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Combating Food Safety Recalls Upstream, Dissecting the Recalls, Market, and Safety Alert Registry

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Abstract: **There exist many recalls of biological, physical, and chemical nature listed on the United States Food and Drug Administration's 'live' Recalls, Market, and Safety Alert Registry, which indicates failure in the production process. Of the 1593 entries as of 5/10/2021, 1001 or 62.8% affects the food and beverage industry alone; understanding that not all recalls are listed on this registry. Of the 1001 entries, 679 or 67.8% have been terminated meeting the Food and Drug Administration (FDA) definition of termination. Of the 1001, an estimated 40.16% were biological, 55.44% chemical including allergen, and 3.89% physical by nature. While much focus is placed on ready to eat facilities as the final stage pre-consumer, one cannot overlook further upstream in the production process such as pre-processors, whereby if prevented at this stage it reduces the risk of potential hazards getting to consumers. The verification and validation steps of pre-processors prerequisite programs become vital in this fight to ensuring consumers receive safe and highest quality product. The production process remains a dynamic beast especially during these unprecedented times of a global pandemic, but a quick look at the registry will note that even during such strenuous times, recalls are still being made which impact all processors in the production process as some companies in recent history have even shut their doors permanently after recall. The focus of this paper therefore considers steps that may be taken by pre-processors to verify and validate their prerequisite programs especially when controls are not in place, thereby reducing risk downstream.**

Keywords: **Recall, pre-processors, verification, validation, prerequisite programs, consumers.**

1. INTRODUCTION

The dreaded account of food safety recalls continues to reap havoc even during a global pandemic, rippling through the industry from fork to farm, the direction of impact on businesses. While almost all recalls are voluntary[1], most of the recalls published on the 'live' or always updating, Recalls, Market Withdrawal, and Safety Alerts[2] or mainly from the Food and Beverage Industry. For instance, of the 1593 entries between 1/17/2017 to 5/10/2021, 1001 or 62.8% affects this industry alone; understanding that not all recalls are listed on this registry. Of the 1001 entries, 679 or 67.8% have been terminated, meaning, the Food and Drug Administration (FDA) has determined that all reasonable efforts have been made to remove or correct the violative product in accordance with the recall strategy, and proper disposition has been made according to the degree of hazard[2].

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While recalls are generally initiated downstream such as a customer compliant whether voluntary or involuntary (those mandated by FDA), all can agree that affected product getting to consumers is too late as the unintended consequences can be very severe to consumers, and detrimental to business, some of which have closed permanently after a recall[3,4]. As each product are unique to business so as the production processes, the point at which potential hazards or concerns are detected remains unique. One thing is certain, as long as potential hazard has been detected in hazard analysis, a recall plan becomes mandated[5,6].

All must be done to prevent and/or warn the unsuspecting public of potential danger. For some reason(s), many companies fail to do so, which would explain why an estimated 483 of 556 or 86.9% chemical recalls in the food and beverage industry were related to undeclared allergens over the same period. The industry seemed to have done better with recalls of physical nature with an estimated 3.89% over the same period; and while the impact could be considered just as severe to consumers and business if not more, the data suggest awareness and effort on the part of businesses to keep potential physical hazards from consumers. While many businesses use technologies such as x-rays and metal detectors, some businesses have been adopting the ever-advancing vision systems, which may have an impact on downward trend as of 5/10/2021, or it could simply be due to the COVID-19 lockdowns; while this industry remains protected as essential services[7], many companies had to close their doors due to high turnover rates or furlough due to COVID.

Recalls of biological nature could be considered more abstruse, as if products are not tested, there is really no way to tell the presence of potential pathogens besides spoilage. The product may look good, smell good, and even taste good, but could be detrimental if ingested without interventions such as heat-treated kill steps which may be absent such as at a pre-processor pending nature of business. The Food Safety Modernization Act (FSMA) states: "facilities do not need to have a supply-chain program if they control the hazard in their own facility, or if a subsequent entity (such as another processor) will control the hazard, and the facility follows applicable requirements" [5,6]. Facilities will either have heat-treated kill steps or pass on product to a facility that does, as long as product with potential pathogens does not get to consumers. The problem, some pathogens are toxin producers or spore forming, where heat treatment might not be effective, and of such, having a detailed understanding of product and potential pathogens becomes vital in handling of product pre-heat treatment. For instance, literature review during hazard analysis, an initial validation step looking at peer reviewed publications may reveal that *Staphylococcus aureus* could affect product by forming toxins and that "*S. aureus* toxin does not normally reach levels that will cause food poisoning until the numbers of the pathogen reach 500,000 to 1,000,000 per gram; as toxin formation is not likely at temperatures lower than 50°F (10°C) or at water activities below 0.85"[8], these become crucial parameters. Further literature review will reveal that "the best way to avoid food poisoning by Staph is to prevent food from being held at an unsafe temperature (between 40°F and 140°F) for more than two hours"[9]. As part of the prerequisite program in this case process and/or supplier control, these two hours now need to be factored into handling product with suited temperatures controls; the idea is at best to ensure potential pathogens if present remains in their lag phase. Verification activities therefore would require temperature monitoring of product with thermometers that are calibrated, verified, and validated on scheduled frequencies to ensure that repeated readings are accurate within acceptable tolerance; in short, while the process of calibrating a thermometer require comparison against a known standard of higher accuracy as done at the factory, verification confirms that it continues to read within acceptable tolerance; whilst the process of validation documents these measurements accuracy and changes. Having these verified validation records is one way to be audit ready, but most importantly, the subsequent processor getting the product in the condition they agreed to.

Another pre-requisite program that would be of interest in this fight against potential pathogens and subsequently recalls revolves sanitation control. As it relates to regulation, it would appear visual observation is the minimum requirement on verification stating "a visual check of the food-contact surfaces of equipment and utensils should be made to verify that the utensils are maintained clean and sanitized using the approved manner and frequency. Utensils that are observed to have debris, grease, or other visible contamination should be rewashed and re-sanitized"[10]. "Simultaneously, one must recognize that for cleaning validation, as with validation of other processes, there may be more than one way to validate a process. In the end, the test of any validation process is whether scientific data shows that the system consistently does as expected and produces a result that consistently meets predetermined specifications"[11]. As these guidelines may be limiting, adapting third party certifications to a Global Food Safety Initiative (GFSI) standard[12] such as SQF, BRC, or FSSC22000 would require more, such as implementation of an Environmental Monitoring Program (EMP). Why do more when you can get away with less? Which is more cost effective, a third-party certification aimed at assessment and implementation of a robust program to validate and verify prerequisite programs or a product recall?

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2. 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 1/17/2017 to 5/10/2021. Data from the food and beverage industry further categorized as recalls of biological, chemical, physical nature and others.

3. RESULTS AND DISCUSSION

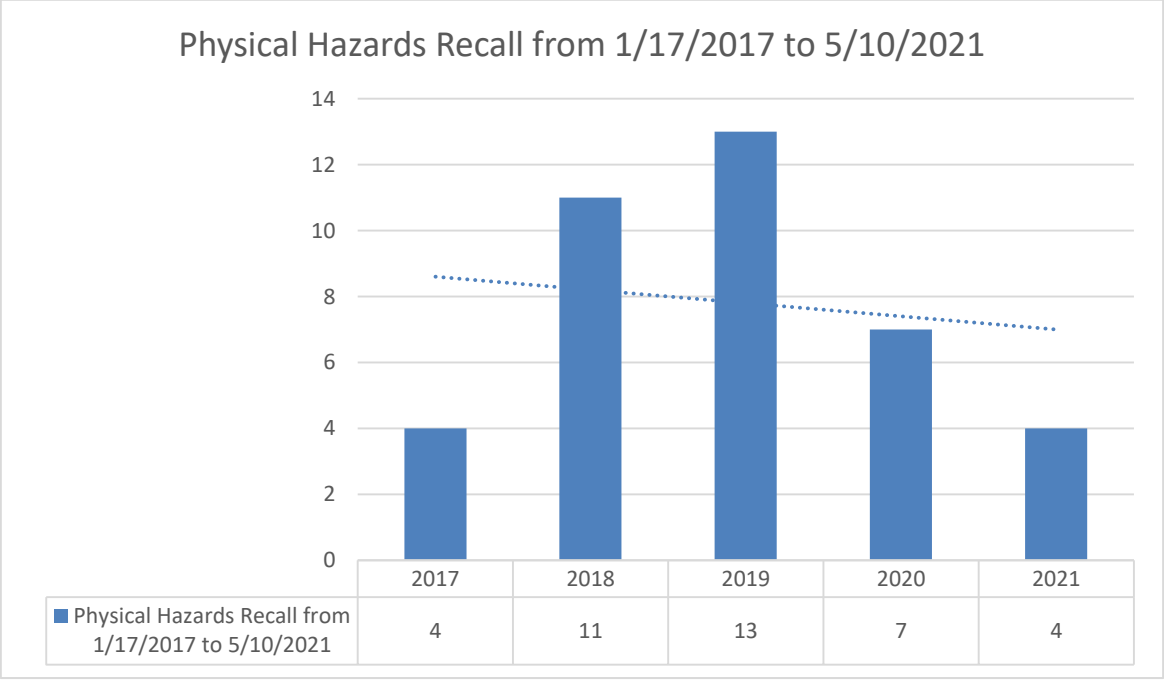
Table 1: Summary of Recalls on the Recalls, Market, and Safety Alert as of 5/10/2021

Recalls, Market, and Safety Alert from 1/17/2017 to 5/10/2021				
Industry	Totals	Percentage (%)	Terminated Totals	Percentage (%) Terminated by Industry
Food and Beverage	1001	62.8	679	67.8
Animal and Veterinary	122	7.7	74	60.7
Biologics	1	0.06	1	100
Cosmetics	8	0.5	4	50
Dietary Supplements	47	2.95	31	65.96
Drugs	333	20.9	112	33.63
Medical Devices	58	3.64	15	25.86
Tobacco	3	0.19	3	100
No Category	20	1.26	17	85
Totals	1593	100	936	

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

Food and Beverage Industry Reported Recalls from 1/17/2017 to 5/10/2021				
Hazards	Totals	Percentage (%)	Terminated	Percentage (%) Terminated by Hazards
Biological	402	40.16	263	65.42
Chemical including Allergen	555	55.44	392	70.63
Physical	39	3.89	23	58.97
Other	5	0.49	2	40
Total	1001	99.54	680	

Figure 1: Trending Physical Hazards Recall from 1/17/2021 to 5/10/2021



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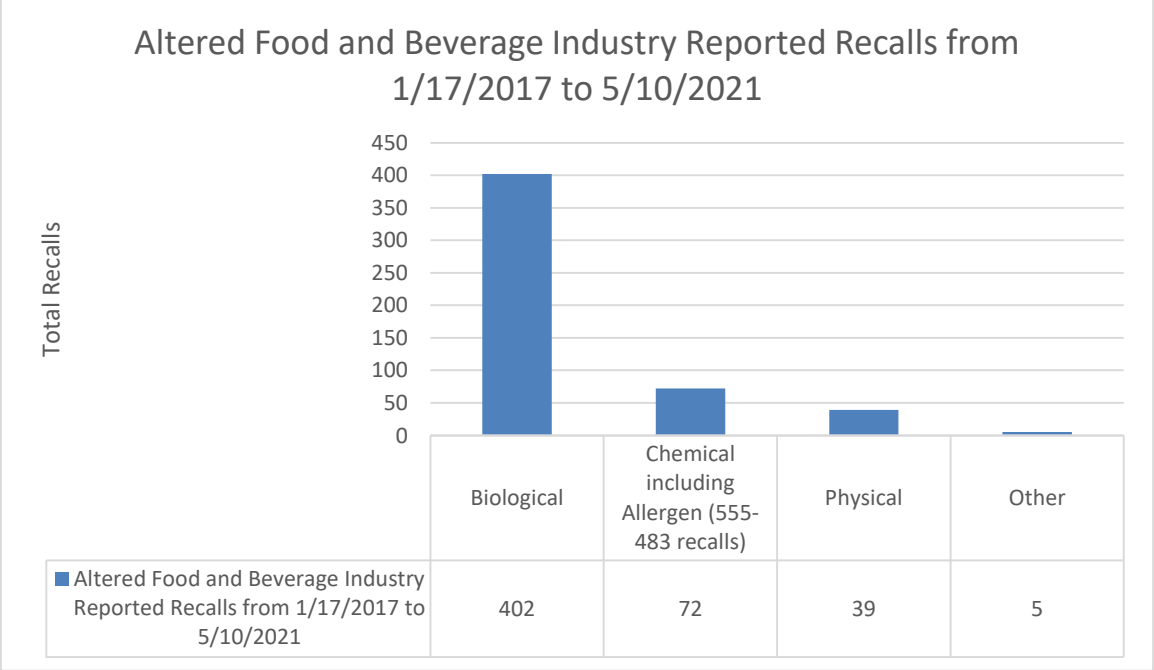
Of the 1001 recorded recalls in the food and beverage industry (table 1 and 2), an estimated 55% were of a chemical nature with undeclared allergens topping the list, an estimated 483 totals of 555 chemical recalls were related to undeclared allergens, or 87%. An estimated 70% chemical recalls were terminated meeting the FDAs requirement. Recalls of biological nature followed with 402 recalls of 1001 total or an estimated 40%. Of the 40%, Listeria were more prevalent, totaling 212 of 402 total or 52.7%. An estimated 65% were terminated meeting the FDAs requirement. The industry seemed to have done better with recalls related to physical hazards with a downward trend observed between 1/17/2017 and 5/10/2021 (figure 1) with a total of 39 of 1001 or 3.89% (table 2). Plastic and rubber material seem to lead this group with a total of 16 of 39 or 41%, followed by metal and glass for a combined 36%, with other materials accounting for an estimated 26%. Of the 39 physical recalls, an estimated 23 of 39 or 59% have been terminated meeting the FDAs requirement. An estimated 5 of 1001 or 0.49% of listed recalls did not fit well with either categories; with an estimated 40% being terminated meeting the FDAs requirement.

If removed the 483 undeclared allergens from the list of chemical recalls which could be considered the easiest of the list that could have been prevented, the recall chart changes drastically (figure 2), with recalls of biological nature topping the list exponentially.



This would also probably be the area where that partnership from pre-processors become even more vital, understanding the nature of the product, shelf life, and optimal storage and transport conditions would all play a pivotal role in keeping potential pathogens in their lag phase pre-heat treated kill step. It is vital that after heat treatment at correct temperatures and dwell time, that handling conditions are clean and sanitary to no introduce potential pathogens. With rigorous requirements, that interventions such as third-party certifications would be most helpful at all stages from farm to fork. The challenge with third party certification from experience, the codes do not outright tell how to prevent or control a particular hazard, but expect it be controlled or prevented. For example, if risk assessment deemed sanitation control to be the likely source of potential biological hazards to impact product, the codes do not tell how to implement an environmental monitoring program, but expect one be implemented, meaning other technical knowhow would be required to help develop program to meet compliance, if such skills are not inhouse.

4. CONCLUSION

Taking steps to protect consumers at all costs while providing their needs remains the focus of preventive food safety and quality assurance. The further upstream in the supply chain potential hazards can be prevented, the better the probability of averting a food safety recall downstream which can be detrimental to brand and business.

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APPENDIX - A

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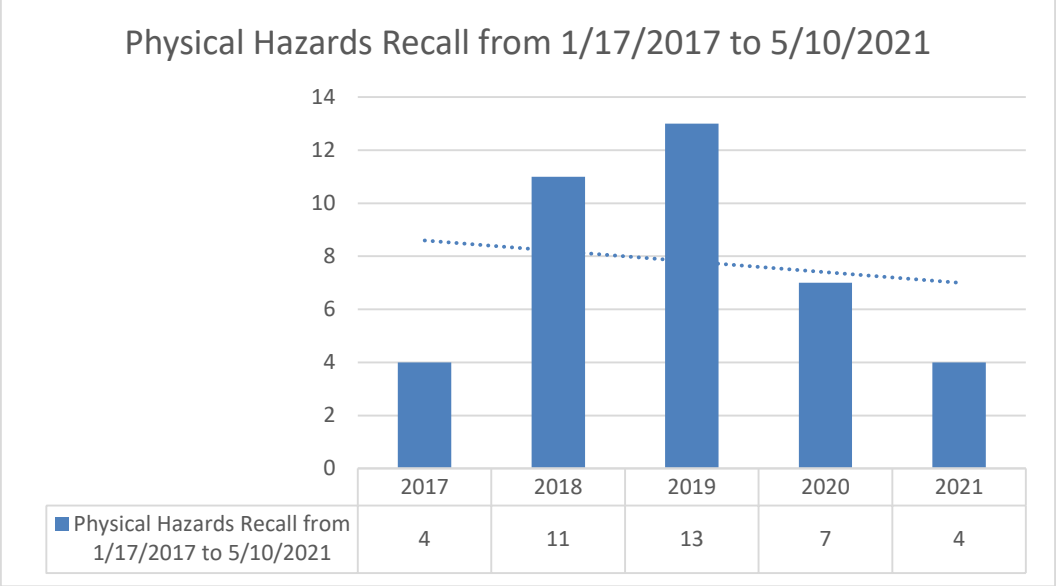

Figure 2: Comparing biological, chemical and physical recalls with altered data from the Food and Beverage Industry Reported Recalls from 1/17/2017 to 5/10/2021.