The Need for Prevention-based Food Safety Programs for Fresh Produce

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SUMMARY

Food safety practices such as Good Agricultural Practices (GAP) and Good Handling Practices (GHP) are employed to reduce food safety risks at the farm level. However, fruits and vegetables are field crops in which sporadic contamination can occur at any point, from production to shipping, and it is difficult to distinguish contaminated produce items from those free of contamination. Employing contaminated agricultural water for production and post-harvest activities poses a significant threat to the safety of produce; exposure of plants to contaminated soil or manure can lead to contamination of the harvestable portion of the crop. Using a prevention-based approach that focuses on comprehensive risk analysis at every step, including growing, harvesting, handling, packaging, and shipping, appears to be a logical way to reduce the risk of foodborne illness associated with fresh produce. Prevention-based approaches are exactly what the U.S. Food and Drug Administration (FDA) Food Safety Modernization Act (FSMA) produce safety rule (PSR), which was established on the basis of science-based minimum standards, is intended to achieve. The objective of this paper is to highlight the various complex routes of fresh produce contamination and emphasize the importance of using a holistic prevention-based food safety system that can reduce the risk of contamination.

OVERVIEW

The Food Safety Modernization Act (FSMA)–Produce Safety Rule (PSR), the first set of mandatory federal standards in the United States for growing, harvesting, packaging, and handling fruits and vegetables *(8)*, was first published in the Federal Register on November 27, 2015. The primary objective of the rule was to strengthen the current produce food safety system through a prevention-based approach by implementing minimum science-based best practices *(34)*. Fruit and vegetable growers in the various categories of the PSR must abide by the rules and regulations of FSMA-PSR to fulfill federal regulations. Based on data obtained from the Centers for Disease Control and Prevention (CDC), between 2000 and 2016, 17,338 illness outbreaks were reported, of which 558 were related to produce. These outbreaks led to 15,482 recorded illness, 816 hospitalization, and 20 deaths *(12)*.

Data obtained from the CDC *(Table 1)* clearly show how outbreaks have been decreasing over the past few years, perhaps because of increased food safety awareness, buyer requirements (third-party audits), and Good Agricultural Practices (GAP) employed by growers. Although the U.S. food safety regulations have made great strides with respect to produce safety, various developments, such as challenges in the U.S. regulatory bodies, foodborne outbreaks due to new forms of contamination, and increasing costs associated with foodborne illnesses, have led to changes in food safety laws and regulations *(3)*.

SUMMARY

It is important to understand that FSMA–PSR, in general, includes minimum science-based standards for growing, harvesting, packing, and holding fruits and vegetables intended for human consumption. In addition, it is essential to understand where fruits and vegetables come from, including routes of contamination and the microbiology not only of fruits and vegetables but also the environment in which they are grown and the various resources used to produce them. Although many different routes of pathogen entry into fruits and vegetables are possible, soil and water have been the top two routes of contamination. Numerous studies have been conducted to understand the way in which contamination occurs when produce is exposed to contaminated water, soil, or manure during production, harvesting, packing, and storage *(2, 9, 14, 20, 21, 24, 25, 26)*.

Foodborne outbreaks in fresh produce have been identified in many parts of the world *(23)*. In 2015, the CDC estimated that approximately 48 million new cases of foodborne illness are reported every year, resulting in 128,000 hospitalizations and 3,000 deaths *(12)*. It was also estimated that the average national cost of foodborne illness was around $55.5 billion *(28)*. The proportion of outbreaks linked to fresh produce in the U.S. has been increasing significantly, from < 1% to almost 6% from 1970 to the 1990s, with 54% of the outbreaks linked to known pathogens *(31)*. Consumption of fruits and vegetables has significantly increased in the United States because of its association

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TABLE 1. Produce-related outbreaks in the United States (2000–2016) *(12)*

Year	2000–2005	2006–2010	2011–2016
Outbreaks	220	179	159
Illnesses	6,305	5,470	3,707
Hospitalizations	169	374	273
Deaths	3	7	10

with a healthy lifestyle *(11)*. Significant amounts of produce are consumed raw, and outbreaks associated with these products are growing correspondingly *(10)*. The complex cycle of bacterial contamination and persistence on plants by adhesion of pathogens to the surfaces restricts the usefulness of conventional processing and chemical sanitizing methods to prevent the transmission of organisms in produce *(23)*. Outbreak investigations conducted over the years have led researchers to analyze different opportunities for contamination at the farm level in the farm-to-fork network *(23)*. Future achievements in preventing produce-related outbreaks depend on understanding the various factors influencing potential contamination, as well as maintenance of best practices to reduce and eliminate contamination *(22)*. Therefore, creating awareness and understanding of pathogen-produce interactions are vital for controlling the growth of unwanted microorganisms on fresh produce and delivering safe food to the community.

PATHOGENS CONTAMINATING FRESH PRODUCE

Various pathogenic microorganisms are associated with the contamination of fresh produce. These include *Campylobacter* spp., *Clostridium botulinum*, *Clostridium perfringens*, enterotoxigenic *Bacillus cereus*, *Escherichia coli* O157:H7 and other Shiga toxin-producing *E. coli* (STEC), *Listeria monocytogenes*, *Salmonella* spp., *Shigella* spp., enterotoxigenic *Staphylococcus aureus*, *Vibrio cholerae*, *Yersinia enterocolitica*, certain viruses, and protozoa *(33)*. The likelihood of fruits and vegetables from a field or orchard becoming contaminated with pathogenic microorganisms during harvesting, post-harvesting, processing, or distribution was analyzed by Beuchat in 1996 *(5)*. Beuchat discussed the ability of pathogenic microorganisms to cause human diseases and to survive and be present in the water which is used for irrigation or in the soil used for growing produce *(Table 2)*.

Numerous outbreaks linked to contaminated fruits and vegetables have been recorded in recent years *(17)*. These outbreaks have called attention to the effect of consumption of contaminated produce on human health, particularly when produce is consumed raw *(33)*. *L. monocytogenes* outbreaks and prevalence in fresh produce was reviewed in 2017 *(36)* by Zhu et al., who focused on fresh produce-related listeriosis outbreaks, the organism's corresponding prevalence in the environment, contamination levels of fresh produce, and challenges associated with fresh produce safety. The author concluded that *L. monocytogenes* is typically present in most fresh produce and ascribed this finding to the crop growing environment, post-harvest processing methods, and the retail setting. Measures to enhance produce safety in order to reduce the presence of these pathogenic microorganisms on fresh produce, including prevention of biofilm formation through effective sanitation methods *(36)*, were highly recommended.

Another major pathogen contaminating fresh produce is Shiga-toxin producing *Escherichia coli (E. coli)*, specifically serotype O157:H7, which has been identified as a causative agent in many foodborne outbreaks of gastroenteritis. Even though infections with STEC have been associated largely with consuming undercooked beef, several outbreaks linked to this pathogen have been traced back to consumption of contaminated produce, such as radishes, sprouts, and pre-packaged spinach *(4)*. It has been demonstrated that these pathogens have the ability to adhere to the leaves of fresh produce, such as salad leaves, through alternative mechanisms involving the filamentous type III secretion system *(29)* or through flagella-mediated attachment *(30)*.

Fruits and vegetables have a high potential to act as vehicles for disease transmission. Fresh produce can be contaminated with pathogens by coming in contact with improperly treated manure, contaminated water or soil, poorly implemented washing/sanitizing operations, or food handlers who are infected and who handle produce improperly *(33)*. *Table 3*, from Harris et al. (2003), details some characteristics of pathogens and their associated contamination sources *(14)*. It is obviously important to review good agricultural and food safety practices periodically to keep up with newly identified microbial problems in order to improve food safety standards.

TABLE 2. Sources of pathogenic microorganisms on fresh produce *(5)*

Harvest	Source
Pre-harvest	Feces
	Soil
	Irrigation water
	Green or inadequately composted manure
	Air (dust)
	Wild and domestic animals
	Human handling
Post-harvest	Feces
	Human handling (workers, consumers)
	Harvesting equipment
	Transport containers (field to packing shed)
	Wild and domestic animals
	Air (dust)
	Wash and rinse water
	Processing equipment (sorting, packing, and cutting)
	Ice
	Transport vehicles
	Improper storage (temperature, physical environment)
	Improper packaging
	Cross-contamination (other foods in storage, preparation, and display areas)
	Improper display temperature
	Improper handling after wholesale or retail purchase

AGRICULTURAL WATER

According to the FDA, any water used in covered activities, i.e., where water is intended for use on fresh produce or on a surface in contact with it, is called agricultural water. Agricultural water can be classified into pre- or post-harvest water, depending on its application and intended use during production, harvesting, and packaging *(8)*.

PRE-HARVEST WATER

In recent years, many pathogens have been isolated with increasing frequency from fresh produce. Wastewater is increasingly employed as a source of irrigation to supplement scarce water supplies and to provide nutrients to crops. Improperly treated irrigation water can contain high levels of foodborne pathogens, which could adversely impact the quality and safety of fruits and vegetables produced using that water. Poor water quality has long been associated with fruit and vegetable contamination by various pathogenic microorganisms *(32)*. Irrigation water as a potential pre-harvest source of bacterial contamination on vegetables was studied by Ikabadeniyi et al. in 2002 *(18)*, who studied the effect of the water source used for irrigation on the bacterial load in the water and the subsequent levels of bacterial contamination found on fresh produce during a 12-month sampling period. They used logistic regression analysis to predict the potential bacterial load of *Salmonella* spp., *L. monocytogenes*, and intestinal *Enterococcus* in irrigation water and vegetables. Analysis of variance ($P \leq 0.05$) was employed to determine whether there were significant differences between the levels of turbidity, oxygen demand, aerobic plate count, aerobic spore former counts, and anaerobic spore-former counts in 36 water samples. Results

TABLE 3. Characteristics of some microbial pathogens that have been linked to outbreaks of produce-associated illnesses *(14)*

Microorganism	Incubation Period	Infectious Dose	Source
Clostridium botulinum	12 to 36 hours	Toxin production in food	River, lakes, decaying vegetation
Escherichia coli O157:H7	2 to 5 days	10 to 1,000	Animal feces, especially cattle, deer, and human: cross-contamination from raw meat, produce
Salmonella spp.	18 to 72 hours	10 to 100,000	Raw meat, poultry, or eggs
Shigella spp.	1 to 3 days	About 10	Human feces
Listeria monocytogenes	1 day to 5 or more weeks	Unknown, dependent upon health of individual	Food processing environments
Hepatitis A	25 to 30 days	10 to 50	10 to 50

indicated that logistic regression of the aerobic colony counts and *S. aureus* counts were statistically dependable in predicting the presence of *L. monocytogenes* on vegetables. Similarly, a significant difference was observed between the aerobic plate counts and the anaerobic spore-former counts *(18)*. These findings were used to predict the potential presence of intestinal *Enterococcus* and *Salmonella*, respectively. The data indicated that the water used for irrigation was a likely source of contamination in fresh produce. Treatment of pre-harvest irrigation water was highly recommended, along with good agricultural practices, especially in producing ready-to-eat vegetables *(18)*.

In 2009, Braker-Reid et al. *(2)* studied the persistence of *E. coli* on injured iceberg lettuce in a field irrigated with contaminated water. The research team conducted assays to evaluate the persistence of *E. coli* on injured lettuce plants irrigated with water applied via overhead irrigation and inoculated with nonpathogenic *E. coli*. Specifically, physically damaged plants were treated on day 0 by applying 1 liter of inoculum (7 $\log_{10}$ CFU/ml) to each plant head, using a watering can. *E. coli* was subsequently detected on all lettuce head samples, and data analysis demonstrated that injury to the leaf prior to *E. coli* inoculation and harvest ($P = 0.00067$) significantly increased the persistence of the pathogen on lettuce samples, thus significant persistence of *E. coli* was seen on plants that had very recent injuries, and it was concluded that growers should avoid using contaminated water for irrigating lettuce crops for a minimum of 2 days before harvesting *(2)*, a recommendation that should minimize food safety risk, since damage from farm management practices or environmental effects may cause pathogen retention on fresh produce. Growers were also advised to consider chlorination or ozonation of water prior to its use, in order to provide safe irrigation water for crops *(2)*.

Mootian et al. (2009) analyzed *(24)* the transfer of *E. coli* O157:H7 from the soil, water, and manure to lettuce plants. The main aim of the study was to determine whether exposure to low levels of the pathogen in the rhizosphere (near root portion) and phyllosphere (above ground portion) of lettuce plants would result in detectable levels of pathogen in the phyllosphere. Plants were exposed to different concentrations of the pathogen through contaminated soil and manure or through surface irrigation with contaminated water. It was observed that 21% of the plants tested positive for *E. coli* O157:H7. Surface sterilization did not result in complete elimination of the pathogen, as the bacteria were protected in crevices of lettuce tissue. Contamination of produce often increases close to harvest and can increase the risk of pathogens being present in the produce at the time of harvest *(24)*. It was concluded that future efforts are necessary to avoid human pathogen contamination of produce, rather than focusing solely on disinfecting technologies *(24)*.

Recovery of *Salmonella enterica* subsp. Newport, introduced through irrigation water, from tomato fruits, stems, and leaves was studied by Hintz et al. in 2010 *(15)*. The objective of the study was to determine whether tomato plants irrigated with the target pathogen had the potential to take up the organisms. The study involved using irrigation water containing 7 $\log_{10}$ CFU/ml of *S.* Newport on commercially-produced 7-week-old tomato plants. Leaves, roots, stems, and fruits were sampled at different stages during development, homogenized, and then enumerated on XLT-4 agar for *S.* Newport. The results indicated that 35 of the 92 obtained samples (65% roots, 40% stems, 10% leaves, and 6% fruits) were positive for *S.* Newport. Significant differences were observed for the presence of *S.* Newport according to the tissue type sampled, but no association was observed between the growth stages and contamination levels *(15)*.

These studies clearly point out the risks of using contaminated water to irrigate crops, especially for fresh produce that may be consumed raw. Recently, the diverse opportunities for plants to become exposed to and contaminated with a huge array of human pathogens have been the focus of much discussion and research. It was previously believed that pathogens exposed to crops during cultivation would not persist through the different stages of harvest, post-harvest storage, handling, and transport *(32)*. The ability of *Salmonella* spp. to survive on the edible portion of cilantro leaves was studied by Brandl and Mandrell in 2002 *(9)*. Researchers demonstrated the ability of *S.* Thompson to survive on the cilantro plants, despite low water availability and dry conditions, for an extended period of time *(9)*. This study provides evidence that outbreaks of foodborne illness can result from pre-harvest contamination of fresh produce.

In addition to pathogens remaining on the surface of the edible portions of plants, potential internalization and persistent survival inside the plant creates additional produce food safety challenges that are yet to be fully investigated. Hence, efforts to reduce microbial contamination during pre-harvest, along with proper post-harvest inactivation or removal of microorganisms, are likely necessary to reduce the microbial load on fresh produce and thereby minimize the incidence of associated foodborne illness outbreaks.

POST-HARVEST WATER

Many outbreaks of human illness related to the consumption of washed produce have been reported in the United States. Changes in agronomy, harvesting, distribution, processing, and consumption patterns have contributed significantly to an increase in foodborne illness *(6)*. Various pathogens, such as *Listeria* spp., *Clostridium* spp., *Bacillus* spp., *Escherichia* spp., parasites, and viruses, are likely to contaminate fresh produce, not only through infected manure, irrigation water, or soil, but also through contaminated wash water employed during post-harvest washing *(6)*. Fresh cut produce processors usually rely on wash water, along with sanitizers, to reduce the risk of microbial contamination of their products. Employing wash water with sanitizers is used specifically to prevent cross-contamination and to improve the hygiene of produce by eliminating soil particles and debris *(13)*. Despite the use of sanitizers with wash water for reduction of microorganisms during washing, epiphytic organisms are capable of growing rapidly during storage. The main problems encountered with using wash water are the type and concentration of sanitizers employed. Treatment with chlorinated water, one of the most common post-processing methods for washing fresh produce, reduces the population of pathogenic and other microorganisms but cannot eliminate them completely. It is clear that current concentrations of chlorine employed by the industry to wash produce cannot be relied upon to eliminate all pathogens *(6)*. The multitude of alternative methods and sanitizers now available for produce washing highlight the problems encountered in using chlorine and suggests that many industries may benefit from supplementing, if not replacing, this traditionally used disinfectant. In addition, many European countries are now using potable water instead of chemical disinfecting agents for washing fresh-cut vegetables and fruits *(13)*.

Evidence of *Salmonella* internalization into fresh mangos during a simulated post-harvest procedure was analyzed by Penteado et al. in 2004 *(26)*. The research team investigated a nationwide recall on mangos in the United States that was due to possible contamination with *Salmonella*, even though the crop had been disinfected with chlorine. *Salmonella enterica* S132, which expresses a green fluorescence protein, was used as the target microorganism for the study. Mangos (immature and ripe) were processed according to the post-harvest handling procedure. Enumeration of the microorganism was carried out on processed mangos by sectioning the fruits into stem-end, middle-side, and bottom-end segments. Samples were homogenized, plated on BHI agar and incubated at 37°C for 18–24 hours. Overnight incubated plates were then examined, using UV light to enumerate colonies. Both the immature and ripened mangos tested positive for *Salmonella* internalization. The degree of ripeness had no significant effect on the frequency of contamination. Internalization was significantly higher ($P < 0.05$) on the stem-end segment (83%) than on the middle (19%) or the blossom end (9%). *Salmonella* levels inside the pulp varied greatly between treatments, and the pathogen was detected within the pulp after 1 week of incubation at various temperatures. The study concluded that poor-quality wash water that was not properly chlorinated or was contaminated during processing may have served as the contamination route. Employing high-quality water for post-harvesting processing is a necessity to minimize the likelihood of contamination. Additional studies are required to establish the effectiveness of existing disinfestation procedures on preventing internalization of pathogens during post-harvesting processes *(26)*.

Pathogens have long been observed to have the ability to be transferred from different sources onto the edible portions of plants at any point from harvest to consumption. Employing high-quality wash water free of organic matter, along with an effective sanitizer, is highly recommended to avoid cross-contamination, especially if the water is recycled. The impact of wash water quality on *E. coli* cross-contamination of fresh-cut escarole was studied by Allende et al. in 2008 *(1)*, who employed different types of wash water (such as potable, recirculated, and diluted recirculated water) inoculated with microorganisms to study the ability of bacteria to cross-contaminate produce. A significant amount of transmission of *E. coli* from the inoculated to the un-inoculated samples occurred during washing. It was concluded that the contamination level may impact water quality and the efficacy of added sanitizers for reducing the concentration of waterborne pathogens. It was also shown that cross-contamination of fresh-cut produce can occur if even a small amount of contaminant is present during washing, thus demonstrating the need for using good quality wash water with an effective sanitizer to control or prevent contamination *(1)*. In 2004, Rodgers et al. compared chemical sanitizers for inactivating *E. coli* O157:H7 and *L. monocytogenes* on apples, lettuce, strawberries, and cantaloupe *(27)*. They employed ozone (3 ppm), chlorine dioxide (3 and 5 ppm), chlorinated trisodium phosphate (100 and 200 ppm) and peroxyacetic acid (80 ppm) with regard to their effect on reduction of *E. coli* O157:H7 and *L. monocytogenes* in an aqueous system. Pathogens employed for the study were prepared by using three different strains of each organism, resulting in a cocktail mixture prepared at a concentration of approximately 6 log CFU/ml. Four sanitizers were prepared at the appropriate concentrations, using distilled water (wash water), which was also employed as a control, at 21° and 23°C. Samples were homogenized and plated on various media to quantify mesophilic bacteria, *E. coli* O157:H7, *L. monocytogenes*, yeasts, and molds. Significant reductions in both pathogens occurred, with ozone being the most effective treatment, followed by chlorine dioxide, chlorinated trisodium phosphate, and peroxyacetic acid (in decreasing order of efficacy). Quantification of organisms yielded relatively similar results for all nine days of sampling, although toward the end of the study, mold and yeast populations were significantly higher for samples treated with chlorine dioxide and ozone. It was concluded that chlorine dioxide, chlorinated trisodium phosphate, and ozone all effectively reduced the counts of *E. coli* O157:H7 and *L. monocytogenes (27)*.

Plain water can be used for reducing the probability of contamination during washing, but it also can transfer pathogenic microorganisms *(13)*. Washing fresh produce with an effective sanitizer is therefore important to obtaining products free of organic matter and especially to preventing cross-contamination between clean and contaminated products. The aforementioned experiments clearly demonstrate the importance of employing good-quality post-harvest wash water along with a sanitizer to reduce pathogens and spoilage organisms on fresh produce.

SOIL AND MANURE

Soil has long been known to provide essential nutrients for the growth and development of plants *(7)*. Soil and manure have both played major roles in exposing plants to a diverse array of microflora comprised of both beneficial and harmful microorganisms. Many foodborne outbreaks have been linked to consumption of fruits and vegetables grown in soil contaminated with manure or polluted irrigation water *(25)*. Contamination of produce with improperly treated or contaminated soil, manure, or compost on the farm can cause pre-harvest contamination of fresh produce *(19)*. Although competition from natural soil flora and unexpected environmental conditions may hinder the growth and development of pathogens *(19)*, the potential of pathogens to persist and survive has led researchers to study their ability to adapt to extreme environmental conditions. Islam et al. in 2004 studied the fate of *Salmonella enterica* serovar Typhimurium on field-grown carrots and radishes exposed to different types of compost inoculated with the target organism *(20)*. The three types of compost employed (poultry manure, dairy cattle manure, and alkaline-pH-stabilized dairy cattle manure), along with irrigation water, were inoculated with 10^7 and 10^5 CFU/ml of *Salmonella*. Crops were grown in the contaminated field, and samples were withdrawn to study the persistence of *Salmonella*, which was shown to survive for an extended time and was detectable in the soil for 203 to 231 days *(20)*. Similar results were observed in the case of contaminated irrigation water. The team concluded that employing either contaminated manure or irrigation water could play a major role in contaminating the soil, leading to prolonged persistence of the pathogen, which could eventually contaminate produce, especially root vegetables *(20)*.

Transfer of *Listeria innocua* from contaminated compost and irrigation water to lettuce leaves was studied by Oliveira et al. in 2011 *(25)*. The objective was to determine the transfer of the pathogen from contaminated compost and water to the edible portion of the plants as well as the survival of the pathogen through two seasons, fall and spring. Viable *L. innocua* were retrievable from the field for up to 9 weeks, at a concentration of 10^5 CFU/gdw in fall and 10^3 gdw (gram by weight) in spring *(25)*. The team was also able to successfully demonstrate the transfer of the pathogen from contaminated soil and water to the edible portion of the plant, especially the outer leaves. It was concluded that the pathogen survived better in fall than in spring, which indicates that temperature and humidity play major roles in regulating growth of the bacteria. In general, employing contaminated compost and irrigation water will contribute to the presence of foodborne pathogens on vegetables *(25)*.

Johannessen et al. in 2005 studied the uptake of *E. coli* O157:H7 from organic manure into crisphead lettuce *(21)*. Lettuce seedlings were planted in soil that was fertilized with contaminated bovine manure containing 10^4 CFU/g of *E. coli* O157:H7 and grown in a climate-controlled greenhouse for 50 days, after which samples were withdrawn randomly and tested for the presence of the pathogen. The pathogen was not detected on the edible portion, the outer leaves, or the roots of the lettuce harvest, despite the persistence of the pathogen in the soil for almost 8 weeks. It was concluded that th *E. coli* O157:H7 was not transmitted from contaminated manure to lettuce under the test conditions *(21)*.

Large quantities of animal manure are applied to agricultural lands in the U.S., with an estimated 1.36 billion tons being applied annually, 90% of which consists of cattle manure *(35)*. Although application of manure or compost improves soil fertility, applying improperly treated or contaminated manure and compost, especially of animal origin, which contains various enteric pathogens, could allow pathogens to enter the food chain *(19)*. Pathogens may be introduced into the soil from contaminated manure, compost, irrigation water, and surface runoff water from production operations such as those used for raising cattle, swine, or poultry. On the basis of results of the aforementioned studies, it can be concluded that application of manure to production fields may result in persistence of microorganisms in the environment for extended periods of time, thereby increasing the risk of contamination of the produce.

CONCLUSION

Increases in production, distribution, and consumption of fresh produce, along with inconsistent agricultural practices and varying production methods, may explain the high incidence of produce-associated foodborne illness outbreaks. In the past decade, food safety has become a major concern, and the frequency of outbreaks has reduced consumer confidence, which has led the food industry to take steps necessary to produce safe food and thus rebuild consumer acceptance. Various environmental factors during pre- and post-harvest may contribute significantly to contamination of fresh produce by spoilage organisms and potential pathogens. It is clear that microorganisms, including human pathogens, have the ability to survive in water, soil, and manure, and on fresh produce, for prolonged periods of time because of their ability to adapt to extreme conditions.

Illnesses associated with produce are sporadic. Although numerous studies have demonstrated the ability of pathogens to contaminate fresh produce, experimental studies do not mimic real farm environments, and their implications are "one size fits all;" prescriptive and reactive approaches have not, to date, provided adequate solutions. Microbial contamination is difficult to remove and can easily become internalized through natural features such as stem scars or leaf injury. Employing effective sanitation plays a major role in eliminating pathogens; however, it is evident that the current options employed for sanitizing produce are insufficient to combat the sporadic contaminations that may occur in a produce growing and handling environment. Emphasis must be placed on employing multi-level sanitation processes that use hurdle technology to make produce safer for human consumption. Because of the numerous routes and weak links in production, storage, and distribution of fresh produce, complete elimination of pathogens is difficult, since contamination can occur at any point along the chain. To prevent produce-related contamination, we need to look at the entire food chain from field to consumption with an eye to identifying major control points and establishing essential risk-based prevention steps. Prevention of produce-related outbreaks also requires a collaborative effort from industry, government, health agencies, and academia *(16)*.

The majority of produce-related outbreaks in the past were associated with leafy greens (25%), sprouts (25%), and melons (10%) *(8)*, leading many people to think that the focus of food safety programs should be only such high-risk commodities. However, restricting food safety practices to these high-risk commodities does not meet the overall purpose of producing safe food for human consumption, because every crop produced in the field has a chance to become contaminated with human pathogens. Thus, employing proactive and prevention-based food safety programs such as those described in GAP/GHP and the FSMA Produce Safety Rule should be most effective in reducing food safety risks.

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