

# Evaluating FDA Food Recalls with Sanitation as a Root Cause

Amit M. Kheradia

MSc Food Safety & Quality Assurance  
Remco, Zionsville, IN 46077 USA

## INTRODUCTION

Cleaning and sanitation programs are a regulatory requirement in the food industry. According to a 2008-2009 FDA study, a quarter of food recalls may have been caused by issues arising from inadequate sanitation controls (17%) and a lack of environmental monitoring programs (9%).<sup>1</sup>

Root Causes of Food Recalls	% of Recalls
Lack of Label Controls	57%
Lack of Supplier Controls	37%
Deficiencies in Employee Training	24%
<b>Lack of Sanitation Controls</b>	<b>17%</b>
Poor Processing Controls	13%
<b>Lack of Environmental Monitoring</b>	<b>9%</b>
<b>Recalls may have more than one root cause</b>	

Moreover, a 2009-2012 FDA study showed that allergen cross-contact issues accounted for about 12% of total allergen-related recalls.<sup>2</sup>

Root Cause of Allergen Recalls	% of Recalls and (#)
Wrong label	35% (82)
Terminology	26% (59)
Failure to carry information from ingredient to final label	18% (41)
<b>Cross-contact</b>	<b>12% (28)</b>
Ingredient mislabeled from supplier	9% (21)
<b>Total Allergen Recalls</b>	<b>100% (231)</b>

Close to half of food recalls are known to be associated with allergens.<sup>3</sup>

- Therefore, the percent of allergen cross-contact incidents out of the total food recalls  $(12\%/2) = 6\%$ .
- The approximate percentage of FDA food recalls related to cross-contamination and allergen cross-contact incidences  $(17\% + 9\% + 6\%) = 32\%$ .

It may be deduced that about 1/3 of FDA food recalls may relate to the cleaning and sanitation, hygiene, and material-handling practices that are required to maintain proper sanitary conditions within a processing facility for the production of safe and quality food.



According to recent industry estimates, a company can expect to spend an average of \$10 million for a food recall, in addition to incurring brand damage and sales losses. It is difficult to accurately calculate the actual recall costs, which means the costs could be significantly higher.<sup>4</sup> The argument follows that a substantial proportion of recall costs may be avoided or lowered by improving plant sanitation requirements.

Therefore, there is the justifiable expectation that FDA Food Recall entries clearly indicate the root cause(s) for each recall for the benefit of the following parties:

- The *industry*, so they can try to establish appropriate preventive control programs to manage food safety risks, reduce operational costs, and improve product safety and quality;
- The *regulators*, so they can focus their inspections and resources on the key root causes;
- The *consumers*, so they are informed of the actual reason for recalling a product.

## OBJECTIVES & METHODOLOGY

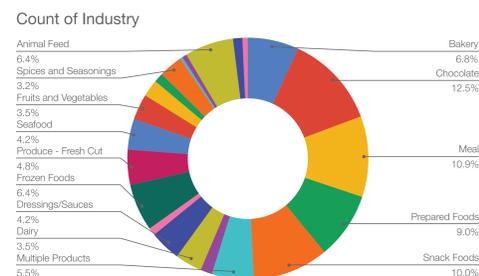
The objective of the study was to evaluate the recent pathogen and allergen-related FDA recalls and use these as a valid basis to provide risk-based sanitation recommendations for the industry.

From the FDA's Recall entries from July 2017-June 2018, 311 relevant data points were analyzed across the industry sectors listed in the chart to the right.<sup>5</sup>

Besides the conventional foods, dietary supplement meals (10.9%) and animal/pet feed (6.4%) were also part of the study.

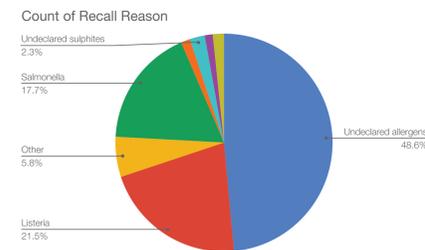
Industries most affected by recalls were chocolate and confections (12.5%), meals (10.9%), and snack foods (10%).

Industries least implicated in recalls were spices and seasonings (3.2%), fruits and vegetables (3.5%), and dairy (3.5%).



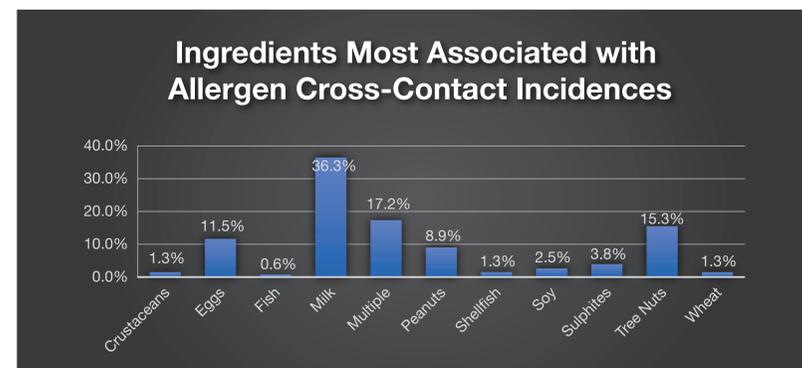
## RESULTS & INTERPRETATION

Based on the analysis of FDA's Recall entries from July 2017-June 2018:



- Almost half (48.6%) of recalls were due to undeclared allergens, even more if sulphites (classified as allergens in some global jurisdictions) are added.
- *Listeria monocytogenes* (21.5%) and *Salmonella* (17.7%) were the significant pathogens implicated in food recalls.
- Other significant recalls (5.8%) included processing defects, foreign matter contamination, and adulteration with undeclared process aids.

Regarding allergen-related FDA recalls, the following points were revealed:



- Milk (36.3%), multiple ingredients (17.2%), and tree nuts (15.3%) were the top three products implicated in potential allergen cross-contact related recalls. A significant proportion of multiple-ingredients products had soy, wheat, and/or milk as the undeclared allergens.
- Industries most likely to be affected by allergen cross-contact issues were chocolates and confections (42.9%), snack foods (18.4%), and bakery items (12.2%).

It was noted that 4.6% to 32.4% of the allergen-related recalls may have happened due to cross-contact issues, but it wasn't clear whether the recalls were due to problems in process separation, product changeover scheduling, or sanitation control requirements.

*Salmonella*-implicated recalls showed a wider variation than *Listeria* related recalls in terms of whether they may be caused by sanitation issues rather than other factors, e.g. process limits or supplier controls. Below is the relevant tabulated data:

Pathogen of concern	% of food recalls	% of specific-pathogen recalls that are sanitation related
<i>Listeria monocytogenes</i>	21.5%	98.5%
<i>Salmonella</i>	17.7%	63.6 - 96.3%

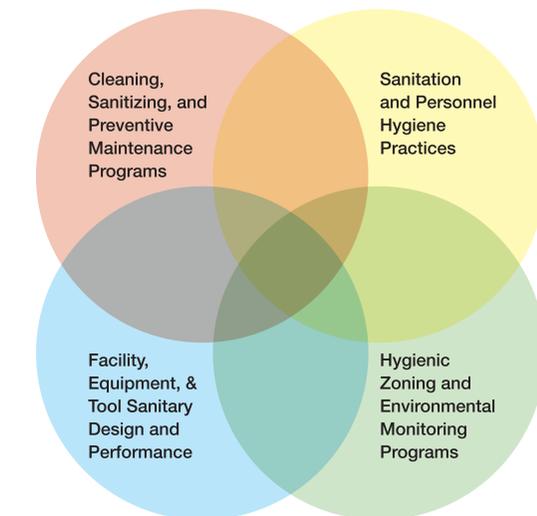
**Overall, 37.9 - 59.8% of FDA recalls could be plant sanitation or environmental hygiene related. This wide percentage range may be attributed to a lack of substantial clarity on the root cause of contamination of the violative product. Even though the etiologies for recalls were clearly listed in the entries, some lacked substantial clarity as to why the contamination occurred.**

## SIGNIFICANCE

FSMA regulations require the industry, and especially the food safety and quality management team, to establish more robust food safety programs and risk-based preventive controls.<sup>6</sup> Sanitation Preventive Controls are a key piece in food safety plans.<sup>7</sup> These proactive measures should not only prevent or minimize food recalls, but also work toward avoiding or reducing site inspectional violations and foodborne illnesses. The industry should also save money and resources spent on potential recalls.

Therefore, if such sanitation-based root cause(s) of product contamination were clearly communicated within FDA's food recall entries, then this data could be used by the industry to improve their sanitary design, performance, and maintenance programs. Typical industry-recommended sanitation controls are illustrated in the diagram below:

### Recommended Sanitation Control Measures



- **Note:** The industry may be able to clearly focus on one or more of the control measures to achieve the required plant sanitation objectives if the specific root causes of a food recall are known.

On a significant note, the hygienic design features of tools used, such as brushes and squeegees, are often overlooked as a probable source of product contamination within food plants.<sup>8</sup> This potentially needs to be examined.

## REFERENCES

- (1) U.S. Government Publishing Office. (2013). *Proposed Rules: Federal Register / Vol. 78, No. 11 / Wednesday, January, 16, 2013*, pp. 3667.
- (2) Gendel, S. M., Zhu, J., Nolan, N., & Gombas, K. (2014). *Learning from FDA food allergen recalls and reportable foods*. Food Safety Magazine, 20, pp. 46-52.
- (3) FDA (2018). *Recalls, Market Withdrawals & Safety Alerts* (07/2017 - 06/2018).
- (4) Grocery Manufacturers Association. (2010). *Recall execution effectiveness: collaborative approaches to improving consumer safety and confidence*. May 2010, pp. 9.
- (5) FDA. *Recalls, Market Withdrawals & Safety Alerts*.
- (6) Kheradia, A., & Warriner, K. (2013). *Understanding the food safety modernization act and the role of quality practitioners in the management of food safety and quality systems*. The TQM Journal, 25(4), pp. 347-370.
- (7) FSPCA. (2016). *Preventive controls for human food participant manual v1.2*. February 2016, pp. 244.
- (8) Smith, D. L. (2015). *The hygienic design of food industry brushware: the good, the bad and the ugly*. Journal of Hygienic Engineering and Design, 12(s 8), 17