

The Cost of Food Safety¹

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Introduction

The cost of implementing a food safety program varies based on company size and segment of the industry (FDA 2012). Food safety prerequisite programs such as Good Manufacturing Practices (GMPs) and Sanitation Standard Operating Procedures (SSOPs) provide the foundation for more extensive food safety programs such as Hazard Analysis Critical Control Points (HACCP). The US Food and Drug Administration (FDA) is continually trying to increase the level of food safety within the industry. Increasingly, more food production facilities use HACCP as a management tool for ensuring safe food products (Tompkin 1995). As food safety becomes commonplace in the work environment, the overall effect of this trend will help reduce the health cost to the consuming public (FDA 2012).

This increased concern for food safety led the FDA to create the Food Safety Modernization Act (FSMA) that was signed into law in 2011 (and was enacted in 2015). The goal of FSMA is to ensure the highest level of quality, safety, and protection against adulteration of the food and feed supply. FSMA was designed to be a more proactive approach towards food safety, focusing on the most vulnerable areas for possible adulteration during food production and processing. There are five foundational rules that exemplify this proactive approach, including protection from intentional adulteration, preventative controls for human food and animal food, standardization of produce safety,

establishment of a foreign supplier verification program for importers, and implementation of a program for the accreditation of third-party auditors. Additionally, FSMA provides regulations for food defense plans, compliance training, and recordkeeping. The initial cost for the first year of FSMA implementation is estimated to be between \$520 and \$860 million. In comparison, the financial burden of foodborne illness in the US in 2012 was estimated to be \$77.7 billion, accounting for loss of productivity, medical expenses, and illness-related mortality (Scharff 2012). Furthermore, the anticipated cost of a terrorist attack on the US food supply approaches \$130 billion. Thus, the cost of prevention is well worth it (FDA 2014).

There are many costs associated with implementing a food safety program, such as construction, waste disposal, employer and employee training, sanitation, and equipment (Tompkin 1995); many of these same costs will be incurred during FSMA implementation as well (FDA 2012). Many small food businesses' struggle with the implementation of food safety program is due to the cost associated with starting-up such a venture. Some processors are afraid that the increased costs could result in economic losses, especially in the short run. However, the implementation of food safety practices must be considered part of the long-term cost of participating responsibly in the food industry and is key to long-term viability of participating companies. Although cost may play a pivotal role in the decision to implement new practices, the long-term benefits

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associated with improved food safety, including fewer foodborne illnesses, fewer litigation costs, reduced health care expenses, and lower employee turn-over must also be considered (Caswell 1998).

History of HACCP

During the 1960s, the US National Aeronautics and Space Administration (NASA) worked in collaboration with the US Army and the Pillsbury company to develop safe food products with zero defects for astronauts (FAO 1998). In the process, Pillsbury developed HACCP as a food safety system that would maximize safety while minimizing end-product testing and inspection. In 1971, Pillsbury presented the HACCP system at a public conference on food protection. Beginning in 1973, HACCP was used as a basis for the development of the low-acid canned food regulations, and then, in 1985, the US National Academy of Science (NAS) recommended that it be applied to all food processing to guarantee safe food production (Pierson 1992). In 1997, the National Advisory Committee on Microbiological Criteria for Foods (NACMCF) encouraged the adoption of HACCP (Saxowsky 2015). HACCP is now widely accepted and utilized internationally in most food production facilities (Ropkins and Beck 2000) and is further backed by the implementation of FSMA (Fowler 2013).

Cost Associated with Application of Food Safety Programs

The food industry is expected to incur the largest financial impact within the first year of FSMA implementation. The FDA defines the cost of implementing FSMA for three tiers of the food service industry based on the number of facilities and generated sales of each business. The first tier, or Option 1, defines a very small business as one producing less than \$250,000 in total annual sales. The second (Option 2) defines a very small business as one producing less than \$500,000 in total annual sales, and the third, Option 3, defines a very small business as one producing less than \$1,000,000 in total annual sales. Based on these numbers, the FDA estimates that the first option will include an additional 34,600 facilities with the existing 11,500 facilities that are currently qualified as very small businesses under the Food Drug and Cosmetic Act. Option 2 will include an additional 45,900 facilities and Option 3 will include an additional 63,500 facilities (FDA 2012).

The total cost associated with set-up, monitoring, and verification of food safety systems will be \$775 million for very small businesses as defined by Option 1 during the first year and \$475 million in recurring annual cost. For very small

businesses as defined by Option 2, the cost of food safety implementation during the first year is projected to be \$717 million, with \$395 million in recurring annual cost. Finally, for those defined by Option 3, first year implementation costs are projected to be \$686 million with \$319 million in recurring annual cost (FDA 2012). Some of these costs include implementation of complementary, prerequisite programs such as GMPs and SSOPs. Additional provisions aimed at reducing foodborne illness include training, hazard analysis, supplier controls, and verification. It is estimated that proper training and education of employees will cost the industry nearly \$93.3 million. Assessing potential hazards associated with the industry through systematic analysis procedures will cost approximately \$62.5 million and the cost of utilizing supplier controls (e.g., review of suppliers' records and auditing) will be close to \$17.4 million. Finally, the cost of applying verification to operating facilities will be approximately \$46.8 million. Overall, the total annualized cost of these food safety measurements is approximately \$647.8 million. While the prevention of all foodborne illnesses is not expected, the FDA estimates that implementing such food safety programs will lead to nearly 1,000,000 fewer illnesses annually, saving the industry nearly \$2 billion per year (FDA 2012).

Reasons to Improve Food Safety

Benefits of improved food safety include better consumer health, avoidance of illness-related costs (medical services, loss of income, etc.), increased consumer confidence in food products, and bolstering the reputation of participating food companies (Caswell 1998). Though not specifically addressed in food safety plans, extension of food shelf life is a noteworthy and welcomed consequence of some of the measures used to ensure food safety (Smith and Stratton 2007).

Most consumers are strongly concerned with the safety of their food. By complying with current standards of food safety, food service companies gain credibility and trustworthiness and, in turn, increase their customer loyalty (Caswell 1998). The marketability of food safety is quantified using a market-based approach in which supply and demand interact to determine the value of goods. Consumers' demand for safe food is measured by their willingness to pay for safer food products. This willingness is derived from the perceived benefits of safer foods, such as the reduced risk of foodborne illness. The supply of food safety is determined by the costs associated with reducing these risks in food products. Assuming that safety measures will increase the cost of producing food, consumers must be willing to pay for these food safety costs

in order for companies to justify them. In order to offset the costs of food safety, food companies must be able to profit from consumers' increased perceived value of the product. Implemented food safety programs will only be sustainable if consumers understand and assume the burden of increased cost. Whether consumers are more likely to accept these increased costs or not is dependent upon their perception of the risks associated with a food product. For instance, a consumer may pay \$0.50 more for a dozen eggs if a packaging claim points out a safety attribute, such as lowering the hazardous risk of *Salmonella*. Unfortunately, not all consumers will reliably choose a safer food product. Dietary and personal preferences may lead some consumers to purchase food products that pose a greater health risk, regardless of cost considerations, such as unpasteurized dairy products. Thus, food companies continue to produce products at a level of food safety that reflects a predetermined level of acceptable risk. This balancing act between supply and demand, as well as acceptable risk and profits, will determine the success of food safety programs (Henson and Traill 1993).

In regards to the cost of illness, food safety measures the avoided liability costs for parties involved in product liability cases; research on liability costs comprises both short- and long-term litigations in the US (Caswell 1998). A 2001 US Department of Agriculture (USDA) report reviewed the outcomes of 175 jury trials involving foodborne pathogens resolved between 1988 and 1997. Their findings showed that the plaintiffs received monetary awards in only 31.4 percent of the cases. The median award for these cases was \$25,560, with a mean award of \$133,280. This indicates that, while some plaintiffs received substantial awards, most plaintiffs did not win their cases, and those that did were likely to receive a nominal payout from food companies. These large awards were often due to cases involving death, hospitalizations, or chronic conditions caused by foodborne illnesses (USDA 2001).

While there are many foodborne illness-related lawsuits filed each year, there are two that stand out and will be reviewed in further detail because of their resounding impact on the food industry and food safety regulations. The more infamous of these two cases involved the fast food chain Jack in the Box. In 1993, undercooked hamburger patties served at Jack in the Box infected 708 people with *E. coli* O157:H7. The outbreak led to 171 hospitalizations and the tragic deaths of four children (AAJ 2015). As a result, the FDA raised the internal temperature required for cooked hamburgers, and the USDA declared *E. coli* O157:H7 as an adulterant in raw ground beef. In the 18 months following

the outbreak, Jack in the Box estimated losses of approximately \$160 million. Individual and class-action lawsuits against the fast food company also resulted in an estimated \$50 million in settlements paid to victims of the outbreak, which includes a \$15.6 million settlement for an individual lawsuit (Marler Clark 1993). The more recent case involved a deadly listeriosis outbreak in cantaloupe that occurred in 2011. Jensen Farms, the source of the outbreak, was held responsible for infecting 147 people and causing 33 deaths (Vanderveen 2013). The two owners of Jensen Farms each received five years' probation and six months' home detention for introducing adulterated food into interstate commerce (Marklein 2014). While the data above suggests that settlements for foodborne illness cases are somewhat rare, these two cases show that unsafe food practices have the potential to cause major outbreaks that result in large-scale litigation, settlements, and possible criminal charges. The threat of foodborne illness litigation should be a driving force that helps food companies justify instituting proper food safety programs.

Impact of Cost Related to Foodborne Illnesses

Food safety regulation and associated programs are predicted to save the industry approximately \$2 billion in costs associated with preventable foodborne illnesses (FDA 2012). According to the Centers for Disease Control and Prevention (CDC), an average of 48 million people suffer illness from foodborne pathogens each year (Scallan et al. 2011). The majority of these illnesses are not reported. Of those that are, the source of infection is often hard to determine. It is estimated that 95% of food-related illnesses are associated with 15 of the 31 identifiable pathogens that are typically linked to causing foodborne illnesses. Among the top 15 causative agents, *Salmonella*, *Toxoplasma gondii*, *Listeria monocytogenes*, *Campylobacter*, and Norovirus are the five pathogens that cause 90% of the economic burden related to foodborne diseases. Of the 48 million foodborne illnesses estimated by the CDC, which had an estimated cost of \$15.5 billion annually, the associated pathogen was identified in only 20% of cases.

Summary

If every pathogen included in FDA-regulated foods could be eradicated, the food industry would save \$6.32 billion annually (FDA 2012). While complete eradication is not possible, food safety plans such as HACCP and FSMA do work to ensure safer food products (Tompkin 1995; Taylor 2011) and could potentially save \$1 to \$2 billion annually. Although small companies may experience the most

financial burden associated with implementing HACCP and other programs, the benefits related to reduced incidence of foodborne illness will outweigh the costs for most businesses (FDA 2012). HACCP implementation has continued expanding internationally (Cusato and Fernandes de Oliveira 2011). Several developed nations including China and the United Kingdom have implemented HACCP, either in part or in its entirety (Henson et al. 1999; Jin et al. 2008). Companies should comply with FSMA by incorporating food safety plans such as HACCP to improve consumer health, avoid illness-related costs, increase consumer confidence in food products, and bolster their reputations as perceived by consumers (Caswell 1998; Taylor 2011).

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