

Preliminary assessment of the Food Safety Modernization Act (FSMA) mandates through the lens of the Recalls Market and Safety Alert Registry, sales reports, and the Food and Drug Administration Warning Letters.

Delano A. Chambers, Ph.D.¹ and Donesh Johnson-Drummond, MPH².

¹*Food safety and quality assurance professional, US private sector.*

²*College of Natural and Applied Sciences, Allied Health and Nursing, Northern Caribbean University, Mandeville, Manchester, Jamaica W.I.*

ABSTRACT: There are many moving variables when considering the mandates of the Food Safety Modernization Act (FSMA) such as company size, compliance dates, exceptions; but along the constant variables are the requirement for covered facilities to implement a food safety plan which includes a recall plan if hazard analysis identifies a hazard requiring a preventive control, describing the procedures to perform a recall of the product. To assess the effective implementation of the plan or mandates, it could be reasoned that if recalls captured by the Recalls, Market, and Safety Alert Registry are on the decrease, whilst overall sales are on the increase, then the provisions of the mandates are having a positive correlation; likewise, if recalls are on the increase, and overall sales are on the increase, an opportunity to further assess the provisions of the mandates or its implementation. As the provisions were first issued in 2015, and compliance thereafter, data from 2015 to 2021 were considered from three industries: food and beverage; dietary supplements; animal and veterinary. Food and beverage saw an increase in sales and reduction in reported recalls. Same correlation noted for dietary supplements. Animal and veterinary noted an increase in both sales and reported recalls. Data set was further categorized to biological, chemical, and physical recalls per industry. While recalls for undeclared allergens was lowest with food for animals, chemical recalls in general were highest across all three industries, followed by biological, and physical hazards respectively. This preliminary assessment suggests gains are being made; compliance to the Food and Drug Administration's warning letters may be a contributing factor.

KEYWORDS: Recalls, sales, correlations, biological, chemical, physical, warning letters.

I. INTRODUCTION

The Food Safety Modernization Act (FSMA) signed into law in 2011, is shifting the focus from responding to foodborne illness to preventing it. In 2015, the Food and Drug Administration (FDA) finalized seven major rules to implement FSMA which are designed to make clear specific actions that must be taken at each of these points to prevent contamination; see specific guidance on the following: Preventive Controls for Human Food; Preventive Controls for Animal Food; Produce Safety; Foreign Supplier Verification Program; Third-Party Certification; Food Defense; and Sanitary Transportation¹. FSMA rules only apply to foods regulated by the FDA, about 75%². In general, a covered facility is required to register with FDA under section 415 of the Federal Food, Drug, and Cosmetic (FD&C) Act³. The other 25% is regulated by other agencies, such as the United States Department of Agriculture (USDA), which oversees meat, poultry, and many dairy products².

There are many moving variables when considering the mandates of the Food Safety Modernization Act (FSMA) such as company size, compliance dates, exceptions; but along the constant variables are the requirement for covered facilities to implement a food safety plan which includes a recall plan if hazard analysis identifies a hazard requiring a preventive control, describing the procedures to perform a recall of the product^{3,4}. The constant theme when developing the food safety plan revolves hazard analysis and of such this language fits well with the traditional means of designing process controls such as establishment of critical control points (CCP) enshrined in Hazard Analysis and Critical Control Points (HACCP). What separates the new rules from the traditional HACCP system, there are more defined paths to preventing known or reasonably likely to occur hazards such as supplier controls, sanitation controls, allergen controls, and other controls as deemed necessary^{3,4}. These additional considerations aimed at boosting the drive for prevention as companies are now challenged to assess all means available during hazard analysis, which were not emphasized or categorized prior, and should translate to safer products for the unsuspecting public, by extension, reduction in food safety recalls.

Recall plans are not used to control hazards in facilities but aimed at reducing the likelihood of the unsuspecting public being impacted by foods containing potential hazards in removing it from commerce, the quicker, the better; and while recalls can be detrimental to brand and business, some of which have closed permanently after such event⁵, its purpose is to protect the unsuspecting public be it man or animal; which could be covered by looking at three industries, (i) food and beverage, (ii) dietary supplements, (iii) animal and veterinary. Growth has been recorded in all three industries with upward projections^{6,7-11}. Consequently, to assess the effective implementation of the plan or mandates, it could be reasoned that if recalls captured by the Recalls, Market, and Safety Alert Registry are on the decrease, whilst overall sales are on the increase, then the provisions of the mandates are having a positive correlation; likewise, if recalls are on the increase, and overall sales are on the increase, an opportunity to further assess the provisions of the mandates or its implementation. A downward recall trend was observed for Food and Beverage along with Dietary Supplements, whilst an upward trend was observed for Animal and Veterinary.

The impact of the Food and Drug Administration (FDA) warning letters which provides 15 days for response² on compliance to the FSMA regulations and by extension potential reduction in recalls, may need to be studied to assess any correlations. For instance, from 1/5/2017 to 12/27/2021, a total of 2743 warning letters were issued, of which approximately 295 impacted the Food and Beverage Industry with 115 closed out or 39% meeting the FSMA requirements; 121 impacted dietary supplements of which 42 closed out or 35%; and 12 impacted animal and veterinary of which 2 closed out or 12%. At the same time, in 2021, of the 66 warning letters closed, none were from either industry¹², yet 2021 recorded the lowest recalls since 2015. As there are no established correlation that the companies that received warning letters were the very same that had a food safety recall recorded by the Recalls Market and Safety Alert Registry over the six year period, the impact of warning letters lends for further study. As implementation is expected to continue into the year 2024¹³, this is only a preliminary overview of trends observed looking at six years of available data since 2015.

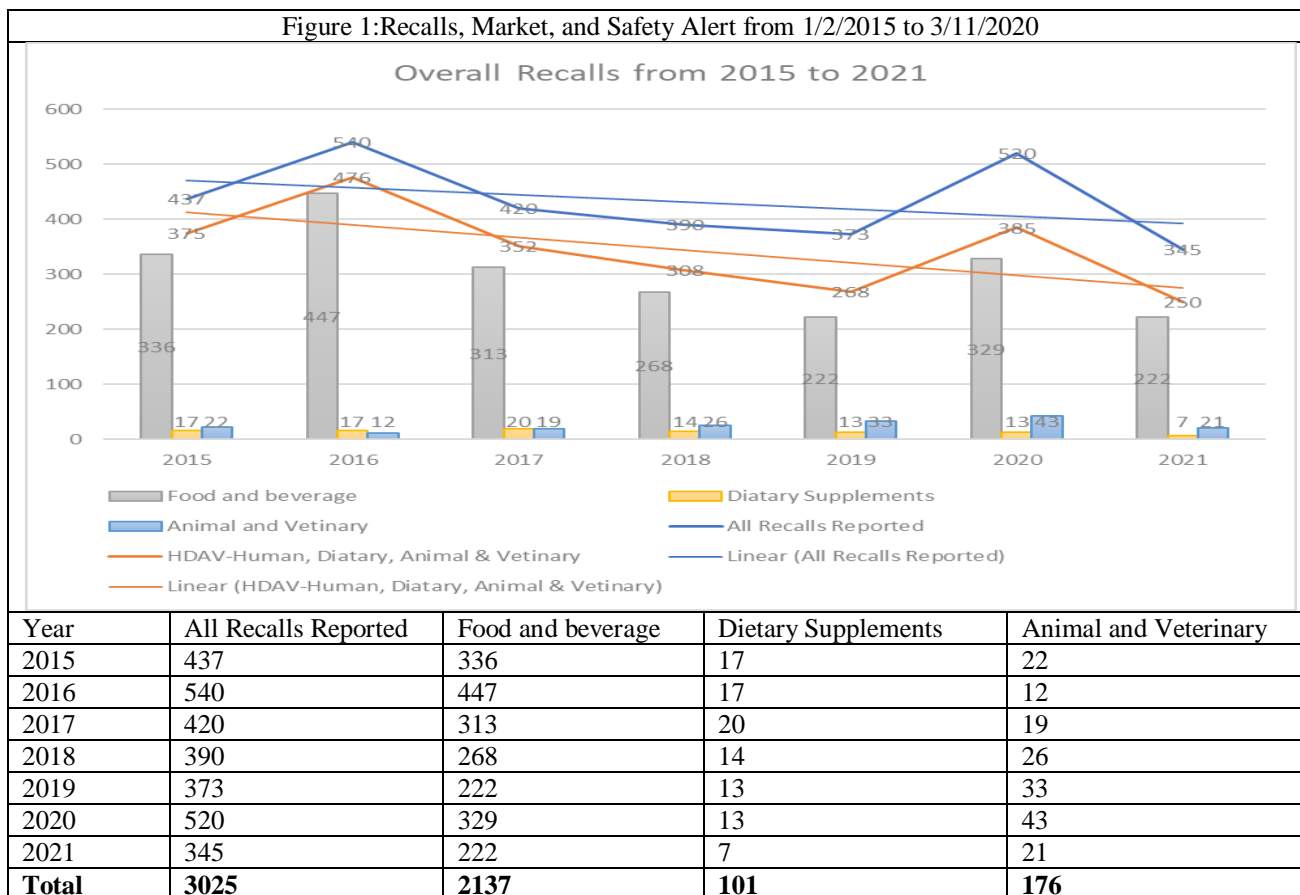
II. MATERIALS AND METHODS

Statistical analysis and summary of recalls published on the Food and Drug Administration's Recalls, Market Withdrawal, and Safety Alerts Registry from 1/2/2015 to 12/30/2021¹⁴. Data from the food and beverage industry, dietary supplement industry, and animal and veterinary industry were further categorized as recalls of biological, chemical, physical, and others. Actual and/or projected sales data from Statista among other sources, along with compliance to the Food and Drug Administration's warning letters were also considered.

III. RESULTS AND DISCUSSION

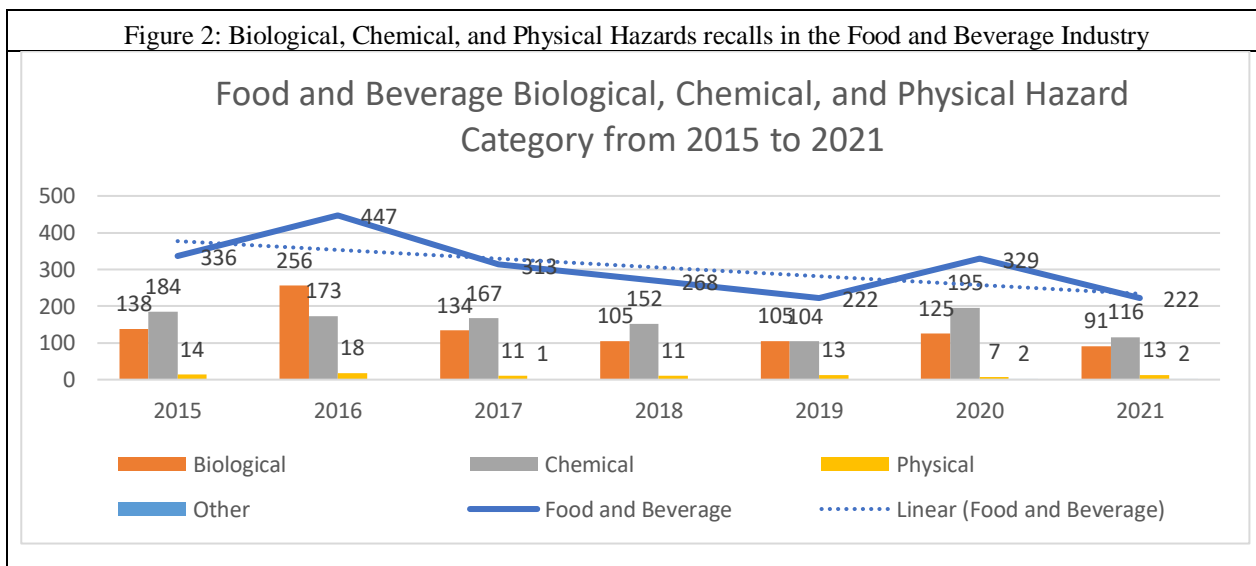
Of the 3025 recalls reported in the US between 1/2/2015 and 12/30/2021 (figure 1), 2137 or 70.64% impacted the food and beverage industry, 101 or 3.34% impacted the dietary supplements industry, and 176 or 5.82% impacted the animal and veterinary industry; a combined total of approximately 79.80% of recalls impacting foods consumed by man and animal. The 611 recalls or 20.19%, the difference between total recalls of 3025 and total recalls for human and animal combined of 2414, not only included medical devices, bath products, I.V flush syringes etc., but also included those foods not assigned to either industry by the regulators, though minute. For instance, a total of 11 food safety recalls of 611 or 1.80%, 9 of which occurred in 2018 and 2 in 2020 where neither categorized as food for human or animal, which lend itself for interpretation; 90% of which were recalls due to biological concerns. Trending charts show that recalls in general (total recalls) over the period along with clearly identified food safety recalls were on the downward trend, which is favorable considering all three industries have either reported consistent growth or/and projected growth over the same period.

Figure 1: Recalls, Market, and Safety Alert from 1/2/2015 to 3/11/2020



A spike was noted in 2016 which may have been due to early implementation as teams were learning about and embracing the new rules; and while implementation continues, a spike was also noted in 2020 which may have been due to the COVID-19 pandemic as a downward trend was observed four consistent years prior, and that numbers seem to be returning to normal as of 12/30/2021, were an overall total recall of 345 have been reported of which 250 or 72.46% were related to human and animal food combined; and would be the lowest recall year overall since 2015; while the markets continued to grow over same period. A closer look at the Food and Beverage industry reveals recalls of chemical nature top the chart at approximately 1091 or 51.05% followed by biological at approximately 954 or 44.64%, physical at approximately 87 or 4.07%, and others by approximately 5 or 0.23% when compared to total of 2137 (figure 2).

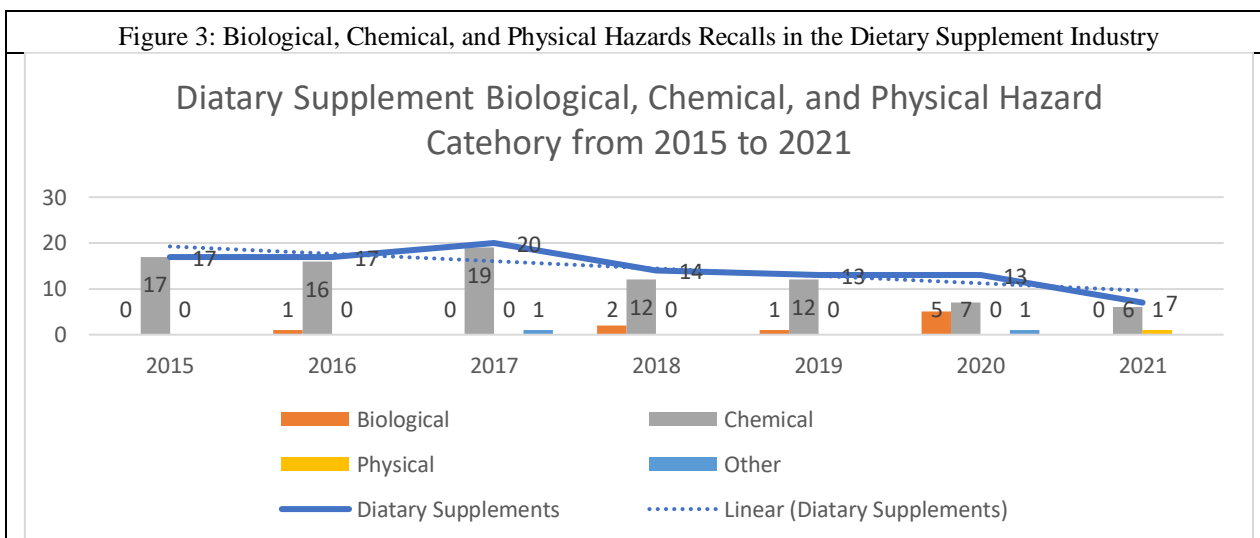
Figure 2: Biological, Chemical, and Physical Hazards recalls in the Food and Beverage Industry



Year	Food and Beverage	Biological	Chemical	Physical	Other
2015	336	138	184	14	
2016	447	256	173	18	
2017	313	134	167	11	1
2018	268	105	152	11	
2019	222	105	104	13	
2020	329	125	195	7	2
2021	222	91	116	13	2
Total	2137	954	1091	87	5

The leading cause for biological recalls over given period was due to *Listeria monocytogenes* with a combined total of approximately 503 of 954 or 52.73% percent; followed by *Salmonella* with 289 or 30.29% percent. *Escherichia coli* was next with 51 of 954 or 5.35% percent, followed by *Clostridium botulinum* with 43 or 4.51% percent. This gave a total of 92.88% percent. The other 7.12% comprised of sporadic organisms where they may show in one year but not necessarily the other. For example, *Staphylococcus aureus* showed in 2015, while *Norovirus*, the first viral agent shown to cause gastroenteritis¹⁵ showed in 2019 and 2020. Undeclared allergen was the leading cause for chemical recalls with an estimated 874 of 1091 or 80.11% percent. While regulated under a different set of regulations than those covering “conventional” foods and drug products¹⁶, dietary supplements can be considered food according to the FD&C Act¹⁷. Dietary supplements also showed a downward trend in overall recalls, while sales have been on the upward projections. While exceptionally low compared to the food and beverage industry (figure 1), recalls of chemical nature top the chart at approximately 89 or 88.12% followed by biological at approximately 9 or 8.91%, physical at approximately 1 or 0.99%, and others by approximately 2 or 1.98% when compared to the total of 101 recalls (figure 3).

Figure 3: Biological, Chemical, and Physical Hazards Recalls in the Dietary Supplement Industry

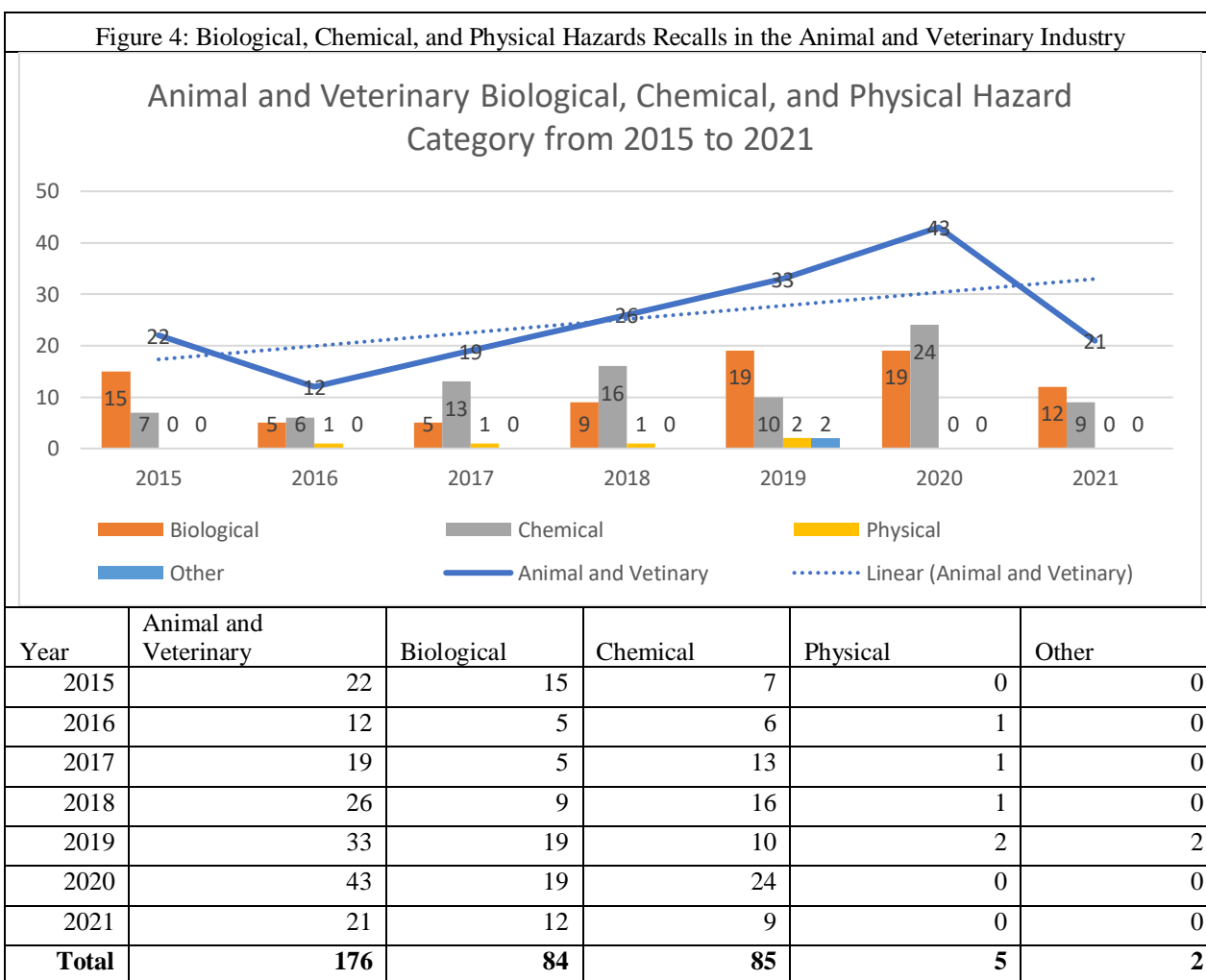


Year	Dietary Supplements	Biological	Chemical	Physical	Other
2015	17	0	17	0	
2016	17	1	16	0	
2017	20	0	19	0	1
2018	14	2	12	0	
2019	13	1	12	0	
2020	13	5	7	0	1
2021	7	0	6	1	
Total	101	9	89	1	2

All bacteria noted in dietary supplement recalls could be considered intermittent where they may show in one year but not necessarily the other. The leading cause for biological recalls over given period was due to *Salmonella* with a combined total of 6 of 9 or 66.67% percent, five of which showed in 2020; the others in 2018, and in 2016 combined with *Staphylococcus aureus*. *Stenotrophomonas maltophilia* only showed in 2019. No specie identified for the remaining biological recall. Undeclared substances including allergens accounted for 41 of 89 or 46.07% percent chemical concerns resulted in recalls.

Unlike food for human consumption, food for animal showed an upward trend in overall recalls over the same period (figure 4), and while significantly low compared to the food and beverage industry (figure 1), a further look into what may have trigged this upward trend may be warranted as that projection started from 2017 long before COVID, and just like food for human consumption, sales have been on the upward trajectory. The highest recalls were during the heart of the lockdown due to the pandemic and could deem a contributing factor, but there may be more to uncover. Like food for human consumption, chemical recalls led at 85 of 176 or 48.29%, followed by biological at 84 of 176 or 47.73%. Recalls for physical hazards were next at 5 of 176 or 2.84%, followed by those categorized as others which were difficult to assign a category and accounted for 2 of 176 or 1.14%.

Figure 4: Biological, Chemical, and Physical Hazards Recalls in the Animal and Veterinary Industry



The leading cause for biological recalls were due to *Salmonella* with 53 of 84 or 63.09%, followed by *Listeria monocytogenes* approximately 17 of 84 or 20.23%. 5 of 84 or 5.95% were a combination of *Listeria* and *Salmonella*, and the others may have only occurred once such as *Clostridium botulinum* which showed in 2020. Unlike food for human consumption, undeclared allergens only occurred twice or 2.35% of the 85 total chemical recalls, once in 2016, and a repeat in 2017 which speaks to the meticulous nature of food for animal consumption industry.

The impact of the FDA warning letters on food safety recalls for both human and animal food is yet to be determined, but as the focus shift from control to prevention, it is not hard to fathom a direct correlation in the near future. For this study, total warning letters from 1/5/2017 to 12/27/2021 were captured (table 1); but noting that in 2021 none were closed despite having the lowest food safety recalls since 2015, its impact lend for further assessment.

Year	Total Issued	Closed Out	Food and beverage		Dietary Supplement		Animal and Veterinary	
			Issued	Closed	Issued	Closed	Issued	Closed
2017	547	146	118	45	43	0	2	0
2018	439	123	56	26	22	1	1	1
2019	484	106	61	32	27	1	4	1
2020	633	72	46	12	24	0	3	0
2021	640	66	14	0	5	0	2	0
Total	2743	513	295	115	121	2	12	2

IV. CONCLUSION

While a preliminary assessment, the new rules of the Food Safety Modernization Act with its preventive focus seem to be making progress in that food safety recalls in general are on the downward trend since 2015 when the rules came into effect, while sales are on the increase. Foods for human consumption were the clearest sign in this correlation, and while recalls on food for animal consumption have been trending upward, 2021 showed a sharp downward trend nearing 2017 totals, a move in the right direction.

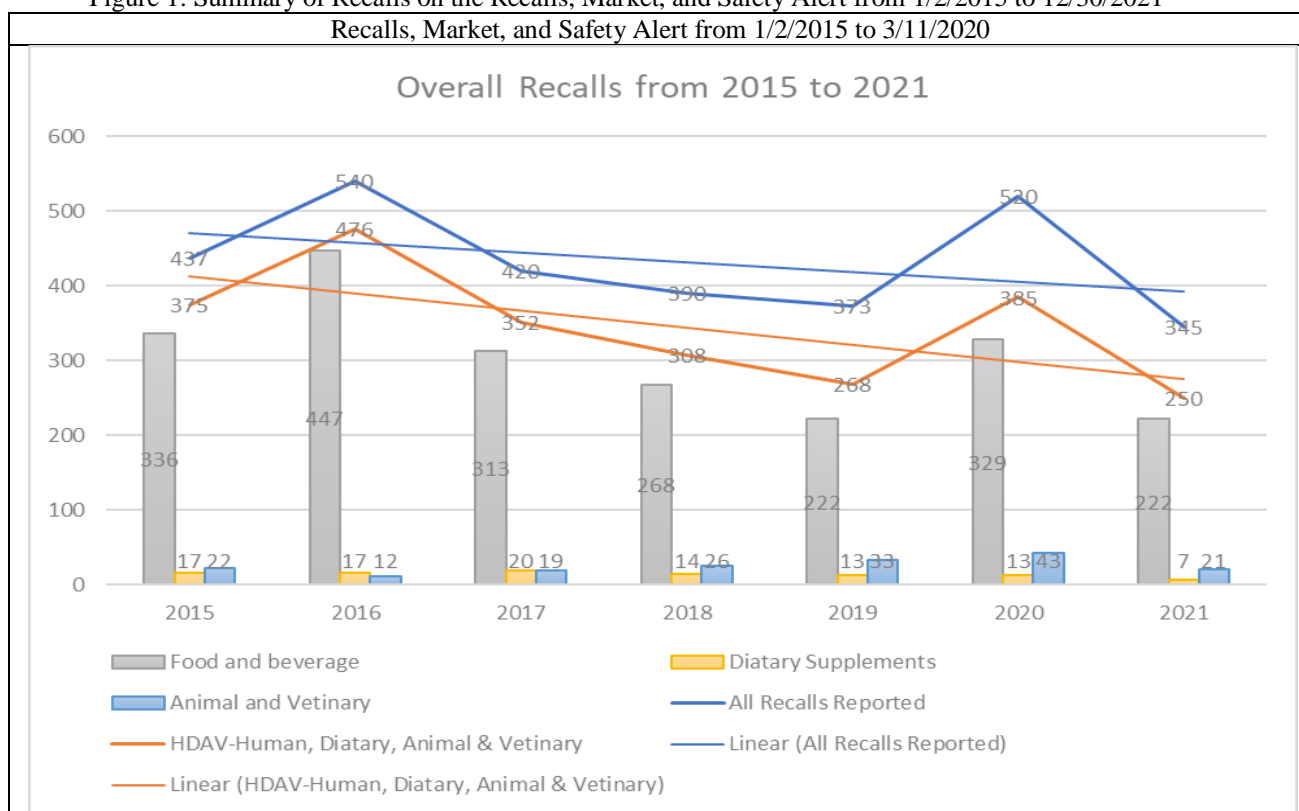
REFERENCE

1. United States Food and Drug Administration., 2021. Food Safety Modernization Act (FSMA). <https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/food-safety-modernization-act-fsma>
2. Thatte D., 2019. The Food Safety Modernization Act in a Nutshell. <https://www.nist.gov/blogs/manufacturing-innovation-blog/food-safety-modernization-act-nutshell>
3. United States Food and Drug Administration., 2020 FSMA Final Rule for Preventive Controls for Human Food. <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-human-food>
4. United States Food and Drug Administration., 2020 FSMA Final Rule for Preventive Controls for Animal Food. <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-preventive-controls-animal-food>
5. Chambers D., Johnson-Drummond D., 2021. Combating Food Safety Recalls Upstream, Dissecting the Recalls, Market, and Safety Alert Registry. International Journal of Life Sciences Research Vol. 9, Issue 2, pp: (20-25), Month: April - June 2021. ISSN 2348-3148 (online) ISSN 2348-313X (Print). <https://researchpublish.com/upload/book/paperpdf-1621509575.pdf>
6. Statista., 2021. Total retail and food services sales in the United States from 1992 to 2020 (in trillion U.S. dollars). <https://www.statista.com/statistics/197569/annual-retail-and-food-services-sales/>
7. Statista., 2021. Annual sales of retail food and beverage stores in the United States from 1992 to 2020 (in billion U.S. dollars). <https://www.statista.com/statistics/197619/annual-food-and-beverage-store-sales-in-the-us-since-1992/>
8. Statista Research Department., 2014. Supplement sales in the United States from 2009 to 2019 (in billion U.S. dollars) <https://www.statista.com/statistics/548918/us-sales-of-supplements/>
9. American Botanical Council., 2021. US Herbal Supplement Sales Increase by Record-breaking 17.3% in 2020. <https://www.herbalgram.org/news/press-releases/2021/record-breaking-us-herbal-supplement-sales-increase-in-2020/>
10. Committee for Economic Development., 2017. Economic Contribution of the Food and Beverage Industry. https://www.ced.org/pdf/Economic_Contribution_of_the_Food_and_Beverage_Industry.pdf
11. Statista., 2021. Pet market sales in the United States from 2011 to 2021, by category (in billion U.S. dollars). <https://www.statista.com/statistics/253983/pet-market-sales-in-the-us-by-category/#:~:text=Approximately%2042%20billion%20U.S.%20dollars%20of%20pet%20food,U.S.%20dollars%20in%202020.%20American%20consumer%20pet%20expenditure>

12. United States Food and Drug Administration., 2021. Warning Letters. <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters>
13. United States Food and Drug Administration., 2019, FSMA Compliance Dates, <https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-compliance-dates#HumanFood>
14. United States Food and Drug Administration., 2021. Recalls, Market Withdrawal and Safety Alerts. <https://www.fda.gov/safety/recalls-market-withdrawals-safety-alerts>
15. Robilotti E., mDeresinski S., Pinshy B., 2020., Norovirus. <https://journals.asm.org/doi/full/10.1128/CMR.00075-14>
16. United States Food and Drug Administration., 2019. Dietary Supplements. <https://www.fda.gov/food/dietary-supplements>
17. Federal Food Drug and Cosmetic Act. <https://web.archive.org/web/20200424095237/https://legcounsel.house.gov/Comps/Federal%20Food,%20Drug,%20And%20Cosmetic%20Act.pdf>

APPENDIX

Figure 1: Summary of Recalls on the Recalls, Market, and Safety Alert from 1/2/2015 to 12/30/2021



Year	All Recalls Reported	Food and beverage	Dietary Supplements	Animal and Veterinary
2015	437	336	17	22
2016	540	447	17	12
2017	420	313	20	19
2018	390	268	14	26
2019	373	222	13	33
2020	520	329	13	43
2021	345	222	7	21
Total	3025	2137	101	176

Figure 2: Grouping Recalls in the Food and Beverage Industry by Biological, Chemical, and Physical Hazards

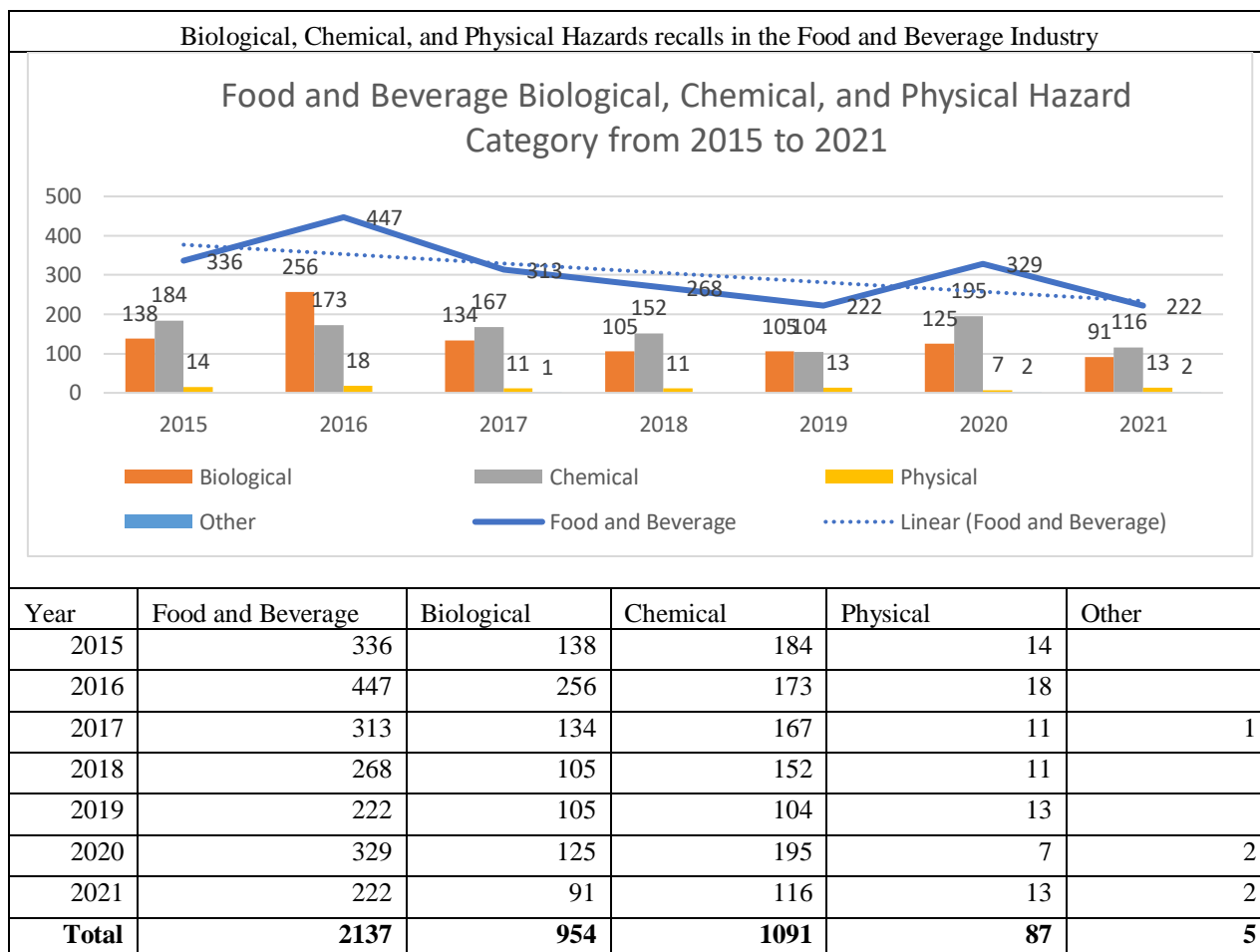
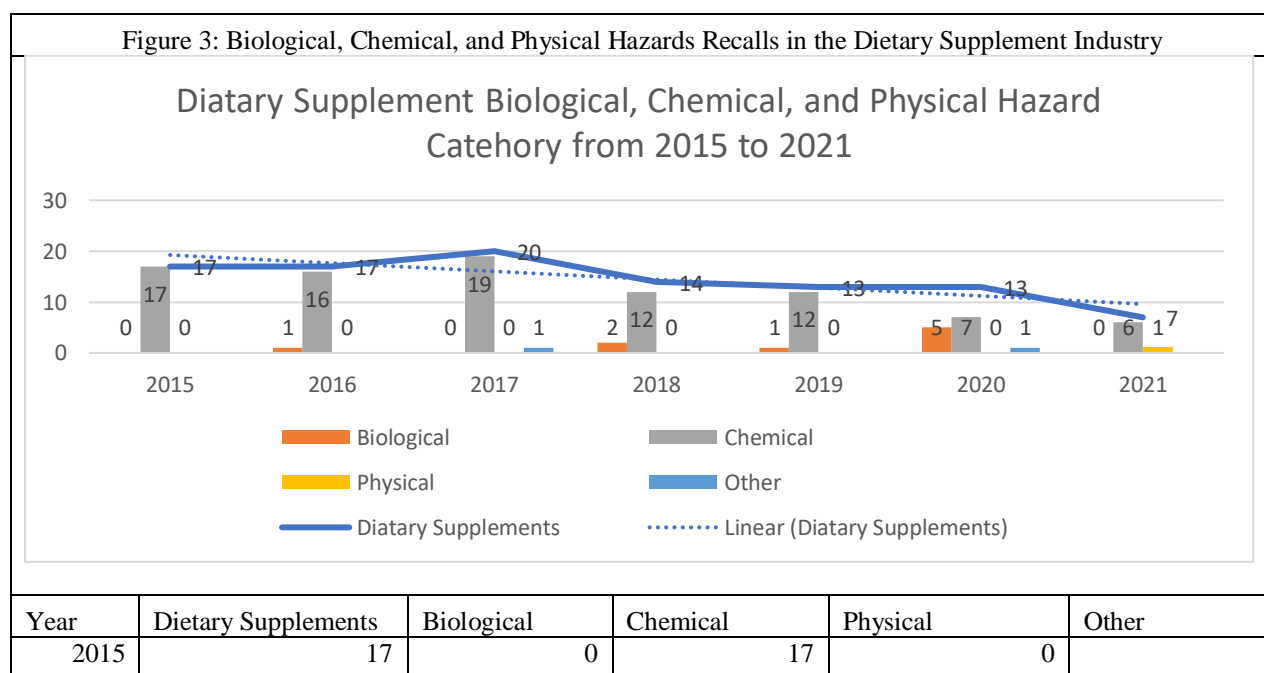


Figure 3: Grouping Recalls in the Dietary Supplement Industry by Biological, Chemical, and Physical Hazards



2016	17	1	16	0	
2017	20	0	19	0	1
2018	14	2	12	0	
2019	13	1	12	0	
2020	13	5	7	0	1
2021	7	0	6	1	
Total	101	9	89	1	2

Figure 4: Grouping Recalls in the Animal and Veterinary Industry by Biological, Chemical, and Physical Hazards

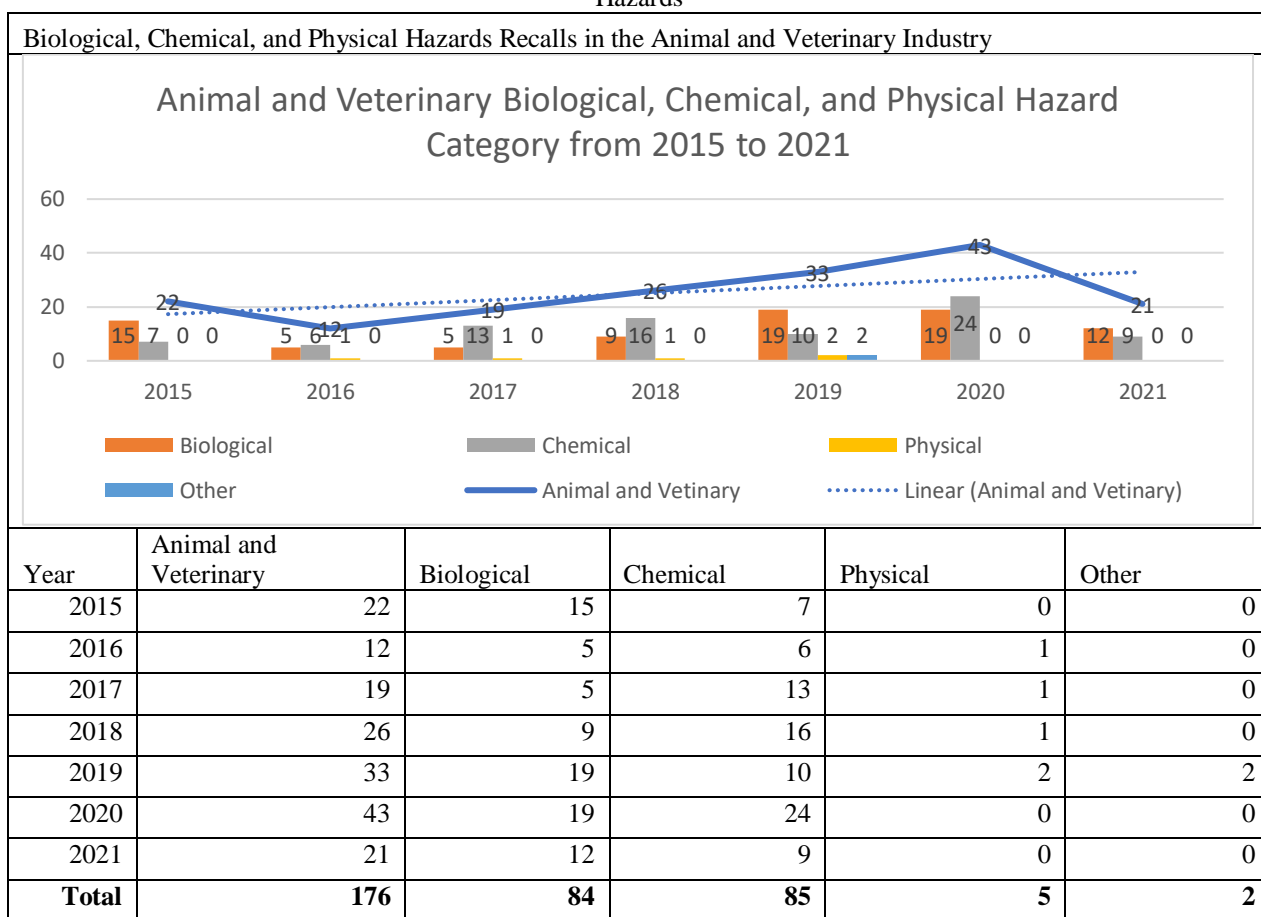


Table 1: Food and Drug Administration Warning Letters from 1/5/2017 to 12/27/2021

FDA Warning Letters from 1/5/2017 to 12/27/2021								
Year	Total Issued	Closed Out	Food and beverage		Dietary Supplement		Animal and Veterinary	
			Issued	Closed	Issued	Closed	Issued	Closed
2017	547	146	118	45	43	0	2	0
2018	439	123	56	26	22	1	1	1
2019	484	106	61	32	27	1	4	1
2020	633	72	46	12	24	0	3	0
2021	640	66	14	0	5	0	2	0
Total	2743	513	295	115	121	2	12	2