Food Safety

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Introduction

Data from the U.S. Center for Disease Control and Prevention (CDC) between 1973 and 1987 indicate that there were 3,699 foodborne illness outbreaks in the United States. Only 2% were associated with fruits and vegetables, and most of those were due to improper home canning. In general, produce is a low-risk food, and it is unlikely that one will become ill from eating raw fruits or vegetables. But a small risk does exist, and it is incumbent on all of those involved in the production and distribution of fresh produce to work to minimize those risks. Safety is the perception of acceptable risk, and if no risk is acceptable, then nothing can ever truly be safe. Many consumers feel that food products should have no risk associated with their consumption. Unfortunately, the reality is that reducing the risk of foodborne illness from consumption of fresh fruits and vegetables to absolute zero is an impossible task. It should also be kept in mind that the health benefits derived from eating at least 5 servings of fresh fruits and vegetables daily far outweigh the very small probability of contracting a foodborne illness.

Fruits and vegetables are unique foods, since they are often consumed raw or with minimal preparation. To date, there have been no effective intervention strategies developed that can completely eliminate food safety risks associated with consumption of uncooked produce. Therefore, preventing contamination with human pathogens, dangerous levels of chemical residues, or physical contaminants is the only way to ensure that these foods are wholesome and safe for human consumption.

Systems that ensure safety and wholesomeness of fruits and vegetables during postharvest handling and fresh-cut processing fall into four prevention programs: Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), Sanitation Procedures**,** and Hazard Analysis Critical Control Points (HACCPs).

The greatest risk to human health from consumption of uncooked produce is from pathogenic microorganisms. Raw agricultural products, such as fresh produce, should be expected to harbor a wide variety of microorganisms including the occasional pathogen. A vigorous population of nonpathogenic bacteria can be an excellent barrier to prevent the growth of pathogens, should they be present. Nonpathogenic bacteria also act as indicators of temperature abuse and age by spoiling the product. In the absence of spoilage, high levels of pathogens may occur, and the item may be consumed because it is not perceived as spoiled. There are four groups of human pathogens associated with fresh produce:

- Soil-associated pathogenic bacteria *(Clostridium botulinum* and *Listeria moncytogenes)*
- Fecal-associated pathogenic bacteria (*Salmonella* spp., *Shigella* spp., *E. coli* O157:H7, and others)
- Pathogenic parasites *(Cryptosporidium* and *Cyclospora)*

- Pathogenic viruses (hepatitis, norwalk virus, and others)

Many of these pathogens are spread from humans or domestic animals to food to humans. Fruits and vegetables may become contaminated by infected field workers, food preparers, consumers, cross-contamination, use of contaminated irrigation water, use of inadequately composted manure, or contact with contaminated soil. To minimize risks, growers should implement practices outlined in the "Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables" published by the Center for Food Safety and Applied Nutrition, Food and Drug Administration (FDA 1998). This publication outlines Good Agricultural Practices (GAPs) which, when followed, can significantly reduce the risk of microbial hazards in produce. Growers should be aware that agricultural practices that may have been acceptable in years past may no longer be acceptable. In addition, fresh-cut processors should adhere to Good Manufacturing Practices (GMPs) 21 [CFR 100-169] to appropriately manage food safety risks during processing. Food handlers and consumers must act responsibly as they are the final link in the food safety chain.

Prevention of contamination is the only way to minimize true food safety risks and ensure food safety. Microbial testing cannot guarantee the absence of pathogens on fresh produce and, in fact, is unlikely to detect pathogens even when they are present. For example, if 5 fruit in a given lot of 100 individual fruit are harboring pathogens (5% contamination rate), how many fruit would have to be sampled to be 95% sure that one of the infected fruit was found? Table 1 shows that at 5% contamination rates, it would be necessary to test 60 fruit to have a 95% chance of finding the pathogen. It is surely not practical to test 60 out of every 100 fruits or vegetables. Yet testing fewer fruits results in a high likelihood that pathogens will be missed, even when they are present. For this reason, negative results from product pathogen testing have little value and can be misleading. Microbial testing can be an effective tool, but sampling the finished product is not an efficient, cost-effective approach. Sampling potential sources of contamination—such as irrigation water, cooling and process water, and food contact surfaces—and monitoring employee hygiene practices are more effective in preventing spread of human pathogens.

Table 1. Probability that a given number of samples will fail to detect microbial contaminants at specified contamination levels

Percent	Number of Samples Analyzed					
Contaminated	5	10	15	20	30	60
	%					
10.0	41	65	79	88	96	>99
5.0	33	40	54	64	79	95
2.0	10	18	26	33	45	70
1.0	5	10	14	18	26	45
0.1	1	1	2	2	3	6

Source: U.S. Food and Drug Administration

Has the Problem Gotten Worse?

Scientists continue to discover new microorganisms that cause foodborne illness, and recent advances in diagnostics allow more rapid detection of smaller numbers of pathogens on foods. Detection methods for pathogenic microorganisms are faster and more sensitive, allowing investigators to better identify causes of outbreaks. In recent years, fresh produce sourcing has undergone significant changes, and centralized local production has been replaced with worldwide sourcing. Agricultural practices and hygienic conditions vary greatly among growing regions around the world, and increased global sourcing increases consumers exposure to diverse endemic microflora carried on fresh fruits and vegetables. Also, global sourcing means longer transportation and handling, giving pathogenic microorganisms additional time to proliferate and reach levels which can cause illness. Population demographics in North America have shifted, with a greater number of individuals that are older or who have compromised immune systems. They are at greater risk from foodborne illness, and the consequences of exposure can be deadly. All of these circumstances have resulted in increased foodborne illness awareness.

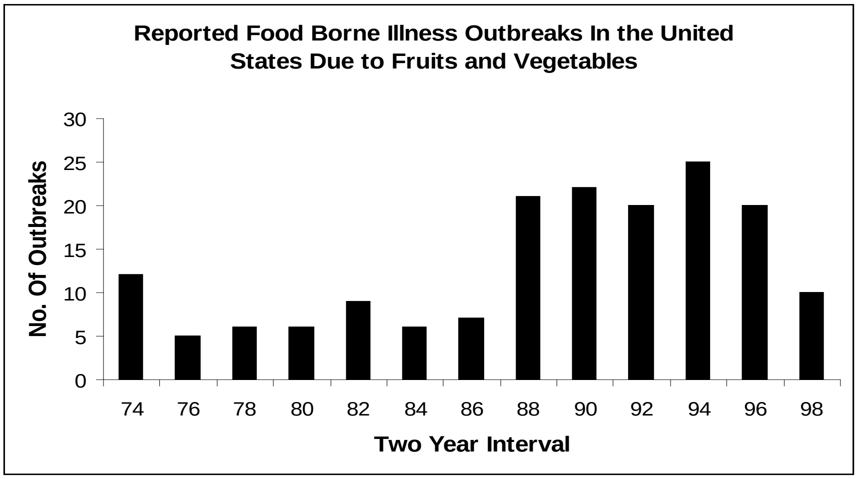

Figure 1. Increasing number of foodborne illness outbreaks associated with fresh produce in the United States. Source: CDC Food Borne Outbreak Surveillance System.

Intervention Strategies

Washing produce before preparation or consumption is recommended but does not guarantee that fresh produce is pathogen-free. Studies have demonstrated that washing produce in cold chlorinated water will reduce microbial populations by 2 or 3 logs (100- to 1000-fold), but sterility is not achieved, because microorganisms adhere to surfaces of produce and may be present in microscopic nooks and crannies on the surface of produce (Zhuang et al. 1995).

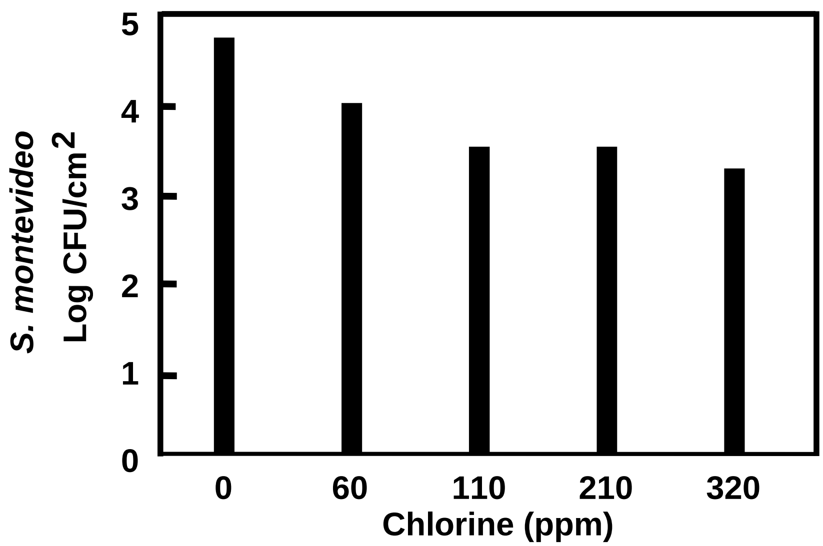

Figure 2. The effect of wash-water chlorine concentration on the fate of *Salmonella montevideo* on raw tomatoes. Adapted from Zhuang et al. 1995.

This is a problem since some pathogens, such as *E. coli* O157:H7, have an infectious dose of as few as 10 to 100 viable cells. To date, there are no wash-water treatments that can completely eliminate human pathogens from fresh produce. Product wash-water, if not properly sanitized, can become a source of microbiological contamination for every piece of product that passes through that water. It is a widespread misconception that chlorinated wash-water cleans or sterilizes produce as it is washed. Chlorinated wash-water does little more to clean produce than potable, nonchlorinated water. Chlorine does sanitize wash-water and maintains a low microbiological count in the water. In this way the water does not become a reservoir for mold spores and bacteria to infest produce.

Sodium or calcium hypochlorite is most commonly used in produce wash-water. The antimicrobial activity of these compounds depends on the amount of hypochlorous acid (HOCl) present in the water. This, in turn, depends on the pH of the water, the amount of organic material in the water, and, to some extent, the temperature of the water. Above pH 7.5, very little chlorine occurs as active hypochlorous acid, but rather as inactive hypochlorite (OCl^-). Therefore, the wash-water pH should be kept between 6.0 and 7.5 to ensure chlorine activity. If the pH falls below 6.0, chlorine gas may be formed, which is irritating to workers. Organic material in the water will reduce chlorine activity, so periodically replacing or filtering the water is important to maintain cleanliness.

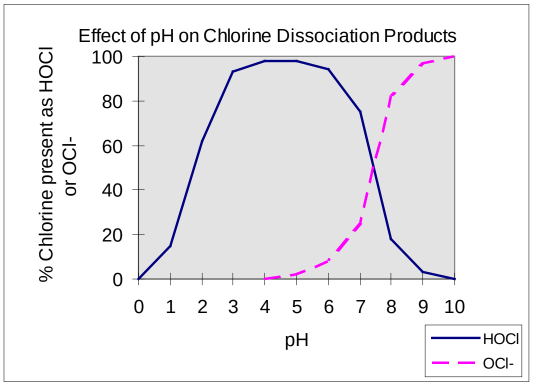

Figure 3. Effect of pH on chlorine dissociation products.

An effective wash-water sanitation system is becoming a necessity in the produce industry due to increased concerns with safety of fresh produce. Since water can be a source of contamination if the water itself becomes contaminated, the ability to ensure clean water is an essential element of a food safety program. Understanding how different sanitizers work and how they are measured and monitored is an important element in operating a food safety system in an effective and cost-efficient manner.

Table 2. Activities and environmental sensitivities of wash-water sanitizers

Sanitizer	pH	Organic Matter	Biocidal Activity
Hypochlorites	6.0 - 7.5	Very sensitive	Oxidizer

Chlorine dioxide	6.0 - 10.0	Sensitive	Oxidizer
Ozone	6.0 - 10.0	Somewhat sensitive	Oxidizer
Peroxyacetic acid	1.0 - 8.0	Somewhat sensitive	Oxidizer
UV light	Not affected	Somewhat sensitive	Disrupts DNA

Irradiation and Cold Pasteurization

Use of nonthermal irradiation, often called cold pasteurization, has been advocated as a means to eliminate human pathogens from produce, similar to current allowable practices in the meat and poultry industry. To date this strategy has been ineffective for a number of reasons, including the expense of irradiating produce, a lack of facilities to treat produce, the damage susceptibility of many produce items to irradiation, and perceived consumer resistance to the use of irradiation for foods. Irradiation with a gamma source, such as cobalt 60, has been studied by many researchers. In the 30 years preceding 1983, more than 1,152 published reports had addressed irradiation of fruits and vegetables (Kader and Heintz 1983). The accumulated data suggest that irradiation may have some applications for disinfestation of fruits and vegetables but that irradiation alone will not resolve most microbiological issues. Different organisms vary in their sensitivity to ionizing radiation and many microbes will not be killed at the maximum allowable dose of 1 kGy (Brackett 1987).

Killing microbes with irradiation occurs when the irradiated energy interacts with water in microbial cells. Reactive chemicals are created that damage the cells' genetic material, or DNA. The ability of irradiation to kill a particular microbe is measured as the "D-value," the amount of energy needed to kill 90% of the cells of the microbe. Thus, a dosage of 2D would kill 99% of the cells, 3D kills 99.9% and so on. Of course, the D-value will differ for different microorganisms.

Insect pests and some parasites (*Cyclospora*, *Cryptosporidium*, etc.) have a relatively large amount of water and DNA in their cells and so are easily killed by irradiation. D-values for gamma irradiation of 0.1 kGy are typical. Thus, a dosage of 0.5 kGy would give a 5-log reduction. Bacteria (*E. coli*, *Salmonella*, *Listeria*, etc.) have less DNA and are more resistant to irradiation. D-values of 0.3 to 0.7 kGy are typical, depending on the bacterium. Thus, it would require 1.5 to 3.5 kGy to achieve a 5-log reduction of bacteria. At this time, the maximum allowable dosage for treating fruits and vegetables is 1.0 kGy. The implication is that gamma irradiation is not approved for use at dosages high enough to effectively eliminate pathogens from fresh produce. There is a petition to the FDA to increase allowable dosage to that used for red meat, which is 4.5 kGy.

Spore-forming bacteria (*Clostridium, Bacillus,* etc) are even more resistant to irradiation, and viruses (hepatitis, norwalk, etc.) are impossible to kill even with the dosages allowable for meat. Compared with the amount of radiation used in medical devices, the dosages approved for food are extremely low. Allowable doses of irradiation do not make food sterile. They do not always kill all the undesirable microorganisms if they are numerous to begin with. Also, an irradiated food can be recontaminated if mishandled. Consequently, while irradiation may have a future role in fruit and vegetable sanitation, it will never effectively guarantee pathogen-free produce, nor will it ever be a substitute for proper sanitation and food safety preventative programs. Different fruits and vegetables differ in the maximum dose that they will tolerate without unacceptable softening or loss of other quality parameters. However, the negative impacts of produce irradiation such as accelerated softening and technical issues (for example, nonhomogenous dosing) have hindered the commercialization of this technology. The USDA has recently been petitioned to allow higher doses to be used, and their decision is pending.

However, it is unclear if irradiation will ever be capable of surface-sterilizing produce without irreparably damaging produce beyond salability. Irradiation dosages necessary to kill viruses and some bacteria are well in excess of the levels which induce damage to produce. Though irradiation has specific uses in produce, such as for phytosanitary and insect quarantine, its effectiveness as a food safety tool is limited. New irradiation technologies such as pulsed electric fields, pulsed UV light, or radio frequency technologies may yet play a role as tools for ensuring the food safety of produce.

Prevention

Good Agricultural Practices (GAPs)

In 1998 the FDA published "Guidance for Industry: Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." Though this document carries no regulatory or legal weight, due diligence requires producers to take prudent steps to prevent contamination of their crops. This document gives guidance on those prudent steps. A number of retail chains have begun to require independent third-party audits of producers based, in part, on this document.

The guide identifies eight food safety principles within the realm of growing, harvesting, and transporting fresh produce and suggests the reader "use the general recommendations in the guide to develop the most appropriate good agricultural and management practices for their operation." The application of the principles is aimed at preventing contamination of produce with human pathogens. The following sections list the eight principles and implementation areas.

The following are the basic principles of GAPs:

- Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred.
- To minimize microbial food safety hazards in fresh produce, growers or packers should use GAPs in those areas over which they have a degree of control, while not increasing other risks to the food supply or the environment.
- Anything that comes in contact with fresh produce has the potential of contaminating it. For most foodborne pathogens associated with produce, the major source of contamination is associated with human or animal feces.
- Whenever water comes in contact with fresh produce, its source and quality dictate the potential for contamination.
- Practices using manure or municipal biosolid wastes should be closely managed to minimize the potential for microbial contamination of fresh produce.
- Worker hygiene and sanitation practices during production, harvesting, sorting, packing, and transport play a critical role in minimizing the potential for microbial contamination of fresh produce.
- All applicable local, State, and Federal laws and regulations, or corresponding or similar laws, regulations, or standards for operators outside the United States for agricultural practices should be followed.
- Accountability at all levels of the agricultural environment (farms, packing facility, distribution center, and transport operation) is important to a successful food safety

program. There must be qualified personnel and effective monitoring to ensure that all elements of the program function correctly and to help track produce back through the distribution channels to the producer.

Land Use. The safety of food grown on any given parcel of land is influenced not only by the current agricultural practices but also by former land use practices. Heavy metals and pesticide residues may persist in soils for long periods of time. Soil should be tested to ensure that dangerously high levels of these compounds are not present. Former land use should also be investigated and documented to ensure that the production land was not formerly used for hazardous waste disposal or for industrial purposes that may have left behind toxic residues. If production land was previously used for agricultural purposes, pesticide use records should be reviewed to ensure that proper pesticide management practices were followed. Production acreage should not have recently been used as a feedlot or for animal grazing, because fecal contamination of the soil may persist.

Fertilizers. Improperly composted or uncomposted manure is a potential source of human pathogens. Human pathogens may persist in animal manure for weeks or even months. *E. coli* O157:H7 has been found to survive in uncomposted dairy manure incorporated into soil for up to 250 days (Suslow 1999). Proper composting via thermal treatment reduces the risk of potential foodborne illness. However, the persistence of many human pathogens in untreated agricultural soils is unknown. Use of inorganic fertilizers, which have been certified to be free of heavy metals and other chemical contaminants, is recommended.

Irrigation Water. Irrigation water is another potential vector by which contaminants may be brought into contact with fruits and vegetables. Deep-well water is less likely to be contaminated with human pathogens than surface water supplies. However, all irrigation water sources should be periodically tested for contamination by pesticides and human pathogens. The presence of *E. coli* is a useful indicator for fecal contamination and possible presence of human pathogens. Inexpensive test kits for generic *E. coli* are available from several vendors. Overhead irrigation systems are more likely than flood, furrow, or drip irrigation to spread contamination since contaminated water is applied directly to the edible portions of fruits and vegetables. Water used to mix or spray agricultural chemicals must be confirmed to be free of pathogens before use.

Pesticide Use. All pesticide use should be done in strict accordance with manufacturer's recommendations as well as Federal, State, and local ordinances. Monitoring and documentation of proper pesticide use should be done to prevent unsafe or illegal residues from contaminating fruits and vegetables. All pesticide applications should be documented, and proper records of application should be available and reviewed by management on a regular basis. Appropriately trained and licensed individuals should perform pesticide use recommendations and applications.

Harvest Operations. During harvest operations, field personnel may contaminate fresh fruits and vegetables by simply touching them with an unclean hand or knife blade. Portable field latrines equipped with hand-washing stations must be available and used by all harvest crew members. Training, monitoring, and enforcement of field worker hygiene practices, such as washing hands after using the bathroom, are necessary to reduce the risk of human pathogen contamination. Once harvested, produce should not be placed on soil before being placed in clean and sanitary field containers. Field harvesting tools should be clean and sanitary and should not be placed directly in contact with soil. Field containers should be cleaned and sanitized on a regular basis and should be kept free of contaminants such as mud, industrial lubricants, metal fasteners, or splinters. Plastic bins and containers are recommended as they are easier to clean and sanitize than wooden ones.

Sanitary Postharvest Handling of Produce. Depending on the commodity, produce may be field-packed in containers that will go all the way to the destination market, or it may be temporarily placed in bulk bins, baskets, or bags that will be transported to a packing shed. Employees, equipment, cold storage facilities, packaging materials, and any water that will contact the harvested produce must be kept clean and sanitary to prevent contamination.

Employee Hygiene. Gloves, hairnets, and clean smocks are commonly worn by packing house employees in export-oriented packing sheds. The cleanliness and personnel hygiene of employees handling produce at all stages of production and handling must be managed to minimize the risk of contamination. Adequate bathroom facilities and hand-washing stations must be provided and used properly to prevent contamination of produce by packing house employees. Shoe- or boot-cleaning stations may also be in place to reduce the amount of field dirt and contamination that enters the packing shed from field operations. Employee training in sanitary food handling practices should be done when an employee is hired, before beginning work, and on a regular basis thereafter. All training should be documented and kept on file.

Equipment. Food contact surfaces on conveyor belts, dump tanks, etc. should be cleaned and sanitized on a regularly scheduled basis with approved cleaning compounds. A 200 ppm (200 $\mu L\ L^{-1}$) NaOCl solution (bleach) is an example of a food-contact-surface sanitizer. Sanitizers should be used only after thorough cleaning with abrasion to remove organic material such as dirt or plant materials. Steam or high-pressure water should be used with care as it may create bacterial aerosols and actually help spread contamination throughout the packinghouse facility.

Cold Storage Facilities. Cold storage facilities, and in particular refrigeration coils, refrigeration drip pans, forced-air cooling fans, drain tiles, walls, and floors, should be cleaned and sanitized on a regular basis. The human pathogen *Listeria monocytogenes* can multiply at refrigerated temperatures in moist conditions and may contaminate produce if condensation from refrigeration units or ceilings drips on to the produce. A common environmental pathogen, *L. monocytogenes*, may get on walls, in drains, and into cooling systems. Comprehensive sanitation programs that target these areas are important in preventing establishment of this pathogen.

Packaging Materials. All packaging materials should be made of food-contact-grade materials to ensure that toxic compounds in the packaging materials do not leach out of the package and into the produce. Toxic chemical residues may be present in some packaging materials due to use of recycled base materials. Packages, such as boxes and plastic bags, should be stored in an enclosed storage area to protect them from insects, rodents, dust, dirt, and other potential sources of contamination. Plastic field bins and totes are preferred to wooden containers since plastic surfaces are more amenable to cleaning and sanitizing. Field bins should be cleaned and sanitized after every use. Wooden containers or field totes are almost impossible to sanitize since they have a porous surface and wooden or metal fasteners, such as nails from wooden containers, may accidentally be introduced into produce. Cardboard field bins, if reused, should be inspected for cleanliness and lined with clean plastic bags before reuse to prevent risk of cross-contamination.

Produce Wash-Water and Hydrocooling Water. All water that comes in contact with produce for washing, hydrocooling, or vacuum cooling must be potable. To achieve this, water should contain between 2 and 7 ppm ($\mu L\ L^{-1}$) free chlorine and have a pH between 6 and 7. Total chlorine up to 200 $\mu L\ L^{-1}$ is allowed by law, though 50 to 100 ppm ($\mu L\ L^{-1}$) is usually sufficient if the pH of the water is between 6 and 7. Alternatively, an oxidation-reduction potential greater than 650 mV using any oxidative sanitizer will ensure that bacteria in the water are killed on contact. Chlorine use prevents cross-contamination of produce in the washing or hydrocooling system but it will not sterilize the produce. Rinsing produce with potable water will reduce the number of microorganisms present on the produce but will not remove all bacteria.

Refrigerated Transport. Produce is best shipped in temperature-controlled refrigerated trucks. Maintaining most perishables below 5 °C (41 °F), except for tropical fruit, will extend shelf-life and significantly reduce the growth rate of microbes, including human pathogens. Cut produce, including tropical fruits, should always be stored below 5 °C (41°F). Trucks used during transportation should be cleaned and sanitized on a regular basis. Trucks that have been used to transport live animals, animal products, or toxic materials should not be used to transport produce.

Recall and Traceback Plans. Recall of product is the last line of defense in a food safety emergency. This action may be initiated by the company, performed on a voluntary basis, or done at the request of the FDA because of a suspected hazard in the product. The FDA has defined three recall classifications and FDA actions. Class I is an emergency situation involving removal of products from the market that could lead to an immediate or long-term life-threatening situation and involve a direct cause-effect relationship; for example, *C. botulinum* in the product. Class II is a priority situation in which the consequences may be immediate or long term and may be potentially life threatening or hazardous to health; for example, *Salmonella* in food. Class III is a routine situation in which life-threatening consequences (if any) are remote or nonexistent. Products are recalled because of adulteration (filth in produce relating to aesthetic quality) or misbranding (label violation), and the product does not involve a health hazard. Every food provider should develop a recall or trace-back plan and an organizational structure that enable it to remove product from the market in a rapid and efficient manner.

Good Manufacturing Practices (GMPs)

GMPs ensure that food for human consumption is safe and has been prepared, packed, and held under sanitary conditions. GMPs are mandatory for the fresh-cut produce industry, but not mandatory for packinghouse or field operations that simply handle whole produce. However, though GMPs are not mandatory for packing sheds, they are mostly good common sense and are recommended for all produce-handling facilities.

The Code of Federal Regulations describes the conditions under which food must be processed and handled. The regulations cover general provisions, buildings and facilities, equipment, production and process controls, and defect action levels. Many of the GMPs are simple good sense, such as washing hands after using the restrooms and wearing hairnets when working with food. Unlike GAPs, GMPs are regulations and have the weight of law: A food processor *must* comply with GMPs. Copies of the Current GMPs (CGMP) can be obtained by subscribing to the Federal Register or by ordering 21 CFR 100-169 **(**Code of Federal Regulations, Title 21, Food and Drugs, Pt. 100-169)**.** Submit a check or money order to Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402; or telephone the Government Printing Office at 202-783-3238 to order by credit card.

Personnel GMPs. Personnel working in food processing plants or packinghouses can be a significant source of food contamination. This includes production employees, maintenance employees, supervisors, and management. It is the responsibility of processing plant management to educate and train all food handlers about sanitary handling of foods. Employees experiencing diarrhea, vomiting, open skin sores, boils, fever, or disease should report these symptoms to their supervisor and should not be allowed to work with food products. All food handlers should have clean outer garments or frocks and thoroughly wash their hands before entering a food processing area, especially after toilet use. No jewelry (earrings, pendants, rings, etc.), pens, or wrist watches should be allowed in food processing areas, because these items may fall into food products unnoticed. Intact, clean, and sanitary gloves and hair restraints should be used by all personnel in food handling areas.

Physical Plant and Grounds. Food processing plants and produce packing houses should be constructed so as to segregate food handling activities from the outside environment. The physical building itself should have no openings or gaps which could allow entrance by rodents, insects, or birds. Surrounding grounds should be free of clutter such as equipment, litter, waste, refuse, or animal feces. No unpaved or dusty roads should be adjacent to food handling facilities, and areas surrounding the structure should be adequately drained so that no standing or pooled water is present. Vegetation surrounding the processing plant should be kept down to prevent the formation of breeding grounds for rodents. Rodent traps should be placed on the outside perimeter of the grounds and be inspected and serviced regularly.

Plant Construction and Design. The most important aspect of sanitary food plant and produce packinghouse design is sufficient space for sanitary operations. Processing areas should be designed for easy cleaning and sanitation. Floors, walls, and ceilings should be made of a cleanable, noncorrosive, nonabsorbent material and be in good repair. Floors should have rounded corner joints where they meet the wall to allow for easy cleaning. Processing plant floors should be constructed of sealed concrete or tile to withstand the physical and chemical abuses from machinery and cleaning chemicals. Equipment should be constructed of stainless steel to prevent corrosion. Overhead pipes, ducts, and fixtures should not be suspended over work areas, and horizontal surfaces of these items should be minimized to reduce accumulation of dust and water condensation. Where possible, overhead structures should be hidden above a false ceiling, and all hoses, pipes and electrical conduits should descend vertically from the ceiling so as to not provide horizontal surfaces for accumulation of filth. Adequate lighting should be provided and all light bulbs should be covered to ensure that broken glass cannot contaminate food products.

All water (rinse, flume, cleaning, ice, etc.) used in food processing must be of proper sanitary quality. Plumbing should be of adequate size and design to handle the amount of product being processed. Produce handling environments are usually wet; therefore, sloping floors with drains should be present to remove excess water from the processing area. Sanitary sewer lines should be separate from floor drains to ensure that cross-contamination of the processing area from sewage backflow does not occur.

An adequate number of toilets and hand-washing stations should be available to accommodate all employees. Restroom facilities should not open into processing areas. Hot running potable water, soap, and hand towels should be available at all times. Signs should be posted to instruct employees to wash their hands after using the restroom. Employee frocks, gloves, and knives should never be taken into the restrooms, and adequate storage space should be made available directly outside the restroom door for temporary storage of these items. Heating, ventilation, and air-conditioning (HVAC) systems may feature filtered positive air pressure in processing plants because of the potential for airborne pathogen contamination. HVAC units should blow air along the ceiling and down the walls to keep the walls dry and free of condensation.

Sanitation Procedures. Cleaning and sanitation are some of the most important programs in any food processing plant or packing shed. Cleaning is the removal, through physical action, of debris and filth. Sanitation is the application of antimicrobial compounds. Sanitation cannot be effective until surfaces are cleaned. Regular and scheduled equipment cleaning and sanitizing ensures that food products are being processed under hygienic conditions. Cleaning and sanitation is best done by a specially trained sanitation and cleaning crew and not by production personnel. A sanitation program in a food processing plant consists of two main elements: a master sanitation schedule and a monitoring program.

Master Sanitation Schedule. A written master sanitation schedule should be in place to ensure that all areas of a food processing plant or packing shed are cleaned and sanitized on a regular basis. The master sanitation schedule should detail the area to be cleaned, the sanitation method, tools, cleaning materials, and frequency of cleaning. There are five steps involved in cleaning and sanitizing:

1. Physical debris removal
2. Rinsing
3. Washing with detergent
4. Second rinsing
5. Sanitizing

It is critical that cleaning—that is, removal of debris and food particles—be done prior to any sanitation steps, because many sanitizers are inactivated by organic materials. Once gross or large pieces of food are removed, equipment should be rinsed with potable water to remove smaller particles. Then, soaps and detergents should be applied. Mild abrasion should be used to scrub equipment clean and remove caked-on food particles and biofilms (layers of bacteria). All soaps and detergents used should be approved for use on food contact surfaces. After cleaning, soaps and detergents should be removed by rinsing equipment with potable water. After rinsing, equipment should be sanitized to kill microbes. Sanitizing consists of rinsing all food contact surfaces with bactericidal compounds such as chlorine, iodine, or quaternary ammonia. Product manufacturer’s directions for sanitizers and cleaning chemicals should be strictly followed.

Written sanitation standard operating procedures (SSOPs) for cleaning and sanitation should be prepared for specific pieces of equipment that are cleaned on a regular basis. This ensures that the equipment is cleaned properly regardless of who does the cleaning. SSOPs should specify the following:

- What: identifies task
- Why: purpose of task
- When: frequency of task
- Who: person responsible for task
- How: steps for completing task

A sample SSOP for sanitation of drains might take the following form:
Sanitation of Drains

Goal: Prevent build-up of contaminants (especially *Listeria monocytogenes*) in drains that could cross-contaminate product

Frequency: Daily

Procedure:

a. Remove all grates and coverings over drains.
b. Remove and dispose of all debris in drains.
c. Rinse drains and drain coverings to remove loose debris.
d. Mix chlorine-based soap as follows.
e. Apply soap to drains and drain coverings.
f. Scrub drains and drain coverings vigorously with brushes to remove invisible films.
g. Rinse thoroughly to remove soap. Must rinse thoroughly for sanitizing solution to be effective.
h. Mix quarternary ammonia sanitizer solution as follows.
i. Irrigate all drains and spray (or soak) coverings with sanitizer solution.
j. Replace grates and drain coverings.
k. The Sanitation Crew Chief then inspects all sanitized drains.
l. The Sanitation Crew Chief writes the time and date and signs the sanitation log for drains. If any drain does not pass inspection, the Crew Chief notes that in the log and the crew must rewash and resanitize until it passes inspection.

Cleaners and Sanitizers. There are numerous cleaning and sanitizing compounds available for use in food processing plants and packing sheds. These compounds fall into five categories:

- Chelators: tie up cations or salts; for example, EDTA
- Alkalines: excellent detergents; for example, sodium hydroxide
- Acids: remove mineral deposits; for example, phosphoric acid
- Wetting agents: emulsify and penetrate soil; for example, alkyl sulfates
- Sanitizers: kill microbes; for example, sodium hypochlorite

Sanitizers are important to reduce microbial populations on all food contact surfaces after cleaning. The most common sanitizers are chlorine, iodine, and quarternary ammonia compounds. Some sanitizers, such as quarternary ammonia compounds, are more effective against certain foodborne pathogens, such as *Listeria monocytogenes*, and less effective against others, such as *Salmonella*. Table 3 shows some of the advantages and disadvantages of using these sanitizers.

Table 3. Comparison of common sanitizers

	Chlorine	Iodine	QUATS	Acid-anionic surfactants
Effectiveness against:				
Gram-positive bacteria, (lactics, clostridia, *Bacillus*, *Staphylococci*)	Good	Best	Good	Good
Gram-negative bacteria (*E. coli*, *Salmonella*, psychrotrophs)	Best	Good	Poor	Good
Yeast and molds	Best	Good	Good	Good
Spores	Best	Poor	Fair	Fair
Viruses	Best	Good	Poor	Poor
Effects on property:				
Corrosive	Fairly	Slightly	No	Slightly
Affected by hard water	No	Slightly	Type A*, No Type B†, Yes	Slightly
Irritating to skin	Yes, >100 $\mu L\ L^{-1}$	Not at levels used	No	Yes
Maximum level permitted by FDA without rinse	200 $\mu L\ L^{-1}$	25 $\mu L\ L^{-1}$	200 $\mu L\ L^{-1}$	200-400 $\mu L\ L^{-1}$ based on type
Affected by organic matter	Most affected	Somewhat	Least affected	Somewhat
Cost	Cheapest	Cheap	Expensive	Expensive

Tests for active residual	Simple	Simple	Difficult	Difficult
Stability in hot solution (>150^{o}F)	Unstable; some compounds stable	Highly unstable	Stable	Stable
Leaves active residue	No	Yes	Yes	Yes
Incompatible with—	Phenols, amines, soft metals	Starch, silver	Anionic wetting agents, soaps, wood, cloth, cellulose, nylon	Cationic surfactants, alkaline cleaners
Effective at neutral pH	Yes	No	Yes	No

Source: Adapted from Katsuyama and Strachan (1980)
*Type A: alkyl dimethyl benzyl ammonium chloride.
†Type B: methyl dodecyl benzyl trimethyl ammonium chloride.

Chlorine is by far the most commonly used sanitizer at 100 to 200 µL L^{-1}. It is important that water containing chlorine be free from organic matter and have a pH between 6.0 and 7.0. If either of these conditions is not met, then the chlorine is ineffective.

Monitoring Program. Before processing or packing begins, sanitation crew performance should be evaluated on a daily basis to ensure that conditions are hygienic. Visual inspection should be performed to ensure that no food particles or foreign matter are present on processing equipment. In particular, areas that are difficult to clean should be inspected, such as the underside of conveyors and peeling equipment. Unfortunately, visual inspection is not enough to ensure that equipment has been sanitized properly. The number of microbes present on processing equipment after sanitation operations should be determined on a regular basis to evaluate sanitation crew performance. Such determination can be made using one of three methods: petri contact plate, surface swabbing, or bioluminescence.

Petri Contact Plate. Plastic petri plates or films contain sterile agar with growth media for microbes and the type of microbes that will grow on these plates is determined by the type of medium used. In this method, petri plates or films are pressed up against food contact surfaces and the location is noted. The plates are then incubated in the laboratory; if microbes were present on the sampled surfaces, they will grow on the agar. A low bacteria count per square centimeter means that the sanitation crew is doing a good job at cleaning and sanitizing. If the number of microbes dramatically increases, an evaluation of sanitation procedures is in order.

Surface Swabbing. A variation of the petri plate method is to use sterile swabs to collect samples from food contact surfaces. Wet sterile swabs are used to brush an area of a food contact surface. The swab is then placed in a container with sterile solution. Bacteria are counted after incubation as above. Swabs and films for environmental sampling are commercially available from several companies.

Bioluminescence. The contact petri plate or swab methods are good for monitoring sanitation crew performance, but results are not available immediately. Another microbe detection method, called bioluminescence, is capable of detecting the presence of microbes immediately. This method relies on measuring the amount of ATP (adenosine triphosphate) that is present on food contact surfaces. ATP is present in all living cells and thus is a good indicator of the presence of organic material. This test is similar to the swab testing method except that the cleanliness of equipment is determined within minutes after the swab is taken. In this test, equipment is swabbed and the amount of ATP present is determined by a chemical test kit. These test kits are available from a number of suppliers. Bioluminescence test results are available immediately and can determine if cleaning and sanitation procedures must be repeated before processing or packing begins.

Hazard Analysis Critical Control Points (HACCPs)

HACCP is a food safety system developed by the Pillsbury Company to reduce risk associated with food eaten by astronauts during space flights. HACCP is a system for the prevention of physical, chemical, or microbial contamination of food. The prime function of HACCP is to prevent identified hazards in food preparation through control of the process. HACCP functions as the final stage of an integrated food safety program and includes Good Agricultural Practices (GAPs), Good Manufacturing Practices (GMPs), and Sanitation Standard Operating Procedures (SSOPs). In fact, HACCP can only be effective if these programs are in place and functioning properly. There is no minimum or maximum number of Critical Control Points (CCPs) in any given operation. What is important is that all potential hazards be addressed through prerequisite programs or HACCP. Those hazards that can be controlled or minimized through quantitative control of a process may be designated CCPs and included in a HACCP program. Fresh-cut processors may have as few as two Critical Control Points (CCPs) in a perfectly adequate HACCP plan.

HACCP is a systems approach to ensure safety of a food product; it is not a means of ensuring food quality. Prevention of physical, chemical, and microbial contamination of produce during packing or processing is essential to ensure production of a safe product. It is recommended that each produce handling operation identify an individual for formal HACCP training and to be in charge of a team responsible for implementing the HACCP program. HACCP programs should be a simple as possible, without an excessive number of CCPs. Each HACCP program is unique and must be tailored to the specific operation.

There are seven basic steps in an HACCP program:

1. Conduct a hazard analysis
2. Determine CCPs to control the identified hazards
3. Establish critical limits for each CCP
4. Establish CCP monitoring requirements
5. Establish corrective actions to be taken when a CCP is outside critical limits
6. Establish record-keeping systems to document the HACCP program
7. Establish procedures to verify that the HACCP program is functioning as intended.

Assessment of Hazards. Each unit operation should be evaluated to identify potential sources of microbial, chemical, and physical hazards that may be introduced into produce. Areas that should be evaluated are growing and harvesting operations, packing shed operations, packaging material and storage areas, and all steps in distribution. This process is best accomplished by a team consisting of both management and production personnel. (Example: Hydrocooling water contamination, microbial or chemical.)

Determination of CCPs to Control the Identified Hazards. The next step in developing a HACCP program is to draw a flow diagram for the specific operation and then determine where each of the identified hazards may be prevented. Each point that will be monitored to control a specific hazard may be designated a CCP. (Example: A chlorine injection system on a hydrocooler.)

Establishment of CCP Limits. Once CCPs have been identified, critical limits must be set to determine when corrective actions need to be taken. Limits must be observable and measurable. (Example: Hydrocooler water must have a chlorine level of 100 to 150 $\mu L\ L^{-1}$ total chlorine and a pH of 6.0 to 7.5.)

Establishment of CCP Monitoring Procedures. It is critical to define clearly how often monitoring will be done, how measurements will be taken, and what documentation will be prepared. (Example: Hydrocooler water pH and chlorine levels will be monitored hourly using a test kit and continuously with a strip chart recorder that has been calibrated daily; hourly pH and chlorine level measurements will be recorded in writing; and the records will be made available for inspection at the hydrocooler.)

Corrective Action When Deviations From Critical Limits Occur. When a deviation from the prescribed limits occurs, corrective action must be taken to eliminate potential contamination. All deviations and corrective actions must be documented in writing. (Example: Chlorine levels are determined to be below 25 $\mu L\ L^{-1}$. Hydrocooling of product is stopped, chlorine levels are adjusted, and all products that had been hydrocooled since the last time the system was verified to be within critical limits are disposed of.)

HACCP Recordkeeping Systems. All paperwork related to the HACCP system must be kept in an orderly and accessible manner. Paperwork kept should include production records (for example, supplier audits), harvesting records (for example, harvest dates and lot numbers), CCP monitoring records, and deviation file (HACCP deviations and corrective actions taken).

HACCP Verification. Periodic HACCP plan review, including review of CCP records, deviations, and random sampling must be conducted to ensure that the HACCP program is functioning properly.

Application of HACCP

When considering applying these principles to a farm operation, one can immediately see the difficulty in controlling naturally occurring hazards. For example, bird droppings in an orchard may potentially represent a hazard from the spread of *E. coli* O157:H7 or *Salmonella* spp. However, it may not be a CCP because there is no way to prevent that hazard by controlling a process. Furthermore, there is no way to quantify and measure bird droppings to know if they are within critical limits. The same would also be true of *Clostridium botulinum* spores in soil. Though they may represent a potential hazard, it would not be appropriate to establish soil as a CCP because it is not practical to measure the spores in soil or to control them through any known process. In fact, most agricultural hazards cannot, and should not, be prevented through HACCP. Instead, the use of GAPs has been identified by the FDA and the produce industry as a more appropriate way to address these hazards.

Another example is a cold storage room in a packinghouse where condensed water from refrigeration coils may contain the bacterium *Listeria monocytogenes* and could drip on the product. This is certainly a significant hazard, but is it a CCP? It would not be practical to develop a process to prevent water from dripping or to quantify and monitor water dripping from refrigeration coils. A more appropriate way to deal with this hazard is through SSOPs. Refrigeration coils and drip pans should be cleaned and sanitized according to a predetermined schedule to prevent the growth of *L. monocytogenes* in the condensate. This way, the hazard is prevented more effectively and more simply than by designating a CCP.

There is no minimum or maximum number of CCPs in any given operation. What is important is that all potential hazards be addressed through prerequisite programs or through HACCP. Those hazards that can be controlled or minimized through quantitative control of a process may be designated CCPs and included in a HACCP program. Fresh-cut processors may have as few as two CCPs in an adequate HACCP plan.

The Fresh-Cut Industry

Consumers expect that fresh-cut processors will manufacture wholesome and nutritious foods. To do this, fresh-cut processors must have systems in place to ensure that products being manufactured do not have physical, chemical, or microbial contaminants introduced during processing and packaging. If such systems are not in place, consumers are at risk and a single incidence of personal injury traced back to a specific food manufacturer may put that company out of business and result in criminal prosecution of the owners and management. Ensuring that food products are manufactured in a safe and wholesome manner does add cost to the final product. However, the long-term success of every food processor depends on its ability to consistently produce safe products. Food safety should not be confused with food quality. Food safety programs simply ensure that food products are safe to consume and prevent injury to consumers. Food safety does not begin at the processing plant receiving dock and the production of raw ingredients should be done following GAPs.

Fresh-cut produce can be damaged through peeling, cutting, slicing, or shredding. These same operations can transfer pathogenic microbes from the surface of the intact produce to the internal tissues. Injured cells and released cell fluids provide a nourishing environment for microbial growth. Maintaining low temperature throughout distribution is critical to maintaining quality of fresh-cut fruits and vegetables. Low temperatures reduce enzymatic reactions and greatly slow down the multiplication of spoilage organisms. Low temperatures also prevent the multiplication of most foodborne pathogens, with the exception of *Listeria monocytogenes* and a few others that are capable of growing, albeit slowly, at refrigerated temperatures.

Emphasis should be placed on preventing contamination by pathogens. The best way to prevent the introduction of pathogens into fresh-cut produce is by employing GAPs, GMPs, SSOPs, and, in some cases, by implementing an effective HACCP program. Such a program identifies potential points of contamination and ensures that those potential hazards are controlled and monitored to enhance safety. HACCP and food safety do not begin and end at the doors of the handling facility. They require that the produce handler work with both suppliers and customers to maintain food safety throughout the production, distribution, and marketing chain.

Sprouts—A Special Case

Over the past several years, sprouts have become a common fresh produce item linked to foodborne illness. A scientific advisory group to the FDA has recognized sprouts as a special problem. This is because bacterial pathogens that may be present at very low levels on sprout seeds at the time of sprouting can multiply to very high levels during the 3- to 5-day sprouting process.

Most sprout outbreaks have been caused by seed that was contaminated with a bacterial pathogen before sprouting began. Pathogens can survive for months under dry conditions used for seed storage. Though contaminated alfalfa seeds have been identified as the source in many outbreaks, clover, radish, and bean sprouts have also been associated with outbreaks. Any type of sprout seed may potentially be contaminated with bacterial pathogens before sprouting.

The FDA published guidelines for sprout processors to reduce the potential for foodborne illness related to sprouts. The guidelines include treatment of seeds in a sanitizer solution (currently a special allowance for 20,000 $\mu L\ L^{-1}$ chlorine) prior to sprouting, as well as testing of the sprout wash-water for *Salmonella*, *E. coli* O157:H7, and *L. monocytogenes* prior to harvest.

The FDA has published two related documents, entitled "Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds" and "Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production." These guidelines are intended to provide recommendations to suppliers of seed for sprouting and to sprout producers about how to reduce microbial food safety hazards found in the production of raw sprouts. The guidelines are also intended to help ensure that sprouts are not a cause of foodborne illness and that those in the sprout industry comply with food safety provisions of the Federal Food, Drug, and Cosmetic Act.

References

Brackett, R.E. 1987. Microbiological consequences of minimally processed fruits and vegetables. J Food Quality 10:195-205.

FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Food Safety Initiative Staff, HFS-32, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, Washington, DC.

Kader, A.A., and C.M. Heintz. 1983. Gamma irradiation of fresh fruits and vegetables - an indexed reference list (1965-1982). Postharvest Hort Ser. no. 4, University of California, Department of Pomology, Davis, CA.

Katsuyama, A.M., and J.P. Strachan. 1980. Principles of Food Processing Sanitation. The Food Processors Institute, Washington, DC.

Suslow, T. 1999. Addressing animal manure management issues for fresh vegetable production. Perishables Handling 98:7-9.

Zhuang, R.Y., L.R. Beuchat, and F.J. Angulo. 1995. Fate of *Salmonella montevideo* on and in raw tomatoes as affected by temperature and treatment with chlorine. Appl. Environ. Microbiol. 61: 2127-2131.

Further Reading

Guidance for Industry: Reducing Microbial Food Safety Hazards for Sprouted Seeds, October 27, 1999, Federal Register, vol. 64, no. 207. (U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, Washington, DC.; http://www.gpo.gov/fdsys/pkg/FR-1999-10-27/pdf/99-27976.pdf

Guidance for Industry: Sampling and Microbial Testing of Spent Irrigation Water During Sprout Production, October 27, 1999, Federal Register, vol. 64, no. 207. (U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, Washington, DC.; http://www.gpo.gov/fdsys/pkg/FR-1999-10-27/pdf/99-27976.pdf

FDA. 1998. Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables. Food Safety Initiative Staff, HFS-32, U.S. Food and Drug Administration, Center for Food Safety and Applied Nutrition, 200 C Street, Washington, DC. http://www.fda.gov/downloads/Food/GuidanceComplianceRegulatoryInformation/GuidanceDocuments/ProduceandPlanProducts/UCM169112.pdf

Beuchat, L.R. 1998. Surface Decontamination of Fruits and Vegetables Eaten Raw: A Review. World Health Organization, Geneva, Switzerland.

Current Good Manufacturing Practices (GMPs) Regulations 21 CFR 100-169. Superintendent of Documents, U.S. Government Printing Office, 732 North Capitol Street, NW, Washington, DC.