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General Interest

USDA Food Recalls for the Period 2012–2023 Compared with FDA Regulated Food Recalls Over the Past Two Decades

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ABSTRACT

This manuscript evaluates recalls of food products that are regulated by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS). The FSIS regulates food products made from animals raised on farms including beef, pork, poultry, buffalo, and venison, as well as some egg products and farmed or wild-caught seafood of the order of Siluriformes (catfish). During the 12-year period of 2012–2023, 1,001 food recall incidents occurred representing 205.2 million lbs of recalled product. These recall incidents were classified by the FSIS at 76% as Class I, 20% as Class II, and 4% as Class III. The causes of the recalls were combined for this analysis into three master categories: Product Contaminants, Processing Issues, and Other Reasons. Product Contaminants caused of 68% of the FSIS recalls, Processing Issues added 13%, and Other Reasons contributed 19%. Further evaluation of these recall incidents by product type resulted in Poultry at 29%, Beef at 23%, Mixed Animal meat at 23%, and Pork at 22% of the recall incidents. Evaluation of these recalls by product weight showed Mixed Animal meat at 52%, Poultry at 27%, Beef at 16%, and Pork at 4%. Biological Contamination was a component of the Products Contaminants master category, and 4 bacterial species caused almost 59% of the FSIS recalls by weight. *Listeria monocytogenes* caused 32%, Shiga toxin-producing *E. coli* (STEC) caused 12%, *Salmonella* serovars caused 9%, and *Bacillus cereus* caused 0.5% of these recalls by weight. These FSIS food recalls were compared to the FDA Food & Beverage recalls from a recent publication. *Listeria* was the common cause of the highest percentage for the FDA recalled by incidents and FSIS recalls by weight. Most of the food recalls were caused by human error. Developing a strong Food Safety Culture along with strong cleanup and sanitation procedures is imperative to minimizing and preventing food recalls.

This manuscript reviews recalls of the foods regulated by the United States Department of Agriculture (USDA), Food Safety and Inspection Service (FSIS) and compares them to FDA food recalls from a recent publication (DeBeer et al., 2024). The FSIS regulates the food products raised on farms including beef, pork, poultry, buffalo, venison, and some egg products. The FSIS has also regulated the farmed and wild-caught seafood of the order Siluriformes (catfish) since 2016 (USDA, 2015). If a food product contains more than 3% fresh meat, 2% cooked meat, or 2% cooked chicken, the product is regulated by the USDA/FSIS (USDA, 2024a). A plant that produces both ready-to-eat meat products and nonmeat foods would fall under the authority of both the USDA/FSIS and the Food and Drug Administration (FDA). A good example could be frozen pizza. If a pepperoni pizza with the pepperoni is more than 2% of the net weight of the pizza, the pizza would be a USDA-regulated product. A vegetarian pizza, without meat products, would be an FDA-regulated product. The proportion of foods in the United States (U.S.) regulated by the FDA is 80–90%, while the proportion regulated by the USDA is 10–20% (CRS, 2016). There are many food factories that are regulated by both agencies. According to a FOIA request, in December 2024, there were over 2,100 factories with dual jurisdiction.

The USDA was established in 1862 during the administration of President Lincoln by an act of Congress called The Act to Establish a Department of Agriculture. The act was intended to “acquire and to diffuse among the people of the United States useful information on subjects connected with agriculture in the most general and

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comprehensive sense of the word, and to procure, propagate, and distribute among the people new and valuable seeds and plants" (Library of Congress, 1862). By 1866, the need to inspect and/or regulate meat quickly became apparent to the U.S. government; however, the USDA did not gain the authority to regulate meat until the Pure Food and Drug Act and the Federal Meat Inspection Act (FMIA), which were both published in 1906. The support to regulate meat is widely attributed to public outcry from the novel *The Jungle* by Upton Sinclair (USDA, 2018). Key foundations for food safety in America were created through these two acts to prevent the sale of adulterated foods, including meat and require that food be processed under sanitary conditions. The USDA gained authority over poultry products in 1957 under the Poultry Products Inspection Act (PPIA) which was a result of increased consumer demand for poultry following World War II. The USDA also eventually gained authority over eggs under the Egg Products Inspection Act (EPIA) in 1970 (USDA, 2018).

Current FSIS food processing regulations differ from those of the FDA. The FSIS requires a mandatory Hazard Analysis and Critical Control Program (HACCP) and its implementation for every factory and every food product based on 9CFR§304 (FSIS, 1996a). The FSIS does not have current Good Manufacturing Practices regulations as required by the FDA, but the USDA does maintain very detailed sanitation regulations: 9 CFR§416 (FSIS, 1996b). The FSIS conducts routine mandatory inspections of every USDA-regulated production factory, while the FDA conducts periodic unscheduled inspections of its regulated production facilities (CRS, 2016). An FSIS inspector is required to be on-site every day when an USDA-regulated processing plant is operational. The FDA regulates much of its food products through cGMPs based on the Food Safety Modernization Act of 2011 (FSMA) as well as Seafood and Juice HACCP (FDA, 1995; FDA, 2001; FDA, 2017). A brief comparison of the USDA/FSIS and FDA food regulations is shown in Supplemental Data – Table 1.

The USDA's approach to pathogen regulation, monitoring, and enforcement is also different from that of the FDA. In Appendix 1 of the Hazard Analysis and Risk-Based Preventive Controls for Human Food, the FDA lists the "food-related biological hazards that are most relevant to food safety": *Bacillus cereus, Clostridium botulinum, Clostridium perfringens, Brucella* spp., *Campylobacter* spp., pathogenic *E. coli, Salmonella* spp., *Listeria monocytogenes, Shigella* spp., and *Staphylococcus aureus* (FDA, 2024b). The three most relevant from this recall review study are *L. monocytogenes,* pathogenic *E. coli*, and *Salmonella* spp.

The FDA has a zero-tolerance policy for all three of these pathogens. The zero-tolerance policy means that the presence of any amount of these pathogens in any food results in the food to be considered as adulterated and not allowed to be distributed into interstate commerce. This zero-tolerance policy includes ready-to-eat (RTE), and not ready-to-eat food (NRTE) products as well as raw ingredients. Both NRTE and RTE foods have been recalled for these pathogens under FDA authority (DeBeer et al., 2024).

USDA's Listeria Rule, 9CFR§430, also maintains a zero tolerance for *L. monocytogenes* in RTE foods and requires food processors to control *L. monocytogenes* in these food products (USDA, 2022). USDA handles RTE and NRTE foods differently. The FSIS *Listeria* Guideline "Chart of RTE vs. NRTE Products: Resource 1" is a guide to determine whether a food is NRTE or RTE and what should be addressed in the facility's HACCP Plan to control *Listeria* (FSIS, 2014). The USDA has a more complex approach to the regulation of other bacterial pathogens in NRTE, depending on the type of food and the pathogen. For example, the USDA's *Salmonella* Verification Program for Poultry allows the presence of *Salmonella* in raw poultry products within set performance standards during a 52-week "moving window" (USDA, 2021). Similar regulations exist for beef products (FSIS, 2019).

Each agency employs similar regulations for retorted, shelf-stable food products. These regulations are the FSIS's Thermally Processed, Commercially Sterile Products, 9CFR§431 (FSIS, 2018) and the FDA's Emergency Control Permit, 21CFR§108 (Fed. Reg., 2016) and Low Acid Canned Foods, 21CFR§113 (Fed. Reg., 1979).

A 3-class recall system has been established by both the USDA and the FDA and consists of Class I, II, and III recalls in Supplemental Data – Table 2. Different nomenclatures are used by each agency, but the scope of each recall class is the same. The FSIS has no regulatory authority to order a product recall, so all USDA-regulated food recalls are voluntary and conducted by the food processor that produced the recalled products (FSIS, 2015). The current authority of the FDA to order a mandatory recall was only established after the passage of the FSMA in 2011 (FDA, 2017). Both agencies can seize violative and noncompliant products, and both the USDA and FDA prefer that the food processor conduct the recall voluntarily. The FSIS will issue public health advisories (PHA) when there is an issue with FSIS-regulated food in the supply chain. However, the source or amount of the food product may not be known at the time of the advisory (USDA, 2024d). The FDA will issue safety alerts and PHAs when there are violative and recalled products in the market, as well as when a recall did not completely remove all of the violative products (FDA, 2024a).

A review of the recall incidents of food and beverage products (F&B) regulated by the FDA was published in 2024 (DeBeer et al., 2024). This review separated the recall incidents (35,000 plus) into two broad categories: **Product Contaminants** and **Processing Issues.** The recall categories were further divided into 11 groups. The groups in the Product Contaminants category accounted for 91% of the FDA recall incidents, and those in the Processing Issues category accounted for the remaining 9%. The majority of causes of FDA-managed recall incidents were those recalls for Biological Contamination (48%) and Allergens (28%). The four largest causes of recalls for Biological Contamination were *Listeria monocytogenes, Salmonella* serovars, *Escherichia coli,* and *Closterium botulinum.* The four largest causes for Allergen recalls were for undeclared milk (36%), eggs (14%), wheat (13%), and peanuts (12%).

A review of food-borne illness caused by major pathogens in the U. S. was reviewed by Scallan et al. (2011) using Centers for Disease Control and Prevention data. They estimated that each year, 31 major pathogens caused more than 9 million people to suffer food-borne illnesses and caused more than 1,000 deaths.

The Interagency Food Safety Analytics Collaboration published a report entitled Foodborne Illness Source Attribution Estimates – United States, 2022 where they presented the annual estimates of the percentages of foodborne illness caused by *Salmonella*, *Escherichia coli* O157, and *Listeria monocytogenes*. They analyzed the period from 1998 through 2022 (IFSAC, 2024).

Methodology

A Freedom of Information Act (FOIA) request was submitted to the USDA requesting the last 20 years of food recall data. This request was denied by the USDA/FOIA personnel since such a table of recall data does not exist and FOIA rules do not allow such a table to be developed for an individual request. All individual FSIS food recall incidents are posted on an FSIS website, and the FSIS posts an annual summary as well. These recall summaries were collected for each year from 2012 to 2023, and a database was developed from this summarized information to analyze FSIS recalls (USDA, 2024c). The database was analyzed with MS Excel and Excel pivot tables.

Results

The causes of the FSIS recall incidents, assigned by the FSIS, included eight primary causes: Allergens, Biological Contamination, Extraneous Material, Import Violation, Manufacturing Issues, Mislabeling or Misbranding, Other (Reasons), and Produced without Inspec-

tion. These recall incidents were summarized by the class of recall. The individual FSIS-named causes and number of recall incidents assigned to these causes are listed in Table 1. There were 1,001 food recall incidents for the 12-year period analyzed. The amounts of product weight recalled were also shown by group; there were a total of 205.2 million lbs of products recalled during this 12-year period.

An analysis of the summarized FSIS information provided: determination of the animal species that produced the recall, causes, and classes of each recall, and product weight recalled. However, recall classifications (I, II, or III) were not provided for cause groups or species. Class I recall incidents accounted for 76% of the total recalls, Class II incidents comprised 20%, and Class III incidents comprised 4% of the total recalls. The number of recall incidents and classification by year is shown in Figure 1. In some years, no Class III recalls occurred.

The causes of these FSIS recalls were combined into three master categories: **Product Contaminants, Processing Issues**, and **Other Reasons**. Product Contaminants were the cause of 68% of the FSIS recall incidents, while Processing Issues added 13%, and Other Reasons contributed 19% (Table 2). The highest four FSIS-assigned recall groups based on incident percentage were Undeclared Allergens (33%), Biological Contamination (20%), Other Reasons (19%), and Extraneous Material (15%).

The percentage of recalls by weight of the 205.2 million lbs of products recalled for these four recall groups was different than the percentage by incident (Table 2). The 20% of the total recall incidents caused by Biological Contamination accounted for 53% of the total weight recalled. In contrast, 33% of the total recall incidents were caused by Allergens, but accounted for only 15% of the total weight recalled. Similarly, 19% of the recall incidents that were attributed to Other Reasons comprised only 8% of the recall weight. Extraneous Material comprised 15% of the total recall incidents and 17% of the recall weight.

Table 3 summarizes the FSIS recall incidents and weights of the meat by animal species. Chicken and turkey are both included in the poultry category. The poultry, beef, pork, and mixed species each caused 20% to 30% of the total recall incidents. The mixed species group produced the most recalled weight with over 105 million (M) lbs., followed by poultry with 54 M lbs., and beef with 32 M lbs. The USDA started to regulate Siluriformes (catfish family) in March 2016 (USDA, 2015). The data, though not shown, indicate that the initial USDA recalls for Siluriformes began in 2016.

Table 1
Named causes and categories of FSIS recalls – 2012–2023

FSIS named causes	Total	%	Category
Undeclared Allergen	328	33%	Allergens
Bacillus cereus	1	0%	Biological contamination
Listeria monocytogenes	96	10%	Biological contamination
Salmonella	28	3%	Biological contamination
STEC (*E. coli* serovars)	73	7%	Biological contamination
Extraneous Material	152	15%	Extraneous Material
Import Violation	32	3%	Import Violation
Residue	2	0%	Manufacturing issues
Processing Defect	28	3%	Manufacturing issues
Processing Deviations	4	0%	Manufacturing issues
Insanitary conditions	1	0%	Manufacturing issues
Unapproved Substance	2	0%	Mislabeling
Mislabeling	2	0%	Mislabeling
Undeclared Substance	29	3%	Mislabeling
Other (Reasons)	190	19%	Other Reasons*
Produced without Inspection	33	3%	Produced without Inspection
Grand Total	1,001	100%	

* Other Reasons: As reported by the FSIS. Producing without inspection. Unapproved source material. Specified risk materials. Labeling issues. Adulteration issues. Failure to present for import inspection.

The FSIS recall summaries also indicated the bacterial species or serovars. The four bacterial species identified in the Biological Contaminants recall incidents were *Listeria monocytogenes,* Shiga toxin-producing *E. coli* (STEC), *Salmonella* serovars, and *Bacillus cereus*, as shown in Table 4. *L. monocytogenes* caused almost 10%, and STECs caused over 7%, of the total FSIS food recall incidents.

Discussion

Although a direct comparison between the FSIS food recall incidents and the FDA F&B recall incidents is not possible due to the different methods that the two agencies used to provide the recall data, some relationships are notable. The summarized FSIS recall data documented 1,001 incidents over 12 years, and the FDA database of individual recalls documented over 35,000 recall incidents over 20 years (DeBeer et al., 2024). A comparison of the percentage of Class I, II, and III recalls is shown in Table 5. Class I recalls comprised 76% of the FSIS recall incidents and 53% of the FDA recall incidents. Class II recalls made up 20% of the FSIS recall incidents and 41% of the FDA recall incidents (DeBeer et al., 2024). Some of this difference in the percentage of recall classification levels is likely explained by the different food recall classification methods by the two agencies.

The percentage of recall incidents by recall cause group for each database is shown in Table 6. Although all of the USDA-designated recall groups are not the same as the FDA recall grouping, several of the groups do correlate.

Biological contamination caused 48% of the FDA food recall incidents and 20% of the FSIS food recall incidents. However, Biological Contamination caused 53% of the weight of the FSIS recalls. Allergens recall incidents were relatively similar for both recall databases: 33% for the FSIS, and 28% for the FDA. Extraneous Material was responsible for 15% of the FSIS recall incidents while Foreign Objects caused just 7% for the FDA. Mislabeling recall incidents were similar for both agencies. The Other (Reasons) categories for the FSIS food recall incidents include several different reasons for the groups, but the data available do not allow further evaluation.

Further analysis of Biological Contamination recalls shows that *L. monocytogenes* (*Listeria*) accounted for 9.6% of the total FSIS-recall incidents (Table 7) but accounted for 32% of the total weight of FSIS-recalled products. *Listeria* caused the most FDA recall incidents at 22.1% of the total, as well as 45.8% for Biological Contamination (DeBeer et al., 2024). *Listeria* also caused the highest percentage of FSIS recalls for total weight. High levels of *Listeria*-caused recall incidents indicate inadequate sanitation or cleanup procedures or ineffective GMPs within the factory or processing area.

Salmonella serovars accounted for 2.8% of the total FSIS recall incidents and 9.3% of the recalled product by weight. The recently published FDA F&B recalls dataset shows that *Salmonella* serovars were responsible for 18.6% of the total recall incidents and 38.5% of the recall incidents for the Biological Contamination group (DeBeer et al., 2024). *E. coli* caused 36.9% of the FSIS recall incidents for Biological Contamination and 12.2% of the recalled product weight, while *E. coli* comprised 3.8% of the Biological Contamination group and 1.8% of the total recall incidents for FDA recalls (DeBeer et al., 2024). Recalls for *E. coli* serovars were much more common on a percentage for FSIS recall incidents than for the FDA recall incidents.

As shown in Table 7, *L. monocytogenes* accounted for the highest number of total recall incidents at 9.6%, followed by STEC at 7.3% and *Salmonella* serovars at 2.8%. It is important to note that the number of recall incidents associated with a pathogen is not reflective of the occurrence of foodborne illness outbreaks, hospitalizations, or deaths. According to the US Center for Disease Control (USCDC), the leading cause of foodborne illness outbreaks was norovirus (not related to any FSIS or FDA recall), followed by *Salmonella* serovars which were the leading cause of hospitalizations and deaths. *L. mono-*

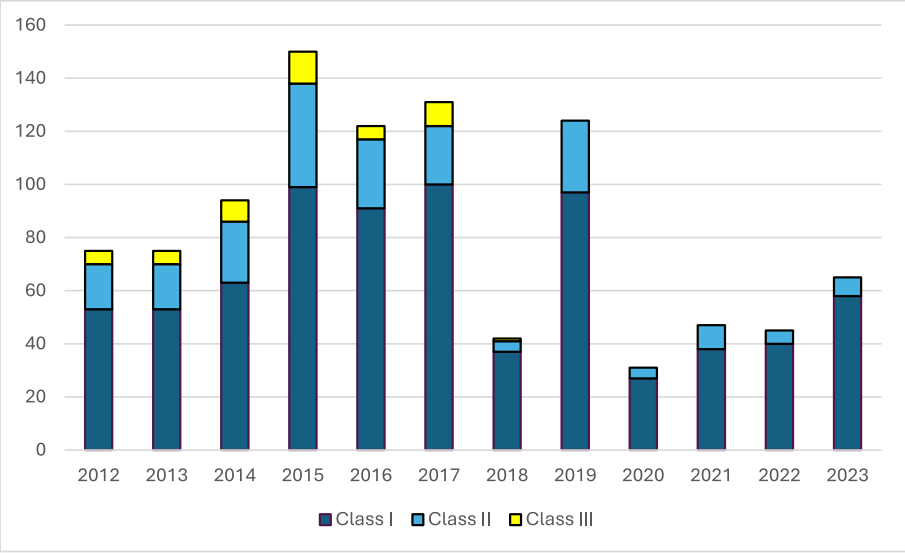

Figure 1. Recall incidents by class by year for the period 2012–2023.

Table 2
FSIS Food Recalls by category for the period 2012–2023 including the number of recalls and weight of recalled product

	Incidents	%	Incidents	%	Million lbs	lbs %	%
Recall Categories							
Allergens	328	33%			31.2	15%	
Biological contamination	198	20%			109.6	53%	
Extraneous Material	152	15%			35.5	17%	
Product contaminants			678	68%			86%
Import Violation	32	3%			1.1	1%	
Manufacturing issues	35	3%			5.8	3%	
Mislabeling	33	3%			3.9	2%	
Produced without Inspection	33	3%			0.8	0%	
Processing issues			133	13%			6%
Other Reasons*	190	19%			17.3	8%	
Other Reasons			190	19%			8%
Total	1001	100%	1001	100%	205.2	100%	100%

* Other Reasons – Produced without inspection, Unapproved source material, Specified risk materials, Labeling issues, Adulteration issues, Failure to present for import inspection.

Table 3
FSIS Food Recalls by animal species and weight for the period 2012–2023

Animal Species	Incidents	%	Millions of lbs.	%
Poultry	286	29%	54.0	27%
Beef	235	23%	32.1	16%
Mixed	233	23%	105.3	52%
Pork	216	22%	7.9	4%
Siluriformes	25	2%	1.0	1%
Sheep	5	>0%	0.1	0%
Goat	1	>0%	0.2	0%
Total	1001	100%	200.7	100%

Table 4
FSIS food recalls by bacterial species for the period 2012–2023.

Bacterial Species	Incidents	% Bio. Contami-nation recalls	% of Total Recalls	Lbs. Recalled (millions)	% of Total Lbs. Recalled
Listeria monocytogenes	96	48%	9.6%	65.6	32.0%
STEC (*E. coli* serovars)	73	37%	7.3%	25.0	12.2%
Salmonella serovars	28	14%	2.8%	19.0	9.2%
Bacillus cereus	1	<1%	0.1%	11.0	0.5%
Total	198	100%	19.8%	120.6	58.9%

Note: Total lbs. recalled in all the incidents were 205 million (M).

Table 5
Comparison of the class of recalls for the FSIS vis-a-vis the FDA recalls

Class	FSIS		FDA	
I	756	76%	18,869	53%
II	200	20%	14,692	41%
III	415	4%	1,987	6%
	1,001		35,548	

Table 6
Comparison of percentage of recalls by recall grouping for the FSIS and the FDA food recall incidents

Food Recall Groups (12 yrs)	FSIS	FDA	Food Recall Groups (20 yrs)
Biological Contamination	20%	48%	Biological Contamination
Allergens	33%	28%	Allergens
Extraneous Material	15%	7%	Foreign Objects
		5%	Chemical Contamination
		3%	cGMP Issues
Mislabeling	3%	2%	Mislabeled
		2%	Undeclared Food Colors
		2%	Refrigeration Issues
		1%	Under-Processed
Manufacturing Issues	3%	<1%	Manufacturing Issues
		<1%	HACCP Issues
Other Reasons*	19%	–	
Produced without Inspection	3%	–	
Import Violation	3%	–	
Total	100%	100%	Total

Data source: DeBeer et al. (2024).
* Other Reasons: see notes for Table 2.

cytogenes was the third leading cause of foodborne illness deaths (Scallan et al., 2011). *Salmonella* serovars present a significant risk to human health, yet the occurrence of recall incidents attributed to *Salmonella* serovars is quite low. The 2024 IFSAC report on a subset of illness data reported 1,355 outbreaks which could be assigned to a single food category (IFSAC, 2024). *Salmonella* caused 74% of the outbreaks, *E. coli* caused 21% of the outbreaks, and *Listeria* caused 5%.

Biological Contaminants causative agents *Listeria, Salmonella,* and *E. coli* serovars, *C. botulinum*, and *Bacillus cereus* together caused 43.5% of the total FDA F&B recall incidents (DeBeer et al., 2024). These same bacterial species together caused 19.8% of the FSIS recall incidents and 58.8% of the weight of the FSIS recalls. These five Biological Contaminants have caused the majority of the recall incidents for food in the United States in the period represented by these datasets. The presence of live mesophilic bacteria and noninactivated bacterial spores indicates inadequate sanitation, cleanup GMPs, and other practices or procedures not achieving designated processing parameters resulting in these illness outbreaks and subsequent product recalls.

Economic losses from recalls. Many recalls result in multimillion-dollar losses to the organizations involved. Recalls resulting in illness or death produce more additional tragic losses and devastating impacts on families and communities. Recalls from at least four well-known, well-publicized cases over the past two decades have resulted in the complete or partial closure of the violative food processing businesses.

Large recall incidents for Castleberry's Food Company, The Peanut Corporation of America, Quality Egg/Wright County Egg, and Boars Head Provisions Co, Inc. are summarized in Supplemental Data – Table 3. The Castleberry's Food Company recall was due primarily to poor maintenance of the retorts that thermally processed canned products to provide safe, shelf-stable food products. This improper maintenance of the retorts resulted in the undercooking of the canned food product and resulted in the growth of the deadly *Clostridium botulinum* in the cans. The Peanut Corporation of America recall was caused by *Salmonella* serovars contaminating the food products due to bad sanitation practices, poor record keeping, and improper or nonexistent pest control. The Quality Egg/Wright County Egg recalls were caused by *Salmonella* Enteritidis caused by bad sanitation practices. The Boars Head recalls were caused by *Listeria* contamination in deli food products due to inadequate sanitation and cleanup of the processing machines and areas. Regardless of the specific cause, the overall reason for these recalls was poor upper management and management control of the food processing factories or human error.

Castleberry's Food Company and Quality Egg/Wright County Egg recalls are both examples of the poor communication that exists among regulatory authorities and the complexity of food regulations within the United States. For example, eggs are regulated primarily by both the USDA and FDA; however, various other federal, state, and local authorities also monitor eggs for quality, handling, and food safety. The FDA regulates the safety of eggs through various regulations, including the Egg Safety Rule which went into effect July 9, 2010 (USDA, 2019). The USDA Animal and Plant Health Inspection Service (APHIS) manages the National Poultry Improvement Plan (NPIP), which created national requirements for poultry breeders and hatcheries intended to help prevent the spread of certain diseases in chickens and eggs. The USDA Agricultural Marketing Service (AMS) regulates the quality of eggs through the Shell Egg Surveillance Program (USDA, 2019). The complexity and overlap of the USDA and FDA authorities and regulations over shell eggs were highlighted in the 2010 egg recall. In fact, the FDA and USDA did not communicate with each other when *Salmonella* serovars were detected in the hatchery environment or when illness outbreaks were linked to the contaminated facilities and when the recall was initiated (Food Safety News, 2013). The new Shell Egg Surveillance Program and the Food Safety Modernization Act regulations were implemented around the same time as the outbreak so that the egg producers involved in the recall were routinely inspected by federal regulators from both the USDA and FDA. The federal inspectors had the authority to investigate and elevate concerns for further investigation, but did not do so. Similarly, USDA or state health inspectors routinely visited the Boar's Head facility. Inspections are not error-proof and only reflect a specific period in

Table 7
Contributions of biological contamination to FSIS & FDA recalls

Bacterial species	Percent of Total Recalls FDA and FSIS Incidents and Weight			Percent of FDA and FSIS Biological Contamination Incidents and FSIS Weight		
	FDA Incidents	FSIS Incidents	FSIS Weight	FDA Incidents	FSIS Incidents	FSIS Weight
L. monocytogenes	22.1%	9.6%	32.0%	45.8%	48.5%	54.4%
Salmonella spp.	18.6%	2.8%	9.3%	38.5%	14.1%	15.8%
STEC (*E. coli* serovars)	1.8%	7.3%	12.2%	3.8%	36.9%	20.7%
C. botulinum	1.0%			2.1%		
Bacillus cereus		0.0%	5.4%		0.5%	9.1%
Total	43.5%	19.8%	58.8%	90%	100.0%	100%

FDA data from DeBeer et al. (2024).

time, but it seems reasonable to expect the major federal agencies to work together when their authorities overlap to protect food safety.

Four recent studies have analyzed the FDA recalls of tuna, seafood, pet food, and all FDA F&B regulated food products (Blickem et al., 2022, 2023; DeBeer et al., 2023, 2024). These publications concluded that human error was the common contributor or cause for the vast majority of the food recalls. These studies also concluded that the recalls could have been prevented. Regardless if the food products are eaten fresh, chilled, cooked, canned, dried, acidified, or processed into another edible form, the knowledge and technology are available to consistently produce safe food for humans and animals for all of these kinds of product forms (Amit et al., 2017).

"Efforts in *Clostridium botulinum* control should be concentrated on reducing human errors in the delivery of the specified process to containers of food" (Pflug, 2010). This approach should be adopted for all food preservation and preparation operations for all types of food products; preventing recalls requires reducing human error. Food preparation facilities, factories, and other food processors need to develop successful food safety control procedures to reduce human error. Food safety control must be a routine focus during all food production procedures including cleaning, sanitation, heating, chilling, freezing, and labeling processes. The operators or food preparers conducting these processes and procedures must be fully trained in food safety control procedures. A C-team with an A-process will be successful and produce a safe product, but an A-team with a C-process will eventually fail (DeBeer, C., pers. comm., 2024).

In every food processing establishment, Standard Sanitation Operating Procedures (SSOPs) must be developed for the specific processes to produce the food product, based on either the USDAs Sanitation regulations (FSIS, 1996b) or the FDA's cGMPs (FDA, 2017). These SSOPs need to be implemented by trained sanitation workers and inspected for cleanliness by trained inspectors. Coupled with the SSOPs, Job Task Analysis (JTAs) need to be developed for each job and task. Food production workers need to be trained and retrained in these jobs and tasks on a routine and ongoing basis. These SSOPs and JTAs need to be validated annually to ensure the controls are effective and that sanitation procedures are completed correctly and effectively. SSOPs for new food processing machinery must be developed and validated prior to installation and implementation.

This review of USDA food recalls clearly shows that relying on regular inspections and on-site federal inspectors is not enough to prevent recalls and foodborne illness outbreaks. Human errors may still occur and not be identified during processing before the food is distributed in the supply chain. Since most of the USDS/FSIS and FDA recalls are caused by human error, the key to reducing human errors and resulting recalls is to create a purposeful, safety-focused food production culture. This culture must ensure that employees completely know and understand their roles and responsibilities. Creating an A-team and an A-process requires the development, implementation, and support of a strong Food Safety Culture (FSC).

Describing and implementing a FSC and changing cultures in food processing facilities has been covered in several publications including Griffith et al. (2010), Powell et al. (2011), and Yiannas, (2009). A Food Safety Culture involves shared values, beliefs, attitudes, and practices within an organization that influence commitment to, and prioritization of, food safety. The culture defines and ensures food safety is integrated into daily operations, decision-making processes, and employee behavior. This concept emphasizes the importance of leadership, employee engagement, communication, and continuous improvement in fostering an environment where food safety is a fundamental aspect in the culture for food producers (Griffith et al., 2010; Powell et al., 2011; Yiannas, 2009).

The Key elements of a Food Safety Culture include:

1. **Leadership commitment:** Organization leaders of food production companies must demonstrate a strong commitment to food safety and set the tone for the rest of the organization. This commitment involves providing resources, training, and support to ensure that food safety is prioritized at every level of the company. Top management must demonstrate a genuine commitment to food safety and its control, including setting clear expectations, providing necessary resources, and especially, leading by example.
2. **Employee empowerment and accountability:** Employees at all levels must feel empowered to take responsibility for food safety. This empowerment includes the ability to report issues impacting food safety, suggest improvements, and act in ways that uphold food safety standards.
3. **Clear communication channels:** Leaders must establish open and effective lines of communication about food safety policies, procedures, and expectations to ensure that everyone in the organization is aware of their role in maintaining food safety. Open lines of communication will encourage employees to report food safety concerns without fear of retribution. Regular meetings and routine updates focusing on food safety issues will support informed and engaged staff and management.
4. **Accountability and responsibility:** Senior management must clearly define food safety roles and responsibilities. Individual employees must be accountable for their actions and understand their roles and capacity in maintaining food safety practices and standards.
5. **Continuous improvement:** Upper management must develop and ensure the culture of food safety by regularly reviewing and improving food safety practices. Actions may include conducting audits, analyzing incidents and near-misses, and learning from mistakes, providing corrective actions, and sharing lessons learned across departments to prevent future issues.
6. **Positive reinforcement:** Employees who demonstrate a strong commitment to food safety should be recognized and rewarded. Positive reinforcement can motivate others and help to build a work culture where food safety is a shared priority.
7. **Risk assessment and management:** Upper management must conduct regular risk assessments to identify potential food safety hazards and implement appropriate control measures and monitor their effectiveness.
8. **Documentation and record-keeping:** Food processors must maintain records that thoroughly document food safety practices, training sessions, and incidents of food safety failures. Maintaining a strong food safety culture includes tracking progress and ensuring compliance with regulations relies on thorough and routine record keeping.
9. **Training and education**: Continuous education and training are needed to keep employees informed about food safety practices. These practices are essential for awareness and understanding of any changes in food regulations or procedures. Food safety training must be provided to all employees with the focus on helping employees understand the reasons behind the procedures and practices.
10. **Consistency in practice:** Employees and all levels of management must recognize that food safety culture is reflected in consistent behavior and practices that uphold food safety across the organization as a daily routine, and not just during inspections or audits.

Building and maintaining a strong food safety culture facilitates practices to prevent foodborne illnesses, prevent recalls, protect consumers, and enhance the reputation of food processing businesses. A strong food safety culture exists where employees feel comfortable informing leadership of an issue and to emphasize that action is

needed to address the concern (Marler, pers. comm., 2024). When food safety is not considered to be a priority, the needed corrections and preventive actions will not be addressed, and, thus, the risk enhanced of the potential of food safety failures and the increased occurrence of recalls of food products. When written or verbal food safety commitments are not reinforced by the leadership, the culture will not be reinforced and supported and will not be followed by employees and staff (Yiannas, 2009).

USDA/FSIS food production facilities are under continuous inspection while they are in production, and a HACCP food safety plan is required for each food product produced. However, these two requirements alone have not prevented life-changing recalls from occurring. During the writing of this manuscript (2024), Boars Head brand was recalling essentially all of the deli items produced at one of their factories in Virginia (PBS, 2024). By the end of August 2024, nine people had died from listeriosis and 50 others were hospitalized in 18 states. A review of the FSIS complaints documented over the past two years shows that the factory had repeatedly violated federal regulations. These violations included mold on walls, as well as meat and fat residues on many different surfaces (USDA, 2024b). According to an investigation by the Washington Post two years ago (2022), the USDA inspection reports stated that “an imminent threat” due to food safety failures had been identified during inspections (Roubein, 2024a). The review also stated that Boar’s Head leadership was notified of food safety violations 57 times (Roubein, 2024b). Production of the deli products was eventually halted in late July 2024. Although this incident raises serious questions about why the USDA/FSIS allowed the facility to continue to produce RTE foods when USDA/FSIS inspectors determined conditions to be an imminent threat, the root cause of the illness and recalls were failures by Boar’s Head leadership and not the USDA/FSIS. The inability of Boar’s Head management to address these failures and control the root causes indicates a cultural problem. The observations reported, and the outbreak itself, suggest that the facilities’ culture focused primarily on production and getting product out the door. The culture was clearly not focused on producing safe food.

Production errors do occur, and those errors may lead to foodborne illnesses. How the company responds in the event of errors is a critical component to improving food safety control that determines the culture. This response includes addressing questions such as, is the risk addressed immediately? Are root causes and corrective and preventive action plans developed? Are regulatory inspections, third-party audits, and internal audit observations reported for review and appropriate actions? Are those corrective actions monitored to ensure effectiveness? Does leadership make decisions that reflect food safety over production and shipping when incidents occur? These are the responses and actions that prove food safety matters to the company. Unless economic adulteration is intentional, food processors do not plan to produce harmful products and attempt to hurt or injure their customers. Besides being criminal and immoral, it is just bad business.

Preventing food processing mistakes requires that workers or management realize and understand the importance of food safety in all procedures and processes. These processes include sanitation and cleanliness, a correct label to a consumer with a food allergy, entering the correct time and temperature recipe for a bacterial kill step in a retort process, or completing simple maintenance procedures to verify that the machines, valves, and switches are functioning correctly. Failures in these routine tasks were some of the causes of Castleberry’s recall of retorted canned chili and other canned food products (Seltzer et al., 2008).

Conclusions

What these recalls tell us is that all of the food processors need to improve their food safety control processes. The USDA/FSIS and the FDA are responsible for regulating the food products in interstate commerce. American consumers expect to be able to purchase food products that are safe to feed to their children, their parents, and themselves. Large-scale recalls like the Peanut Corporation of America and Boars Head certainly can and do cause consumers to lose faith in the commercial food processing industry, their brands, and the agencies that regulate them.

The initial objective of this study was to analyze the USDA/FSIS food recall data and then compare this FSIS recall data with the recently published FDA F&B recall data. This analysis determined that Biological Contamination with live mesophilic bacteria is the most common cause for FDA F&B recall incidents, as well as the recalled product weight for the FSIS-managed recalls. In both cases, the most common bacterial species causing these recalls were *L. monocytogenes, Salmonella* serovars, and *E. coli* serovars. Live bacteria is a certain sign of improper cleaning and sanitation methods, uncontrolled procedures and processes like GMP failures, or lack of proper thermal process control which resulted in the recalls.

Although undeclared Allergens were the cause of most of the FSIS recalls by incident at 33%, they were only 15% by product weight, while Biological Contaminants caused 20% of the recall incidents and over half (53%) of the product weight recalled. Three recall categories, Allergens, Biological Contamination, and Extraneous Materials were responsible for 68% of the recall incidents and 86% of the weight of all of the FSIS recalls for the period reviewed.

The evaluation of recalls from the USDA/FSIS and FDA databases indicates a similar result. Biological Contaminants and Allergens are the most common causes of food recalls in either incidents or weight. These recalls are the results of human error in properly executing basic clean-up and sanitation procedures or verifying ingredients in food products for labeling purposes. Easy-to-clean equipment design can facilitate proper sanitation control, along with successful cleanup and sanitation procedures as well as preoperational inspections all while backed by a strong Food Safety Culture.

The cost and effort of introducing, implementing, and maintaining an effective FSC is much less expensive than addressing a food product recall. As is often stated, “Smart people learn from their mistakes; wise people learn from others' mistakes” (Unknown authors).

Employee training and retraining must be routine practice for all food processors. The armed forces are an example of enforcing routine training and retraining as a continuous cycle. For example, the U.S. Navy employs a “Safety Stand-Down” status for nondeployed units when aircraft crash and service personnel are killed. This process provides the aircrew the opportunity to review safety protocols and evaluate personal actions that involve aircraft operational safety (CBS8, 2022).

Recording and evaluating the causes of the “near-misses,” as well as the actual process of safety failures, has proved to be very beneficial to this study team. Studying recalls from other companies has also been very helpful and informative. Senior management must listen to and support the company’s independent auditors on a routine daily basis. The Quality Assurance manager and the Operations manager should accompany the visiting independent auditors at all times, making the effort to learn what the auditor is seeing, as well as what the auditor is teaching. Good independent auditors are walking libraries, and they will often share teachable moments or experiences as they complete their inspections and walk-throughs. Food recalls, for both USDA/FSIS and FDA-regulated products, are very serious events deserving focused effort and follow through. These events and efforts can seriously impact on the food companies’ business, and every recall can provide multiple lessons to be learned.

CRediT authorship contribution statement

Erika Rene Blickem: Writing – review & editing, Writing – original draft. **Jon W. Bell:** Writing – review & editing, Writing – original draft. **Mona Baumgartel:** Writing – review & editing, Writing – original

draft. **John DeBeer:** Writing – review & editing, Writing – original draft.

Declaration of competing interest

The authors declare that they have no known competing financial interests or personal relationships that could have appeared to influence the work reported in this paper.

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The individual authors of this study have worked in multiple parts of the seafood sector for many years. This experience includes leading or serving on teams that conducted recalls and participated in the postrecall self-evaluations and risk analysis. There was no funding agency for this study. The authors declare no conflicts of interest and contributed equally to this manuscript.

Appendix A. Supplementary material

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