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SERVICES FOR SCIENCE AND EDUCATION

Preliminary Assessment of the Food Safety Modernization Act Analyzing the Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices

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ABSTRACT

As the rules of the Food Safety Modernization Act (FSMA) of 2011 takes root, foodborne outbreaks, and by extension related recalls, illnesses, and death should decrease. The Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices provides data from October 2006 to current; a glimpse of food safety practices pre FSMA to date. An estimated 198 outbreak notices were reported October 2006 to December 2023 with 145 affiliated recalls, 23064 illnesses, and 132 deaths. While all organisms in the outbreak notices contributed to illnesses, *Salmonella spp., Escherichia coli spp.,* and *Listeria spp.* could be considered the deadly three. Of the 198 outbreak notices, *Salmonella spp*. accounted for an estimated 50.51% outbreaks notices, 55.17% associated recalls, 68.56% illnesses, and 26.52% death; *Escherichia coli spp*. accounted for 24.75% outbreak notices, 21.38% recall, 9.35% illnesses, and 12.87% death. *Listeria spp.* accounting for 15.66% outbreak notices, 17.24% recall, 2.31% illnesses, and 60.61% death. Outbreak notices with associated recalls trended upwards from October 2006 to December 2023; illnesses slightly trended upwards; deaths appeared to flatline with a negligible downward movement. Data suggests more time needed to fully assess the impact the Food Safety Modernization Act has on foodborne outbreaks and resulting consequences post implementation.

Keywords: Foodborne outbreak notices, recalls, illness, death.

INTRODUCTION

The Food Safety Modernization Act (FSMA) of 2011[1] could be considered one of the most swiping mandates in recent years geared towards protecting the unsuspecting public from potentially contaminated food that could cause illness or worst death. Consequently, one would expect a decline in foodborne outbreaks, associated recalls, illness, and death as the rules of FSMA takes root with its preventive focus impacting not only domestically produced food, but also imports to be consumed in these United States, re: the Foreign Supplier Verification Program (FSVP)[2], which expects the same preventive food safety standards apply to food consumed in the U.S., regardless of where the food is produced; compliance began for covered importers May 30, 2017.

It has been over ten years since FSMA was signed into law; while varied components are still being implemented such as the January 20,2026 compliance date in meeting requirements for additional traceability records for certain foods [3], much of the component's compliance dates [4] have past, and of such, one would expect marginal improvements at minimum. One cannot

overlook the onslaught of the COVID19 pandemic, many companies are still recovering post COVID; at the same time, the food industry classification as 'essential, critical infrastructure'[5,6] underpins the fact that protecting the unsuspecting public cannot be placed on paused even during crisis, and of such, the expectation of marginal improvements at minimum.

While FSMA rules only apply to foods regulated by the FDA, about 75% [7], this remains the lion share of the U.S. food supply, presenting a challenge in assessing the impact of FSMA. In prior studies, the Recalls Market and Safety Alert Registry, sales reports, and the Food and Drug Administration Warning Letters, were used to gain a preliminary understanding of the progress being made [8]. While recalls aimed to curb the spread of outbreaks, not all food safety recalls result from or associated with outbreaks. Likewise, not all outbreaks resulted in recalls as shown on the CDC List of Multistate Foodborne Outbreak Notices [9], the focus of this study.

The Center for Disease Control and Prevention paints a grim picture regarding consequences from foodborne illnesses, stating that about 48 million people in the U.S. (1 in 6) get sick, 128,000 are hospitalized, and 3,000 die each year from foodborne diseases [1,10]. The CDC's National Outbreak Reporting System Dashboard (NORS) [11] provides a comprehensive overview of outbreaks and primary mode of transmission with data from 1971 to 2021. Data for foodborne outbreaks span 1998 to 2021, showing downward trend in outbreaks and illnesses, while upward trend in hospitalization and death; the year 2020 recorded the lowest number of outbreaks of 313, and illnesses of 6110; 2009 recorded the lowest number of illnesses of 553, and the years 2009 and 2019 recorded the lowest number of deaths of 7. Neither the dashboard nor the downloaded excel spreadsheet provide data on associated recalls, information captured in the CDC's Multistate Foodborne Outbreak Notices [9]; of such, looking at these notices should provide glimpse of overall food safety practices pre and post signing FSMA into law considering the notices span 2006 to current; and those recalls are intended to mitigate the spread of foodborne outbreaks. Furthermore, the Multistate Notices provides data on closed and active investigations, such as active investigation of *Salmonella* outbreak linked to Charcuterie Meats, first posted January 5, 2024.

MATERIAL AND METHODS

Statistical analysis and summary of foodborne outbreaks published in the Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices with data from 2009 to current. Data relating to outbreak notices, recalls, illnesses and deaths were numerically assessed or captured in excel spreadsheet as deemed necessary for analysis. Data from the CDC's National Outbreak Reporting System Dashboard (NORS) were also assessed which covered foodborne outbreaks for 1998 to 2021 (figure 2).

RESULTS AND DISCUSSION

As foodborne outbreaks continue to be a challenge, an upward trend in outbreak notices and associated recalls (figure 1) questions how aggressively companies are meeting the requirements of FSMA's preventive approach. Outbreak notices last reviewed by CDC January 5, 2024, recorded a notable reduction to single digit in 2023, last seen in 2017, 2006 to 2009 (table 1), a turn in the right direction despite an upward trend (figure 1). While all organisms in the outbreak notices contributed to illnesses, *Salmonella spp., Escherichia coli spp.,* and

Listeria spp. could be considered the deadly three (table 2). *Salmonella spp.* was presented as the leading cause for outbreak notices and associated recalls over 50%, whereby simple hand washing [12] techniques could stem the spread; being mindful that hand soaps have also been subjected to recalls due to presence of bacteria [13]. Nonetheless, how seriously do companies take their respective personnel GMP programs? Are employees held accountable for violations; do managers lead by example? How often do companies check cleaners for expiration, concentration, or follow up with subcontractors were applicable? While *Salmonella spp.* could also be spread through raw or undercooked foods [12], a check on heat treated kill steps where applicable, understanding that some individuals appreciate semi-cooked or raw foods, poses a real challenge in this area; for instance, outbreak investigation of *Salmonella*: Raw Cookie Dough (May 2023) [9,14] consumed raw. This recall demonstrated that while necessary, a one-back trace may not necessarily provide any conclusive result; consequently, taking stock of internal practices plays an integral role in this continued fight to protect the unsuspecting public. The second leading cause for outbreaks notices and associated recalls over 20%, the gut bacteria *Escherichia coli spp.* further emphasizes the significance of being keen on internal practices. Not all companies subscribe to a glove program, maybe due to cost, or increased risk of foreign material getting into products, a physical hazard that could trigger a recall. Notwithstanding, the requirements for hand washing remain irrespective of having a glove program or not. How seriously do companies take their sanitation program, positive releases, not only product, but equipment? Are restroom facilities monitored for hygienic purposes? What about drains, are those areas being monitored for presumptive presence of pathogens? The leading cause of death among the outbreak notices was the environmental pathogen *Listeria spp.* accounting for over 60% death, that can be found in constantly wet areas such as drains [15], which again points back to sanitation and environmental monitoring programs. Some facilities are aged with drainage systems needing to be revamped, a significant capital expense; notwithstanding, consistently monitoring these areas plays a vital role in the continued fight to protect the unsuspecting public. While constant monitoring of products plays a pivotal role in protecting the unsuspecting public, the conditions under which they are produced are just as important and deserve just as much attention.

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Appendix

Table 1: Reported foodborne outbreaks per year and associated recalls, illness, and death per the Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices

Date	Outbreaks Notices	Recalls due to outbreak	Illness	Death
2006	3	0	453	3
2007	5	4	823	0
2008	4	3	1542	2
2009	6	6	1071	11
2010	10	9	2611	0
2011	13	10	782	35
2012	10	7	1071	8
2013	11	8	1233	2
2014	13	9	535	12
2015	11	9	1857	12
2016	14	11	756	5
2017	8	4	1381	5
2018	24	19	2932	11
2019	17	13	1163	5
2020	10	7	2173	6
2021	17	12	1465	8
2022	13	8	740	1
2023	9	6	476	6
Total	**198**	**145**	**23064**	**132**

Footnote*: see List of Multistate Foodborne Outbreak Notices | CDC

Table 2: Organisms and associated outbreaks, recalls, illness, and deaths per the Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices

Organism	Outbreaks		Recalls		Illness		Death	
	Total	Percentage	Total	Percentage	Total	Percentage	Total	Percentage
Salmonella spp.	100	50.51%	80	55.17%	15812	68.56%	35	26.52%
Escherichia coli spp.	49	24.75%	31	21.38%	2157	9.35%	17	12.87%
Listeria spp.	31	15.66%	25	17.24%	533	2.31%	80	60.61%
Cyclospora spp.	9	4.54%	3	2.07%	3698	16.03%	0	0.00%
Hepititis A	5	2.52%	4	2.76%	331	1.44%	0	0.00%
Vibrio spp.	2	1.01%	1	0.69%	130	0.56%	0	0.00%
Norovirus	2	1.01%	1	0.69%	403	1.75%	0	0.00%
Total	**198**	**100.00%**	**145**	**100.00%**	**23064**	**100.00%**	**132**	**100.00%**

Footnote*: see List of Multistate Foodborne Outbreak Notices | CDC

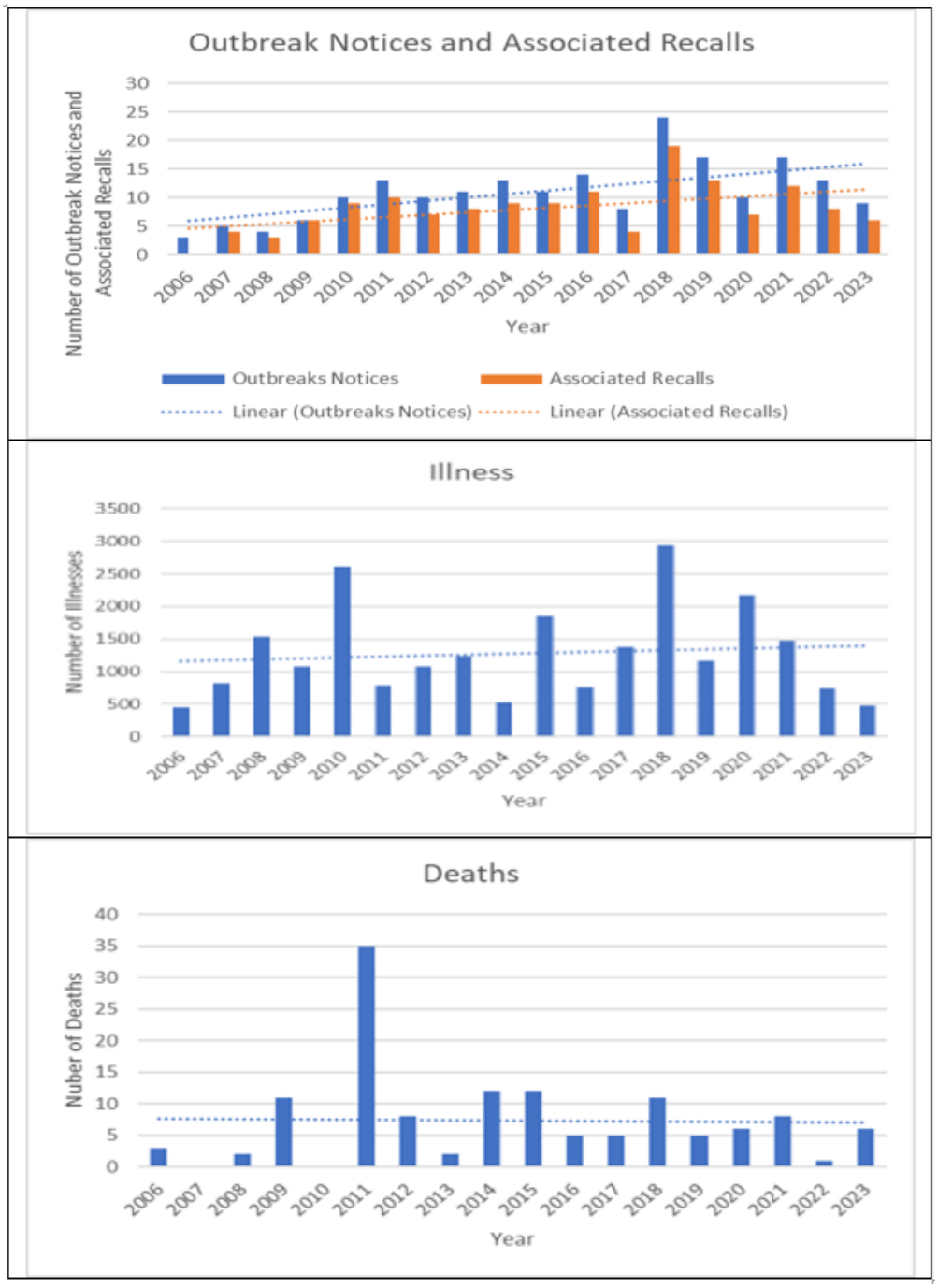


Figure 1: Center for Disease Control and Prevention Multistate Foodborne Outbreak Notices from 2006 to 2023

Outbreak notices with associated recalls trended upwards from October 2006 to December 2023; illnesses slightly trended upwards; deaths appeared to flatline with a negligible downward movement.

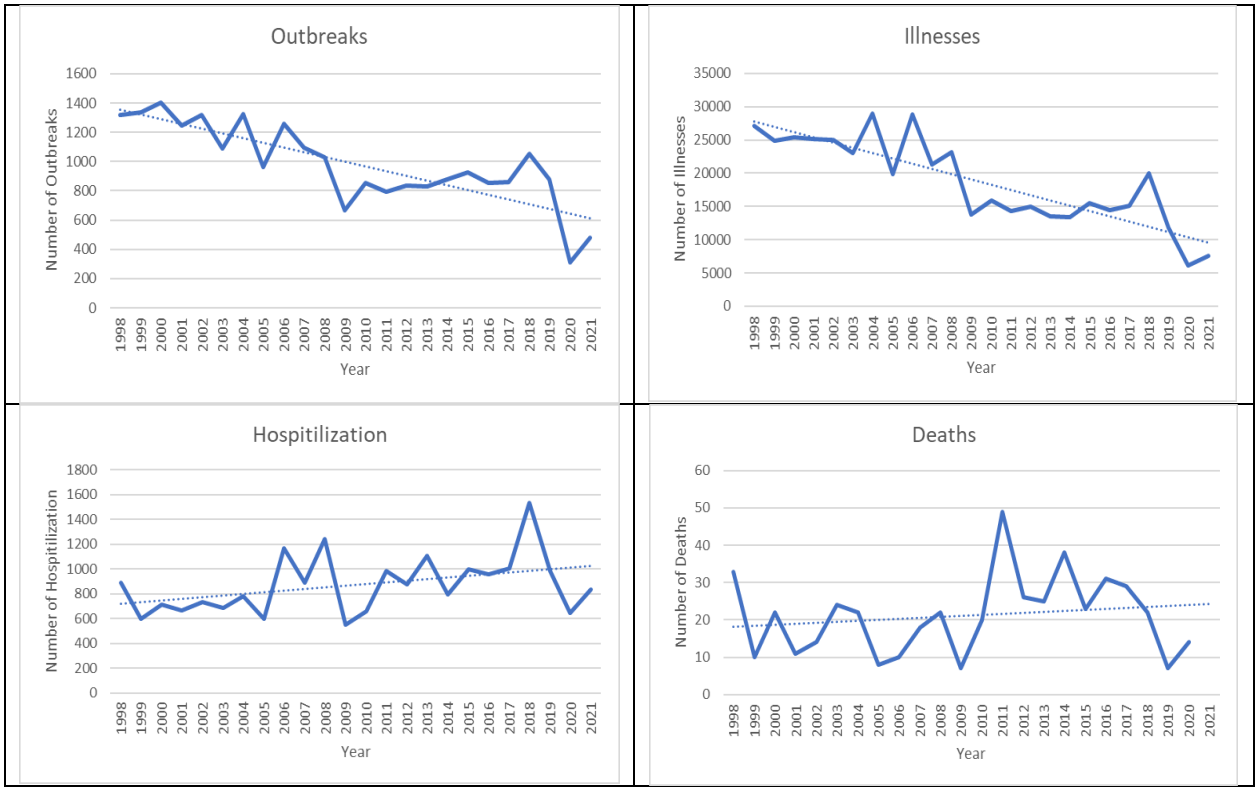


Figure 2: Center for Disease Control and Prevention National Outbreak Reporting System Dashboard (NORS) from 1998 to 2021.