How Safe Is Our Food?

U.S. PIRG

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Executive Summary

Americans rely on a vast network of farms and businesses to provide safe food daily. But in recent years, a string of high-profile recalls ranging from romaine lettuce to millions of pounds of beef to Ritz and Goldfish crackers has called into question the system developed to ensure safe food reaches people's plates. The ubiquity of the problem can make grocery shopping a game of Russian Roulette where what a family has for dinner could make them seriously sick.

While our food safety system has improved significantly over the last 100 years, when toxics, fake foodstuffs, and bacteria regularly infiltrated the supply, it is clear there is more work to do. A modern society relies on ensuring that the daily act of eating does not undermine the health of the population. Unfortunately, it is often difficult to get a handle on trends within the food system as ongoing, individual testing results are hard to access and may not indicate what hazards are reaching people's mouths.

In 2011, the United States made significant upgrades to the food safety system by passing the FDA Food Safety Modernization Act (FSMA).¹ This law, pushed through in the wake of a number of significant food recalls, was supposed to help the nation identify additional dangers by ensuring we were using modern techniques to track outbreaks of contamination such as *Salmonella* and dangerous strains of *E. coli*, improve regulatory oversight of the food production system to minimize contamination, and update recall laws.

Our food safety system has two lines of defense. First, a series of protections including health standards, inspections, and enforcement help keep contaminants out of the food supply in the first place. Second, when contaminated products make it to store shelves, the recall system helps remove these products from stores, homes and restaurants to keep people safe.

Evaluating recalls since 2013 can, therefore, provide insight into whether our food is getting safer and can expose critical holes in our food safety infrastructure. Unfortunately, our research based on recall data from the Food and Drug Administration (FDA) and Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS) shows that the number of food recalls have been increasing from 2013 to 2018:²

- The most hazardous meat and poultry recalls (Class 1) nearly doubled with an 83 percent increase, while overall all recalls of meat and poultry by the FSIS increased by 67 percent.
- Recalls of produce and processed foods from the FDA rose slightly, with a 2 percent increase over 2013 levels.
- All food recalls increased 10 percent, with the most hazardous of these edging up slightly at 6 percent.

The ability to link infections together and trace them back to the source has improved significantly in the last decade using new technology such as Whole Genome Sequencing (WGS). This may explain some of these findings. But whether we've always had a food safety problem and now we can see it, or the problem is getting worse in recent years, misses the point.

Americans should be confident that our food is safe and uncontaminated from dangerous bacteria like *E. coli* and *Salmonella*.

In addition, high profile recalls that stick in the public mind are the tip of the iceberg. The Centers for Disease Control and Prevention estimate that 1 in 6 people in the U.S. get foodborne illness every year, with 128,000 individuals hospitalized and 3,000 dying. These infections include *E. coli* and *Salmonella* poisoning as well as *Clostridium*, *Campylobacter*, and *Toxoplasma gondii*. The cumulative public health risk of foodborne illness warrants further study into causes and solutions.

Several case studies demonstrate the risk posed by gaps in our safety system.

Source and production safety: Often the cause of recalls can be traced back to contamination during production. For example:

Romaine lettuce recall from Yuma Arizona: An outbreak of *E. coli* in March of 2018 sickened more than 200 people and killed five. After 6 months, the FDA determined the outbreak of bacteria most likely originated from infested water used to irrigate the crop. A nearby Concentrated Animal Feed Operation (CAFO) could be responsible. ⁴

Foster Poultry Farms Recall: In 2013, federal inspectors cited Foster Poultry Farms more than 480 times for failing to meet food safety standards at three plants in Central California.⁵ Those plants were the source of drug-resistant *Salmonella* outbreak across 29 states and Puerto Rico that sickened 634 people and hospitalized 240. ⁶

JBS Beef Recall: 12 million pounds of raw beef products possibly contaminated with antibiotic-resistant *Salmonella* were recalled starting in October of 2018. Despite being a dangerous pathogen, plants can sell products even if testing reveals *Salmonella*.⁷ ⁸

Ritz Crackers & Goldfish: Three million packages of popular snacks were recalled due to possible *Salmonella* contamination of the whey used in production. This shows companies should be more be diligent about inspecting their own suppliers. ⁹

Still contaminated food may reach stores and homes, making the recall system the last line of defense.

Failure of the Recall System: When risky products make it to stores, we need to ensure that removing products from shelves, company stocks, and consumers' homes happens completely and at lightning speeds. Unfortunately, recent examples make it clear improvements are needed:

Honey Smacks: This popular children's cereal was recalled after it was linked to a *Salmonella* outbreak. Later, the FDA issued two additional notices as some stores apparently failed to remove adulterated cereal from their shelves.¹⁰

Caito Cut Melon Recall: In the United States, nearly half of foodborne illnesses are caused by bacteria on fresh fruits and vegetables. Pre-cut cantaloupe, watermelon and melon mixes from Caito's stores in nine states were linked to possible contamination from a strain of *Salmonella* Adelaide in 2018. Because these products are perishable

and raw, a quick and efficient recall system is necessary because any delay risks more illnesses. The CDC linked 60 illnesses to this recall -- and that climbed to 77 by mid-July.

Soy Nut Butter Recall: I.M. Healthy Soy Nut Butter spreads and granolas were recalled in March 2017 after *E. coli* caused 32 illnesses and 12 hospitalizations (9 of which developed a type of kidney failure). However, the FDA found online companies and some stores still selling contaminated butter after the recall was issued. ¹⁴

The food recalls illustrated by these case studies raise concerns about the efficacy of current policies. Adding to these issues, while we buy our food at the same stores, farmer stands, and restaurants, the current, convoluted system splits primary responsibility for different foods between the USDA's Food Safety and Inspection Service (FSIS) and the FDA. This has caused inconsistent oversight, ineffective coordination, and inefficient use of resources. ¹⁵

Americans should be able to trust the food they eat is safe from hazards.

Policy Solutions

Our findings make it clear that our food safety defenses need an across the board upgrade. Gaps in public health protections, enforcement and inspection make it too likely that dangers will reach Americans plates with potentially disastrous consequences. And, when these dangers are identified through analysis of disease vectors and health impacts, our recall system often allows hazards to continue to impact people's health.

To solve these problems, we recommend a serious boost to our food safety system.

Food Production and Testing

- Test water used for irrigation or watering of produce for hazardous pathogens.
- Set health based bacterial load levels for agriculture watering to prevent contamination.

Inspection and Monitoring

- Require plants to identify most common pathogens associated with meat and poultry products as hazards likely to occur and address them in their safety plans.
- Establish clear enforcement consequences for recurring violations of food safety protections or plans.
- Update food safety standards at facilities every 3 years.
- Declare antibiotic resistant strains of Salmonella as an adulterant in meat and poultry;

Traceability

- Improve traceability throughout the food supply chain through network-based tracking technologies.
- Retailers notify consumers that products they may have in their homes are recalled.

Recall Effectiveness

- Grant USDA mandatory recall authority for mandatory meat and poultry
- Require disclosure of retailers selling products for all Class I and Class II recalls, establish a timeline for release of that information, and include packaged goods.

- Penalize companies who continue to sell products after a recall.
- Develop programs for retailers to directly notify customers about food recalls.

Embarged until 11/11/19 & AMILET

Introduction

For lunch one day, you decide to go to a nearby pizza shop and because you want to be healthy, decide to order a salad. Starting soon after, violent diarrhea racks your body with convulsions and soon bloody vomit follows. That's when you head to the hospital because something is clearly wrong. Doctors spend days trying to figure out how a healthy man quickly became so sick—and eventually they identify the salad. The romaine lettuce in it was contaminated with an extremely dangerous variety of *E. coli*. 16 17

That's the story of William Whitt, a young father whose lunch turned into a serious health ordeal. And he wasn't alone as Romaine lettuce grown at the time in Yuma, Arizona sent over 200 people to the hospital, and killed five. Soon romaine lettuce was pulled from many shelves across the country. From family tables to conference centers to cafeterias, millions more heads and bags were thrown out.

The end culprit was farms watering leafy greens with bacteria-contaminated water that hadn't been tested.

This story may not harken back to the days of Upton Sinclair at the turn of the 20th century when rotting ham and poisoned rats were ground up into sausage. The outrage at that time eventually lead to the passage of the Pure Food and Drug Act which gave the federal government "permanent and comprehensive responsibility for the health and safety of the American food and drug supply." ¹⁸

We should celebrate this progress. Our ability to produce food continues to evolve, prioritizing producing food faster, cheaper and abundantly. But as stories like the above illustrate, at times the safety and quality of that food gets left behind. Those dangerous decisions can turn a simple meal into a trip to the emergency room. And that does not need to be the case in modern America.

Foodborne Illness Remains a Public Health Threat

Few people have not experienced an unpleasant moment of foodborne illness in the past few years from upset stomachs to fever and diarrhea. According to the World Health Organization, over 200 diseases are caused by unsafe food containing bacteria, viruses, parasites, toxins and chemicals. ¹⁹ In particular, foodborne illnesses affect vulnerable populations (children, pregnant women, elderly, and sick people) disproportionately. ²⁰ While most incidents pass quickly, some can cause serious health consequences including chronic diseases and death.

Safety has improved over the last few decades due to government action. After the 1993 *E. coli* outbreak at Jack in the Box fast food restaurants, the USDA began to increase its regulation of beef.²¹ More recently, increased surveillance, whole genome sequencing, required pathogen monitoring and microbial testing has markedly advanced our ability to detect outbreaks.

There is still much left to do: limiting possible sources of contamination, better tracing the cause of contamination, identifying the multitude of products affected by a single contamination, removing food from shelves, and notifying consumers who may have already purchased items. Identifying contamination is only the tip of the iceberg.)

Despite these improvements, there have been a number of high-profile food recalls from romaine lettuce to Ritz Crackers to poultry in recent years. Some illustrate issues with contamination at the source whether it's at the farm, butcher or due to flaws in inspection practices. Other recalls demonstrate gaps in our food safety system that leave dangerous products on store shelves and in people's' homes months after a recall was issued leading to additional, largely preventable, illnesses. The recall system is the last line of defense in our food system, and it is necessary that it function well so we can still protect consumers when poisoned

food slips through.

Comparison of Selected Agency Responsibilities for Food Safety and Quality Responsibility Food and Drug Administration (FDA) Food (but not meat) Dietary supplements Bottled water Seafood Eggs in the shell U.S. Department of Agriculture (USDA) Grading of raw fruit and vegetables Meat and poultry
Eggs, processing and grading Certifying organic production National Oceanic and Atmospheric Administration Grading of fish and seafood Environmental Protection Agency (EPA) Drinking water Pesticide residues Customs and Border Protection (CBP) Front-line enforcement and referral Department of Justice (DOJ) Federal Trade Commission (FTC) Alcohol and Tobacco Tax and Trade Bureau (TTB) Alcohol Source: CRS, as adapted by N. D. Fortin, Introduction to Food Regulation in the United States, Part 1, May 2008.

The United States food supply has grown increasingly complex and industrialized. Food passes through a variety of stages from farm production, slaughtering or harvesting and processing to storage, transport, and distribution. Each one of these links in the food supply chain can present opportunities for contamination to take place. Additionally, a drive to provide cheap food through technology and pushing production limits occurs with little consideration for the quality and safety of the food itself. The complexity of our food system is amplified by the number of local,

state, and federal agencies that share the responsibility for regulating the food supply. On the federal level, the responsibility of maintaining a safe food supply and effective recall system mainly lies with Food and Drug Administration (FDA) and the Department of Agriculture's (USDA) Food Safety and Inspection Service (FSIS). While these agencies have improved our system in the past 25 years through policy and technological advancements, contamination still occurs, and food safety concerns can often slip through the cracks.

Increased Surveillance (shadow box/pullout)

In the last decade, our ability to detect and traceback infections related to food contamination have improved significantly. hole genome sequencing may be one of the more notable technological improvements, revealing the complete DNA make-up of an organism. This has allowed regulators to link seemingly disparate clinical diseases across the country because of matching genomes and better tie those illnesses back to the original source. It goes further than previous techniques that were unable to differentiate some strains of a pathogen, as was the case for some types of *Salmonella*. ²²

Combining this advance with traceback analysis and more effective data tracking on what people have eaten through loyalty cards, credit cards and other purchase histories, have allowed more effective investigations by the CDC, FDA, and USDA. Some say that the increase in recalls does not actually reveal a problem with the food system, but simply demonstrates we've gotten better at tracking contamination.²³

Second, increasing numbers of recalls, even driven by better surveillance, demonstrate a that there were previously unidentified problems in the food supply. If the levels of contamination and outbreak being identified were always present and just now being identified, this shows that the safety problems in the food system are still in need of work.

Regardless of the reason for the increased number of recalls, the trend is still worrisome. No matter the cause (better surveillance or increased contamination) actions need to be taken to ensure a safe food supply by reducing the risk of contamination and outbreak.

Health Risks of Foodborne illness

Foodborne illness is an ongoing danger in the United States. Data from the CDC showed that the overall number of diagnosed infections *Campylobacter*, *Listeria*, *Salmonella*, *Shigella*, *Vibrio*, and *Yersinia* infections sourced from food increased 96 percent in 2017 compared with the 2014–2016 average. This is in due to use of culture-independent diagnostic tests (CIDT), which allows the identification of the general bacteria type within hours. While most people who are affected by foodborne illness recover without lasting effects, some suffer long-term consequences such as kidney failure, nerve damage, or chronic arthritis. Foodborne illnesses can also spread to the bloodstream, kidneys, and liver to cause life threatening infections.

A Cambridge University study found the United States population loses over 100,000 "life years" as a result of foodborne illness in the United States every year. ²⁷ A "life year" is often used in public health analysis to quantify the impact of different diseases. It could mean 10,000 individuals losing 10 years of their life or 100,000 people losing 1 year of their life, or another variation. While some of these incidents are caused by unsafe food preparation, gaps in the safety of our food supply contributes to the risk of contamination and increases the number of those affected in the United States every year.

Common Foodborne Illnesses²⁸ 29

Pathogen	Illness caused	Symptoms	Common foods that contain risks	Other Facts	
Norovirus	Gastroenteritis	- nausea - vomiting	- leafy greens - fresh fruits	Leading cause of foodborne illness	

		- diarrhea - stomach pain - dehydration	- shellfish	in the United States
STEC (Shiga toxin-producing <i>E. coli</i>)	Hemolytic uremic syndrome (HUS)	vomitingdiarrheafeverHUS can leadto kidney failureand death	- meat - poultry - dairy - juices	Most commonly identified type in the United States is <i>E. coli</i> O157:H7
Salmonella	- Salmonellosis -Typhoid / Enteric fever	- nausea - vomiting - diarrhea - cramps - fever - can spread from intestines to bloodstream which can cause death ³⁰	- eggs - meat - poultry - fruits - vegetables	
Listeria monocytogenes	- Listeriosis	- nausea - vomiting - diarrhea - fever - Listeriosis can cause blood infection, meningitis, and other deadly problems	- milk - cheese	Listeriosis mainly affects pregnant women, newborns, and older adults with weaker immune systems
Campylobacter	Campylobacterio sis	- nausea - vomiting - diarrhea - cramps - can spread to bloodstream and cause life- threatening infection	- contaminated water - unpasteurized milk or cheese - poultry	
Hepatitis A	Liver infection	- low appetite	- water	Many children

Risk factors in the United States food system

A World Health Organization assessment showed that as the population grows, there is a corollary increase in intensification and industrialization of agriculture and animal production that can create challenges for food safety by increasing the risk of contamination.³¹ Over the last few decades, that is exactly what has happened in the United States as increasing demand for cheap food has led to a more interconnected and industrialized system. The EPA estimates there were more than 19,000 CAFOs in 2016 up from 3,600 three decades ago. ³²

After a series of foodborne illnesses on a wide range of products from spinach to cookie dough to beef were reported in the first decade of the 2000s, Congress made the first major legislative update of the nation's food safety law since 1938.³³ The eventual passage of the FDA Food Safety Modernization Act (FSMA) attempted to address some of the nations' food safety system by placing responsibility on farmers and food processors to prevent contamination.

The law shifted the focus of our food safety system towards preventing contamination of food and placed more of the onus for ensuring a safe food supply on food producers with the FDA acting as a check on implementation and effectiveness. 34

Food facilities are required to establish "food safety plans" that include analysis of hazards and risk-based preventive controls to minimize potential food safety problems in their facilities. As new threats emerge, such as changes in production or antibiotic resistant strains of bacteria, the food producer is supposed to update those plans to address these problems. These controls were already in place for seafood and juice industries after a number of high-profile outbreaks in the 90s but would now be expanded to other food producers.

FDA finalized preventive control, known as a food safety plan, starting in 2016. Under the rules, businesses with more than 500 employees and sales averaging more than \$1 million over three years must have complied by September 19, 2016. Small businesses, defined as having less than 500 full time employees, must have adopted food safety plans by September 18, 2017. Businesses with less than \$1 million in sales averaged over three years had until September 17, 2018. So far this may be one of the most significant updates to food safety laws since the passage of FSMA.

Inspections are intended to catch issues in plan implementation, failure to follow food safety protections and otherwise identify safety hazards.

While the legislation took significant steps to improving our food safety system, core issues within our food production and the failure to implement critical protections still leave Americans vulnerable to preventable foodborne illnesses.

Industrialization

One potential cause of increased contamination risk in our food supply is the rising industrialization of our food supply. Technological advancements have brought with them the

ability to efficiently produce food, often at extremely low prices, but there are risks associated with that as production grows in scale, becomes more concentrated, or automated.

Concentrated Animal Feeding Operations (CAFO), also known as factory farms, are sometimes a conduit for contamination of meat because overcrowded conditions mean that when one animal gets sick, they pass the disease on to other animals.³⁵ In particular, the failure to effectively sanitize and treat animal waste risks *E. coli* contamination in our food supply. The USDA went so far as to call feces contaminating animals a "cosmetic blemish", allowing the livestock to be processed after rinsing off the offending matter.³⁶ These contaminations can spread beyond the CAFO to nearby produce farms as



runoff from animal waste from cattle operations can contaminate irrigation water for clean crops and cause contamination. This problem was present in a 2006 *E. coli* outbreak in spinach.³⁷ The FDA found the same strain of *E. coli* discovered in the spinach also in river water, cattle feces and wild pig feces in the cow pasture next to spinach fields. ³⁸ A similar source was also a likely cause of the spring 2018 romaine lettuce recall that had the FDA ordering all Americans to stop eating lettuce from Yuma—though because it was hard to identify the source on packaging it practically meant avoiding most romaine lettuce. ³⁹

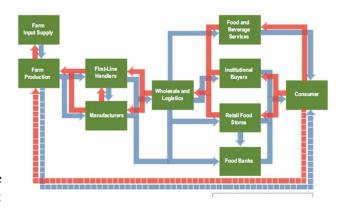
In poultry, microbial contamination can occur easily due to the animals' smaller size, use of water baths, and additional processes involved such as defeathering. The slaughterhouse environment and equipment used can contaminate poultry with *Salmonella* and *Campylobacter* which can grow and survive during food processing and storage. And the drive to slaughter more animals in shorter periods of time through higher "line speeds", creates a greater risk for cross contamination or other hazards expanding into the food supply.

Interconnectedness:

The United States food supply chain is increasingly interconnected and disaggregated. The path from the farm to the grocery store has become increasingly complex. There are separate processes for food production, distribution, processing, retailing, and preparation. Each one of those steps from farmer to consumer can also involve additional processes like aggregating, storing, and further processing food. These additional connections increase potential points of contamination and risk contamination spreading throughout large sections of our foodstuffs. 42

The picture grows slightly more complicated when considering imported foods. As the food needs to be warehoused and transported long distances before reaching the consumer, it can open up gaps in the food supply chain where safety problems could occur.⁴³

The complicated interconnections and opacity of the food supply chain has made tracking the source of the contamination extremely arduous. It could take weeks to locate the source of an outbreak in something like fruit



and vegetables by which time dozens of people could have gotten sick because the food is perishable. Delays risk serious health consequences and point to the need to streamline the process of agriculture supply chain transparency. Transaction information can be vital to containing the public health impacts of contamination.

Recalls on the Rise

The frequency and severity of recalls issued by food safety agencies can provide an insight into the quality of the nation's overall food safety infrastructure. Each recall is a moment, or sometimes a long stretch of time, when some failure allowed contamination to invade our food supply and dangerous food to reach people's plates. Since the last overhaul of our food safety system through the FSMA, food safety plans, improved surveillance technologies, and recalls should have strengthened the plethora of protections to ensure our food was safer than ever. Our analysis shows that a failure to address the safety of meat and poultry exposes Americans to increased risk.

As for produce and processed foods, the results are less clear. It is possible that recent implementation of food safety plans has started to secure our food supply from contamination. However, as later case studies reveal, some protections are being delayed, others are failing to move forward, and some major issues remain.

Recall Class (shadow box/pullout):

The FDA and FSIS decide the threat level classification while a recall investigation is occurring based on the below system, but the agencies can also change (upgrade or downgrade) the level of the recall over time. Food recalls are usually voluntary and initiated by manufacturers or distributors. However, under the FSMA, the FDA does have authority to make mandatory recalls and shut down food production if there is a significant threat to public health.

FSIS:45

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

FDA:46

Class	Definition

Class I	Situation in which there is a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death.
Class II	A situation in which use of, or exposure to, a violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote.
Class III	Situation in which use of, or exposure to, a violative product is not likely to cause adverse health consequences.

Meat and Poultry Recalls Increasing

Recall data on meat and poultry indicates a rapidly increasing trend within this subsection of our food. From 2013 to 2018, FSIS recalls increased by 66 percent (See Appendix 1). Even discounting the spike of recalls in 2015 as an outlier, there is still a clear trend that more meat and poultry being recalled due to contamination.

Beef recalls were up 55 percent, pork up 67, and poultry recalls up the most at 70 percent from 2013 to 2018.⁴⁷ The USDA projected Americans will eat a record amount of meat in 2018 meaning this trend could impact a significant portion of the public.⁴⁸ In addition, recalls of mixed meat products have increased by 60 percent during the same time period, though it is hard to analyze the cause without more information about what is contained within each product.

As we'll see in case studies, a number of unique issues plague our meat industry that make it more likely contaminated meat could reach stores, restaurants and homes.

Most Hazardous Meat and Poultry Recalls Nearly Double

Even more troubling, Class I recalls of meat and poultry increased by 83 percent since 2013, according to FSIS data (See Appendix 1). Class I recalls are the most serious kind, and involve "a health hazard situation in which there is a reasonable probability that eating the food will cause health problems or death." The severity of the hazard posed by Class I recalls and their increased prevalence shows that the risk of serious contamination slipping through our food inspection and verification systems is still high.

Produce and Processed Food Recalls Hold Steady

FDA enforcement reports show the number of recalls for most non-meat food has remained nearly constant (a 2 percent increase). Overall, there were 564 recalls in 2013 compared to 578 in

2018 (See Appendix 1). Similarly, the most dangerous Class I recalls have actually decreased by 12 percent since the passage of FSMA.

Prior to 2018, there seemed to be a steady increase in recalls of food overseen by the FDA. We analyzed the number of recalls beginning in 2013 to evaluate the efficacy of the law over the past six years. From 2013 to 2017, there was an 18 percent increase in FDA recalls of produce and processed foods (See Appendix 1). However, preliminary data from this past year showed a decrease in recalls from 301 in 2017 to 197 in 2018.

We have identified two potential explanations for this drop. First, it may be an outlier in the data, as there was a fairly steady increase in recalls prior to 2018. And, as we'll see in the case study section, some of the most significant recent recalls, including Romaine lettuce and Ritz crackers, fall within FDA jurisdiction, suggesting the number of recalls tell an incomplete story in this case. As we will explore through a series of case studies, there is more work that needs to be done to keep these foods safe.

A second explanation may be that the drop recalls coincides with the September 2017 compliance deadlines on parts of the FSMA that require food producers to implement preventive controls, also known as food safety plans. These plans include an analysis of potential contamination risks, preventative controls based on that analysis, recall plans in case of problems, and an examination of supply chain risks. ⁴⁹ The recall data does not shed enough light to determine whether these plans have made such an impact in this timeframe. We will need to continue monitoring the situation and examine the effectiveness of these plans in more detail to determine the likelihood of this explanation.

Overall Recalls Rise Slightly

Combining FDA and FSIS data provides a full picture of food safety trends in the United States—recalls increased by 10 percent (See Appendix 1). This trend also holds for the most hazardous Class I recalls, which are up 6 percent during the timeline examined. This rise shows that underlying food safety problems have not been adequately addressed.

Case Studies

Romaine Lettuce Outbreak (2018)

In late March of 2018, millions of Americans heard a startling announcement: do not eat any Romaine lettuce because it was likely grown in Yuma the source of an *E. coli* outbreak. This mass call was prompted after the CDC and the FDA, identified an outbreak of *E. coli*

O157:H7, a particularly dangerous strain. By the end, there were over 200 people reported as infected with 96 hospitalized and 5 killed across 36 states, making it the largest outbreak of this strain of *E. coli* in over a decade. The FDA's and CDC's investigation eventually traced the contamination to Yuma, Arizona where 90 percent of all leafy vegetables are grown in the winter in the United States. The investigation was unable to identify a single grower, harvester, or distributor as the cause, only the growing region. The outbreak ended as of June 28, 2018. States are grown in the contamination to Yuma, Arizona where 90 percent of all leafy vegetables are grown in the winter in the United States.

While investigators were able to quickly identify the general location of the contaminated romaine lettuce, it took almost 6 months for government agencies to determine the likely cause. In the end, they found the same strain of *E. coli* in a large cattle feedlot, also known as Concentrated Animal Feeding Operations (CAFOs).⁵⁴

A large cattle feedlot can hold an excess of 100,000 cattle at any one time: clustered close together near large feeding troughs. An unavoidable consequence of keeping these thousands of animals in such a concentrated area is that there is an egregious amount of waste produced. In fact, a dairy farm with just 2,500 cows can generate as much waste as a city of 411,000 people. Improper disposal of the waste that accumulates on factory farms can contaminate the water used to irrigate and clean crops. ⁵⁵ A likely chain of events is apparent. Bacteria found their way from the cattle operation into the canal, perhaps as leaking waste. Contaminated canal water was then used to water lettuce or found its way onto the farm. And from there, contaminated lettuce was shipped to stores around the country, providing a fast route to widespread illness.

While in their Environmental Assessment, the FDA did not conclude that the cattle farm was the cause of contamination because they could not find an obvious route of contamination, the team found "no evidence in support of alternative explanations". ⁵⁶

In 2006, the CDC and FDA conducted a similar investigation that showed an outbreak that impacted 26 states was related to Spinach grown in San Benito County, California. This region was also home to a large cattle ranch where animals were kept close to the river that irrigated the spinach farms. Agencies found that the *E. coli* in people affected by contaminated spinach matched the *E. coli* in fecal samples from cattle and pigs that had access to the river.⁵⁷

On September 20, 2018, Arizona growers released new voluntary protocols to help control outbreaks in the future that increased traceability measures, daily cleaning of equipment, review of crop impact after weather events, and establishes a 1,200-foot buffer zone between growing fields and feed lots.⁵⁸ This is a welcome advancement but fails to address some of the underlying problems. These new protocols do not even mention testing the canal water for pathogenic *E. coli* before using it again on crops which could cause continued contamination. Additionally, placing the solution in the hands of crop producers ignores the likely source of contamination: CAFOs. And growers could decide to abandon this action at any time. Unfortunately, in September 2017, the Trump Administration delayed implementation of a rule that would test for bacterial loads and set public health standards for the findings.⁵⁹

These outbreaks show how the industrialization combined with lax safeguards to monitor and limit use of bacteria-contaminated water on leafy greens can have a significant impact on our overall food system.

Foster Farms Poultry Recall (2013-14)

For over a year starting in March of 2013, an outbreak of *Salmonella Heidelberg* infected 634 people, hospitalizing 38 percent of them according to the CDC. The outbreak stretched across 29 states and Puerto Rico. 60

In this case, the strains of *Salmonella* caused high level hospitalization compared to other outbreaks potentially because many of the strains were antibiotic resistant.⁶¹ Ultimately, this outbreak was traced back to chicken raised by Foster Farms, a conglomerate that produces a significant amount of the chicken eaten by Americans.⁶²

It's possible this outbreak could have been avoided if more significant action was taken after federal inspectors cited Foster Poultry Farms 480 times in 2013 for not complying with food-safety standards at three plants in central California linked to a *Salmonella* outbreak. 63 Citations noted fecal matter on carcasses, chicken being directly contaminated, and food contact on sources that could spread disease. 64 Additionally, in their food safety plan at the facility, Foster Farms facilities had not identified *Salmonella* as a hazard reasonably likely to occur despite it often being found in chicken. 65

This failure helps identify three critical issues in our food safety system: self-regulation, lax enforcement, and problematic testing protocols.

First, meat producing plants are expected to self-regulate.⁶⁶ While government inspectors are present at every processing plant, they operate through the FSIS food safety program known as Pathogen Reduction/Hazard Analysis and Critical Control Points (PR/HACCP). This system places the primary safety responsibility on the meat plants and slaughterhouses themselves with government inspectors providing oversight. Since poultry producers like Foster Farms identify *Salmonella* as a "hazard not reasonably likely to occur" in their HACCP plans, effective controls were not put in place.^{67 68} In fact, this deficiency was not identified until FSIS inspectors came into the plants in September 2013.⁶⁹ The problem was only realized retrospectively by FSIS after hundreds were already exposed to the bacteria.

Second, this reveals that plants that violate critical food safety HACCP protocols face little consequence. According to Reuters, even after Foster Farms had been cited more than 480 times in one year by the FSIS for not complying with food safety standards, no shutdown of operations or significant fine occurred to help force changes.⁷⁰

Finally, the Foster Farms situation reveals the danger of FSIS's failure to list *Salmonella* as an adulterant. When a bacteria is declared an adulterant, no meat batches that test positive can be sold, ensuring safe food. While a remarkably high level of *Salmonella* contamination was found in poultry from Foster Farms, this failure means products could still legally be sold. There is no regulatory requirement that raw poultry or ground beef should be free from this pathogen. Page 1972

Instead, FSIS often sets performance standards for reducing *Salmonella* contamination, known as baseline studies.⁷³ The baseline is also determined with little regard for public health, instead looking at the current average number of inspected samples with the bacteria in them and using that to set a goal for producers to meet. While this forces companies with a high number of contaminated samples to improve, it does not push the industry to go further to ensure all food that reaches individuals' plates doesn't make them sick.

JBS Beef Recall (2018)

On October 4, 2018, JBS Tolleson Inc. announced a recall for 6.9 million pounds of various raw beef products as a result of *Salmonella* contamination—this was later expanded to more than 12 million pounds.⁷⁴ This was more than four-times the amount of beef recalled in the previous 3 years combined.⁷⁵ JBS Tolleson is a part of the US branch of the world's largest meatpacking company, JBS S.A., which has 22 percent of the market-share of beef. ⁷⁶

This outbreak of *Salmonella Newport*, an antibiotic resistant strain, has caused at least 333 illnesses and 91 hospitalizations in 28 states.⁷⁷ Antibiotic resistant bacteria are particularly dangerous because they cannot be easily be treated. In fact, this serotype of *Salmonella* has been linked to fourteen independent outbreaks that caused over 800 illnesses, 126 hospitalizations and 4 deaths.⁷⁸

Under current policy, even if JBS found *Salmonella* contamination during testing of their beef, they wouldn't be required to refrain from selling the tested batch because the pathogen is not considered an adulterant. ⁷⁹ ⁸⁰ This has created a food safety regime where companies retrospectively recall contaminated meat only after major outbreaks are identified. This policy is riskier for beef which is often not cooked to the necessary 165 degrees to kill *Salmonella*, as is recommended for chicken.

Consumer groups and legislators have long fought to change this policy. In 2014, FSIS rejected a petition from The Center for Science in the Public Interest (CSPI) to declare four strains of antibiotic-resistant *Salmonella* as adulterants in meat and poultry.⁸¹ They claimed they needed more data linking resistant *Salmonella* and illness, despite the numerous scholarly articles and real-world evidence.⁸²

In 2015, Senator Kirsten Gillibrand introduced the Meat and Poultry Recall Notification Act, which would give the USDA mandatory authority to recall food if they find an adulterant or contamination.⁸³ However, this attempt by legislators and advocates to make progress on this commonsense issue did not even leave committee.⁸⁴

Outbreaks like this are probably preventable if we change the rules that determine what products can be sold. The FDA already considers *Salmonella* an adulterant, and it is necessary that the USDA/FSIS follows suit. ⁸⁵

Ritz Crackers, Goldfish, and other popular snacks Recall (2018)

Only July 26th, 2018, the FDA announced a voluntary recall of Ritz crackers, Pepperidge Farm's Goldfish, Flowers Foods' Swiss Rolls, and other products due to potential *Salmonella* contamination.⁸⁶ In total, over 3 million packages of Goldfish products and 16 varieties of Ritz Crackers were recalled.⁸⁷

These diverse food products all had one common ingredient that tied them: whey powder. Each product sourced the whey powder, a common binding agent for many popular snacks, used in their foodstuff from a company most people haven't heard of: Associated Milk Producers Inc. (AMPI). ⁸⁸

This contamination points to a problem with the interconnected nature of our food supply. Because AMPI was a common ingredient supplier in the production process, gaps in protections can spread through large sections of the food supply. Michael Moss, an investigative journalist noted that "companies need to be more diligent about inspecting their suppliers because they're using this global food chain of ingredients over which they don't have enough control". ⁸⁹ The complexity of our food production process makes it difficult to track which products were affected by contamination. Multiple companies all having their hands in the pot makes it harder to triangulate where the contaminate could have been introduced. The interconnection means potential contamination of individual products increases potential size of sourced contamination overall.

The whey protein recall also raised a critical transparency issue. The FDA does not release information about food ingredients that are sold solely on a business-to-business basis because it is "confidential corporate information" (CCI). This means it is still unknown how many food companies used the possibly contaminated whey powder in their products or how many pounds of whey powder were affected. AMPI refuses to reveal its customers or distributors but says it contacted each business. Unfortunately, when dealing with such a critical public health issue, that is insufficient. Regulators should already have a list of who provides each ingredient in their food so that relevant companies can quickly be notified. The failure to release information about business-to-business dealings reflects an unnecessary opacity that could cause people to unknowingly consume potentially harmful products.

Honey Smacks (2018)

In May 2018, the FDA and CDC tracked a *Salmonella* outbreak to the popular Kellogg's Honey Smacks cereal. On June 14th, Kellogg announced a voluntary recall of the cereal and stopped producing the product after the FDA determined the source of the contamination. By the end of the outbreak Honey Smacks poisoned 135 individuals and hospitalized 34. ⁹²

Salmonella can produce serious, and sometimes fatal, infections in children and others with weakened immune systems. Children are especially vulnerable to Salmonella infections, making the contamination of a cereal largely marketed to children of special concern. ⁹³

Follow-up investigations by the FDA in July and again in August discovered some grocery stores and retailers were still selling the contaminated batch. ⁹⁴ The names of these sellers were not publicly disclosed making it nearly impossible for people to identify if they had bought dangerous cereal and sending government agents and consumer groups on a scavenger hunt. Instead, the agency simply issued a "reminder" that these products should no longer be sold but issued no known consequences for stores failing to meet the recall. ⁹⁵

Soon after this issue, the FDA proposed a draft guidance to disclose information on which stores sold recalled food in a narrow set of instances. The guidance indicates that information that was confidential, like retailer lists, can be published to protect public health. And it requires disclosure of lists in the case of Class 1 recalls where there aren't clear identifier labels on the product, such as a UPC. 96 But, this policy leaves many recalls uncovered including the Honey Smacks recall because you could still identify the food by looking at the code and other recalls because they start as Class 2 recalls, but get upgraded to Class 1 later. U.S. PIRG, and other consumer groups, have advocated for these changes in the wake of many incidents of contamination that could have had their impacts reduced with the provision of retailer information. But they do not go far enough as looking at individual UPC codes to determine if a recall was completely executed strains credulity.

The Honey Smacks recall also again identifies serious issues with lax regulatory oversight and enforcement. In September of 2018, the FDA confirmed that Kerry Inc. manufactured the Honey Smacks related to the recall. ⁹⁷ The FDA also released a letter they sent earlier in July of that year to Kerry Inc.'s CEO citing their long-term *Salmonella* contamination. The warning letter revealed that between September of 2016 and May of 2018, the manufacturing plant showed 81 positive *Salmonella* samples including in some production lines and rooms used for the manufacture of cereal. As in the case of Foster Farms, Kerry Inc.'s food safety plan did not identify *Salmonella* as a food safety hazard. ⁹⁸

The only action the FDA took in response to these practices was to inform Kerry Inc. that they should have changed their hazard analysis protocols. 99 This retrospective warning is not an adequate response to protect the health and safety of consumers. It is necessary that the FDA take up more expansive protocols to make sure that producer hazard analyses are effective and prevent outbreaks.

Caito Cut Melon Recall (2018):

In June of 2018, Caito Foods issued a voluntary recall of fresh cut fruits due to potential contamination with *Salmonella* Adelaide. The recall covered stores in 9 different states for a variety of products including fresh cut watermelon, honeydew melon, cantaloupe and fresh-cut mixed fruit containing one of these melons. ¹⁰⁰

According to the CDC, raw fruits and vegetables can contain harmful germs, such as *Salmonella*, *E. coli*, and Listeria that can make you sick. In the United States, nearly half of foodborne illnesses are caused by bacteria on fresh fruit and vegetables. ¹⁰¹

CDC eventually linked 77 illnesses to the strain of *Salmonella* under investigation. ¹⁰² While the recall occurred in June, most of the illness occurred between April 30 and May 28. Some time lag is to be expected but given the short shelf life of produce like fresh fruits, it is necessary to increase the speed of traceability to discover the source of foodborne illness outbreaks in the United States.

The number of illnesses increased to 77 illnesses and 36 hospitalization by mid-July when the CDC announced the outbreak to be officially over. This increase may be attributed to the fact that many people had not removed the products from their homes or restaurants.

Because fruits and vegetables are perishable products with short shelf times, people eat them within a week of purchasing. This creates a demand on the speed and efficacy of the recall system. Any delay, even if just for a few weeks, can lead to dozens of people getting unnecessarily sick.

Soy Nut Butter Recall (2017)

On March 3, 2017, SoyNut Butter Co. recalled their "I.M. Healthy Original Creamy SoyNut Butter" product because it may have been contaminated with *E. coli* O157:H7. The recall was expanded 3 days later to all SoyNut Butters and Healthy Granola products. ¹⁰³

The outbreak caused 32 illness and 12 hospitalizations, including 9 which developed kidney failure, in 12 states. ¹⁰⁴ The products were present in childcare centers and schools in multiple states which was concerning because *E. coli* related kidney failure is most likely to occur in young children and the elderly. Additionally, it is easy for stores to stock or people to keep products like these without knowing that they had been recalled because of their long shelf lives.

The manufacturer Dixie Dew Products Inc. had food safety violations going back 15 years. This contamination was the final straw, leading the FDA to shut down the facility. Of course, this should have happened much earlier and again illustrates the problem of lax regulatory consequences for safety violation. While the FSMA requires safety programs for food suppliers, some problems continue to slip through the cracks.

Despite the shutdown and the recall, 6 months later the FDA discovered this contaminated SoyNut Butter was still being sold online and some storefront locations. 106

Policy Recommendations

While our food safety system has improved over the past 30 years, the number of dangerous recalls highlights the need for further action to protect public health. And the case examples outlined in this report make it clear that continued implementation of the Food Safety Modernization Act alone will not solve the issues facing our food system.

Ultimately, any additional policy action must address four areas based on the above analysis.

Food Production and Inspection

Our first lines of defense are efforts to limit contamination of our food supply during production and ensuring any contamination is caught prior to leaving the facility.

Concentrated Animal Feeding Operations: As seen in the case of the romaine lettuce outbreak, the failure to reign in the activities of CAFOs has led to the emergence of antibiotic resistant infections that have far reaching consequences in our food supply. HACCP programs may help as an ex-post review of safety standards but maintaining a clean source would go a long way in preventing contamination.

To prevent these operations from continuing to damage food safety, U.S. PIRG recommends:

- 1. Establish and set bacterial load for agricultural water as required by proposed rules under the FSMA.
- 2. Test water in the proximity of CAFOs or used for agricultural water for bacteria such as pathogenic *E. coli* and *Salmonella* that could be used to irrigate crops. The use of molecular-based testing technology instead of the standard culture-based technology will shorten time needed for detection and increase its accuracy.¹⁰⁷

Inspection and Monitoring: \land

As noted above, slaughterhouses are allowed to develop their own food safety plans and monitor their tracking. Without robust oversight and intervention, a number of contaminated foods are reaching the market.

To deal with these two critical issues U.S. PIRG recommends that we:

- 1. Require plants to identify pathogens most commonly associated with particular meat and poultry products as hazards likely to occur and address them in their HACCP plans.
- 2. Establish clear procedures and repercussions for recurring violations including significant fines and potentially plant shutdown until violations are remedied.
- 3 Update performance standards at least every 3 years based on standards that will reduce incidents of foodborne illness due to contamination.
- 4. Improve FSIS sampling programs to target riskiest facilities and products.
- 5. Declare dangerous antibiotic resistant strains of *Salmonella* as an adulterant in meat and poultry.

Traceability: Tracing the cause of outbreaks or identifying contaminated food in the market often takes too long, which has serious public health consequences. From identifying the cause of contamination, identifying the variety of products affected by the contamination, removing them from shelves, to notifying consumers who may have already purchased them; identifying that there was a contamination only scratches the surface of the problem.

Transaction information can be vital to containing the public health impacts of contamination, like in the romaine lettuce case. Similarly, this information can help in identifying the cause of contamination.

To improve traceability, U.S. PIRG recommends:

- 1. Implementing network-based food tracking technologies from farm to fork.
- 2. Amending the FDA Food Safety Modernization Act to require the collection of data during every part of the food supply chain.

Network based food tracking technologies can make our recall systems more effective. Information could be added about products placed on shelves which can help stores in implementing recalls. The information could potentially also be used to notify customers that a certain batch was contaminated. Information from harvest crew, date, and time, to temperature, storage, and sanitization along each step of the path from farm to store could be uploaded. This both has the added benefit of detailing the food's voyage and improving the ability to trace the place in the supply chain contamination could have happened.

Recall Effectiveness

Improving the recall system remains of utmost importance. It is the last line of defense in our food system. An effective recall system, in addition to implementing the above, will help ensure that if foodborne disease outbreak occurs, we can minimize or prevent the public health impact.

To make sure our recall system is effective, U.S. PIRG recommends:

- 1. The FDA makes its final guidance on naming retailers during food recalls more comprehensive by requiring disclosure for all Class I and II recalls, establishing a timeline for information release, and commitment to apply guidance to packaged goods.
- 2. The FDA ensures enforcement of recalls by increasing consequences for companies continuing to sell products. This would include requiring information about products being pulled off shelves and requiring retailers to confirm that they executed the recall with haste.
- 3. Retailers establish a more effective recall system to notify consumers that products they may have in their homes are recalled. This can involve using information from store loyalty programs to notify consumers that products they've purchased could be contaminated. 108

These improvements to all lines of defense for our food system will help ensure that people's health will be protected from a number of preventable foodborne illnesses.

Blockchain (ShadowBox/Pullout)

If consumers don't have the information and tools to protect themselves from unsafe products, the incidence of foodborne illness will only continue to increase. Our food safety

system needs updating. The romaine lettuce recalls show the need to have a system that makes recalls faster, more effective, and increases transparency and traceability in the food supply chain.

One potential solution to these problems that is gaining popularity is blockchain, which many know as the technological backbone of cryptocurrencies like Bitcoin. Tech innovators are working on using blockchain technology to monitor supply chains in everything from retail and pharmaceuticals to health insurance and industrial emissions. In agriculture, companies like Walmart are working with IBM to use this technology to quickly identify food inventories that are contaminated on store shelves to ensure removal. Blockchain is a decentralized cloud-based ledger that, as Frank Yiannas, former Vice President for Food Safety for Walmart and now Deputy Commissioner for Food Policy and Response at the FDA, says could become the "equivalent of FedEx tracking for food." ¹⁰⁹ Each time there is a transaction in the food's journey, information about it is added as a "block" to the online network ledger. Information from harvest crew, date, and time, to temperature, storage, and sanitization along each step of the path from farm to store can be easily and quickly uploaded. This both has the added benefit of detailing the food's voyage and improving the ability to trace the place in the supply chain contamination could have happened.

This transaction information can be vital to containing the public health impacts of contamination, like in the romaine lettuce case. Similarly, the information can help in identifying the cause of contamination. Delays risk serious health consequences and point to the need to streamline the process of agriculture supply chain transparency.

In addition, blockchain or other network-based food tracking technologies can make our recall systems more effective. Information could be added about products placed on shelves which can help stores in implementing recalls. The information could potentially also be used to notify customers that a certain batch was contaminated.

The obvious challenge in implementing blockchain technology in food safety is in accurately collecting and inputting the data into the ledger. Additionally, producers, who already backlash to food safety auditors, may not buy into the process. However, increasing consumer demand for traceability, may push the use of transformational technology like blockchain into the public eye. 110 It could also limit the number of items that need to be recalled by allowing more pinpoint accuracy on which products are contaminated—decreasing cost for businesses and consumers.

Methodology

We collected information on recalls from two sources. The USDA/FSIS publishes yearly summaries on recall data on their website that we used for our recall analysis. For the FDA data, we submitted a FOIA request requesting information on issued recalls to help address gaps on the data on their website.

The total number of recalls from the FSIS and FDA were combined to produce an average for the total number of recalls. In order to isolate the number of FDA recalls, only recall events were counted and duplicate recall numbers were excluded. This was because there were multiple recall numbers associated with single recall events. This report was concerned with the number of recall events.

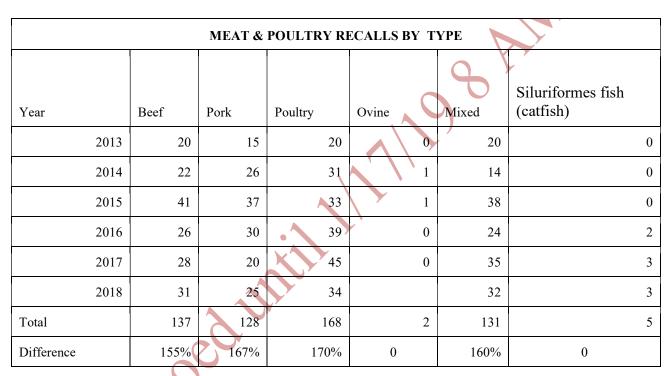
APPENDIX 1: Recall data

TOTAL FOOD RECALLS 2013-2018						
Year	Class I	Class II	Class III	Total		
2013	276	295	68	639		
2014	308	281	58	647		
2015	399	292	46	737		
2016	469	371	65	905		
2017	401	371	45	817		
2018	294	344	65	703		
Total	2147	1954	347	4448		
Difference	106.5%	116.6%	95.6%	110%		

MEAT AND POULTRY RECALLS 2013-2018							
Year	Class I	Class II	Class III	Grand Total			
2013	53	17	5	75			
2014	63	23	8	94			
2015	99	39	12	150			
2016	91	26	5	122			
2017	100	22	9	131			
2018	97	21	7	125			
Total	503	148	46	697			
Difference	183%	123.5%	140%	166.7%			

Produce, Processed Food & Other FDA recalls 2013-2018							
Distinct Count of Recall Event	Column Labels						
Row Labels	Class I	Class II	Class III	Total			
2013	223	278	63		564		

2014	245	258	50	553
2015	300	253	34	587
2016	378	345	60	783
2017	301	349	36	686
2018	197	323	58	578
Total	1644	1806	301	3751
Difference	88%	116%	92%	102%



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