisonous or deleterious substance which may render it injurious to health.

By declaring *Escherichia coli* (*E. coli*) O157:H7 an adulterant, the FSIS ensured legal recourse against those who knowingly allow entry of *E. coli* O157:H7 into the food supply. Furthermore, FSIS mandated a 5 log-reduction of bacteria, such as *E. coli* O157:H7, along with a new zero tolerance policy for *E. coli* O157:H7 as well as *Listeria monocytogenes* (LM). A 5 log-reduction of bacteria is the decrease in a representative sample's bacteria load by 100,000-fold. For example, a sample with a 100,000 colony forming units of bacteria would contain only 1 colony forming unit after a 5 log-reduction. The implementation of these regulations required all USDA inspected facilities to have a set of sanitation standard operating procedures, a process to prevent and remove fecal contamination, and a hazard analysis and critical control point (HACCP) plan (Pathogen Reduction HACCP Systems, 1996). From those beginnings, the FSIS has continued to update their policies and regulations in accordance with the ever-changing needs of the food safety realm.

The HACCP plan was designed to proactively evaluate slaughter and packing facilities to anticipate where problems may occur and have plans in place to mitigate those problems. During the construction of their HACCP plans, facilities would identify where and when they needed to better monitor their product for possible contamination. Knowing these places also ensured that the company knew where and when they needed to have microbiological testing in place to assess the competency of their HACCP plan with regards to the 5-log reduction plan and zero tolerance policy (Pathogen Reduction HACCP systems, 1996). Enforcement of the HACCP plans commenced in 1998, when it first became a requirement for a companies to have written HACCP plans on file to maintain their mark of inspection from the USDA (FSIS 2013b). The date by which companies were required to have their HACCP plans completed was dependent on the size of the facility. The "HACCP size" of a facility was defined by the FSIS in the Pathogen

Reduction HACCP System (1996) notice that was enacted in 1998 as a way of setting an implementation schedule for the requirement of HACCP plans. Large facilities, defined as any facility that had 500 or more employees, were required to have their HACCP plans implemented by January 26, 1998 (Pathogen Reduction HACCP Systems, 1996). In contrast, the implementation date for small facilities, defined as those with more than 10 employees but less than 500 employees, was January 25, 1999 (Pathogen Reduction HACCP Systems, 1996). Furthermore, the implementation date for very small facilities, defined as those with fewer than 10 employees or annual sales of less than $2.5 million, was January 25, 2000.

HACCP plans enabled facilities to have a more proactive approach to food safety. The HACCP plan is also meant to assist with mitigating the need to recall product due to outbreaks because the facility knows the path that the product takes and where and at what time each sample was taken therefore allowing the firm to be able to find that product in their holding facility before it goes into commerce. Likewise, if the meat has already gone into commerce, the facility will know which lot went where and have a more precise location from which to recall their product. Part of the mandated plans and requirements is the holding of ground meat until microbiological testing results have returned (Pathogen Reduction HACCP systems, 1996). These plans allow for better monitoring of the products so that when there is an outbreak of *E. coli*, the product can be traced back to the facility it came from and that facility is able to reevaluate the safeguards they have in place with regards to *E. coli*.

To be able to reevaluate safeguards for *E. coli*, an understanding of its sources and reservoirs in the environment, the routes by which it enters the food supply, its infectious dose, and the means by which it can be controlled in both the food processing environment and food products are needed. *E. coli* is a rod shaped, gram negative, facultatively anerobic bacteria which

has many serotypes (*E. coli*, 2005; Lim, Yoon, & Hovde, 2010; Marler & Clark, 2013). In 1992, Ørskov and Ørskov (1992) indicated that there are likely more than 100,000 serotypes of *E. coli*, which are part of the normal microflora of the large intestine. The microflora that is in our large intestine is integral in the process of breaking down nutrients for absorption into our bodies (Marler & Clark, 2013). Even so, some strains of *E. coli* have been associated with human disease. In particular, a group of *E. coli*, which are classified as enterohemorrhagic, e.g. *E. coli* O157:H7, cause hemorrhagic enteritis when they are introduced into the human digestive tract (Madappa & Bronze, 2019; Marler & Clark, 2013). Interestingly, it is toxins of the bacteria, specifically shigella-like toxins, rather than the direct action of the bacteria which causes the bloody diarrhea.

Both *E. coli* O157:H7, and those *E. coli* non-O157:H7 considered to be adulterants by the FSIS, are of that group of *E. coli* which has mutated and adopted extra biological material that make them produce toxins (Lim et al., 2010). This group of *E. coli* is generally referred to as Shiga toxin-producing *E. coli* (STEC). The group of STEC has been so named because of the gene for the toxins which is conferred to these *E. coli* by a plasmid. A plasmid is a mobile piece of extrachromosomal DNA capable of replicating outside of the nucleus of a cell (Lim et al., 2010). Plasmids, in general, can provide various benefits to its host including virulence factors such as the plasmid which contains the genetic code for the *E. coli* toxins (Lim et al., 2010). These toxins cause the hemorrhagic colitis, as well as a more serious set of complications known as hemolytic uremic syndrome (HUS), which is characterized by three major symptoms: hemolytic anemia, thrombocytopenia, and renal insufficiency (Adams et al., 2014; Lim et al., 2010; Rivas, Chinen & Guth, 2016). The toxins are resistant to heat, cold, acid, pressure, and many other general controls used in food safety (Lim et al., 2010). In the United States, the most

well-known, and most studied of the STEC group is *E. coli* O157:H7. Of the other serotypes of STEC, six are major causes of foodborne illness in the United States. These six serotypes are *E. coli* O23, O45, O103, O111, O121, and O145. In 2012, due to their discovery in raw beef products, including non-intact and intact beef products, the FSIS added all six serotypes to its adulterant list (STEC, 2012).

When a person consumes raw or undercooked meat, they run the risk of becoming infected with these STEC. Each year, there are approximately 73,000 people who become ill from STEC infections in the United States and more worldwide (Frenzen, Drake & Angulo, 2005). When an outbreak occurs in the United States, the FSIS in conjunction with the Centers for Disease Control and Prevention (CDC), attempts to locate the facility from which the suspected contaminated product originated and advise the facility as to how to remove the potentially contaminated meat from public availability. This process, known as a food recall, is voluntary but highly encouraged.

Food recalls happen when the producer of a certain food product wishes to remove that product from the hands of the consumer. Some of the many reasons that a company may want to recall their product are the presence of an infectious agent such as STEC, mislabeling of the product, or potential foreign body presence. Not only does the FSIS assist the company with what to do in the event of a food recall, they also put out a press release or a public health alert to notify the public that there is a recall and why.

The mission of the USDA is to "provide leadership on food, agriculture, natural resources, rural development, nutrition, and related issues based on sound public policy, the best available science, and efficient management" (USDA, 2018). Whereas the FSIS is "responsible for ensuring that the nation's commercial supply of meat, poultry, and egg products is safe,

wholesome, and correctly labeled and packaged" (FSIS, 2018a). One of the major challenges that the FSIS has faced throughout the last two and a half decades has been from biological contamination of food stuffs that needed to be recalled for safety reasons (Gorton & Stasiewicz, 2017). Of the biological contaminants, the most frequent two have been LM and STEC. Over the years, the number of food recalls has fluctuated. These fluctuations can be considered as subject in part to changes in the public policy.

In Healthy People 2010, the Office of Disease Prevention and Health Promotion (ODPHP) published that the baseline incidence of *E. coli* O157:H7 was 2.1 cases per 100,000 people, and their goal by 2010 would be to reduce the incidence of *E. coli* O157:H7 to 1.0 cases per 100,000 people (ODPHP, 2010). In order to assess that goal of reducing the incidence of *E. coli* O157:H7 by more than half, as many sources as possible of *E. coli* O157:H7 infection needed to be tracked. For example, ground beef, an FSIS-regulated food, is one of the known sources of *E. coli* O157:H7 infections. Once data regarding sources of *E. coli* O157:H7 have been identified and the incidence of illness has been determined, plans must be put into place to mitigate the risk of *E. coli* O157:H7 infections if the Healthy People objectives are to be met. To be able to mitigate the risk of *E. coli* O157:H7, the potential sources of infection must be known. In addition to epidemiologic investigation, analyzing recalls of foods due to the presence of *E. coli* O157:H7 provides information on some potential sources of *E. coli* O157:H7 infections. Nevertheless, there are very few scientific papers which track recall data specific to the FSIS.

Gorton & Stasiewicz (2017) published a review of FSIS recalls from 1994 through 2015 and evaluated those recalls for food safety points as well as food waste, analyzing 1,515 food recall records. Gorton & Stasiewicz (2017) found the most common recall class, Class I, comprised 71% of the 1,515 recalls and the most common reasons a food product was recalled

were LM, undeclared allergens, and *E. coli* O157:H7. Gorton and Stasiewicz's review of records of food recalls of FSIS-regulated food products was the most comprehensive review to date. In 2000, Raharjo (2000) analyzed recalls from 1995 through 1999 using similar methods. Raharjo (2000) reported that from 1995 through 1999, there were 197 recalls of foods regulated by the FSIS of which 85% were categorized as Class I, and 80% of the bacterial contamination recalls were due to either LM or *E. coli* O157:H7. Likewise, Green, Seys, Douris, Levine, & Robertson (2014) reported on 88 illness outbreaks associated with STEC that resulted in regulatory action from 2006 through 2010. Green et al. (2014) noted that 43% (38) of the reported outbreaks resulted in regulatory action of either a food recall or a food safety assessment. Of that 43%, Green et al. noted that 76% (29) resulted in a recall of the FSIS-regulated foods associated with the illness.

Murray, Rosenthal & Pfaller (2016) state that the most commonly thought of serotype associated with human disease is *E. coli* O157:H7. Often when a patient presents with symptoms of STEC infection, *E. coli* O157:H7 is the serotype tested for, even though there are many other serotypes also associated with human disease (Murray et al., 2016). Early identification of STEC was often determined by whether it fit into the O157:H7 category or not (Murray et al, 2016). Now, as scientists learn more about this bacteria, they are realizing that less than 50% of the human STEC cases are due to O157:H7 and that it may be more prudent to test for the presence of the shiga toxins rather than the serotype (Murray et al, 2016). Furthermore, STEC can be considered important because they have an infectious dose of less than 100 colony forming units (CFU) meaning it takes very small amounts of bacteria to cause illness as opposed to LM which has an infectious dose of 10 million to 100 million CFU (Farber, 1996; Thorp, 2004). Preventing STEC from entering the food supply is particularly important not only due to the low infectious

dose, but also because there are no effective treatments; antibiotics are contraindicated during treatment because they can increase the risk of serious complications such as HUS (Madappa et al., 2019; Mayo Clinic, 2018). Consequently, it is important to track those food recalls that occured because of a connection to STEC.

Chapter 2. Learning Objectives and Project Description

Field Experience Details

This field experience was carried out with the Branch Chief of Domestic Operations within the Recall Management and Technical Analysis Division (RMTAD) of the FSIS, a branch of the United States Department of Agriculture (USDA). The field experience began June 04, 2018 and continued through September 28, 2018. Although the field experience itself was conducted in Washington, DC, there were team members all over the United States and US Territories who interacted with the headquarters team regularly and were also a large part of the learning experience.

Learning Objectives

The objectives that needed to be met to fulfill the intentions of the FSIS RMTAD goals for the internship included:

- Develop an understanding of FSIS as it relates to operating as a regulatory agency and a public health agency.
- Develop an understanding of food recalls as overseen by FSIS to include:
    - FSIS statutory authority
    - why recalls happen
    - the process FSIS uses for determining whether to recommend a recall
    - the process FSIS uses for determining the scope of recalls
    - the process FSIS uses when a firm refuses to recall a product
    - the process FSIS uses to close out a recall

- Develop an understanding of the intra-agency and inter-agency relationships that exist to ensure recalls of FSIS-regulated products are effective.
- Create a digital archive of the paper copies of records of food recalls dating back to January of 1994 and perform a data analysis of those recalls.

The FSIS is responsible for ensuring the safety of food products as described in the Federal Meat Inspection Act (2016), the Poultry and Poultry Products Inspection Act (2008), the Egg Products Inspection Act (2016), and the Humane Methods of Livestock Slaughter Act (FSIS, 2013c). These acts entrust FSIS inspectors with the oversight responsibility for the humane slaughter of cattle, sheep, swine, goats, horses, mules, or other equines; all domesticated birds such as chickens, turkeys, ducks, geese, and guinea fowl; as well as all eggs once removed from the shell such as dried, frozen or liquid eggs. These animals and animal products are governed under specific regulations outlined in Title 9 of the Code of Federal Regulations (9 C.F.R.) under Chapter 3 (FSIS, 2004). The FSIS regulatory ability comes from Title 21 of the United States Code (USC) starting with Section 601 for the Federal Meat Inspection Act (2016), Section 451 for the Poultry and Poultry Products Inspection Act (2008), and section 1031 for the Egg Products Inspection Act (2016). These laws and regulations empower the FSIS to be able to regulate animal and meat processing facilities to ensure the safest food possible.

As a public health agency, the FSIS is committed to ensuring that food products originating from FSIS-regulated slaughter plants and packing facilities are as safe and free of harmful agents as possible. Their oversight attempts to ensure that everything from the time the animal enters the slaughter facility to the time it is served to a person is appropriate, legal and safe for consumers. The FSIS ensures that companies are held to the high standards of food safety that the United States requires and has set forth as law.

Food recalls can happen for any number of reasons such as physical or biological contaminants, undeclared allergens, mislabeling or other reasons as indicated in Title 21 of the Code of Federal Regulations. Although every recall has its own unique circumstances, the FSIS has designed a standard yet flexible process for recommending that a facility recall product into which most potential recall cases can be integrated. The process by which FSIS recommends a recall usually begins with a USDA-regulated facility's notification to FSIS. As per 21 USC 612 (2011), if a facility believes that an adulterated product has entered commerce, they will promptly notify the USDA through the FSIS, providing the type of product, amount of product, where the product originated, and where it is being transported. Once notified, the FSIS RMTAD begins the process of identifying what went wrong, where it went wrong, how it went wrong, and how much product should be involved in a recall. Once they have this information, they look at many factors that could affect whether or not a recall is needed, such as distribution, expiration date, or previous recalls, which might have set a precedent.

There are many steps that are taken to determine the scope of a recall. The scope of a recall is defined as the number of pounds of product that is being recalled. To determine the scope of a recall it is important to begin with the reason the product needs to be recalled. This is relevant because of the different processes which occur in a facility that determine the starting point of the problem, such as metal being detected in a lot, versus *E. coli* being detected in a lot. The scope is delineated to include all of the product that may have been affected by the identified problem. The amount of product actually recalled varies depending on multiple factors including sanitation schedules in the cases of biological contaminants and cleaning and maintenance schedules in the cases of foreign matter. Once the scope of the recall has been determined, and sometimes before the scope is determined, the FSIS decides to either recommend a recall,

recommend a public health alert, or not recommend a recall; however not recommending a recall is rare.

Once the FSIS RMTAD has all of the information they need, they conduct a phone meeting with the appropriate FSIS departments that are part of the standing Recall Team. The departments that are generally involved in recalls are OFO, OPHS, OPACE, OPPD, OIEA (Table 2-1). Once the aforementioned departments have given and received all of the information they need, then the phone conversation is joined by the local inspector who is assisting the facility, and a representative of the facility where the notification originated. The information is relayed to the firm in question, and they are informed about the decision to either recommend a recall, place a public health alert, or to not recall.

Table 2-1 - FSIS departments typically involved in regulating recalls

OFO – Office of Field Operations OPHS – Office of Public Health Science OPACE – Office of Public Affairs and Consumer Education OPPD – Office of Policy and Program Development OIEA – Office of Investigation, Enforcement, and Audit ODIFP – Office of Data Integration and Food Protection

Occasionally, the facility where the problem was discovered does not want to recall their products. Depending on the recall class (see Table 2-2), the inspectors still have actions they can take to keep the public safe. According to 9 CFR 500, the FSIS can take regulatory action against the firm by withholding the mark of inspection or withdrawing the mark of inspection. Under 21 USC 672 and 467 (2011), for product that has been misbranded or adulterated, the FSIS can also detain that product for up to 20 days. However, most of the time, the firms agree with the recommendation and their product is recalled. After the recall has been initiated, the local

inspectors along with their district office oversee the recall and disposition of the returned product. Once the facility has made all reasonable attempts to bring back the product that was sent out, the inspectors verify their work and the recall is then closed.

To be effective with the recall process, it is important to have good communication skills and be able to work as a team. Outside offices are sometimes called upon for their input such as the Office of Planning, Analysis and Risk Management. On larger recalls, other agencies can be involved such as the Centers for Disease Control and Prevention (CDC), the Food and Drug Administration (FDA), or the Environmental Protection Agency (EPA).

Table 2-2 – Food recall class description (FSIS, 2015)

Class I – A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death
Class II – A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food
Class III – A Class III recall involves a situation in which eating the food will not cause adverse health consequences

Project Objectives

The objectives of this project were to:

- Graphically depict the number of recalls of FSIS-regulated products per year from January 1, 1994 through August 31, 2018, and evaluate the annual number of recalls based on certain characteristics including:
    - Recall class
    - Facility size as defined by HACCP regulations

    - Types of meat products involved
    - Source or route by which the recall was initiated
    - Reason for the recall (i.e., contaminant, defect, etc.)
- Further evaluate those characteristics based on:
    - Number of recalls of FSIS-regulated products due to pathogen sources versus non-pathogen sources
    - Which pathogens were prominent
- Further evaluate the number of recalls of FSIS-regulated products per year from the period of January 1, 1994 through August 31, 2018 resulting from *Escherichia coli* contamination, using additional characteristics including:
    - By month
    - Whether the recall was in response to an illness, outbreak, or neither
    - By the seven primary serotypes of *Escherichia coli* O157:H7, O26, O45, 0103, O111, O121, and O145

Project Description

Data from different sources and in different media forms, including hard copy paper food recall records, records which were partially kept electronically but still contained a hard copy paper backup, and databases that contained documentation of the remaining recalls in digital format with no paper backup records, were organized during this project. The project involved sorting the paper files and scanning them into electronic format for digital backup copies as well as gathering the necessary data from both paper and electronic sources for a general evaluation of the recall records, which will be referred to in the remainder of this report as a trend analysis.

The data evaluation considered whether changes in the incidence of food recalls over time may have been impacted by new programs or laws. This information could help indicate whether control measures may have potentially increased or decreased the number of recalls over time. The importance of tracking recalls of FSIS-regulated foods that occurred due to STEC is demonstrated every time there is an *E. coli* illness outbreak due to a FSIS-regulated food products, because it points out areas that can be reevaluated to mitigate future illness outbreaks. The primary goal of food recalls is to ensure that harmful food is removed from commerce before it has the opportunity to cause damage.

Materials and Methods

Prior to 2006, all records of recalls of FSIS-regulated foods were kept as hard copy paper-based files. Starting in 2006, some of the information was captured in the paper files, but the rest of the information was captured electronically in both the Recall Web, where the documentation contains all of the paperwork associated with the recall, and in the Recall Case Archive, where a brief overview of each recall case and any additional paperwork is kept. Recall Web is the intranet program where digital files of recalls of FSIS-regulated food products are kept and are accessible to only those within the FSIS. Beginning in 2012, all information was kept electronically, and paper files were no longer used. Because the project covered the time period from January 1, 1994 through August 31, 2018, information was retrieved from both hard copy paper-based files as well as electronic and digital sources.

To make the files available for this project, the paper recall files were scanned, and a digital library was created for the FSIS team members which will make it easier in the future to gather data for Freedom of Information Act requests. For this digital library, the collected

paperwork regarding each food recall was scanned into a portable document format or PDF file and labeled with the seven-digit recall tracking number indicating the order in which the recall was initiated followed by the year in which the recall was conducted. For example, 035-2018 is the file for the 35th incidence of a food recall in the calendar year 2018. A total of 1,165 paper files were scanned and categorized for further use.

As noted above, there were two primary sources of digital information that were used during this project. The first is the FSIS intranet program called Recall Web. This is the current location of the digital records of food recall archives. The second source is a publicly available portion of the FSIS website called the FSIS Recall Case Archive which contains the basic information regarding closed food recalls; this archive is available to the general public through the FSIS website (FSIS, 2019).

Table 2-3 - Initial information taken from the paper files of food recalls of FSIS-regulated products entered into Recall Web and Microsoft Excel for internal use by the FSIS RMTAD

* Recall Tracking Number	* Problem Type or Reason for the Recall
* Date Recall Opened	* Source/What or Who Initiated the Recall
* Class of Recall	* Establishments Name
* Size of the Firm	* USDA Establishment Number
* Total Pounds Indicated as the Scope	* State Where the Establishment is Located
* Type of Product Being Recalled	* Date the Recall is Closed
* Animal Type Category of Meat	* Total Pounds Recovered During the Recall

To evaluate the recalls that occurred from 1994-2018, a set of standard information was gathered for each recall (See Table 2-3). As the records were digitized, the required data at the time of the recall was not always the data that was needed for this project. Possible reasons that the data needed was missing include differences in collection methods and differences in required documentation at the time. Therefore, for this project it was necessary to collect the data involved by reviewing the paperwork from food recall paper archives and transcribe the data from the paper file into a Microsoft Excel spreadsheet focusing on the categories listed in Table 2-3. For a detailed explanation of each of these categories, see Appendices 1, 2, and 3. Appendix 1 contains definitions of the categories of information used in recall case files (as seen in Table 2-3). Appendix 2 contains the definitions for the different problem types, also known as reasons the recalls were initiated such as descriptions of pathogens or standard operating procedure deviations. Appendix 3 contains the definitions for the sources of who or what initiated the review for a potential recall, such as a third party or state lab or an illness or outbreak.

Table 2-4 - Attributes of recalls of FSIS-regulated food products that were used for this data analysis

* Recall Class	* Reason for the Recall
* Facility Size	* Source that Initiated the Recall
* Pounds Recalled	* The Month and Year
* Type of Product	* The District Office Responsible
* Animal Type Category of Meat	* Pounds Recovered

A total of 1,810 recalls of FSIS-regulated food products were documented between January 1, 1994 and August 31, 2018. The common attributes that were used to evaluate the recall data are shown in Table 2-4. The attributes indicated in Table 2-4 were used to chart and

compare FSIS-regulated food recalls according to RMTAD-specified comparisons to give insight into the reasons and numbers of recalls.

RMTAD required that not only the digital library be completed, but the trend analysis be run to compare incidence of food recalls in several ways. RMTAD requested comparisons by class, recall reason, manner in which the problem was discovered, pathogen type, allergen type, and extraneous material discovery. Furthermore, for each of the comparisons previously mentioned, the RMTAD wanted further categorization by either month, calendar year, or both.

Table 2-5 - Subset of information used to specifically evaluate the recalls of FSIS-regulated foods in relation to STEC

* Recall Case Number * Recall Class * HACCP Facility Size * The Month and Year * The Source or Who or What Initiated the Recall * Specific Serotypes

Recalls were evaluated by specific pathogen type to analyze the number of recalls of FSIS-regulated food products that resulted due to STEC. For the more specific analysis of STEC, the following subset of attributes were used (Table 2-5). These more specific analyses may give the ability for future research to further analyze the trends of recalls of FSIS-regulated food products due to STEC. Future research may also propose possible explanations of the data regarding the changes in numbers of recalls and how those changes may relate to food policy changes regarding STEC during the same time frame.

Chapter 3. Results

General Recall Data

Figure 3-1 shows the total number of recalls, by calendar year, beginning in January 1994 through August 2018. This graph represents a simple count of the number of recalls for each year retrieved from Recall Web, the software that the FSIS uses to keep track recalls of food that the FSIS regulates. There were 1810 recalls during the study time period. The lowest number of recalls per year was observed in 1996 (25 recalls) and the highest number (150) in 2015.

The entire study period included data from 24 full calendar years (1994-2017) and one partial calendar year (January-August of 2018). For purposes of calculating annual averages only data from the 24 full calendar years (1994-2017) were used. On average, there were 73 recalls each calendar year. The final year of the project, 2018, had 73 recalls by August, potentially indicating that there may be more than the average number of recalls for the entire calendar year of 2018. Furthermore, during the period 1994-2017, there were 10 years that had more than the 73 average recalls per year, and 14 that had less. Figure 3-1 demonstrates an increase in recalls beginning in 1998 and continuing until 2002. Then, in 2003, the number of recalls decreased by almost 40% from the number of recalls in 2002, and again in 2004 the number of recalls decreased another 30% from 2003. Since a low point in 2006 with 34 recalls, the number of recalls increased by an average of 11% over the next 9 years until it peaked again in 2015. There was a small decrease in 2016, but an increase again in 2017.

Figure 3-2 shows the total number of pounds (in millions) of FSIS-regulated food products that were recalled, by calendar year. The total number of pounds of FSIS-regulated food products recalled during the study period from January 1994 through August 2018 was

774,259,875. Using data from 1994-2017, an average of 32.1 million pounds of product were recalled each year, with an average of 444,070 pounds per recall. Between January 1 and August 31, 2018, 2.9 million pounds of product was recalled with an average of 39,868 pounds per recall. Interestingly, even though Figure 3-1 shows that 2007 and 2008 were in the lower 30% for overall number of recalls of FSIS-regulated foods, Figure 3-2 shows the total pounds of recalled products in 2007 and 2008 were 2.4 and 2.6 times higher, respectively, than the next closest year in terms of pounds of product recalled. The large quantity of product recalled in 2007 and 2008 was due primarily to two recalls, one in each year. The first, in 2007, was due to a *Salmonella* outbreak in chicken pot pies, which forced the company to recall nearly 85 million pounds of product from the previous two years of production (Eamich, 2007). In 2008, a facility in California was cited with improper antemortem inspection of cattle, due to processing of a non-ambulatory cow causing a recall of more than 143 million pounds of beef (FSIS, 2008). Each of these two years had one major recall that made the total number of pounds recalled larger than the rest of the years.

Figure 3-3 shows the total number of recalls per year by Recall Class, either Class I, Class II or Class III (See Table 2-2 for definitions of Recall Classes). Figure 3-4 shows the total number of recalls of FSIS-regulated foods by Class for all years combined. In total, 71% of all recalls (1289) were Class I, 21% (382) were Class II and 8% (137) were Class III. Of the 1810 recalls, two recalls were not attributed to any Class. The two recalls that were not attributed a Recall Class were recall numbers 026-1994 and 001-1995 (FSIS, 1994; FSIS 1995). Recall 026-1994 was due to sulfadimethozine drug residue and Recall 001-1995 was due to being produced without the benefit of inspection (FSIS, 1994; FSIS, 1995). There is no clear reason as to why those two recalls were not attributed a Recall Class.

FSIS began to use HACCP-defined facility size in 1998 but did not capture this information in recall reports until 2004. From January 2004 through August 2018 there were a total of 1,216 recalls of FSIS-regulated food products of which 1,052 had facility size documented. It is unknown why the remaining 164 recalls did not have a documented facility size; these recalls were disbursed across the 2004-2018 timeframe with at least one recall per year with no attributed facility size. Figure 3-5 shows that from 2004 to 2018 (the time period in which HACCP-defined facility size was documented), larger numbers of recalls of FSIS-regulated food products were attributed to small facilities than to very small or large facilities. Furthermore, from 2004 through 2017, small facilities were attributed an average of 38 recalls per year, very small facilities an average of 21 recalls per year, and large facilities an average of 11 recalls per year. Between January 1, and August 31, 2018, there were 35 recalls attributed to small facilities, 16 to very small facilities, and 13 to large facilities.

From 2004 through 2018, in every year but one (2015), more recalls were attributed to small facility size than to very small or large facility size (see Figure 3-5). In 2015, the largest number of recalls were associated with very small facilities. Figure 3-5 also indicates gaps in the data where no facility size was recorded, including the final year in the study, 2018. Reasons for gaps in this collected data are unknown. Furthermore, Figure 3-6 demonstrates that gap in records to be 11% (126/1178) of the total number of recalls of FSIS-regulated foods during the time period of January 2004 through August of 2018 not recording the HACCP-defined facility size. The remainder of the recalls for which HACCP-defined facility size was documented further demonstrates that more recalls were attributed to small facilities than large and very small facilities.

Figures 3-6 and 3-7 demonstrate the percentage of the total number of recalls of FSIS-regulated foods by HACCP-defined facility size. When including those recalls for which data regarding facility size was not available, 48% (570) of all recalls during the time period of January 2004 through August 2018 were attributed to small facilities, as per Figure 3-6. Furthermore, very small facilities were attributed 27% (316) of the total number of recalls, and large facilities were attributed 14% (166). Data about facility size was not available for the remaining 11% (126).

The total number of recalls of FSIS-regulated foods can also be analyzed by which type of meat (species) was involved. FSIS categorizes meat products into seven broad types: beef, poultry, pork, ovine, mixed, exotic, and other. The category beef includes all products that contain only cattle parts. Poultry, on the other hand, combines all the different types of poultry included in the Poultry and Poultry Products Inspection Act (2016). Pork and ovine, like beef, only count products from pigs or sheep respectively. The term “exotic” currently encompasses bison, buffalo, and fish from the order Siluriformes. Figure 3-8 shows the total number of recalls of FSIS-regulated food products by meat type per calendar year. Using data from 1994 through 2017, an average of 23 recalls per year were attributed to beef, 18 to poultry, 18 to a mixed variety, and 13 to pork; the remaining classifications, exotic, ovine and other, each had averages of less than one. As shown in Figure 3-9, which depicts the percentage of the total number of recalls of FSIS-regulated foods by meat type, the largest number of recalls (32%) were attributed to beef products. This does not include those recalls which may be labeled as mixed or containing beef. The second largest percentage of the total number of recalls by animal type category was poultry with 25%, followed closely by those recalls of mixed origin at 24%. Pork accounted for 18% of all recalls. The final 1% was divided between exotic and ovine.

The term “exotic” first appeared as a meat type category in 2010, and ovine first appeared in 2012. The first usage of the term “exotic” was for an outbreak investigation of *E. coli* O157:H7 in 2010 that, with the help of the FDA and CDC, was discovered to have originated in bison (Khan, 2010). Bison represented two of the recalls within the “exotic” category, and the remaining seven recalls classified as “exotic” were attributed to Siluriformes. Furthermore, only four recalls from January 1994 through August 2018 were attributed to ovine, with one annually from 2012 to 2015. Within Figure 3-9, ovine appears as 0% due to rounding; however, ovine actually represented 4/1810, or 0.22% of the total number of recalls.

Each potential recall, whether it went through the full recall process or not, also had a route of initiation by which it can be categorized. There are many different categorizations of the route by which a recall can be initiated. For the purposes of tracking recalls, FSIS categorizes the route of initiation of each recall into the following: 3rd Party, CDC/ INV, Compliance, Consumer, CP Inv, FDA, Follow-Up, Foreign, Health Code Violation, IIC, Illness, Import, Monitor, Outbreak, Plant, Retail, State, State Lab, Trace Back (for detailed descriptions and definitions see Appendix 3). Per Table 3-1 (which spans multiple pages), not every route of initiation was observed in every year. There were five recalls within the study period for which no initiating factor was indicated, four in 1994 and one in 1995.

Within Table 3-1, the first column of each year shows the total number of recalls of FSIS-regulated foods that were attributed to that specific route of initiation category. The second column of each year shows the percentage of that route of initiation category in that year compared to the total number of times that route of initiation category was observed during the study period of January 1994 through August 2018. Table 3-1 also shows (in the furthest right column) the total number and percentage of recalls that were attributed to each route of initiation

category for the entire study period. Table 3-1 is organized from the most common category of the route of initiation at the top to the least common on the bottom.

Figure 3-10 and Table 3-2 show an expanded view of the data in the far-right column of Table 3-1. Figure 3-10 shows the percentages of the total number of recalls of FSIS-regulated foods attributed to each route of initiation for the entire study period. According to Table 3-2, the three most common routes of initiation were; Plant, Monitor, and IIC. These three represented the initiation route for almost 2/3 (65.6%) of the total number recalls of FSIS-regulated food products with a specified route of initiation category during the entire study period (1805), with the remaining 34.4% of recalls being initiated by one of the other 16 initiation routes. In contrast, the four least common category of the route of initiation were <2% of the 1805 recalls during the study period.

Another important attribute to consider is the reason a recall was initiated; that is, the contaminant, problem or defect that caused the recall to be initiated. Table 3-3 shows the reason (i.e., contaminant, defect, pathogen, etc.) for which FSIS-regulated food products were recalled. These reasons are categorized as: Undeclared Allergens, *Listeria monocytogenes*, *Escherichia coli* O157:H7, Other, Extraneous Material, Undeclared Substance, *Salmonella*, Misbranded, Processing Defect, Under Processed, Residue – Chemical, *Escherichia coli* Non O157:H7, Residue – Drug, Process Deviation, Unapproved Substance, Miscellaneous, Spoilage Bacteria, Other Pathogens, Traceback, Non-Potable Water, *Escherichia coli* O157:Non-Motile, and *Escherichia coli* Positive Water (for detailed description see Appendix 2). As shown in Table 3-3, the top three reasons recalls were initiated were: Undeclared Allergens, *Listeria monocytogenes*, and *Escherichia coli* O157:H7. Collectively, these three represented 54.8% of all recalls (1810). Unlike the data seen in Table 3-1, the data in Table 3-3 included the entire data

set of 1810 recalls. Table 3-3 is organized in the same manner as Table 3-1. Within Table 3-3 the first column of each year shows the total number of recalls of FSIS-regulated food products attributed to a given reason. The second column of each year shows the percentage of that reason in that year compared to the total number of times that reason was observed during the study period of January 1994-August 2018. Table 3-3 also shows (in the furthest right column) the total number and percentage of recalls that were attributed to each reason for the entire study period. Furthermore, the final row shows the total number of recalls that occurred in that year, and the percentage of the total number of recalls from the study period that were attributed to that year. Figures 3-11 and 3-12 along with Table 3-4 show the percentages of the total number of recalls attributed to each initiation reason. The nine least common initiation reasons made up 2% of the total number of recalls, with seven of them comprising the lowest 1%.

Figure 3-12 represents an expanded view of the least common reasons which made up 2% of the total. The three least common reasons a recall was initiated had one incident each. One incident, non-potable water, refers to recall 035-1994 where a facility had to recall their product due to a notification that the water used on a specific day had been deemed non-potable. One incident, *E. coli* O157:NM (non-motile), refers to recall 062-2011 where an outbreak investigation confirmed that five illnesses were linked to the recalling facility. Finally, the third individual category of *E. coli* positive water refers to recall 078-2016, in which a facility received notification from the city municipality that the water that was used for their carcass rinsing was found to be contaminated with *E. coli*.

Recalls of FSIS-regulated products can be divided into two categories: those that occurred due pathogen contamination and those that occurred for reasons other than pathogen contamination. Reasons other than pathogen contamination include: Undeclared Allergens,

Other, Extraneous Material, Undeclared Substance, Misbranded, Processing Defect, Under Processed, Chemical Residue, Drug Residue, Process Deviation, Unapproved Substances, Miscellaneous, Spoilage Bacteria, Traceback, Non-Potable Water, and *E. coli* Positive Water. Pathogen contaminants can include: *Listeria monocytogenes*, *Escherichia coli* O157:H7, *E. coli* non-O157:H7, *E. coli* O26, O45, O103, O111, O121, O145, *E. coli* O157:NM, *Salmonella*, and Other Pathogens. Figure 3-13 shows the total number of recalls of FSIS-regulated food products for each calendar year that were pathogen-related versus non-pathogen-related. The years 1999, 2000, 2001, 2002, 2005, 2007 and 2008 are highlighted because the number of pathogen-related recalls was greater than the number of non-pathogen related recalls. Additionally, 1998, a year in which recalls due to pathogens equaled recalls due to non-pathogens, is highlighted. In total, just over one-third (38%) of recalls during the study period were due to pathogens. Figure 3-14 shows the percentage of recalls of FSIS-regulated food products that were pathogen-related versus non-pathogen-related.

Figure 3-15 shows the number of recalls per year by specific pathogen including: shiga toxin-producing *Escherichia coli* (STEC) serotypes, *Listeria monocytogenes* (LM), *Salmonella*, and other pathogens. Of the 692 recalls due to pathogens, four were classified as being attributed to "other pathogens." Recalls 004-1995 and 032-1995 were due to the potential presence of the Human hepatitis A virus. In September of 2001, Recall 048-2001 was due to the potential presence of botulinum toxin. Finally, Recall 067-2003 was due to a single cow imported from Canada, which tested positive for bovine spongiform encephalopathy (BSE) (FSIS, 2003). LM and STEC represent the pathogens that caused the majority of recalls due to pathogens and were identified as the reason in 89% of the total number of pathogen-related recalls of FSIS-regulated food products, with 51% attributed to LM and 38% to STEC, as shown in Figure 3-16. Even

though overall more recalls were due to LM than to STEC, in a given year STEC recalls occasionally outnumbered LM recalls. As shown in Figure 3-15, those years for which the total is highlighted in blue indicates that there were more recalls that year due to STEC than LM. With all the changes that have been made to policy regarding STEC, it is important to focus on those recalls to see if there is any change in the numbers of recalls.

E. coli Recall Data

Looking at the total number of recalls of FSIS-regulated food products per year that were due to STEC, no readily apparent trend was observed. As per Figure 3-17, which shows the total number of recalls due to the presence of STEC by calendar year, the greatest number of recalls attributed to the presence of STEC occurred in 2007 in which there were 22 recalls. The least number of recalls attributed to the presence of STEC occurred in 1996 in which there were two recalls. Calculating the calendar year average using the 1994-2017 data gave an average of 11 recalls per calendar year. For 2018 there were six recalls due to STEC as of August 31. Even so, the percentage of all recalls of FSIS-regulated food products due to STEC varied differently than the total number of recalls, in that it did not show the same high points and low points throughout the study period from January 1994 through August 2018. Figure 3-18 shows the percentage of total recalls per year that were due to STEC. The year with the greatest percent was 2007, in which 38% (22/150) of all recalls that year were attributed to STEC. The smallest percentage of the total number of recalls attributed to STEC in a given year was 5% in both 2014 and 2015 (5/94 and 8/150). Using the 1994 through 2017 calendar year data, the average annual percentage of recalls which were attributed to STEC was 15%. As of August 31, 2018, 8% (6/73) of recalls in 2018 were attributed to STEC.

Figure 3-19 shows the number of recalls due to STEC categorized by month of the year during the study period. The month with the largest number of observed recalls was October followed closely by August, with 39 and 37 recalls, respectively. The month with the least number of recalls due to STEC was February with six. The average number of recalls due to STEC for each month of the year, calculated with the 1994-2017 calendar year data was 22. From January 1 to August 31, 2018 there were six recalls due to STEC with the largest number (two) occurring in August.

Recalls due to STEC can also be evaluated by the HACCP-defined size of the facility which recalled the product. Figure 3-20 shows the number of recalls of FSIS-regulated food products each year due to STEC, categorized by facility size. In all calendar years except 2012 and 2015, more STEC-related recalls were attributed to small facilities than to very small or large facilities. For recalls related to STEC, no data related to the HACCP-defined facility size is available for the period1994-2004. As shown in Figure 3-21, it is apparent that during the period from January 2005 through August 2018 small facilities accounted for almost half of the STEC-related recalls, with 73 (48%) recalls from small facilities, 38 (24%) recalls from very small facilities, and 23 (15%) from large facilities. Using calendar year data from 2005-2017 for facility sizes, the average number of recalls per year due to STEC was five recalls for the small facility size, three for the very small facility size, and two for large facility size. From January 1 through August 31, 2018 there were two recalls due to STEC associated with small facility size, two with medium facility size, and one with large facility size, as well as one recall which did not indicate the size of the facility.

Recalls that occurred due to STEC can be grouped into two categories, those that occurred in response to a reported illness or outbreak and those that occurred in response to

another source. Figure 3-22 shows the number of recalls of FSIS-regulated food products due to STEC divided between those which were due to illness/outbreak versus those that were due to reasons other than illness/outbreak. Figure 3-22 indicates that 2005 was the only year in which the number of STEC-related recalls of FSIS-regulated food products associated with illness was larger than the number of recalls not associated with illness. The years 2004 and 2007 had equal number of STEC-related recalls due to illness and not due to illness. Using the 1994-2017 calendar year data, the average number of recalls per year not due to illness was eight, and the average number of recalls per year due to illness was three. In 2018, by August 31, there was one STEC recall due to illness and five that were due to non-illness. Overall, there were more than three times the number of STEC-related recalls not due to illness versus those due to illness, as demonstrated in Figure 3-23, with 61 (23%) due to illness and 206 (77%) not due to illness.

Since 2010, FSIS began serotyping of STEC-positive samples to verify if the serotype is *E. coli* O157:H7, O26, O45, O103, O111, O121, O145, or another serotype. *E. coli* O157:H7, O26, O45, O103, O111, O121, and O145 have been declared adulterants and are tested for. Since there are some recalls which contained multiple serotypes, Figure 3-24 demonstrates the number of times a serotype was identified during the years that they were tested for but does not correlate directly to the number of recalls. An example of multiple serotypes being identified during one recall is Recall 010-2014 where *E. coli* O26, O45, O103, O111, O121, and O145 were all found in the sample that was associated with one company's product recall (FSIS, 2014b). Consequently, Recall 010-2014 was attributed to all five of these serotype categories (FSIS, 2014b). Finally, Figure 3-25 shows the total number of recalls of FSIS-regulated food products due specifically to *E. coli* O157:H7 during the entire study period. Since 2007, there has been a downward trend in the number of recalls due to *E. coli* O157:H7.

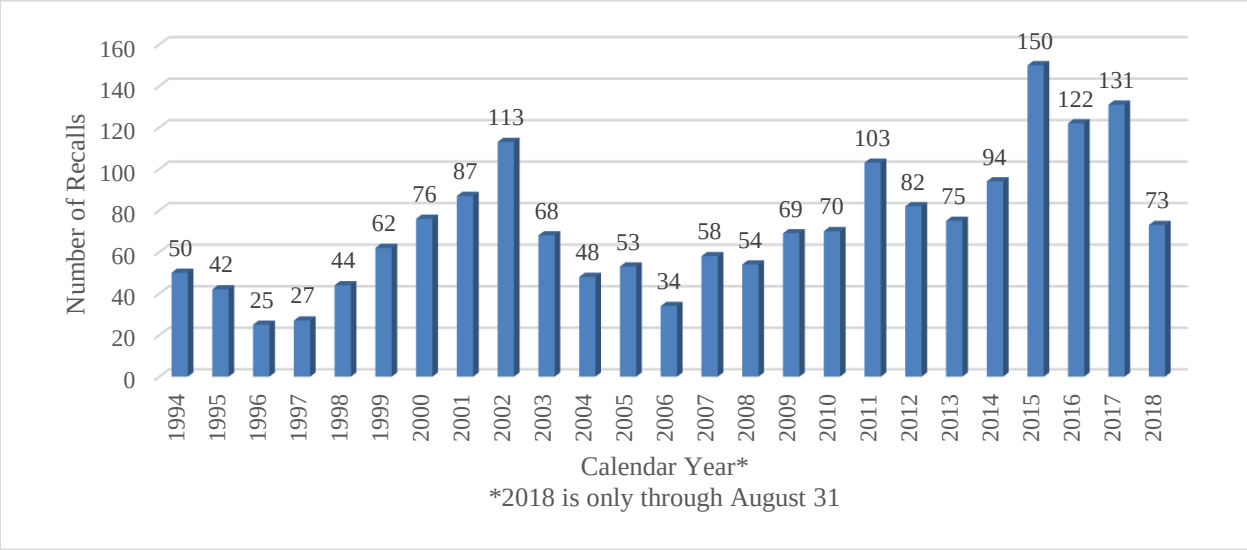

Figure 3-1 - Total number of recalls of FSIS-regulated food products per calendar year from January 1994 through August 2018

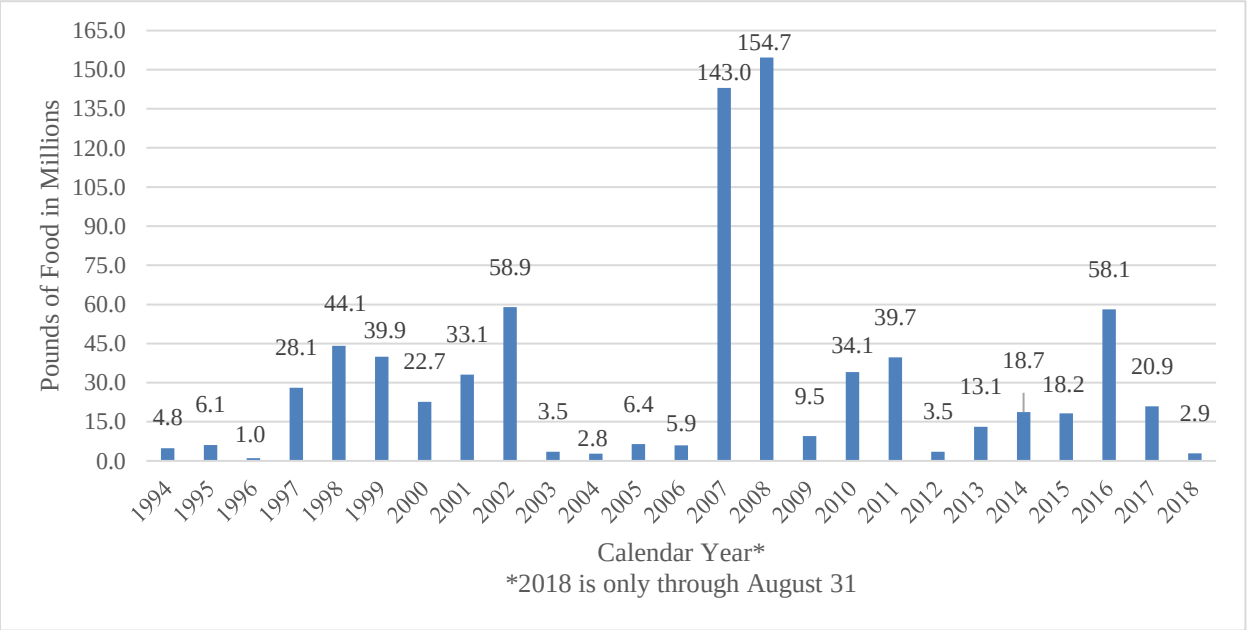

Figure 3-2 - Total pounds (in millions) of recalls of FSIS-regulated food products per calendar year from January 1994 through August 2018

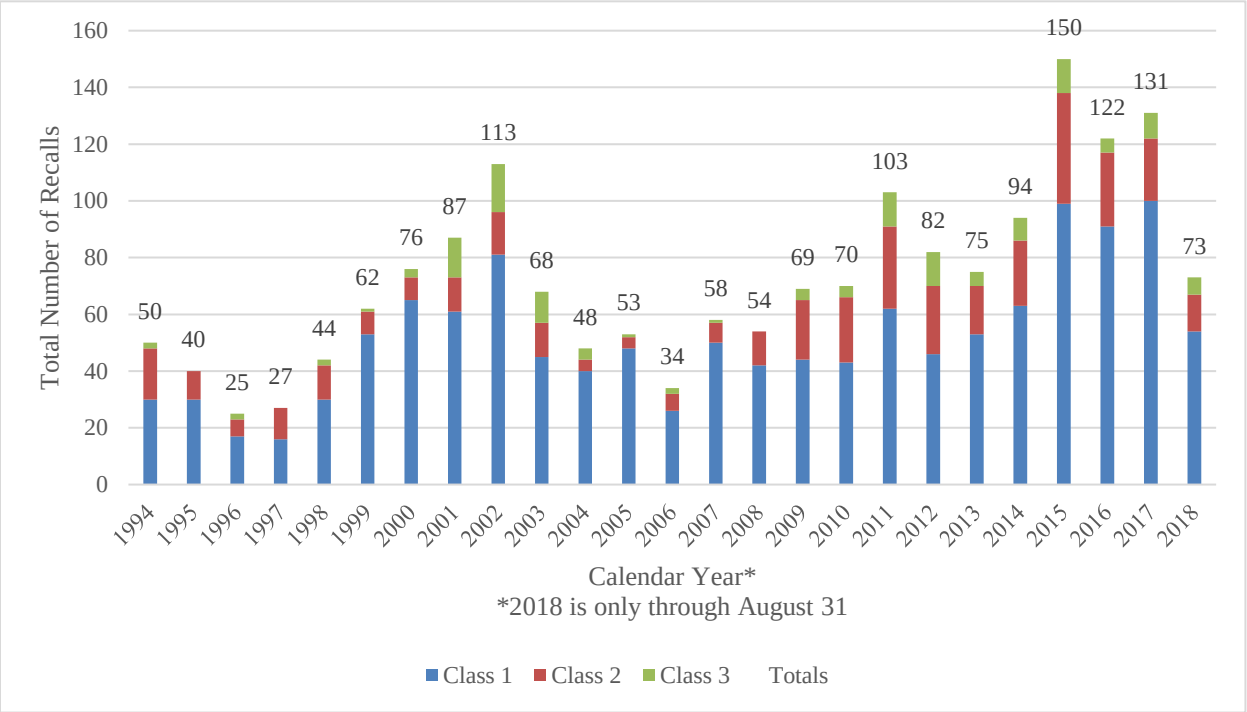

Figure 3-3 - Total number of recalls of FSIS-regulated food products by recall class per calendar year from January 1994 through August 2018

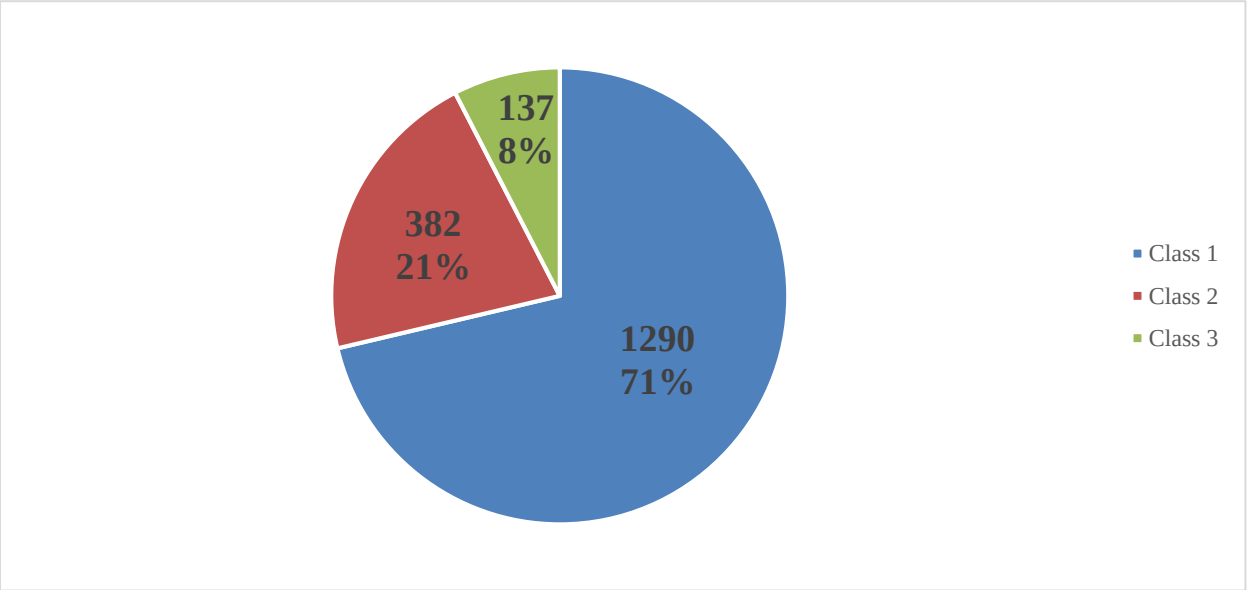

Figure 3-4 - Percentage of all recalls of FSIS-regulated food products by recall class from January 1994 through August 2018

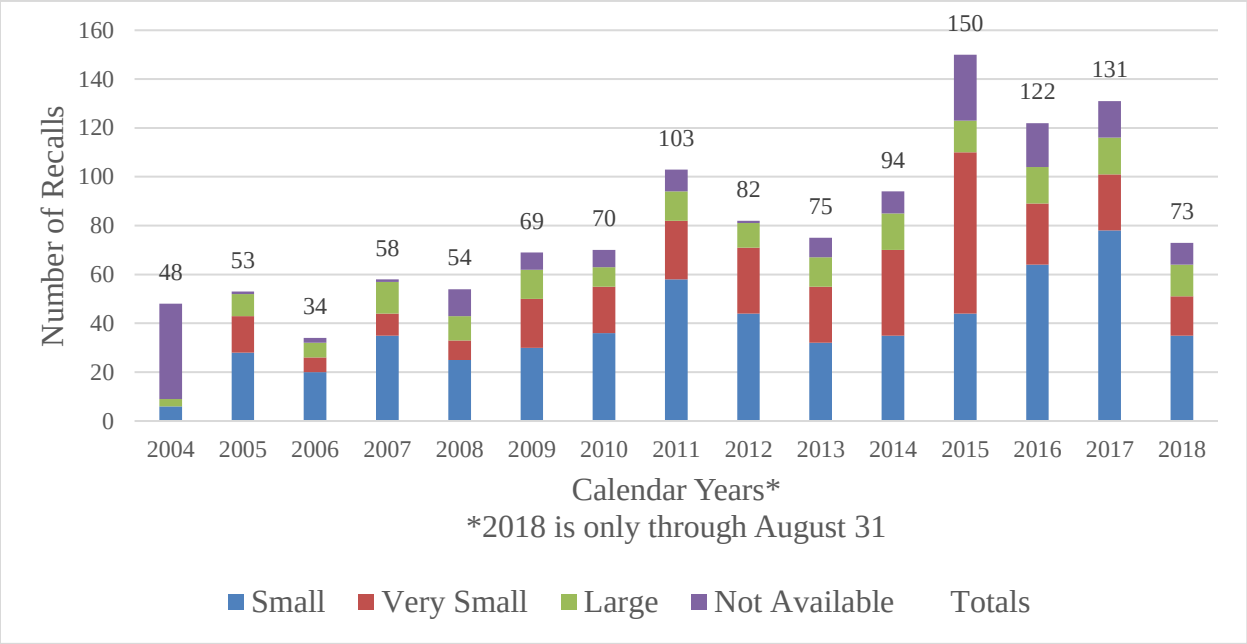

Figure 3-5 - Total number of recalls of FSIS-regulated food products classified according to HACCP-defined facility size per calendar year from January 2004 through August 2018

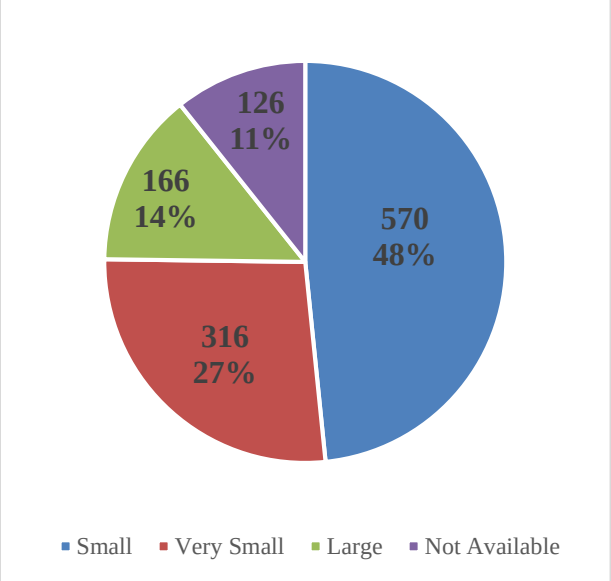

Figure 3-6 - Percentage of total number of recalls of FSIS-regulated food products by HACCP-defined facility size from January 2004 – August 2018

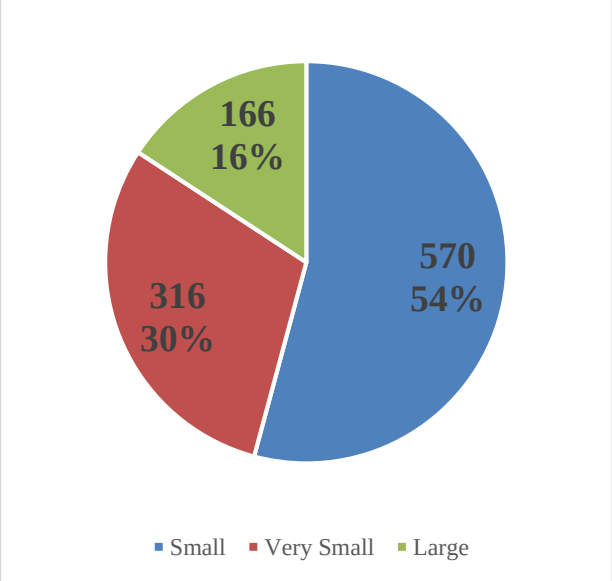

Figure 3-7 - Percentage of total number of recalls of FSIS-regulated food products by HACCP-defined facility size, excluding those recalls for which facility size was not designated from January 2004-August 2018

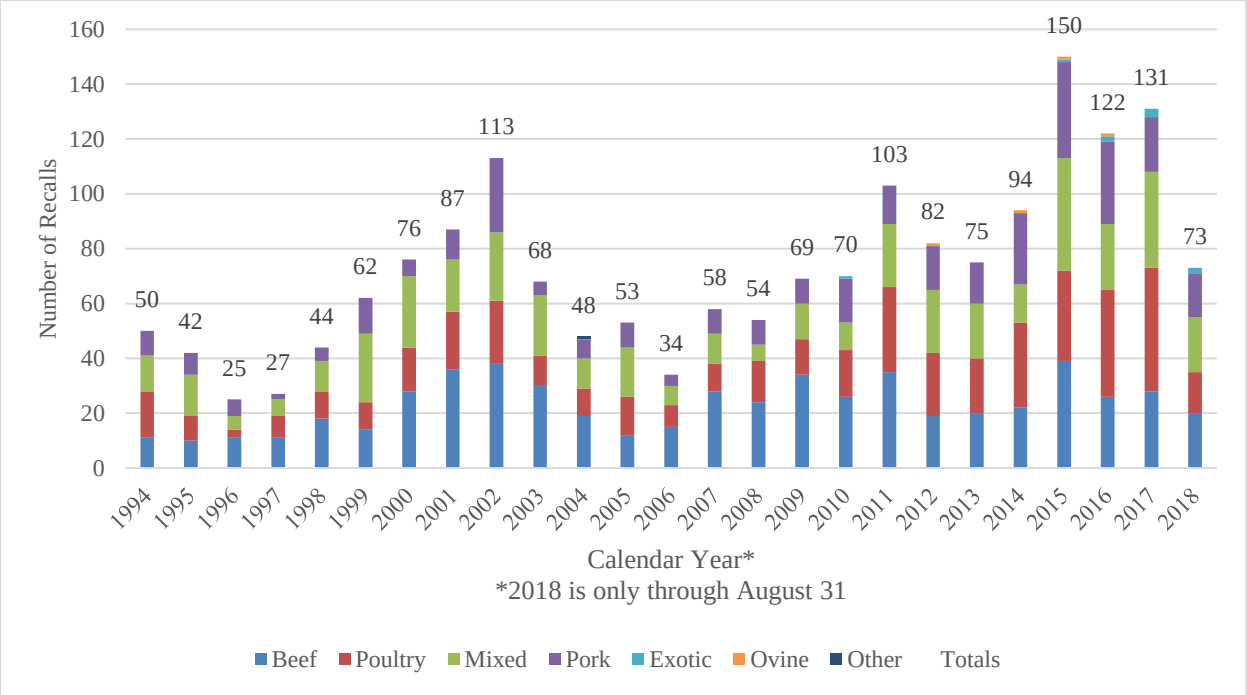

Figure 3-8 - Total number of recalls of FSIS-regulated food products distributed by the animal type category of meat involved in the recall per calendar year from January 1994 through August 2018

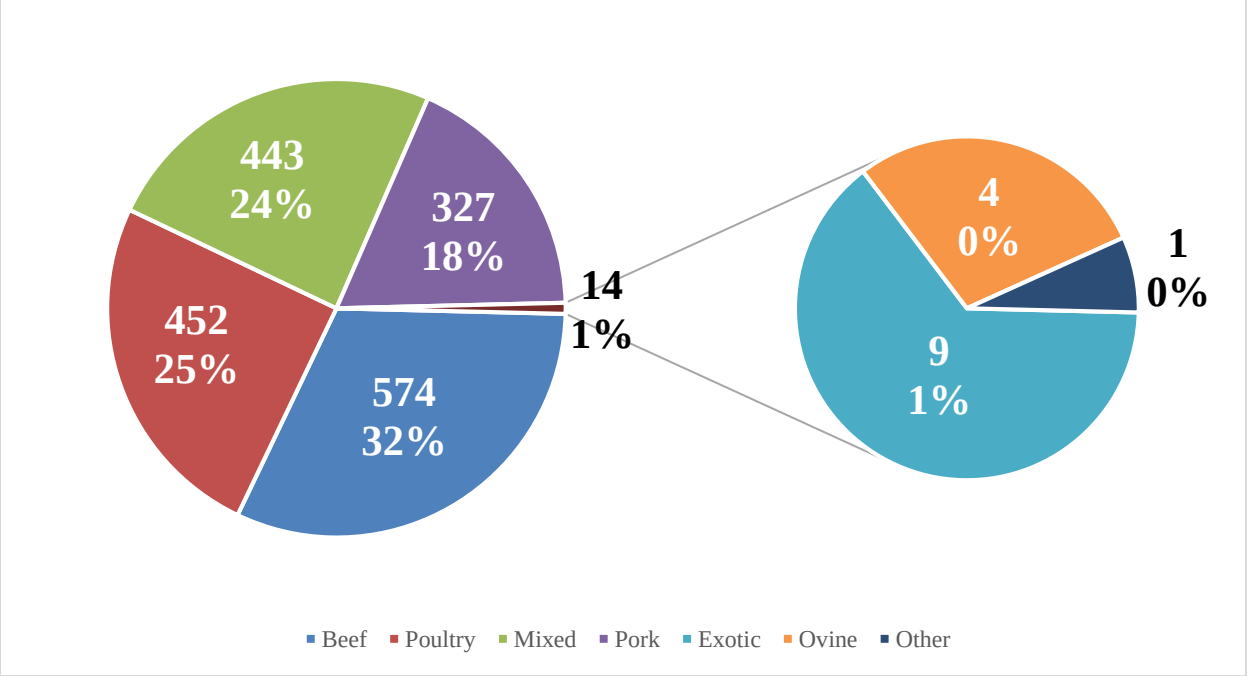

Figure 3-9 - Percentage of the total number of recalls of FSIS-regulated food products distributed by animal type category of meat involved in the recall from January 1994 - August 2018

Table 3-1 - Total number of recalls of FSIS-regulated food products per year from January 1, 1994 through August 31, 2018 categorized according to the source or route by which the recall was initiated

Year	1994		1995		1996		1997		1998		1999		2000		2001		2002		2003		2004		2005		2006	
Plant	9	2.1%	3	0.7%	9	2.1%	11	2.6%	11	2.6%	11	2.6%	14	3.3%	27	6.4%	38	9.1%	21	5.0%	23	5.5%	20	4.8%	15	3.6%
Monitor	15	3.9%	20	5.2%	7	1.8%	6	1.6%	13	3.4%	32	8.3%	42	10.9%	35	9.1%	42	10.9%	18	4.7%	10	2.6%	16	4.2%	10	2.6%
IIC	0	0.0%	0	0.0%	1	0.3%	2	0.5%	1	0.3%	1	0.3%	3	0.8%	3	0.8%	16	4.2%	11	2.9%	1	0.3%	6	1.6%	4	1.0%
Consumer	11	6.7%	14	8.5%	0	0.0%	3	1.8%	1	0.6%	0	0.0%	2	1.2%	3	1.8%	0	0.0%	2	1.2%	4	2.4%	2	1.2%	2	1.2%
3rd Party	1	0.7%	0	0.0%	1	0.7%	1	0.7%	4	2.9%	1	0.7%	1	0.7%	0	0.0%	0	0.0%	1	0.7%	0	0.0%	2	1.4%	0	0.0%
Outbreak	0	0.0%	0	0.0%	0	0.0%	1	1.7%	1	1.7%	0	0.0%	0	0.0%	1	1.7%	3	5.2%	1	1.7%	0	0.0%	1	1.7%	1	1.7%
CP Inv	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	4.4%	0	0.0%	0	0.0%
Illness	1	2.7%	3	8.1%	1	2.7%	0	0.0%	5	13.5%	5	13.5%	1	2.7%	2	5.4%	1	2.7%	0	0.0%	3	8.1%	2	5.4%	0	0.0%
Import	0	0.0%	0	0.0%	2	7.1%	1	3.6%	1	3.6%	0	0.0%	2	7.1%	10	35.7%	6	21.4%	4	14.3%	1	3.6%	0	0.0%	0	0.0%
FDA	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	3.8%	3	11.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Compliance	5	20.0%	0	0.0%	4	16.0%	0	0.0%	2	8.0%	3	12.0%	2	8.0%	4	16.0%	1	4.0%	4	16.0%	0	0.0%	0	0.0%	0	0.0%
Retail	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	4.3%	0	0.0%	0	0.0%
State	2	10.5%	0	0.0%	0	0.0%	0	0.0%	2	10.5%	2	10.5%	4	21.1%	1	5.3%	3	15.8%	4	21.1%	1	5.3%	0	0.0%	0	0.0%
State Lab	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	11.1%	0	0.0%
Follow-Up	2	13.3%	0	0.0%	0	0.0%	1	6.7%	1	6.7%	2	13.3%	0	0.0%	1	6.7%	1	6.7%	1	6.7%	0	0.0%	2	13.3%	1	6.7%
Foreign	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	22.2%	0	0.0%	1	11.1%
Trace Back	0	0.0%	0	0.0%	0	0.0%	1	11.1%	0	0.0%	2	22.2%	4	44.4%	0	0.0%	2	22.2%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
CDC/ INV	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	33.3%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%
Health Code Violation	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Yearly Totals	46	2.5%	41	2.3%	25	1.4%	27	1.5%	44	2.4%	62	3.4%	76	4.2%	87	4.8%	113	6.3%	68	3.8%	48	2.7%	53	2.9%	34	1.9%

* Footnote – The first column of each year shows the total number of recalls of FSIS-regulated foods that were attributed to that specific route of initiation category. The second column of each year shows the percentage of that route of initiation category in that year compared to the total number of times that route of initiation category was observed during the study period of January 1994 through August 2018. In the furthest right column, the total number and percentage of recalls that were attributed to each route of initiation category for the entire study period are listed. This table is organized from the most common category of the route of initiation at the top to the least common on the bottom.

Table 3-1 cont. - Total number of recalls of FSIS-regulated food products per year from January 1, 1994 through August 31, 2018 categorized according to the source or route by which the recall was initiated

Year	2007		2008		2009		2010		2011		2012		2013		2014		2015		2016		2017		2018		Initiation Method Totals	
Plant	14	3.3%	14	3.3%	18	4.3%	15	3.6%	15	3.6%	21	5.0%	12	2.9%	27	6.4%	40	9.5%	10	2.4%	14	3.3%	7	1.7%	419	23.2%
Monitor	15	3.9%	19	4.9%	13	3.4%	11	2.9%	13	3.4%	5	1.3%	6	1.6%	3	0.8%	17	4.4%	9	2.3%	7	1.8%	1	0.3%	385	21.3%
IIC	8	2.1%	6	1.6%	12	3.1%	25	6.6%	41	10.8%	25	6.6%	28	7.3%	34	8.9%	74	19.4%	32	8.4%	30	7.9%	17	4.5%	381	21.1%
Consumer	4	2.4%	1	0.6%	4	2.4%	5	3.0%	13	7.9%	13	7.9%	6	3.6%	5	3.0%	4	2.4%	20	12.1%	26	15.8%	20	12.1%	165	9.1%
3rd Party	1	0.7%	3	2.2%	2	1.4%	2	1.4%	5	3.6%	3	2.2%	10	7.2%	12	8.6%	7	5.0%	33	23.7%	39	28.1%	10	7.2%	139	7.7%
Outbreak	3	5.2%	6	10.3%	8	13.8%	4	6.9%	5	8.6%	1	1.7%	7	12.1%	5	8.6%	3	5.2%	4	6.9%	1	1.7%	2	3.4%	58	3.2%
CP Inv	0	0.0%	0	0.0%	8	17.8%	4	8.9%	2	4.4%	3	6.7%	2	4.4%	7	15.6%	0	0.0%	6	13.3%	4	8.9%	7	15.6%	45	2.5%
Illness	9	24.3%	0	0.0%	0	0.0%	2	5.4%	2	5.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	37	2.0%
Import	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	3.6%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	28	1.6%
FDA	1	3.8%	0	0.0%	3	11.5%	0	0.0%	3	11.5%	9	34.6%	2	7.7%	0	0.0%	1	3.8%	2	7.7%	1	3.8%	0	0.0%	26	1.4%
Compliance	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	25	1.4%
Retail	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	8.7%	6	26.1%	6	26.1%	8	34.8%	23	1.3%
State	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	19	1.1%
State Lab	2	11.1%	2	11.1%	0	0.0%	1	5.6%	2	11.1%	1	5.6%	2	11.1%	1	5.6%	2	11.1%	0	0.0%	3	16.7%	0	0.0%	18	1.0%
Follow-Up	1	6.7%	0	0.0%	0	0.0%	1	6.7%	1	6.7%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	15	0.8%
Foreign	0	0.0%	3	33.3%	1	11.1%	0	0.0%	1	11.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	11.1%	9	0.5%
Trace Back	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	9	0.5%
CDC/ INV	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	3	0.2%
Health Code Violation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.1%
Yearly Totals	58	3.2%	54	3.0%	69	3.8%	70	3.9%	103	5.7%	82	4.5%	75	4.2%	94	5.2%	150	8.3%	122	6.8%	131	7.3%	73	4.0%	1805	

* Footnote – The first column of each year shows the total number of recalls of FSIS-regulated foods that were attributed to that specific route of initiation category. The second column of each year shows the percentage of that route of initiation category in that year compared to the total number of times that route of initiation category was observed during the study period of January 1994 through August 2018. In the furthest right column, the total number and percentage of recalls that were attributed to each route of initiation category for the entire study period are listed. This table is organized from the most common category of the route of initiation at the top to the least common on the bottom.

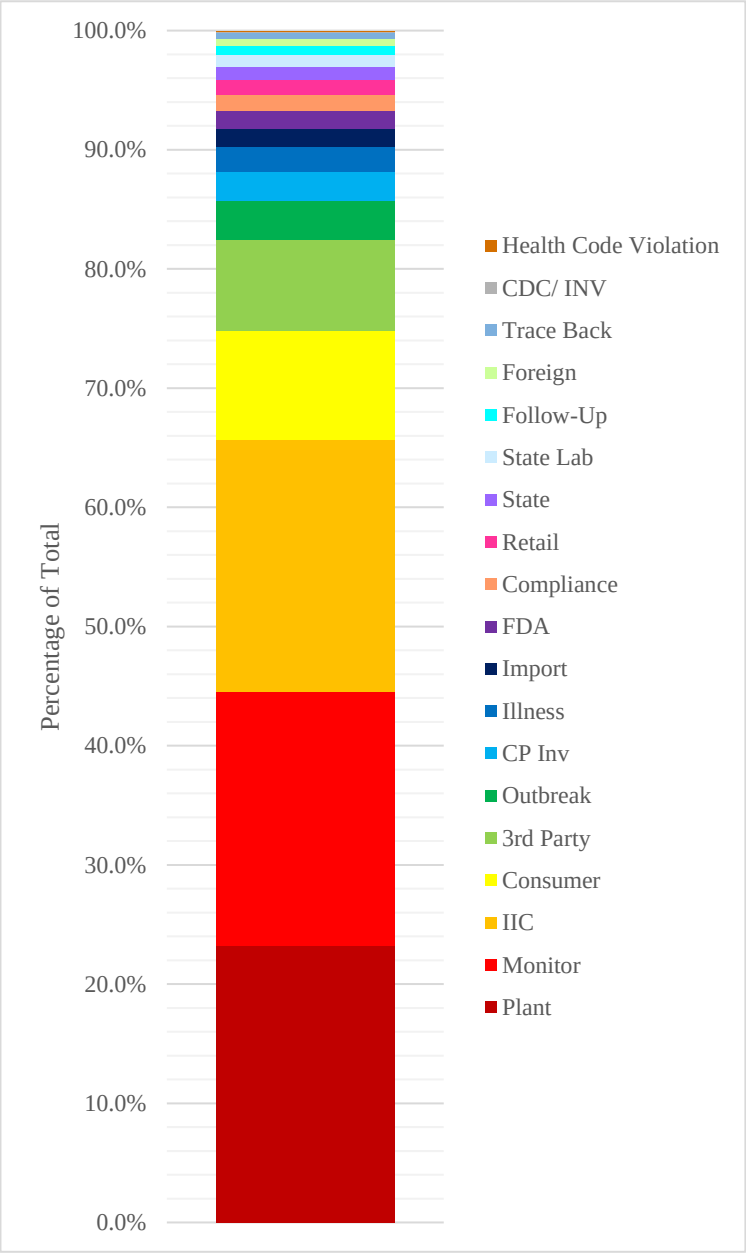

Figure 3-10 - Percentages of the overall total number of recalls of FSIS-regulated food products attributed to each initiation source or route from January 1994 through August 2018

Table 3-2 - Percentage of the total overall numbers of recalls of FSIS-regulated food products attributed to each initiation source or route from January 1994 through August 2018

Category	Percentage of Total
Plant	23.2%
Monitor	21.3%
IIC	21.1%
Consumer	9.1%
3rd Party	7.7%
Outbreak	3.2%
CP Inv	2.5%
Illness	2.0%
Import	1.6%
FDA	1.4%
Compliance	1.4%
Retail	1.3%
State	1.1%
State Lab	1.0%
Follow-Up	0.8%
Foreign	0.5%
Trace Back	0.5%
CDC/ INV	0.2%
Health Code Violation	0.1%

Table 3-3 - Total number of recalls of FSIS-regulated food products per year from January 1, 1994 through August 31, 2018 categorized by reason (i.e., contaminant, defect, etc.) the recall was initiated

	1994		1995		1996		1997		1998		1999		2000		2001		2002		2003		2004		2005		2006	
Undeclared Allergen	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	3	0.8%	12	3.1%	0	0.0%	0	0.0%	8	2.1%	8	2.1%	9	2.3%
Listeria monocytogenes	16	4.5%	11	3.1%	6	1.7%	3	0.8%	6	1.7%	30	8.4%	35	9.8%	24	6.7%	41	11.5%	15	4.2%	13	3.7%	30	8.4%	6	1.7%
E. coli O157:H7	3	1.2%	5	2.0%	2	0.8%	6	2.4%	13	5.3%	10	4.1%	22	8.9%	19	7.7%	21	8.5%	11	4.5%	6	2.4%	5	2.0%	8	3.3%
Other	1	0.4%	1	0.4%	1	0.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.4%	4	1.7%	5	2.1%	3	1.3%	4	1.7%
Extraneous Material	14	7.1%	9	4.6%	2	1.0%	6	3.1%	6	3.1%	2	1.0%	4	2.0%	6	3.1%	5	2.6%	4	2.0%	8	4.1%	1	0.5%	4	2.0%
Undeclared Substance	1	1.1%	0	0.0%	1	1.1%	4	4.3%	0	0.0%	6	6.4%	3	3.2%	1	1.1%	24	25.5%	11	11.7%	2	2.1%	0	0.0%	0	0.0%
Salmonella	0	0.0%	2	3.0%	1	1.5%	1	1.5%	3	4.5%	6	9.1%	4	6.1%	2	3.0%	3	4.5%	2	3.0%	2	3.0%	0	0.0%	0	0.0%
Misbranded	0	0.0%	1	1.8%	3	5.5%	0	0.0%	4	7.3%	0	0.0%	2	3.6%	12	21.8%	14	25.5%	14	25.5%	3	5.5%	2	3.6%	0	0.0%
Processing Defect	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	2.2%	1	2.2%	0	0.0%	0	0.0%	2	4.4%	2	4.4%
Under Processed	7	17.5%	5	12.5%	5	12.5%	4	10.0%	4	10.0%	4	10.0%	2	5.0%	6	15.0%	3	7.5%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Residue - Chemical	0	0.0%	1	5.3%	1	5.3%	1	5.3%	2	10.5%	1	5.3%	1	5.3%	3	15.8%	0	0.0%	1	5.3%	0	0.0%	1	5.3%	0	0.0%
E. coli Non O157:H7*	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Residue - Drug	1	7.1%	3	21.4%	2	14.3%	1	7.1%	3	21.4%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	7.1%
Process Deviation	0	0.0%	2	15.4%	1	7.7%	0	0.0%	1	7.7%	3	23.1%	0	0.0%	0	0.0%	0	0.0%	5	38.5%	1	7.7%	0	0.0%	0	0.0%
Unapproved Substance	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	20.0%	0	0.0%
Miscellaneous	3	75.0%	1	25.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Spoilage Bacteria	3	75.0%	0	0.0%	0	0.0%	1	25.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Other Pathogen	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	33.3%	0	0.0%	1	33.3%	0	0.0%	0	0.0%	0	0.0%
Traceback	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Non-Potable Water	1	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
E. coli NM	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
E. coli positive water	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%
Yearly Total	50	2.8%	42	2.3%	25	1.4%	27	1.5%	44	2.4%	62	3.4%	76	4.2%	87	4.8%	113	6.2%	68	3.8%	48	2.7%	53	2.9%	34	1.9%

*For this table, all *E. coli* which are indicated in a recall, fell under either O157:H7 or Non-O157:H7 with those containing both falling into the Non-O157:H7 since the main serotype was not specifically indicated as O157:H7 and could have been that or another O serotype also found in that particular recall

** Footnote - The first column of each year shows the total number of recalls of FSIS-regulated food products attributed to a given reason. The second column of each year shows the percentage of that reason in that year compared to the total number of times that reason was observed during the study period of January 1994-August 2018. Table 3-3 also shows (in the furthest right column) the total number and percentage of recalls that were attributed to each reason for the entire study period. Furthermore, the final row shows the total number of recalls that occurred in that year, and the percentage of the total number of recalls from the study period that were attributed to that year.

Table 3-3 cont. - Total number of recalls of FSIS-regulated food products per year from January 1, 1994 through August 31, 2018 categorized by reason (i.e., contaminant, defect, etc.) the recall was initiated

	2007		2008		2009		2010		2011		2012		2013		2014		2015		2016		2017		2018		Overall Reason Total	
Undeclared Allergen	12	3.1%	7	1.8%	13	3.3%	18	4.6%	40	10.3%	29	7.5%	25	6.4%	43	11.1%	58	14.9%	34	8.7%	53	13.6%	17	4.4%	389	21.5%
Listeria monocytogenes	11	3.1%	15	4.2%	8	2.2%	8	2.2%	11	3.1%	16	4.5%	9	2.5%	7	2.0%	6	1.7%	11	3.1%	15	4.2%	3	0.8%	356	19.7%
E. coli O157:H7	22	8.9%	17	6.9%	16	6.5%	11	4.5%	12	4.9%	5	2.0%	7	2.8%	4	1.6%	6	2.4%	8	3.3%	4	1.6%	3	1.2%	246	13.6%
Other	3	1.3%	7	2.9%	18	7.6%	13	5.5%	13	5.5%	9	3.8%	14	5.9%	23	9.7%	54	22.7%	27	11.3%	17	7.1%	20	8.4%	238	13.1%
Extraneous Material	2	1.0%	5	2.6%	5	2.6%	7	3.6%	5	2.6%	13	6.6%	10	5.1%	6	3.1%	11	5.6%	21	10.7%	24	12.2%	16	8.2%	196	10.8%
Undeclared Substance	2	2.1%	0	0.0%	1	1.1%	1	1.1%	7	7.4%	7	7.4%	2	2.1%	2	2.1%	5	5.3%	7	7.4%	6	6.4%	1	1.1%	94	5.2%
Salmonella	1	1.5%	0	0.0%	3	4.5%	7	10.6%	10	15.2%	2	3.0%	4	6.1%	4	6.1%	3	4.5%	2	3.0%	1	1.5%	3	4.5%	66	3.6%
Misbranded	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	55	3.0%
Processing Defect	5	11.1%	0	0.0%	3	6.7%	2	4.4%	2	4.4%	1	2.2%	2	4.4%	4	8.9%	4	8.9%	5	11.1%	5	11.1%	6	13.3%	45	2.5%
Under Processed	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	40	2.2%
Residue - Chemical	0	0.0%	3	15.8%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	5.3%	2	10.5%	1	5.3%	19	1.0%
E. coli Non O157:H7*	0	0.0%	0	0.0%	0	0.0%	1	5.6%	0	0.0%	0	0.0%	2	11.1%	1	5.6%	2	11.1%	5	27.8%	4	22.2%	3	16.7%	18	1.0%
Residue - Drug	0	0.0%	0	0.0%	0	0.0%	2	14.3%	1	7.1%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	14	0.8%
Process Deviation	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	13	0.7%
Unapproved Substance	0	0.0%	0	0.0%	2	40.0%	0	0.0%	1	20.0%	0	0.0%	0	0.0%	0	0.0%	1	20.0%	0	0.0%	0	0.0%	0	0.0%	5	0.3%
Miscellaneous	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4	0.2%
Spoilage Bacteria	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	4	0.2%
Other Pathogen	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	3	0.2%
Traceback	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	2	0.1%
Non-Potable Water	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.1%
E. coli NM	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	0.1%
E. coli positive water	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	0	0.0%	1	100.0%	0	0.0%	0	0.0%	1	0.1%
Yearly Total	58	3.2%	54	3.0%	69	3.8%	70	3.9%	103	5.7%	82	4.5%	75	4.1%	94	5.2%	150	8.3%	122	6.7%	131	7.2%	73	4.0%	1810	

*For this table, all *E. coli* which are indicated in a recall, fell under either O157:H7 or Non-O157:H7 with those containing both falling into the Non-O157:H7 since the main serotype was not specifically indicated as O157:H7 and could have been that or another O serotype also found in that particular recall

** Footnote - The first column of each year shows the total number of recalls of FSIS-regulated food products attributed to a given reason. The second column of each year shows the percentage of that reason in that year compared to the total number of times that reason was observed during the study period of January 1994-August 2018. Table 3-3 also shows (in the furthest right column) the total number and percentage of recalls that were attributed to each reason for the entire study period. Furthermore, the final row shows the total number of recalls that occurred in that year, and the percentage of the total number of recalls from the study period that were attributed to that year.

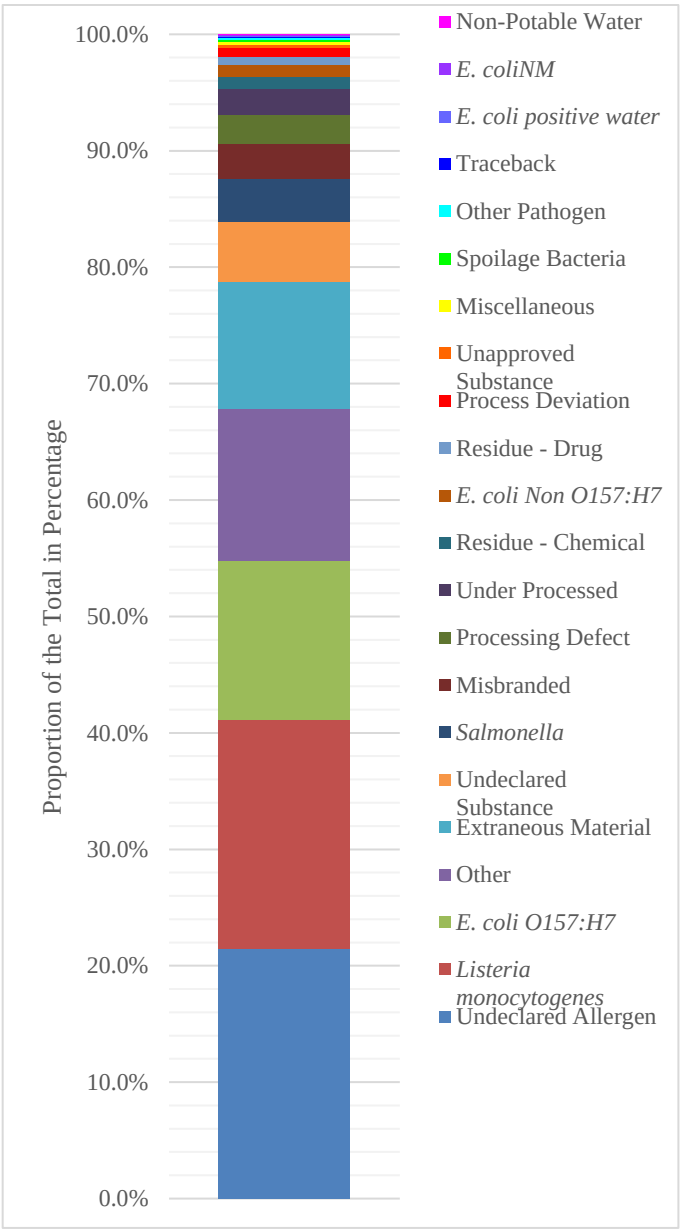

Figure 3-11 - Percentage of recalls of FSIS-regulated food products categorized by the reason the recalls was initiated from January 1994 through August 2018

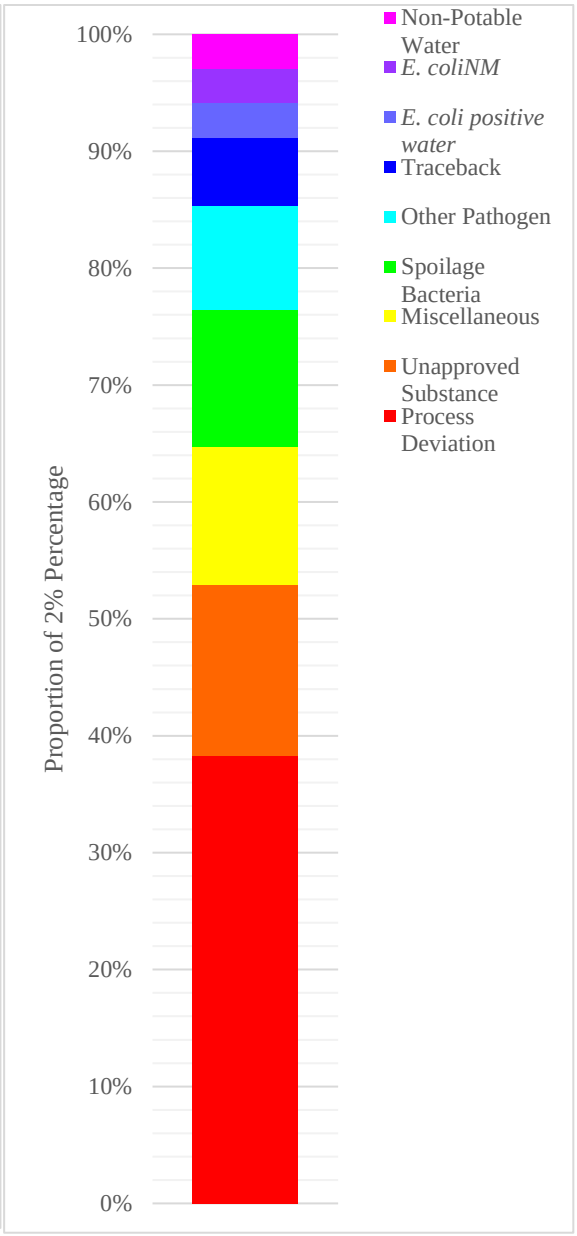

Figure 3-12 - Expanded distribution of the bottom 2% of the percentage of recalls of FSIS-regulated food products broken down by the reason the recall was initiated from January 1994 through August 2018

Table 3-4 - Percentage of the total overall numbers of recalls of FSIS-regulated food products attributed to each category of the specific reason for initiation from January 1994 through August 2018

Specific Reason for Initiation	Percentage of the Total Number
Undeclared Allergen	21.5%
Listeria monocytogenes	19.7%
E. coli O157:H7	13.6%
Other	13.1%
Extraneous Material	10.8%
Undeclared Substance	5.2%
Salmonella	3.6%
Misbranded	3.0%
Processing Defect	2.5%
Under Processed	2.2%
Residue - Chemical	1.0%
E. coli Non O157:H7*	1.0%
Residue - Drug	0.8%
Process Deviation	0.7%
Unapproved Substance	0.3%
Miscellaneous	0.2%
Spoilage Bacteria	0.2%
Other Pathogen	0.2%
Traceback	0.1%
Non-Potable Water	0.1%
E. coli NM	0.1%
E. coli positive water	0.1%

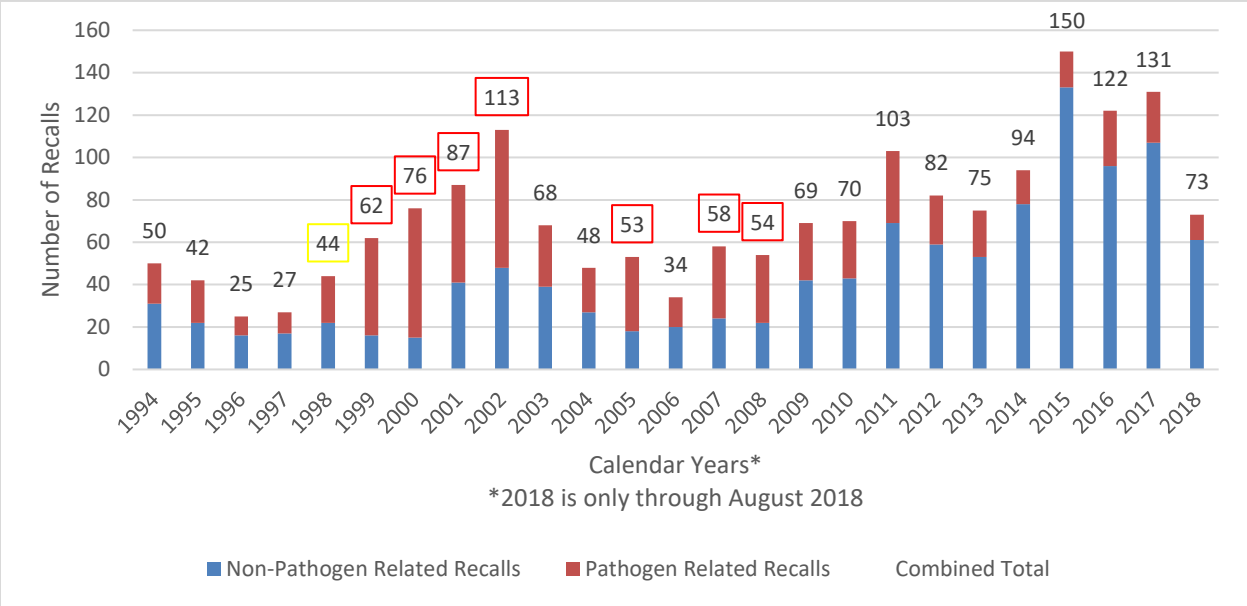

Figure 3-13 - Total number of recalls of FSIS-regulated food products that were pathogen related and non-pathogen related highlighting incidents where pathogen related recalls out-numbered non-pathogen related recalls from January 1994 through August 2018

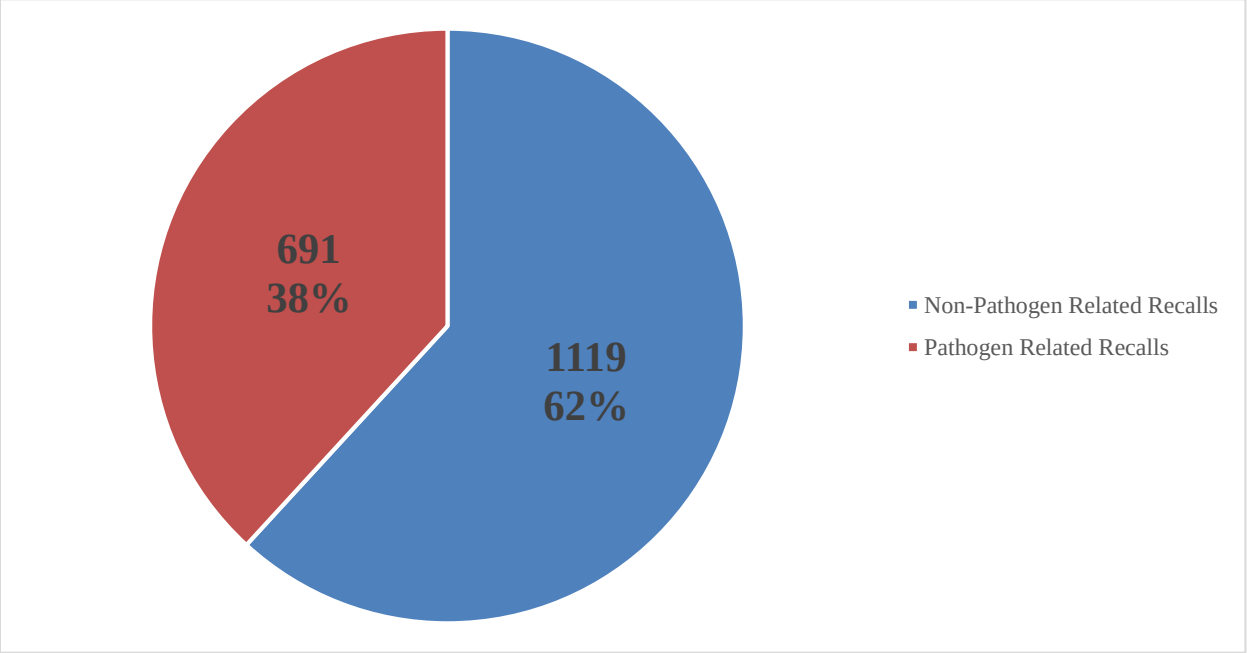

Figure 3-14 - Percentage of the total number of recalls of FSIS-regulated food products that were pathogen related versus non pathogen related from January 1994 through August 2018

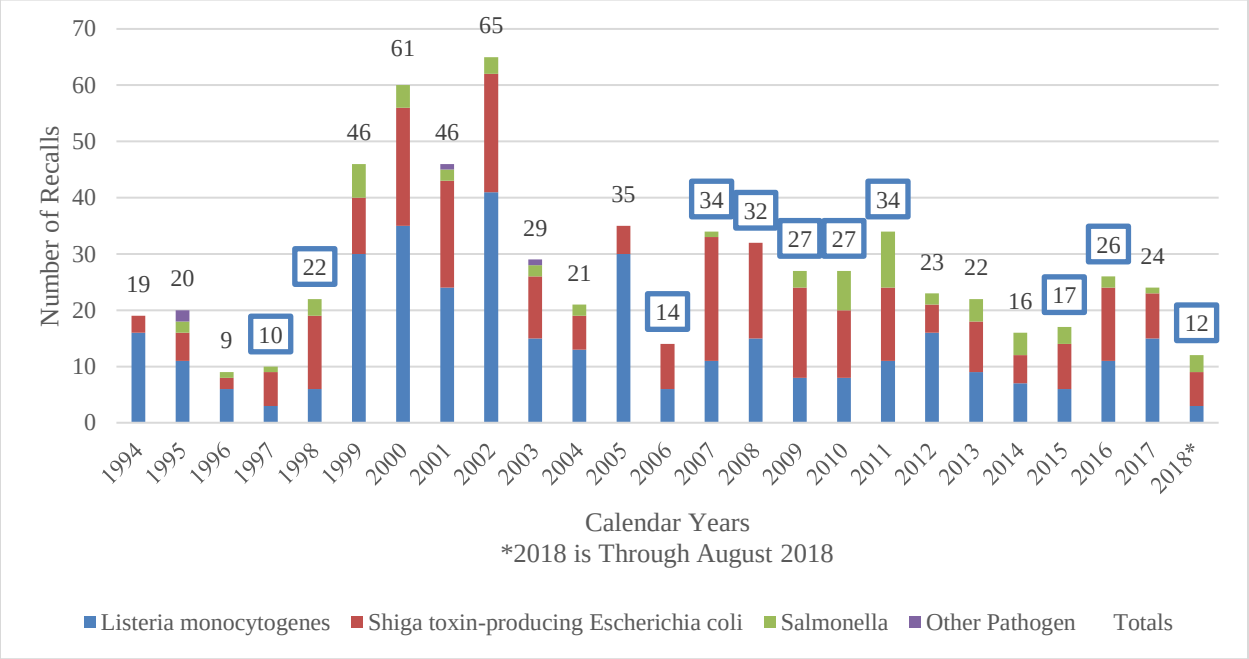

Figure 3-15 - Total number of recalls of FSIS-regulated food products due to pathogens and separated by the FSIS-specified pathogen highlighting when STEC outnumbered *Listeria monocytogenes* from January 1994 through August 2018

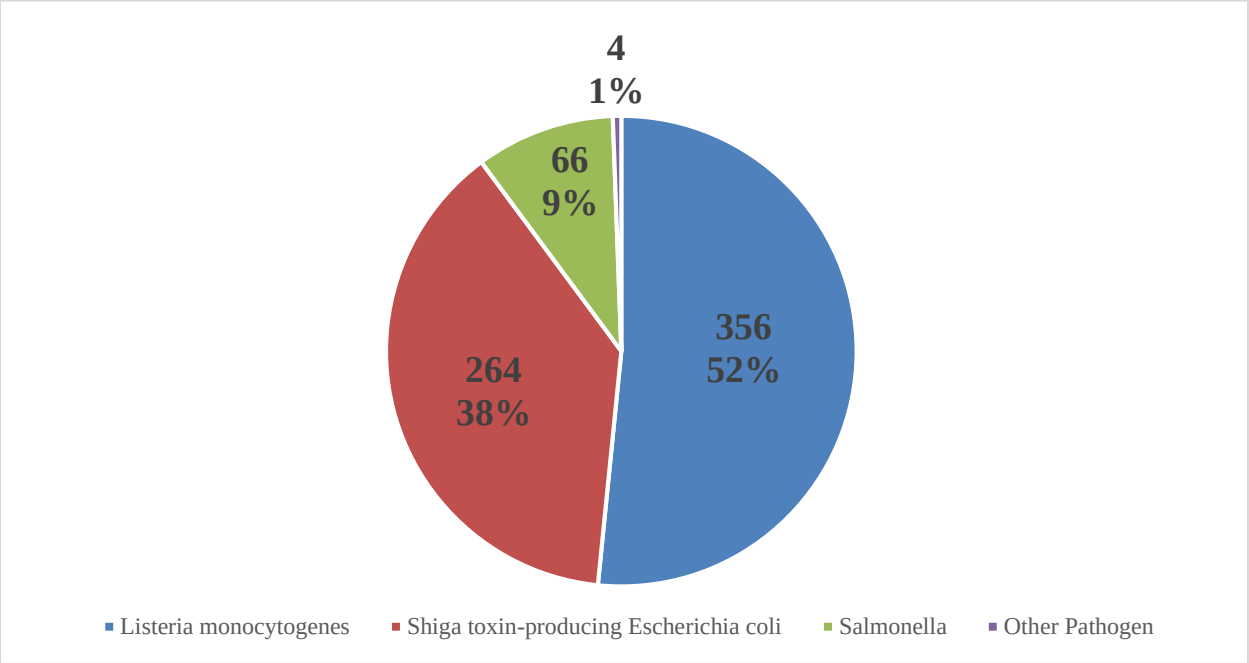

Figure 3-16 - Percentage of the total number of recalls of FSIS-regulated food products due to involvement of pathogens and separated by the specific pathogen from January 1994 through August 2018

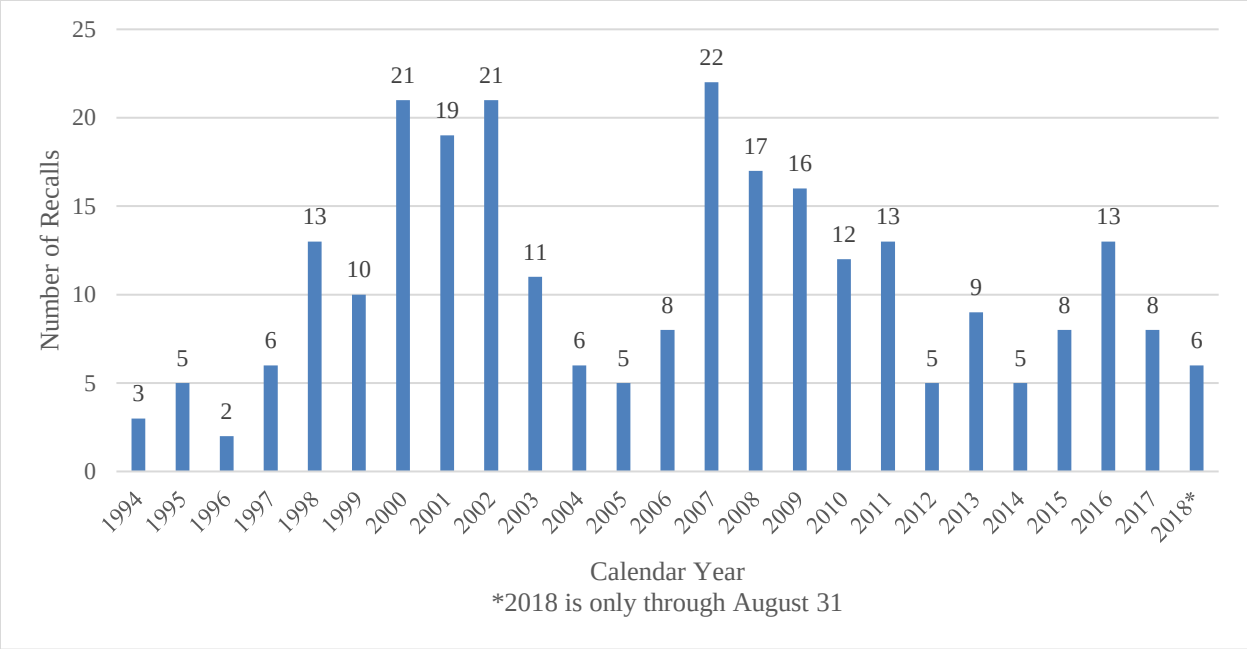

Figure 3-17 - Total number of recalls of FSIS-regulated food products due to STEC per calendar year January 1994 through August 2018

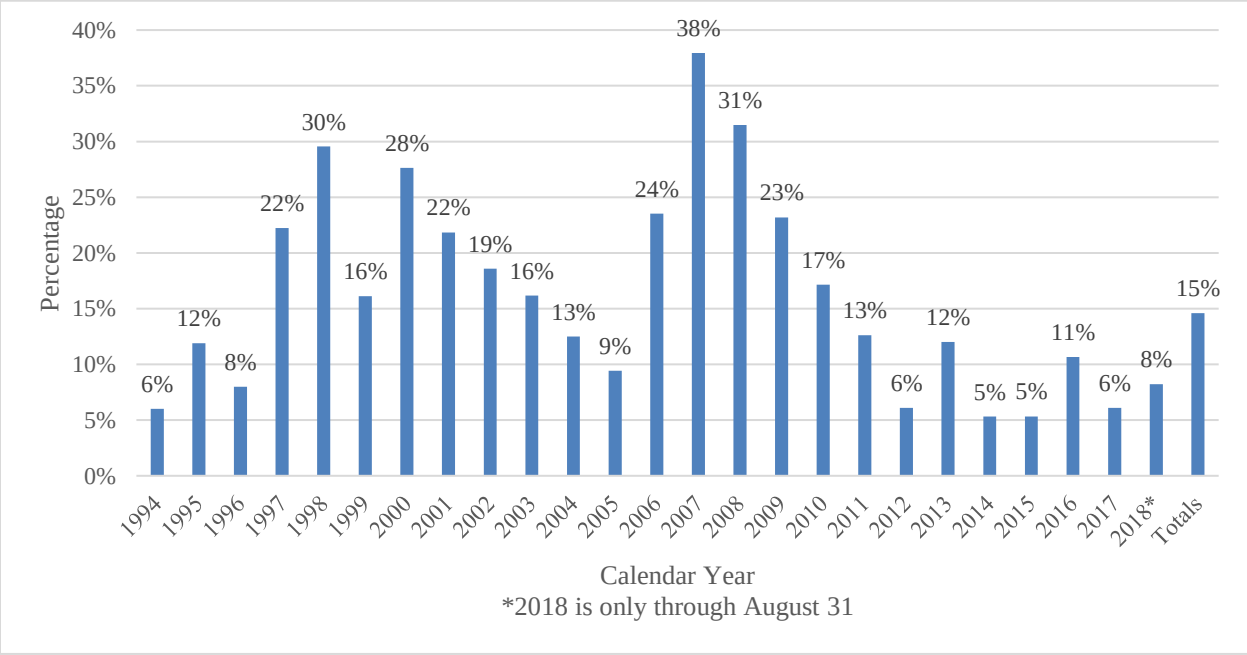

Figure 3-18 - Percentage of the total number of recalls of FSIS-regulated food products due to STEC per calendar year from January 1994 through August 2018

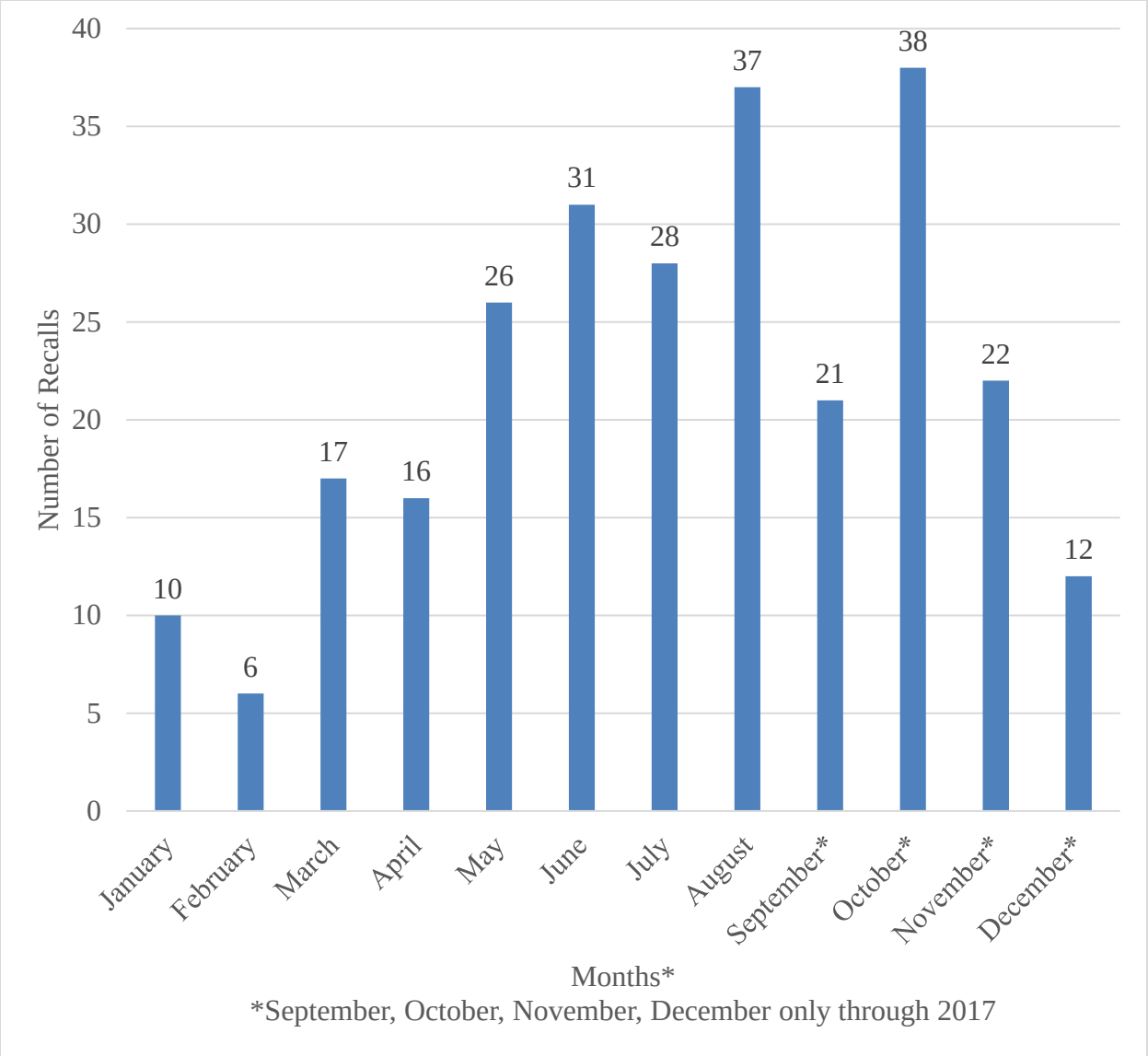

Figure 3-19 - Total number of recalls of FSIS-regulated food products due to STEC per month from January 1994 to August 2018

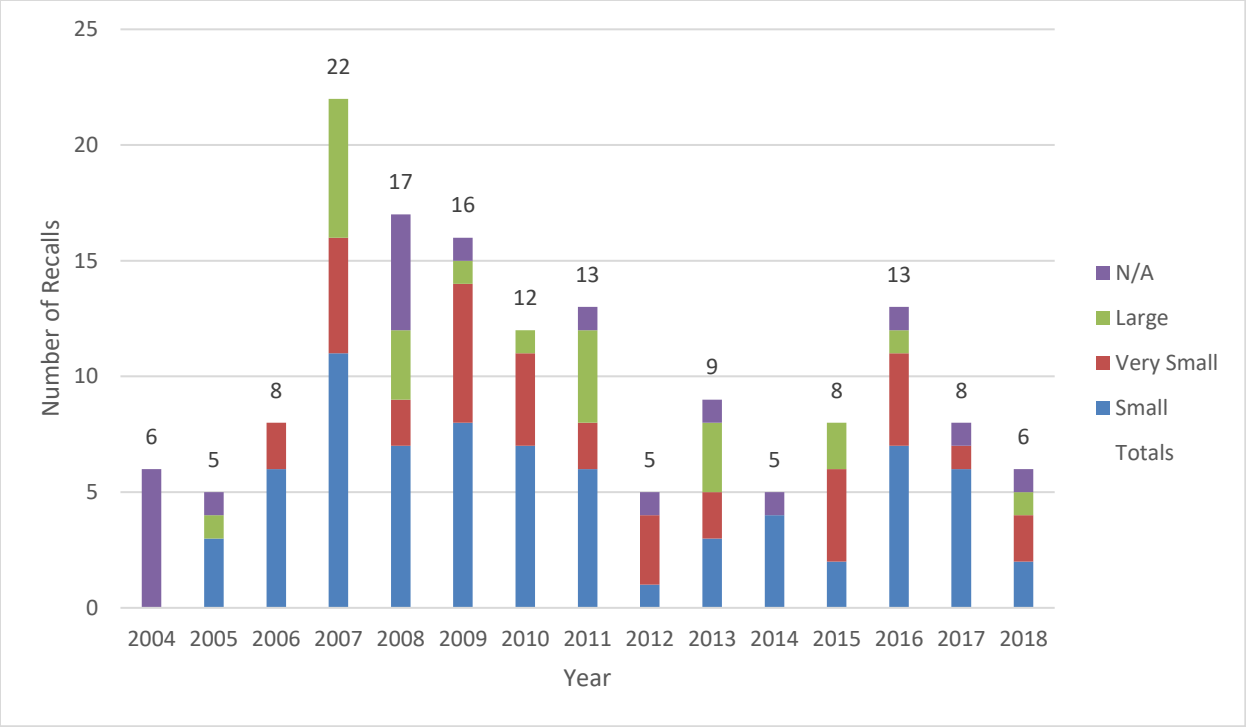

Figure 3-20 - Total number of recalls of FSIS-regulated food products due to STEC by HACCP facility size per calendar year from January 2005-August 2018

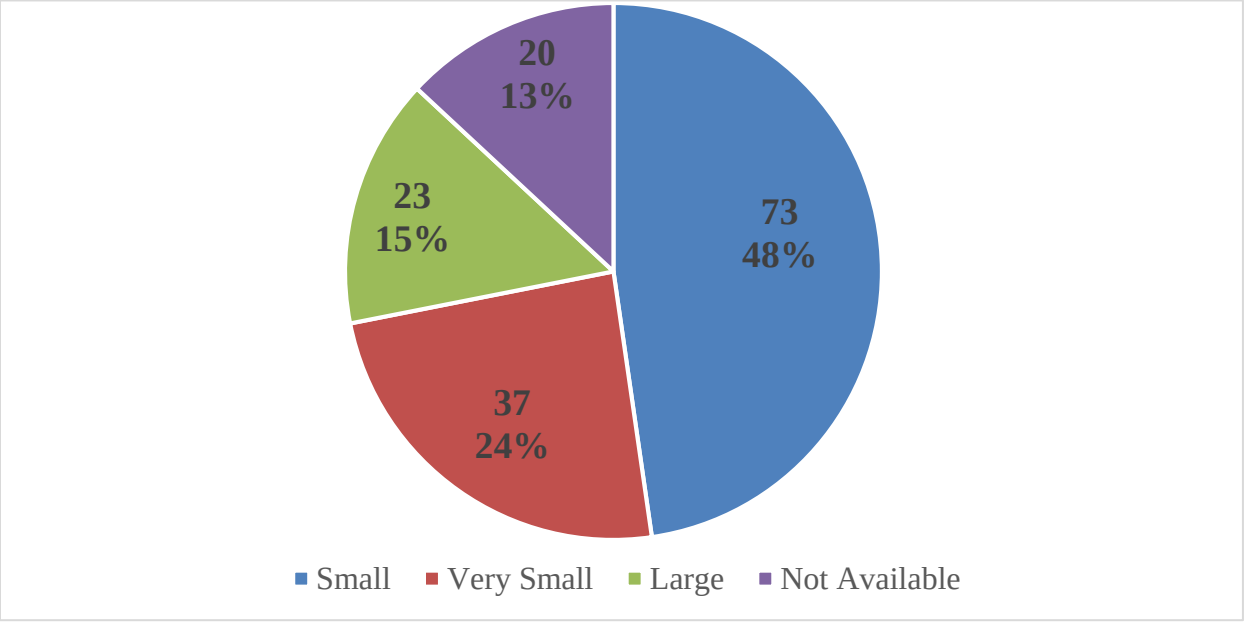

Figure 3-21 - Percentage of the total number of recalls of FSIS-regulated food products due to the presence of STEC by the HACCP-defined facility size of the facility from which the recall originated from January 2005 through August 2018

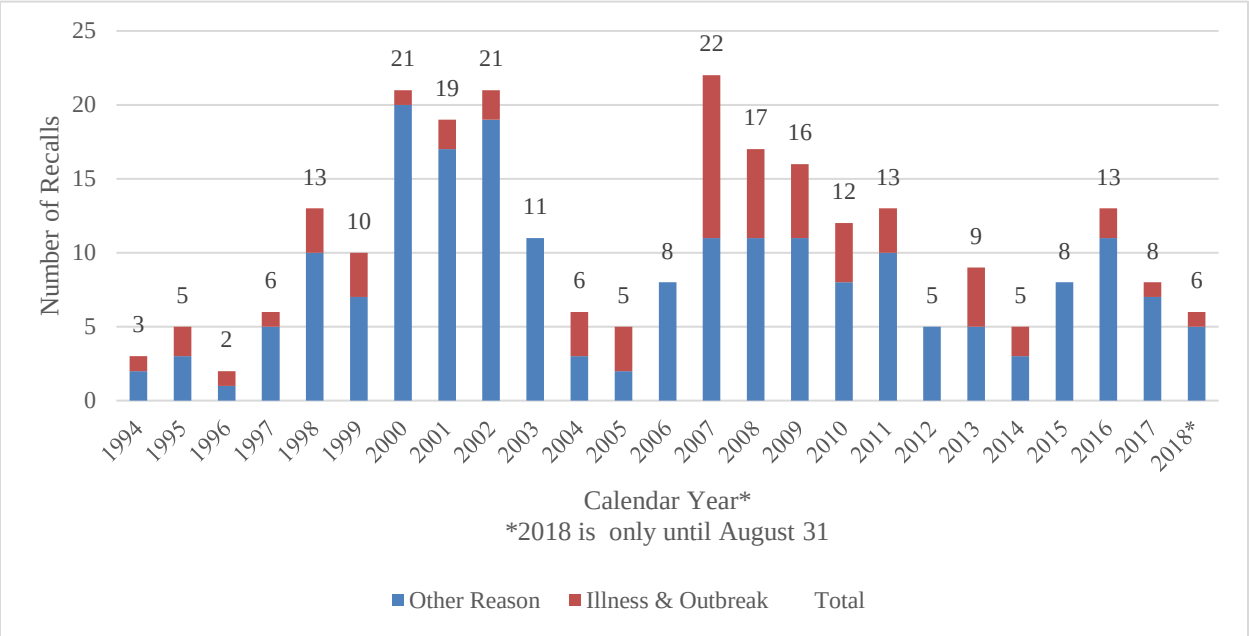

Figure 3-22 - Total number of recalls of FSIS-regulated food products per year due to STEC by whether or not they were associated with an illness, from January 1994 through August 2018

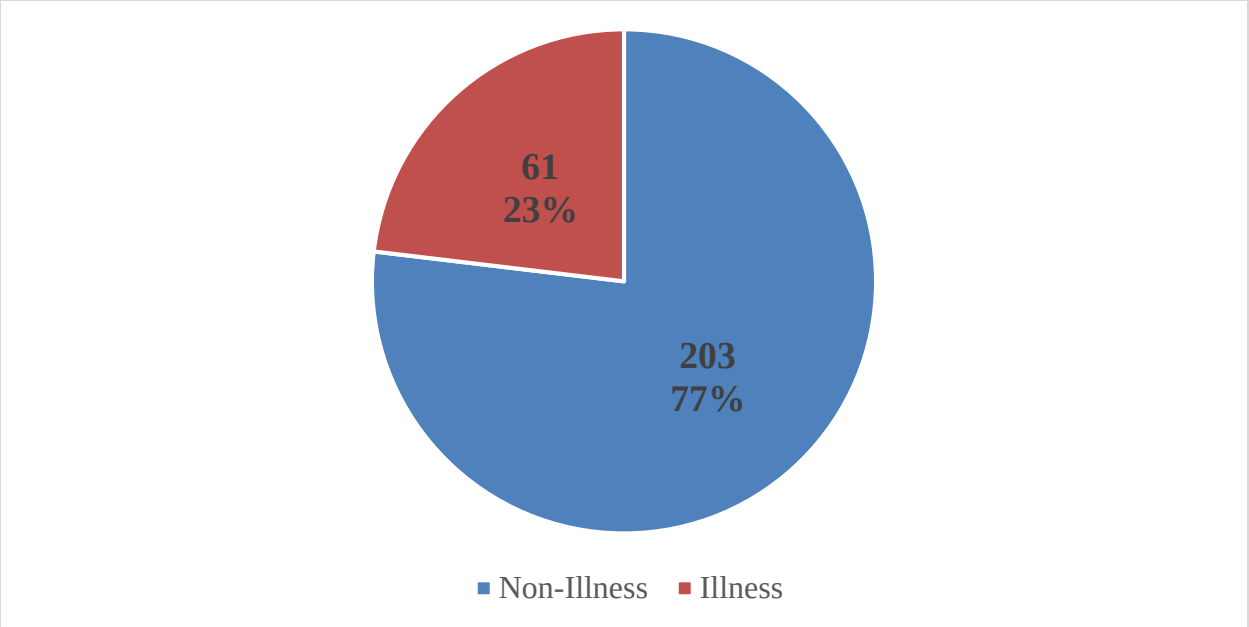

Figure 3-23 - Percentage of recalls of FSIS-regulated food products due to STEC by whether or not they were associated with an illness, January 1994 through August 2018

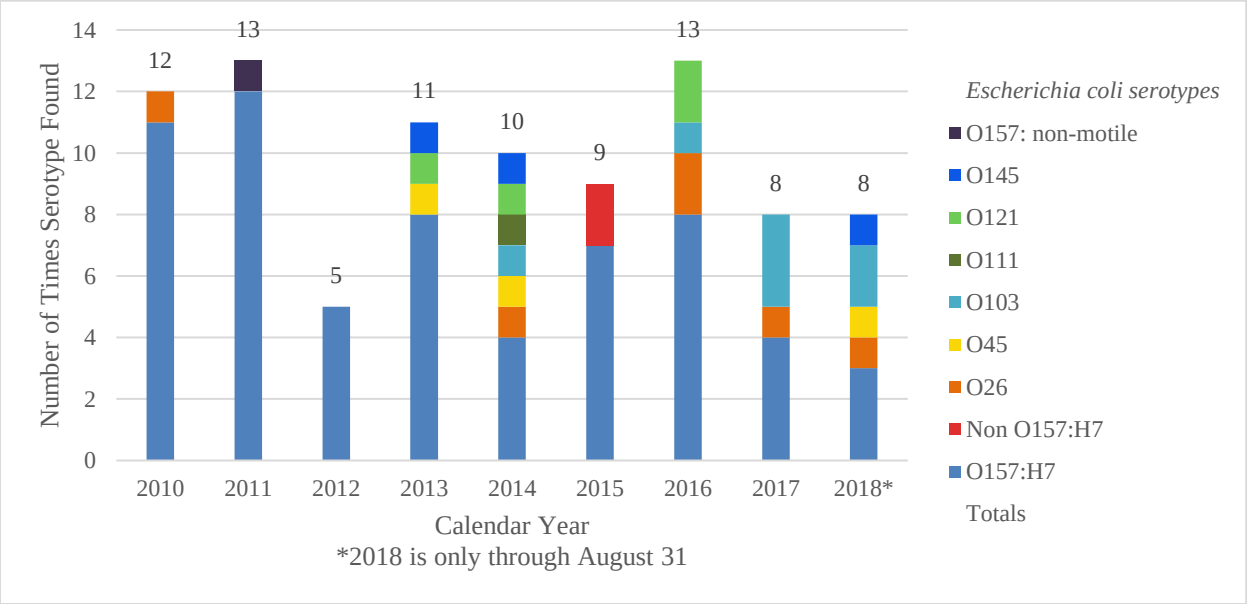

Figure 3-24 – Number of times an STEC serotype was found in a recall of FSIS-regulated foods per calendar year from January 2010 through August 2018

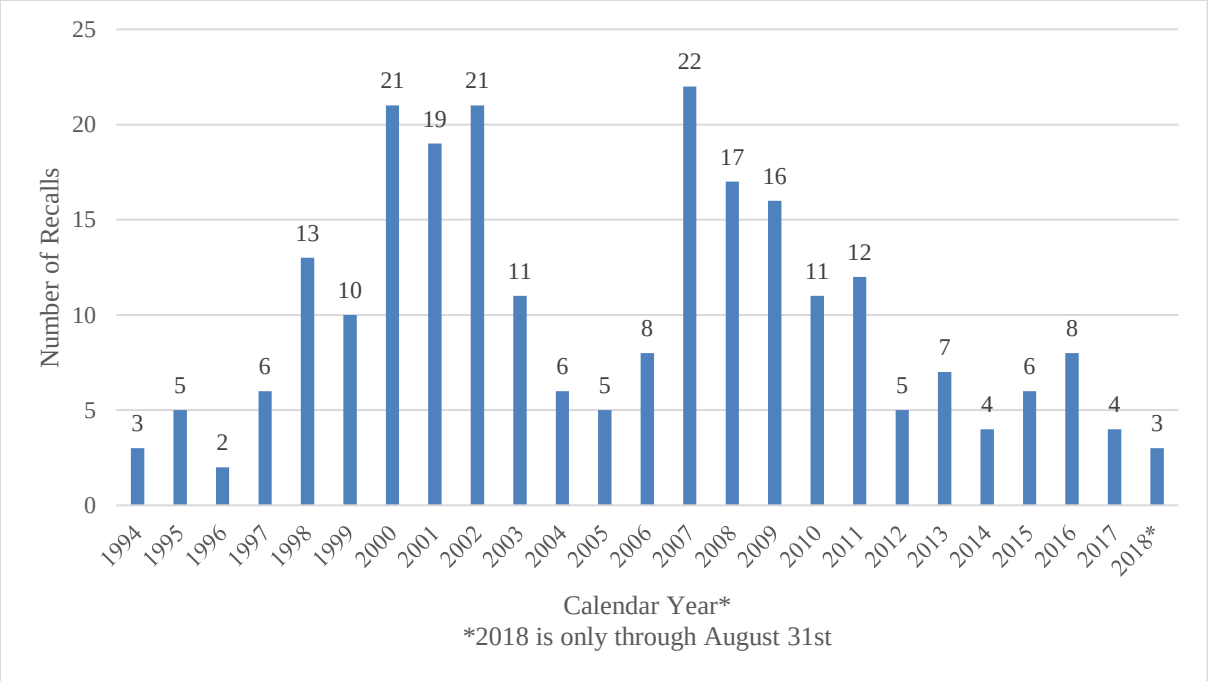

Figure 3-25 - Total number of recalls of FSIS-regulated food products due to *E. coli* O157:H7 per calendar year from January 1994 through August 2018

Chapter 4. Discussion

The current study, which evaluated recalls of FSIS-regulated food products from January 1994 through August 2018, showed similarities and differences to prior studies which evaluated similar recall data across a variety of different time periods. Results from the current study will be compared to those of three such prior studies. The first by Gorton and Stasiewicz (2017) is an analysis of recalls of FSIS-regulated food products from January 1994 through December 2015. The second by Rajaro (2001) is a review of recall cases from January 1995 through December 1999. The third by Green et al. (2014) is a review of STEC-related illness investigations and corresponding recalls associated with products regulated by the FSIS from January 2006 through December 2010.

Gorton and Stasiewicz (2017) reported a total of 1515 recalls during their study period (1994-2015), with an average of 69 recalls per calendar year. By contrast, during the equivalent time period (1994-2015), the current study (i.e., the study described in this field experience report) identified a total of 1484 recalls, with an average of 67 recalls per year. Although these results are very similar, Gorton & Stasiewicz (2017) identified a total of 31 more recalls than were identified in the current study. Gorton & Stasiewicz (2017) reported a total of 690 million pounds of recalled product, resulting in an average of 31.4 million pounds of product recalled per year, and an average 455,446 pounds of product per recall. Comparatively, during the equivalent time period, the current study identified a total of 692 million pounds of recalled product, resulting in an average of 31.5 million pounds of product recalled per year, and an average of 466,307 pounds of product per recall. The top three recall reasons identified by Gorton and Stasiewicz (2017) were Undeclared Allergens (22% of all recalls), *Listeria monocytogenes* (22%

of all recalls), and STEC (18% of all recalls). During the equivalent time period, the current study data showed the same top three reasons which were Undeclared Allergens (26% of all recalls), *Listeria monocytogenes* (24% of all recalls) and STEC (18% of all recalls). Both the current study and Gorton & Stasiewicz (2017) reported 71% of all recalls were categorized as Class I. Overall, the results of the current study are consistent with those reported by Gorton and Stasiewicz (2017).

For the time period 1995-1999, Rajaro (2001) identified a total of 179 recalls and noted that 85% were attributed to Class I, 15% to Class II and none to Class III. During the equivalent period (1995-1999), the current study identified a total of 200 recalls with 73% attributed to Class I, 24% to Class II, and 3% to Class III. Rajaro (2001) and the current study had similar findings with respect to pathogen-related recalls. Rajaro (2001) noted that 50% of all recalls were due to pathogens, whereas the current study reported 54%. Of the pathogen-related recalls, Rajaro (2001) reported 55% were due to LM and 33% were due to STEC, while the current study reported 52% were due to LM and 34% were due to STEC. One area in which the results of the current study and those of Rajaro (2001) differed is in the average pounds of product involved per recall—Rajaro (2001) reported an average of 2 million pounds of product per recall, whereas the current study identified an average of 596,450 pounds of product per recall.

Green et al. (2014), evaluated STEC-related foodborne illness investigations involving food products regulated by FSIS that occurred from January 2006 to December 2010. Their objective was to determine which of these investigations resulted in recalls and/or public health alerts. They identified 88 STEC-related illness investigations that involved foods regulated by FSIS; of those, they reported that 29 resulted in recalls. These results are similar to those of the

current study, which, for an equivalent time period (2006-2010), identified 26 recalls of FSIS-regulated products that were attributed to STEC and associated with an illness.

When compared to the works by Gorton and Stasiewicz (2017), Rajaro (2001), and Green et al. (2014), the current study found similar results during equivalent time periods. Despite the overall consistencies some differences were noted. For example, Gorton & Stasiewicz (2017) reported 31 more recalls than were reported in the current study during an equivalent time period. Additionally, in the data reported by Rajaro (2001) the average number of pounds of product per recall was almost three times that which was reported in the current study during an equivalent time period. One possible reason for the differences in reported data could be that much of the data for the current study was initially mixed between paper copy and digital format so in combining all of the recall data into digital format there may have been differences noted there. Another possible explanation for the differences is that the online database of recalls included those initiated by retail facilities (which are not regulated by the FSIS). For example, in 2000, there were 11 recalls conducted by retail facilities which are listed on the Recall Case Archive (FSIS, 2000) which were not included in the current study because they are not regulated by the FSIS.

Chapter 5. Public Health Foundational Competencies

Figure 5-1 - Competencies

Number and Competency		Description
1	Apply epidemiologic methods to the breadth of settings and situations in public health practice	Track food recall lot numbers to different companies to ensure all product was recalled effectively
4	Interpret results of data analysis for public health research, policy or practice	Evaluation of trend analysis to establish pattern in concert with changes in technology and changes in policy
9	Design a population-based policy, program, project or intervention.	Whereas the project of creating the digital library of archived food recalls for easier access by population through the Freedom of Information Act was not designed by me, this project may help others with further study of recalls of FSIS-regulated food to help better establish baselines in the data and potentially make improvements which can benefit all those who are affected by the United States food supply

17	Apply negotiation and mediation skills to address organizational or community challenges	Participated in the analysis of more than 35 food recalls before they became recalls, analyzed many more that did not become recalls, participated in multiple public health alert investigation meetings giving a college student perspective negotiating the points that not all people are educated at a college level about food safety and do not always follow written instructions thereby decreasing the likelihood of the efficacy of a heat kill step and increasing the risk of illness or injury by allowing foods which may contain pathogens to remain in commerce
19	Communicate audience-appropriate public health content, both in writing and through oral presentation.	Created a data evaluation and presentation of records of recalls of FSIS-regulated foods from January 1994 through August 2018
21	Perform effectively on interprofessional teams.	Assisted with the brainstorming, development and refinement of a new

		food recall handling software that is currently in the developmental stages
22	Apply systems thinking tools to a public health issue	Participate in daily food recall proceedings

Over the course of the integrated learning experience conducted with the Recall Management and Technical Analysis Division, under the Food Safety and Inspection Services, seven competencies were primarily focused on to ensure and educational experience. Two competencies (1) **Apply epidemiological methods to the breadth of setting and situations in public health practice** and (22) **Apply systems thinking tools to a public health issue** were applied in the numerous weekly meetings. Whenever there was notification of a potential recall, the team came together to brainstorm the possibility of tracing back the affected product from its current place in commerce to the facility it came from. Indeed, some recalls began as customer complaints of the wrong product in the packaging, possible foreign material sightings, samples that tested positive for a microbiological agent and sometimes illness outbreaks. When the reports came in indicating there may be a problem with an FSIS-regulated food product it was imperative for the team to brainstorm quickly on how to traceback where the product started from its current end point or trace forward where the product went when it left the recalling facility. Many times, there were limitations to the abilities to perform these epidemiologic methods due to partial or missing information, incomplete and messy records, or uncooperative facilities. In addition to these first two competencies (1) and (22), competencies (17) and (21) were also applied during the numerous weekly meetings.

Competency (17) **Apply negotiation and mediation skills to address organization or community challenges** was applied during the potential recall case review. Once notified of a potential problem or potential need to recall, the FSIS begins an investigation to determine the disposition of the potential problem. Although every recall has its own unique circumstances, the FSIS has designed a standard yet flexible process for the recommendation of a facility to recall product for which most potential recall cases can be assimilated into. Even so, some require much more input from subject matter experts and cause debates between colleagues for which there is much discussion. During the integrated learning experience there were many instances where this was the case and having the perspective of a college student aided in explaining why particular recalls may need to be handled differently. In particular, there was a long debate regarding a potential recall which involved seasoning mix that was applied to a microwave meal which contained FSIS-regulated food products. The overall consensus was that since there was a heat kill step that would be applied to the microwave dinner that it was not necessary to recall. The debate came in when it was mentioned that often times the general public does not understand that the heating step is not only to make the food a desirable temperature but also to kill potential bacteria. The thought process was changed when the question was posed regarding mixing microwave dinners half way through the cooking process in that how many people stir that meal and then place the spoon or fork they used to stir the meal into their mouth while the meal finishes cooking and can we truly rely on people completing the full heat kill step before consuming it – especially in the case of that meal being fed to a child whose parent does not want the meal to be too hot when they serve it and so cooks it for less time. The committee agreed that this was a likely scenario and put out a public health alert because the FDA had already recalled the ingredient (FSIS, 2018c) Those potential recall discussions were also

appropriate times to apply other competencies such as (21) **Perform effectively on interprofessional teams** as these potential recall discussions were sometimes attended by many different agencies outside of the FSIS as there were roles to be filled by those parties. Some of the potential recalls required consultation with financial offices, many required the legal department and others involved other government agencies such as the Center for Disease Control and Prevention or the Food and Drug Administration. Public safety was the uniting factor and allowed all who participated in the opportunity to contribute.

One objective of the integrated learning experience was to create a trend analysis of food recalls. That process required the use of competencies (9), (19), and (4). Competency (9), **Design a population-based policy, program, project or intervention** was not exactly applied in the traditional sense in that the creation of the digital library was not something which was personally designed but may help those in the future to design a policy, program, project or intervention. Even though this was only a partial application of this competency it will be beneficial to those in the FSIS as well as those who may do future work for the government agency. The creation of the digital library of archived files of recalls of FSIS-regulated foods as well as a generalized data analysis of those recall records was vital to assist in finding patterns among recalls. Before 2006, all records of recalls of FSIS-regulated food products were kept in paper files. Between 2006 and 2012, parts of the records were stored electronically but still had a hard copy backup file with the complete set of records that the FSIS retained for that recall. Beginning in 2012, all records of recalls of FSIS-regulated food products were kept in digital format. The project was to create a digital library of the paper copies of the records for each recall and organize them in a manner which would be conducive to further analysis and study. Each file was scanned into the computer as a portable document file (PDF) and saved to the

server under its assigned recall number. Furthermore, competency (19) **Communicate audience-appropriate public health content, both in writing and through oral presentation** was then applied through the analysis of those scanned recall records first by creating a spreadsheet in Microsoft Excel and then by manipulating that data to give a visual representation of the data contained in the recalls of FSIS-regulated food products. The product of that competency is the Integrated Learning Experience written paper and oral defense. These products will be shared and distributed with those who were part of the oversight of the participant in the learning experience, those members of the committee who supported the learning experience, and any person interested in learning more about FSIS-regulated recalls through online posting in the database K-Rex. During the writing and presentation of this learning experience, competency (4) **Interpret results of data analysis for public health research, policy or practice** was put into practice for the purpose of completion of the project. For example, the written report goes into depth regarding the total number of recalls of FSIS-regulated food products comparing those recalls with other recalls to determine percentages of the total numbers as well as look for and identify potential patterns in the data.

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Appendix 1

Definitions of Categories of Information Used in Recalls of FSIS-Regulated Foods

Recall Tracking Number – Each recall is given a unique tracking number for continuity purposes. Each tracking number consists of the numeric designation of which recall it was during the calendar year followed by the year in which the recall was initiated and I.e. the 15th recall that occurred in 2018 would be labeled "015-2018"

Problem Type or Reason for the Recall – Recalls are initiated based on categories that indicate what went wrong which prompts the initiation of the recall. These reasons are listed in Appendix 2.

Date Recall Opened – The date on which the company confirms with the FSIS that they indeed will conduct their recall is the date the recall opened.

Who is the Source/What or Who Initiated the Recall – recalls may be initiated for many reasons. A list and explanation of those reasons are in Appendix 3

Class of Recall – Each recall is classified depending on the likelihood of harm coming from consuming the food being recalled. There are three classes of recall. A Class I recall involves a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death. A Class II recall involves a potential health hazard situation in which there is a remote probability of adverse health consequences from eating the food. A Class III recall involves a situation in which eating the food will not cause adverse health consequences.

Establishments Name – Each establishment that receives a mark of inspection from the USDA has filed with he USDA their name. Many facilities can have the same name but will be

differentiated by their establishment number. An example of a group of facilities with the same name is Cargill.

Size of the Firm – In 1998, the FSIS created a regulation requiring companies to acquire HACCP plans. To institute the plans, the FSIS defined three categories of size to encompass all of the USDA establishments using this size system to determine when the establishment needed to have their HACCP plan implemented by. The three sizes are Large Establishments which have over 500 employees, Small Establishments which have more than 10 employees but less than 500, and Very Small Establishments which have less than 10 employees or have less than $2.5 million in sales annually.

USDA Establishment Number – the USDA Establishment number is a unique identifier given to each of the establishments that apply for and are awarded the USDA seal. These numbers are alpha-numeric and may correspond with the general category of product being produced in that facility. Examples include P7221 is the establishment number for a Tyson facility located in New Jersey which produces poultry products, and M245C which is an establishment number for a Tyson facility in Nebraska which produces meat products – in this instance ground beef

Total Pounds Indicated in the Scope of the Recall – The scope defines the amount and type of product in question. Several factors are used in determining the scope of a recall, such as the plant's processing and sanitation procedures, the definition of a lot, or specific grouping, and whether there is any finished product reincorporated into fresh product (rework). The findings of epidemiological investigations that link certain lots of product with known cases of foodborne illnesses may also affect the scope of a recall.

State Where the Establishment is Located – Because establishments can have the same name, it is important for differentiation purposes to know the state in which the facility is located. This

also helps decide which district office is responsible for the regulation of that facility as states are grouped into districts.

District Office – Each of the states and territories which are regulated by the FSIS have been divided out by regions. Each region contains a district offices out of which the Office of Field Operations runs. Originally there were 15 district offices. The restructured district offices which were eliminated from the FSIS body of district offices were officially closed at the beginning of the fiscal year of 2013. District offices are listed as such: Location of the Office city and state, the district number, list of states covered, number of states covered.

The Original 15 OFO district offices:

1. **Alameda, CA** - *District 05* - States: California – 1
2. **Albany, NY** - *District 65* - States: Connecticut, Maine, Massachusetts, New Hampshire, New York, Rhode Island, Vermont – 7
3. **Atlanta, GA** - *District 85* - States: Florida, Georgia, Puerto Rico, Virgin Islands – 4
4. **Beltsville, MD** - *District 75* - States: Delaware, District of Columbia, Maryland, Virginia, West Virginia – 5
5. **Chicago, IL** - *District 50* - States: Illinois, Indiana, Ohio – 3
6. **Dallas, TX** - *District 40* - States: Texas – 1
7. **Denver, CO** - *District 15* - States: Alaska, American Samoa, Arizona, Colorado, Guam, Hawaii, Idaho, New Mexico, Nevada, Northern Mariana Islands, Oregon, Utah, Washington – 13
8. **Des Moines, IA** - *District 25* - States: Iowa, Nebraska – 2
9. **Jackson, MS** - *District 90* - States: Alabama, Mississippi, Tennessee – 3

10. **Lawrence, KS** - *District 30* - States: Kansas, Missouri – 2
11. **Madison, WI** -*District 45* - States: Michigan, Wisconsin – 2
12. **Minneapolis, MN** - *District 20* - States: Minnesota, Montana, North Dakota, South Dakota, Wyoming – 5
13. **Philadelphia, PA** - *District 60* - States: New Jersey, Pennsylvania – 2
14. **Raleigh, NC** - *District 80* - States: Kentucky, North Carolina, South Carolina – 3
15. **Springdale, AR** - *District 35* - States: Arkansas, Louisiana, Oklahoma – 3

Reorganization to the current 10 District Offices.

1. **Alameda, CA** - *District (05)* - Arizona, California and Nevada - 3
2. **Atlanta, GA** - *District (85)* - Florida, Georgia, Puerto Rico, South Carolina and the Virgin Islands; - 5
3. **Chicago, IL** - *District (50)* - Illinois, Indiana, Michigan and Ohio - 4
4. **Dallas, TX** - *District (40)* - Louisiana, New Mexico, Oklahoma and Texas - 4
5. **Denver, CO** - *District (15)* - Alaska, Colorado, Idaho, Guam, Hawaii, Northern Mariana Islands, Montana, Nebraska, Oregon, Utah, Washington and Wyoming. - 12
6. **Des Moines, IA** - *District (25)* - Iowa, Minnesota, North Dakota, South Dakota and Wisconsin. - 5
7. **Jackson, MS** - *District (90)* - Alabama, Kentucky, Mississippi and Tennessee - 4
8. **Philadelphia, PA** - *District (60)* - Connecticut, Massachusetts, Maine, New Hampshire, New York, Pennsylvania, Rhode Island and Vermont - 8
9. **Raleigh, NC** - *District (80)* - Delaware, Maryland, North Carolina, New Jersey, Virginia and West Virginia - 6

10. **Springdale, AR** - *District (35)* - Arkansas, Kansas and Missouri.- 3

Type of Product Being Recalled – This is a description of the actual product that is being recalled. Examples include ground beef, breaded chicken strips, prosciutto slices etc.

Date the Recall is Closed – Once all efforts to recover the recalled product have been exhausted, the FSIS conducts effectiveness checks to ensure that the establishment which is conducting the recall has made every effort to remove the product from consumers hands, the FSIS then decides that the recall is complete and then it is considered closed.

Animal Type Category of Meat – The FSIS is categorizes products according to generalized animal type category of meat: beef, poultry, pork, ovine, Siluriformes, mixed products, and other.

Total Pounds Recovered During the Recall – Each company makes every attempt to remove recalled products from the consumers. The total pounds recovered during a recall indicates the amount of product that the establishment was able to remove from commerce. This can range anywhere from 0 lbs to more pounds than were recalled.

Appendix 2

Problem Type or Reason for the Recall

E. coli – Escherichia coli (E. coli) - indicates the potential presence of one or more of seven specific serotypes or unidentified serotypes according to their O and H antigens. The seven specific serotypes are O26, O45, O103, O111, O121, O145, O157:H7. The non-indicated serotypes are referred to as either "*E. coli"* or non-O157. Recall 062-2011 is labeled with "*E. coli* NM" which indicates that the presences of Non-motile *E. coli* was found in the ground beef used in the recall.

***E. coli* positive water –** This is a problem type that has only been utilized once. The recall associated with *E. coli* positive water (078-2016) was initiated because the facility received a notification that the external water source that was being used during processing had received a report indicating that there was a positive sample test for *E. coli* in the water. Due to the potential contamination, the food products were recalled

Extraneous Material – according to the FSIS (1997), extraneous materials or foreign particles or objects are categorized under "Physical Hazards". There are many sources of extraneous materials and can include: glass, metal, stones, plastic, bone, needles. This is not an exclusive list of all types of extraneous materials.

***Listeria monocytogenes* –** According to Bush & Perez (2017), "*Listeria* are small, non-acid fast, non-capsulated, nonsporulating, beta-hemolytic, aerobic and facultative anaerobic gram-positive bacilli with characteristic tumbling motility". *Listeria* is ubiquitous in the environment, it can grow in refrigeration temperatures.

Misbranded – "Food may deemed to be misbranded: If the label, brand, tag or notice under which it is sold is false or misleading in any particular as to the kind, grade or quality or composition; If it is sold as the product of one manufacturer when in reality it is the product of another manufacturer; or If on the label, brand, tag or notice under which it is sold there is any false statement concerning the sanitary conditions under which it is manufactured." (USLegal, 2018)

Miscellaneous – The miscellaneous problem type has been used only one time for a turkey ham recall in 1994 (Recall 023-1994). This recall was classified as a class 3 recall

Non-Potable Water – Non-potable water problem type was used one time when the facility was notified by the state that the water they were using was considered non-potable or not fit for human consumption. Recall 035-1994

Other – The classification "other" has been used when there are no better options to classify a recall reason as. These recalls typically contain notes to indicate what the exact reason for recall was.

Other Pathogen – Pathogens other than *Escherichia coli, Listeria monocytogenes, Salmonella,* or spoilage bacteria.

Process Deviation – A process deviation is when the actual process is less than the process schedule, any critical factor does not meet the value required by the process schedule, or any operating parameter of the thermal processing system is not met (FSIS, 2018b). Mostly used before 2003.

Processing Defect – See Process Deviation – Processing Defect term used mostly after 2001.

Residue - Chemical – Any residue of a chemical nature of any non-drug substance that is not supposed to be in the final product.

Residue - Drug – Any residue of a drug that is discovered post-mortem. “Tolerances established in this part are based upon residues of drugs in edible products of food-producing animals treated with such drugs. Consideration of an appropriate tolerance for a drug” includes finite residues present in foodstuffs which requires a finite tolerance level; inability to determine finite residue which will be considered negligible; the drug may induce cancer in humans or animals but will not if used appropriately and must not be detected in edible products; in the case that the drug is metabolized to the rate that it is undistinguishable from normal tissue which will not require establishing a tolerance; finally, no tolerance level will be altered to be greater than the published tolerance level as prescribed in Title 21, Chapter 1, Subchapter E, Part 556, subpart B (FDA, 2010)

***Salmonella* – “**Non-typhoidal *Salmonella*e are gram-negative bacteria that primarily causes gastroenteritis, bacteremia, and focal infection. Human disease occurs by direct or indirect contact with numerous species of infected animals, the food stuffs derived from them, and their feces. Contaminated meat, poultry, raw milk, eggs, egg products and water are common sources of *Salmonella.*” (Bush & Perez, 2018)

Spoilage Bacteria – Those bacteria which are natural recyclers that break down organic matter is what is considered spoilage. This category includes bacteria, yeasts and molds.

Traceback – Following an illness outbreak, the epidemiological process of following the sources to the original facility is called a traceback. Ill persons will be interviewed to find out what their eating habits had been in correspondence with the incubation period of the diagnosed illness. Where there is a common ingredient to those who became ill, then that ingredient is traced back to its source of sale whether it was a consumer store or restaurant, or a dining facility or commercial operation that services institutional foods. Then it is traced back to the company

that packaged it. Then to the company who created the food, and in the case of the FSIS, the slaughter house if possible. Very few tracebacks are successful due to the lack of information provided by outbreak victims who do not remember all of what they ate or where it came from.

Unapproved Substance – Each food product that is produced is required to have a detailed ingredients list to help ensure the consumers ability to be aware of the contents of their food. When non-deleterious chemicals are found in those foods which have not listed that chemical it is an unapproved substance. This category is used when the risk of injury is low or non-existent.

Undeclared Allergen – There are eight primary foods that are considered major sources of allergens according to the FSIS which indicates that more than 90% of food allergen recalls involve the following foods: milk, eggs, fish (such as bass, flounder, cod), crustacean shellfish (such as crab, lobster, shrimp), tree nuts (such as almonds, walnuts, pecans), peanuts, wheat, and soybeans (FSIS, 2016a).

Undeclared Substance – An undeclared substance is one which is typically found in food products, is not considered an allergen and is not indicated as being present on the label. An example is Recall 077-2018 which was a recall due to the presence of sesame seeds which were not on the label as an ingredient (Ghering, 2018).

Under Processed – Every facility that is regulated by the FSIS has been required to have a Hazard Analysis and Critical Control Point (HACCP) plan in place as part of the requirements of receiving and maintaining the USDA Mark of Inspection. The HACCP plan indicates the entire process of the product from when it enters the facility to when it leaves the facility. It outlines the time ranges that are necessary during the processing of the products to help ensure safety of the foods. When a product moves through the process at a rate of speed that is shorter than the rate of speed that is indicated in the HACCP plan, it is considered to be under processed.

Appendix 3

Who is the Source/What or Who Initiated the Recall

3 Party – Some facilities have a third-party lab run their biological testing. When they have a positive result, it will initiate a recall for any product that has left the facility

CDC/INV – The Center for Disease Control and Prevention was involved in these cases.

Compliance – The product was discovered during a compliance investigation.

Consumer – Recalls that were initiated because of a consumer complaint.

CP INV – These recalls are discovered by compliance personnel known as Enforcement Investigation and Analysis Officers (EIAO). "The FSIS EIAO conducts comprehensive food safety assessments (FSA) at establishments in which they consider all food safety aspects that relate to that establishment and its products, the nature and source of all materials received, the establishment's processes, and the environment of the establishment. The EIAO primarily focuses on the design and validity of the hazard analysis, HACCP plan; Sanitation Standard Operating Procedures (Sanitation SOPs), pre-requisite programs, testing programs, e.g., its generic *E. coli* written procedures; and any other programs that constitute the establishment's food safety system." (FSIS, 2016b)

FDA – the recall was initiated due to the presence of a food product that is regulated by the Food and Drug Administration in a product that is also regulated by the FSIS

Follow-Up – When a facility has been found in violation, there is always an inspector who follows up on that inspection. If upon returning, the inspector finds another incidence, then that recall is initiated because they were following up on a different recall.

Foreign/Import – These recalls were related to foods that crossed international borders and needed to be recalled whether it was a recall that was initiated by a foreign company which had sold its products to the United States or it was a recall conducted in the United States to recall product that was exported.

Health Code Violation – These recalls were recalled due to some type of health code violation

IIC – Inspector In Charge – These recalls were initiated due to a report from the inspector that is in charge of the plant.

Illness – These recalls were recalled due to a reported illness.

Monitor – The FSIS regularly monitors the facilities it regulates. In the process of monitoring, samples of product are taken and sent to FSIS Laboratories for microbiological testing. If a sample becomes positive then the FSIS Laboratory notifies the person who submitted the sample, the company the sample came from, and the RMTAD

Outbreak – These recalls were recalled due to an illness outbreak

Plant – These are recalls that are needing to be recalled due to a report from the plant where the product was produced. This can be the plant recalling its product from consumers, or recalling product it sold to other production plants to use in their foods

Retail – These recalls are initiated by complaints from retail or against retail establishments.

State – Some states hold more stringent standards than the FSIS and they may initiate a recall according to their standards.

State Lab – Product that has been tested and found positive for biologic contamination at a state-run laboratory would initiate these recalls.

Traceback – When an epidemiologic investigation reveals that a product may be associated with an illness outbreak then that product, which was traced back to the initial facility, will be recalled