Food and Drug Administration U. S. Department of Agriculture Centers for Disease Control and Prevention October 26, 1998

# Guidance for Industry Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables

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U.S. Department of Health and Human Services Food and Drug Administration Center for Food Safety and Applied Nutrition (CFSAN) October 26, 1998

### GUIDANCE FOR INDUSTRY<sup>1</sup> **GUIDE TO MINIMIZE** MICROBIAL FOOD SAFETY HAZARDS FOR FRESH FRUITS AND VEGETABLES

			Table of Contents
<b>Prefa</b>	<u>ice</u>		
Intro	duction		
	Use of This	Guide	
	Basic Princip	ples	
I.	<b>Definitions</b>		
II.	Water		
	A.	Microbial Hazard	
	B.	Control of Potential	Hazards
		1.0	Agricultural Water
		1.1	General considerations
		1.2	Microbial testing of agricultural water
		2.0	Processing Water
		2.1	General Considerations
		2.2	Antimicrobial Chemicals
		2.3	Wash Water
		2.4	Cooling Operations
III.	Manure An	d Municipal Biosolic	
	A.	Microbial Hazard	_
	B.	Control of Potential	Hazards
		1.0	Municipal Biosolids
		2.0	Good Agricultural Practices for Manure Management
		2.1	Treatments to Reduce Pathogen Levels
		2.1.1	Passive treatments.
		2.1.2	Active treatments.
		2.2	Handling and Application
		2.2.1	Untreated Manure
		2.2.2	Treated Manure
		3.0	Animal Feces
IV.	Worker Hea	alth and Hygiene	
	A.	Microbial Hazards	
	B.	Control of Potential	Hazards
		1.0	Personal Health and Hygiene
		2.0	Training
		3.0	Customer-Pick Operations and Road-Side Produce Stands
V.	Sanitary Fa	cilities	•
	A.	Microbial Hazards	
	B.	Control of Potential	Hazards
		1.0	Toilet Facilities and Handwashing Stations
		2.0	Sewage Disposal
VI.	Field Sanita	<u>ıtion</u>	
	A.	Microbial Hazards	
	B.	Control of Potential	Hazards
		1.0	General Harvest Considerations
		2.0	Equipment Maintenance
VII.	<b>Packing Fac</b>	cility Sanitation	
	A.	Microbial Hazard	
	B.	Control of Potential	Hazards
		1.0	General Packing Considerations
		2.0	General Considerations for Facility Maintenance
		3.0	Past Control

VIII. Transportation

A. Microbial Hazard

B. Control of Potential Hazards

1.0 General Considerations

2.0 General Transport Considerations

IX. <u>Traceback</u> X. <u>Conclusion</u>

References Appendix

#### **PREFACE**

Fresh fruits and vegetables are important to the health and well being of the American consumer. Consumers enjoy one of the safest supplies of fresh produce in the world. However, over the last several years, the detection of outbreaks of foodborne illness associated with both domestic and imported fresh fruits and vegetables has increased. In a January 1997 radio address, President Clinton announced a Food Safety Initiative to improve the safety of the nation's food supply (Ref. 1). In May of 1997, as part of the President's Food Safety Initiative, the Department of Health and Human Services, the U.S. Department of Agriculture (USDA), and the Environmental Protection Agency (EPA) sent to the President a report that identified produce as an area of concern (Ref. 2). On October 2, 1997, President Clinton announced a plan entitled "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables" (produce safety initiative) to provide further assurance that fruits and vegetables consumed by Americans, whether grown domestically or imported from other countries, meet the highest health and safety standards (Ref. 3). As part of this initiative, the President directed the Secretary of Health and Human Services, in partnership with the Secretary of Agriculture and in close cooperation with the agricultural community, to issue guidance on good agricultural practices (GAPs) and good manufacturing practices (GMPs) for fruits and vegetables (Ref. 3).

In response to this directive, the FDA and USDA are issuing "Guidance for Industry -- Guide to Minimize Microbial Food Safety Hazards for Fresh Fruits and Vegetables." This guidance document ("the guide") addresses microbial food safety hazards and good agricultural and management practices common to the growing, harvesting, washing, sorting, packing, and transporting of most fruits and vegetables sold to consumers in an unprocessed or minimally processed (raw) form. This voluntary, science-based guidance can be used by both domestic and foreign fresh fruit and vegetable producers to help ensure the safety of their produce. The voluntary guidance is consistent with U.S. trade rights and obligations and will not impose unnecessary or unequal restrictions or barriers on either domestic or foreign producers.

The produce guide is guidance and it is not a regulation. As guidance and if applied as appropriate and feasible to individual fruit and vegetable production operations, the guide will help to minimize microbial food safety hazards for fresh produce. Because it is guidance, and not a regulation, the guide does not have the force and effect of law and thus is not subject to enforcement. Operators should use the general recommendations in this guide to tailor food safety practices appropriate to their particular operations. In no case do the recommendations in this guide supercede applicable Federal, state, or local laws or regulations for U.S. operators. Operators outside of the U.S. should follow corresponding or similar standards, laws or regulations.

The guide is one of the first steps under the President's produce safety initiative to improve the safety of fresh produce as it moves from the farm to the table. The guide focuses on the production and packing of fresh produce. However, the food safety initiative is not limited to the farm. It will focus on all stages of the farm-to-table food chain. For example, FDA's Food Code provides advice and information to state and local agencies about safe food handling practices in grocery stores, institutions, restaurants, and other retail establishments (Ref. 4). FDA is also actively seeking assistance from the Conference for Food Protection (a consortium of state, local and Federal agencies, academia, and consumer and industry representatives) in identifying practical interventions that may assist in reducing or eliminating microbial contamination of fresh produce at the retail level. In addition, as part of the President's food safety initiative, educational outreach programs, such as the recently initiated "Fight Bac" campaign, will promote improved safe food handling by consumers.

Identifying and supporting research priorities designed to help fill gaps in food safety knowledge is another focus of the food safety initiative. In the longterm, research and risk assessment on fresh produce will be incorporated in the multi-year food safety initiative research planning process. The overall goal of research is development of cost-effective intervention and prevention strategies to reduce the incidence of foodborne illness. Research will also support development of improved detection methods targeted to sources of contamination.

Growers, packers, and shippers are urged to take a proactive role in minimizing food safety hazards potentially associated with fresh produce. Being aware of, and addressing, the common risk factors outlined in this document will result in a more effective, cohesive response to emerging concerns about the microbial safety of fresh fruits and vegetables. Furthermore, operators should encourage the adoption of safe practices by their partners along the farm-

to- table food chain, including transporters of produce, such as distributors, exporters, importers, retailers, food service operators, and consumers, to ensure that each individual effort will be enhanced.

#### **Footnotes**

<sup>&</sup>lt;sup>1</sup> This document has been prepared as guidance by the Food and Drug Administration (FDA) and the USDA. This guidance represents the current thinking of FDA and USDA on a number of microbial food safety hazards and on good agricultural and management practices common to the growing, packing, and transport of most fresh fruits and vegetables. It does not create or confer any rights for or on any person and does not operate to bind FDA or USDA or the public. The agencies encourage growers, packers, and shippers to use the general recommendations in this guidance to tailor food safety practices appropriate to their particular operations. An alternative approach may be used if such approach would effectively serve to reduce microbial hazards that could result in foodborne illness and if such approach satisfies applicable statutes and regulations.

<sup>&</sup>lt;sup>2</sup> FDA and USDA, "Initiative to Ensure the Safety of Imported and Domestic Fruits and Vegetables: Status Report," February 24, 1998.

#### INTRODUCTION

The importance and influence of the diet on health is undisputed. Several chronic diseases of major public health concern in the U.S., such as coronary heart disease and some types of cancer, are associated with dietary excess or imbalance. Current dietary guidelines from Federal government agencies and nationally recognized health professional organizations recommend decreased consumption of fats (especially saturated fat) and cholesterol, maintenance of desirable body weight, and increased consumption of fruits and vegetables (five or more servings daily) and grain products (six or more servings daily). Recognition of the importance of routine fruit and vegetable consumption, together with the marked increase in the year-round availability of fresh produce from a global market, has contributed to the substantial increase in consumption of fresh fruits and vegetables in the United States over the past two decades.

Whereas the health benefits associated with regular consumption of fresh fruits and vegetables have been clearly demonstrated, an increasing- though still small- proportion of reported outbreaks of foodborne illness are traced to fresh produce (Ref. 15). Recent outbreaks of foodborne illness associated with produce, including *E. coli* O157:H7 in mesclun mix lettuce and *Cyclospora* in imported raspberries, have raised concerns regarding the potential safety of fruits and vegetables that are not subsequently processed to reduce or eliminate pathogens. However, no estimates are available on the incidence and prevalence of foodborne infection associated with the consumption of fresh produce.

#### Use of This Guide

Because of the diversity of agricultural practices and commodities, practices recommended to minimize microbial contamination will be most effective when adapted to specific operations.

This guide is intended to assist the U.S. and foreign produce industry in enhancing the safety of domestic and imported produce by addressing common areas of concern in the growing, harvesting, sorting, packing, and distribution of fresh produce. The guide identifies the broad microbial hazards associated with each area of concern, the scientific basis of that concern, and good agricultural and management practices for reducing the risk of microbial contamination in fresh produce.

The scientific basis for reducing or eliminating pathogens in an agricultural setting is evolving and not yet complete. Thus, the examples of good agricultural practices and good management practices presented in the guide may not apply to all types of fresh and minimally processed produce and are intended to be implemented where appropriate by all industry operators. Therefore, the examples are intended to build broad industry understanding and awareness of those practices that individual growers, packers, and shippers may consider and incorporate in their own operations. Because of the diversity of agricultural production practices and commodities, procedures recommended to minimize microbial contamination will be most effective when these general concepts are adapted to specific operations.

Government agencies recognize that the agricultural community has made a significant effort to adjust and adopt good agricultural practices to help minimize microbial food safety hazards in produce. Several fresh fruit and vegetable trade organizations, universities, state and local government agencies, and countries exporting produce to the United States have taken strong leadership roles in assisting growers, packers, and shippers in identifying potential hazards associated with their operations. These efforts have included the development of quality assurance programs, good manufacturing practices, and good agricultural and management practice guidance documents; funding of agriculture research studies; and sponsoring educational initiatives. The intent of the guide is to build on those earlier and continuing efforts and to develop national guidelines to enhance the consistency and scientific basis of food safety initiatives throughout the country.

This document represents generally accepted, broad-based agricultural guidance, developed from current knowledge of food safety practices of FDA, USDA, and others. It was developed in cooperation with experts from several Federal and state government agencies and the fresh produce industry. The guide cannot address all microbiological hazards potentially associated with fresh produce, but it can provide the framework for identifying and implementing appropriate measures most likely to minimize risk on the farm, in the packinghouse, and during transport.

There are several important considerations to remember when using this guide.

- 1) The guide focuses on microbial hazards for fresh produce. The guide does not specifically address other areas of concern to the food supply or the environment (such as pesticide residues or chemical contaminants). In evaluating the recommendations in this guide that are most appropriate for reducing microbial hazards in their individual operations, growers, packers, and shippers should strive to establish practices that do not inadvertently increase other risks to the food supply or the environment (e.g., excessive packaging or improper use and disposal of antimicrobial chemicals).
- 2) The guide focuses on risk reduction not risk elimination. Current technologies cannot eliminate all potential food safety hazards associated with fresh produce that will be eaten raw.

- 3) The guide provides broad, scientifically based principles. Operators should use the guide to help assess microbiological hazards within the context of the specific conditions (climatic, geographical, cultural, economic) that apply to their own operation and implement appropriate and cost effective risk reduction strategies.
- 4) As new information and technological advances expand the understanding of those factors associated with identifying and reducing microbial food safety hazards, the agencies will take steps (such as revising this guide or providing supplements or additional guidance documents, as appropriate) to update the recommendations and information contained in this guide.

Operators are encouraged to seek additional advice from their state and local Departments of Public Health, Environment, Agriculture, extension services and Federal agencies.

**Basic Principles** 

Use the general recommendations in this guide to develop the most appropriate good agricultural and management practices for your operation.

This guidance document is based upon certain basic principles and practices associated with minimizing microbial food safety hazards from the field through distribution of fresh fruits and vegetables.

By identifying basic principles of microbial food safety within the realm of growing, harvesting, packing, and transporting fresh produce, users of this guide will be better prepared to recognize and address the principal elements known to give rise to microbial food safety concerns.

<u>Principle 1.</u> Prevention of microbial contamination of fresh produce is favored over reliance on corrective actions once contamination has occurred.

<u>Principle 2.</u> To minimize microbial food safety hazards in fresh produce, growers, packers, or shippers should use good agricultural and management practices in those areas over which they have control.

<u>Principle 3.</u> Fresh produce can become microbiologically contaminated at any point along the farm-to-table food chain. The major source of microbial contamination with fresh produce is associated with human or animal feces.

<u>Principle 4.</u> Whenever water comes in contact with produce, its source and quality dictates the potential for contamination. Minimize the potential of microbial contamination from water used with fresh fruits and vegetables.

<u>Principle 5.</u> Practices using animal manure or municipal biosolid wastes should be managed closely to minimize the potential for microbial contamination of fresh produce.

**<u>Principle 6.</u>** 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.

<u>Principle 7.</u> Follow all applicable local, state, and Federal laws and regulations, or corresponding or similar laws, regulations, or standards for operators outside the U.S., for agricultural practices.

<u>Principle 8.</u> Accountability at all levels of the agricultural environment (farm, 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.

#### I. DEFINITIONS

The following definitions are applicable to this guidance document.

Agricultural water refers to water used in the growing environment (for example, field, vineyard, or orchard) for agronomic reasons. It includes water used for irrigation, transpiration control (cooling), frost protection, or as a carrier for fertilizers and pesticides. Occasionally a more specific term may be used, such as "irrigation water." Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches, open canals, impoundments (such as ponds, reservoirs, and lakes), wells, and municipal supplies.

<u>Adequate</u> means that which is needed to accomplish the intended purpose in keeping with good practice. <u>Clean</u> means that food or food-contact surfaces are washed and rinsed and are visually free of dust, dirt, food residues, and other debris.

<u>Composting</u> refers to a managed process in which organic materials, including animal manure and other wastes, are digested aerobically or anaerobically by microbial action.

<u>Control</u> means (a) to manage the conditions of an operation in order to be consistent with established criteria, and (b) to follow correct procedures and meet established criteria.

<u>Control measure</u> means any action or activity that can be used to prevent, reduce, or eliminate a microbiological hazard.

<u>Facility</u> means the buildings and other physical structures used for or in connection with the harvesting, washing, sorting, storage, packaging, labeling, holding, or transport of fresh produce.

<u>Food-contact surfaces</u> are those surfaces that contact fresh produce and those surfaces from which drainage onto the produce or onto surfaces that contact the produce may occur during the normal course of operations. "Food-contact surfaces" includes equipment, such as containers and conveyor belts that contact fresh produce, used in harvesting, post harvesting, and packing operations. It would not include tractors, forklifts, handtrucks, pallets, etc. that are used for handling or storing large quantities of contained or packed fresh produce and that do not come into actual contact with the food.

<u>Fresh fruits and vegetables</u> refers to fresh produce that is likely to be sold to consumers in an unprocessed or minimally processed (i.e., raw) form. Fresh produce may be intact, such as strawberries, whole carrots, radishes, and fresh market tomatoes, or cut during harvesting, such as celery, broccoli, and cauliflower. The guidance in this document is also applicable to "fresh cut" produce, such as pre-cut, packaged, ready-to-eat salad mixes. However, some fresh produce specialty items, such as fresh cut produce, may be subject to additional processing steps and/or handling that may warrant consideration of specific good manufacturing practices in addition to the good agricultural and management practices covered in this guidance document.

Good management practices refers to general practices to reduce microbial food safety hazards. The term may include both "good agricultural practices" used in growing, harvesting, sorting, packing, and storage operations and "good manufacturing practices" used in sorting, packing, storage, and transportation operations.

<u>Microorganisms</u> includes yeasts, molds, bacteria, protozoa, helminths (worms), and viruses. Occasionally, the term "microbe" or "microbial" is used instead of the term "microorganism."

Microbial hazard means occurrence of a microorganism that has the potential to cause illness or injury.

<u>Municipal biosolids</u> (biosolids) are the by-product of human waste treatment by local government that may be used as fertilizer or as a soil amendment.

<u>Operator</u> means the person or persons who have day-to-day responsibility for the production, harvesting, washing, sorting, cooling, packaging, shipping, or transportation of fresh fruits and vegetables, and responsibility for management of all employees who are involved in each of these activities.

Pathogen means a microorganism capable of causing disease or injury.

<u>Pest</u> refers to any animal or insect of public health importance including, but not limited to, birds, rodents, cockroaches, flies, and larvae, that may carry pathogens that can contaminate food.

<u>Processing water</u> means water used for post-harvest treatment of produce, such as washing, cooling, waxing, and product transport.

<u>Sanitize</u> means to treat clean produce by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the product or its safety for the consumer.

<u>Sanitize</u> (food contact surfaces) means to adequately treat clean food-contact surfaces by a process that is effective in destroying or substantially reducing the numbers of microorganisms of public health concern, as well as other undesirable microorganisms, without adversely affecting the quality of the involved product or its safety for the consumer. It means the application of cumulative heat or chemicals on cleaned food-contact surfaces that, when evaluated for efficacy, is sufficient to reduce populations of representative microorganisms by 5 log or 99.999% (Ref. 4).

<u>Transporter</u> means the operator of a conveyance such as a truck, railcar, vessel, or aircraft used to transport fresh produce from grower to market.

# Wherever water comes into contact with fresh produce, its quality dictates the potential for pathogen contamination.

Water use in crop production involves numerous field operations including irrigation, applications of pesticides and fertilizers, cooling, and frost control. Post-harvest uses include produce rinsing, cooling, washing, waxing, and transport. Water of inadequate quality has the potential to be a direct source of contamination and a vehicle for spreading localized contamination in the field, facility, or transportation environments. Wherever water comes in contact with fresh produce, its quality dictates the potential for pathogen contamination. If pathogens survive on the produce, they may cause foodborne illness.

#### A. Microbial Hazard

Water can be a carrier of many microorganisms including pathogenic strains of *Escherichia coli*, *Salmonella* spp., *Vibrio cholerae*, *Shigella* spp., *Cryptosporidium parvum*, *Giardia lamblia*, *Cyclospora cayetanensis*, *Toxiplasma gondii*, and the Norwalk and hepatitis A viruses. Even small amounts of contamination with some of these organisms can result in foodborne illness.

As discussed in Section V. (Traceback), it is often difficult to identify with certainty the source of microbial contamination for fresh produce. It is not currently known what proportion of produce may become contaminated by water used in agricultural or packing facility operations. However, research has shown that the use of contaminated irrigation water can increase the frequency of pathogen isolation from harvested produce (Refs. 5 and 6). In 1990 and 1993, two outbreaks, involving at least 300 cases in four states attributed to *Salmonella* species, were linked to consumption of fresh tomatoes (Refs. 7 and 8). Tomatoes from both outbreaks were traced back to a single packing facility where a water-bath appeared to be the likely source of contamination. Growers and packers are urged to take a proactive role in minimizing those microbial hazards over which they have some control.

#### **B.** Control of Potential Hazards

In general, the quality of water in direct contact with the edible portion of produce may need to be better than the quality of water in which contact with the edible portion of the plant is minimal.

The quality of water, how and when it is used, and the characteristics of the crop influence the potential for water to contaminate produce. In general, the quality of water in direct contact with the edible portion of produce may need to be of better quality compared to uses where there is minimal contact. Other factors that influence the potential for contact with waterborne pathogens, and their likelihood of causing foodborne illness, include the condition and type of crop, the amount of time between contact and harvest, and post-harvest handling practices. Produce that has a large surface area (such as leafy vegetables) and that with topographical features (such as rough surfaces) that foster attachment or entrapment may be at greater risk from pathogens, if they are present, especially if contact occurs close to harvest or during post-harvest handling. Some sectors of the produce industry use water containing antimicrobial chemicals to maintain water quality or minimize surface contamination.

Operators should consider the following issues and practices when assessing water quality and in applying controls to minimize microbial food safety hazards. Not all of the following recommendations will be applicable or necessary for all operations. Rather, growers and packers should select practices, or combinations of practices, appropriate to their operations and the quality of their water supply, to achieve food safety goals.

#### 1.0 Agricultural Water

Water quality should be adequate for its intended use. Where water quality is unknown or cannot be controlled, growers should use other good agricultural practices to minimize the risk of contamination.

Agricultural water quality will vary, particularly surface waters that may be subject to intermittent, temporary contamination, such as waste water discharge or polluted runoff from upstream livestock operations. Ground water that is influenced by surface water, such as older wells with cracked casings, may also be vulnerable to contamination. Practices to help ensure adequate water quality may include ensuring that wells are properly constructed and protected, treating water to reduce microbial loads, or using alternative application methods that reduce or avoid water-to-produce contact. The feasibility of these and other practices will depend on available water sources, the intended water use and the needs and resources of the particular produce operation.

#### 1.1 General considerations

 Identify the source and distribution of water used and be aware of its relative potential for being a source of pathogens.

Typical sources of agricultural water include flowing surface waters from rivers, streams, irrigation ditches, and open canals; impoundments such as ponds, reservoirs, and lakes; groundwater from wells; and municipal supplies. It is generally assumed that groundwater is less likely to be contaminated with high

levels of pathogens than surface water. Under certain conditions, shallow wells and improperly constructed or older wells may be under the influence of surface water and thus more likely to be susceptible to contamination.

#### • Maintain wells in good working condition.

Growers with older wells (e.g., wells constructed 30 - 40 years ago, and especially wells constructed before 1925), or who have other reasons for concern about the condition of their well and possible contamination, may want to have their well examined by a water quality expert. Programs available from County Extension Offices, and state and local Public Health and Environmental Protection Agencies may help growers determine the condition of their wells.

#### Review existing practices and conditions to identify potential sources of contamination.

Agricultural water can become contaminated, directly or indirectly, by improperly managed human or animal waste. Human contamination may occur from improperly designed or malfunctioning septic systems and sewage treatment facility discharges such as combined sewer overflows and storm sewer overflows. Examples of on-site sources of contamination from animal waste are animal pasturing in growing areas; manure storage adjacent to crop fields; leaking or overflowing manure lagoons; uncontrolled livestock access to surface waters, wells, or pump areas; and high concentrations of wildlife. These and other potential sources of water contamination should be assessed and controlled to the extent feasible to minimize microbial food safety hazards.

#### Be aware of current and historical use of land.

Agricultural water is frequently a shared resource. In some regions, agricultural water comes from surface waters that travel some distance before reaching the produce growing area. While growers may not have control over factors that affect the watershed, awareness of potential problems helps determine which control options are most appropriate. In assessing water quality, operators should consider what affects their portion of the watershed. Growers may consider questions such as:

- -What is the prevalence of animal production in the region?
- Do feedlots, animal pastures, and dairy operations in the region use fences or other barriers to minimize animal access to shared water sources?
- Is manure applied to land by many farms in the region?
- Do local rainfall patterns and topography impact the likelihood of contaminated runoff from these operations reaching surface waters?
- Are controls generally in place to minimize contamination of agricultural waters from other farm or animal operations?

At the individual field, orchard, or vineyard level, the topography of the land and current and historical use of adjacent lands all affect the potential for water to become contaminated, if pathogens are present, and for spreading pathogens to fruits and vegetables. Growers should evaluate their production areas in terms of their proximity to surrounding land uses that pose a potential for polluted runoff from heavy rainfall.

#### Consider practices that will protect water quality.

As mentioned above, growers may not have control over factors that affect the watershed. However, where a potential source of microbial contamination can be identified and controlled, growers should consider practices to protect the quality of agricultural water. Good agricultural practices may include protecting surface waters, wells, and pump areas from uncontrolled livestock or wildlife access to limit the extent of fecal contamination. Soil and water conservation practices such as grass/sod waterways, diversion berms, runoff control structures, and vegetative buffer areas may help prevent polluted runoff water from contaminating agricultural water sources and produce crops.

#### • Consider irrigation water quality and use.

There is general scientific agreement that irrigation practices that expose the edible portion of plants to direct contact with contaminated water may increase microbial food safety risks (Ref. 10), especially for those crops and regions where irrigation is likely to occur close to harvest. To the extent feasible, growers should follow good agricultural practices that minimize the potential for contaminated water to contact the edible portion of the crop .

Irrigation needs will vary with crop and region. Growers should first concentrate on protecting and maintaining water quality. However, where water quality is unknown or cannot be controlled, growers may want to consider irrigation practices that minimize contact between water and the edible portion of the crop. Where available and appropriate, growers may want to consider low volume sprays, drip, furrow, or underground irrigation as part of their overall program. Alternative approaches may also be used. Conversely, if knowledge or testing indicates water quality is good (such as water from properly constructed wells or municipal water supplies), the risk of water serving as a direct source of microbial contamination is low, regardless of the type of irrigation system used. Further, for some crops, such as root crops or low growing crops, it may not be possible to effectively minimize contact between irrigation water and the edible portion of the crop.

#### 1.2 Microbial testing of agricultural water

There are a number of gaps in the science upon which to base a microbial testing program for agricultural water and microbial testing of agricultural water may be of limited usefulness. Growers concerned about water quality should first focus their attention on good agricultural practices (such as manure management and runoff controls) to maintain and protect the quality of their water sources. Growers interested in testing the microbial quality of agricultural water sources may want to consider the following:

- Growers may elect to test their water supply for microbial contamination on a periodic basis, using standard indicators of fecal pollution, such as *E. coli* tests, which may be performed by commercial, State, or local government laboratories. However, bacterial safety of water does not necessarily indicate the absence of protozoa and viruses.
- Where agricultural water comes from public sources, information on microbial analysis of the water may be available from the local water authority.
- Water quality, especially surface water quality, can vary with time (e.g., seasonally or even hourly), and a single test may not indicate the potential for water to be contaminated. Furthermore, testing water may not reveal specific pathogens if they are present in low numbers. However, appropriate microbiological testing may be useful for confirming water quality concerns in extreme situations (e.g., polluted water source) and in assessing the effectiveness of certain control programs (e.g., clean-up of well water).
- Growers can consult local water quality experts, such as state or local Environmental Protection or Public Health agencies, extension agents or land grant universities, for advice appropriate for individual operations.

#### 2.0 Processing Water

Processing water should be of such quality that it does not contaminate produce.

Water used during the post-harvest handling of fruits and vegetables often involves a high degree of water-to-produce contact. Although water is a useful tool for reducing potential contamination, it may also serve as a source of contamination or cross-contamination. Reusing processing water may result in the build-up of microbial loads, including undesirable pathogens from the crop. Operators should institute practices to ensure that water quality is adequate for its intended use, both at the start and at the end of all post-harvest processes.

#### 2.1 General Considerations

- Follow good manufacturing practices to minimize microbial contamination from processing water.
  - Water quality needs may vary depending on where the water use falls within the series of processes and whether a particular process is followed by additional cleaning processes. For example, water quality needs may be greater for water used for a final rinse before packaging compared with water in a dump tank where field soil from arriving produce quickly mixes with the water.
  - Water quality consistent with U.S. EPA requirements for drinking water, or similar standards, is recommended (Currently, the Total Coliform Rule and the Surface Water Treatment Rule, See Appendix 2 for information on obtaining copies of EPA rules and regulations). While water quality management may vary throughout all operations, packers should follow good manufacturing practices to minimize the potential for the introduction or spread of pathogens via processing water. Water that meets the microbial standards for drinking water is considered "safe and sanitary."
  - Where water is reused for a series of processes, it is recommended that whenever possible, water flow counter to the movement of produce through the different unit operations. For example, water might be used first in a final rinse then reused in an earlier unit operation, such as a dump tank.
  - Good Manufacturing Practices (GMPs) for water used for food and food contact surfaces in processing facilities are in Title 21 of the Code of Federal Regulations (CFR), sections 110.37(a) and 110.80(a)(1). 21 CFR 110.19 provides an exemption from the requirements in 21 CFR part 110 for establishments engaged solely in the harvesting, storage, or distribution of raw agricultural commodities. However, U.S. operators using water for post-harvest operations in the field or packing facility are encouraged to consider those good manufacturing practices in part 110, that are applicable to their operations. Foreign operators are encouraged to consider corresponding or similar provisions. (See Appendix 2 for information on how to order copies of the CFR.)
- Consider practices that will ensure and maintain water quality. Such practices may include:
  - Perform periodic water sampling and microbial testing;
  - Change water as necessary to maintain sanitary conditions. Consider developing SOPs (standard operating procedures or sanitary operating plans), including water change schedules, for all processes that use water;
  - Clean and sanitize water contact surfaces, such as dump tanks, flumes, wash tanks, and hydrocoolers, as often as necessary to ensure the safety of produce;
  - Install backflow devices and legal air gaps, as needed, to prevent contamination of clean water with potentially contaminated water (such as between potable water fill lines and dump tank drain lines; and
  - Routinely inspect and maintain equipment designed to assist in maintaining water quality, such as chlorine injectors, filtration systems, and backflow devices, to ensure efficient operation.

# Prevention of contamination is preferred over application of antimicrobial chemicals after contamination occurs.

#### 2.2 Antimicrobial Chemicals

Prevention of contamination is preferred over corrective actions once contamination has occurred. However, antimicrobial chemicals in processing water are useful in reducing microbial build-up in water and may reduce microbial load on the surface of produce. Thus, antimicrobial chemicals may provide some assurance in minimizing the potential for microbial contamination.

The effectiveness of an antimicrobial agent depends on its chemical and physical state, treatment conditions (such as water temperature, acidity [pH], and contact time), resistance of pathogens, and the nature of the fruit or vegetable surface. Chlorine, for example, is commonly added to water at 50 - 200 ppm total chlorine, at a pH of 6.0 - 7.5, for post-harvest treatments of fresh produce, with a contact time of 1 - 2 minutes.

Ozone has been used to sanitize wash and flume water in packinghouse operations. Ultraviolet radiation may also be used to disinfect processing water. Chlorine dioxide, trisodium phosphate, and organic acids (such as lactic and acetic acids) have been studied for use as antimicrobial agents in produce wash water, although more research needs to be done. Operators should consider options for water sanitation most appropriate for their individual operations.

- All chemical substances that disinfect wash water and contact food must be used in accordance with FDA and EPA regulations. Operators outside the U.S. should follow corresponding or similar national or regional laws or regulations. (See Appendix 2 for information on obtaining copies of FDA and EPA regulations.)
- Operators should carefully read antimicrobial chemical labels, regulations, and other relevant information. Operators should follow manufacturers' directions for correct mixing of antimicrobial chemicals to obtain effective concentrations and to minimize safety hazards. Operators should not exceed recommended levels and must not exceed allowable levels of antimicrobial chemicals in wash water. Excessive concentrations of antimicrobial chemicals (such as chlorine) can damage equipment, reduce produce quality, be harmful to worker health, and may pose a hazard to consumers.
- Antimicrobial chemical levels should be routinely monitored and recorded to ensure that they are maintained at appropriate concentrations. Other parameters (such as pH, temperature, and oxidation reduction potential [ORP]) that indicate levels of active agents or that affect the effectiveness of the antimicrobial used, should also be monitored and recorded. Operators should establish SOPs for monitoring, recording, and maintaining antimicrobial chemical levels.
- As organic materials and microbial load increases in wash water, the efficacy of antimicrobial chemicals decreases, rendering them inactive against microorganisms. For some operations, filtering recirculating water or using a net to scoop plant material or debris from tank surfaces, may help reduce the build-up of organic material.
- -Surface treatments with some antimicrobial chemicals may need to be followed by a clean water rinse to remove any treatment residues.
- -Operators should contact chemical companies that sell antimicrobial chemicals for additional technical assistance.

#### 2.3 Wash Water

Washing fresh produce (also known as surface treatment) can reduce the overall potential for microbial food safety hazards. This is an important step since most microbial contamination is on the surface of fruits and vegetables. If pathogens are not removed, inactivated, or otherwise controlled, they can spread to surrounding produce, potentially contaminating a greater proportion of the produce.

A number of post-harvest processes, such as hydrocooling, use of dump tanks, and flume transport, involve a high degree of water-to-produce contact. Packers should follow good manufacturing practices to maximize the potential for these processes to assist in cleaning produce.

#### • Use appropriate wash methods.

- Vigorous washing of produce not subject to bruising or injury may increase the likelihood of pathogen removal. Brush washing is more effective than washing without brushes. Brushes used in brush washing must be cleaned frequently.
- Different methods are used to wash different types of produce, including submersion, spray, or both. Spray wash treatments may be less likely to directly spread microbial contaminants. However, spray wash treatments may spread pathogens by splashing or by aerosol, or on food contact surfaces, such as brushes and utensils. Further, if water is contaminated during washing and then reused, it can be a vehicle for spreading contamination. Therefore, regardless of wash method used, operators are encouraged to follow good management practices that ensure and maintain adequate water quality.

#### • Maintain the efficacy of wash treatments.

Wash water, even with antimicrobial chemicals, likely reduces but may not eliminate pathogens on the surface of produce. Antimicrobial washes generally reduce microbial populations by 10- to 100-fold. Operators should adopt practices to maintain the efficacy of wash treatments.

- -For some operations, a series of washes may be more effective than a single wash. For example, packers may consider using an initial wash treatment to remove the bulk of field soil from produce followed by additional washes and/or a sanitizing dip and a final fresh, clean water rinse.
- Consider the wash water temperature for certain produce.

- Removing field heat is a primary consideration in maintaining the quality of many types of produce. However, for some types of produce (apples, celery, tomatoes) the temperature of wash water should be greater than that of the produce or a pressure differential results that can cause water to be pulled into the plant material, causing pathogens that may be present on the produce surface or in the water to be internalized. If pathogens are pulled into the produce, washing is unlikely to reduce these pathogens (Refs. 9 and 10). Denser products (such as carrots) do not appear to be affected by water temperature differences. For products that may be susceptible to internalization of pathogens, the recommended temperature differential may be achieved either by heating water or by air cooling produce before immersion.
- When it is not practical to expose produce to warmer water temperatures, good manufacturing practices to minimize pathogens in the water or on the surface of produce are especially important. Such practices may include using antimicrobial chemicals in the wash water, using spray-type wash treatments instead of submerging produce, and ensuring that both produce and water are clean before produce is submerged.

#### • Consider alternative treatments for water-sensitive produce.

- Dry cleaning (e.g., brushing, scraping, blowing air) may be used with some produce that cannot tolerate water. In these cases, periodic equipment clean up and sanitation will reduce the potential for cross-contamination.
- Treatment of produce with ionizing radiation at doses up to 1 kGy (1 kiloGray or 100 krad) is permitted for inhibition of ripening or sprouting, and for insect control (21 CFR 179.26). At these doses, there would also be some reduction in pathogens that may be present. The extent of any reduction will be dependent on the radiation sensitivity of the particular pathogen as well as the actual dose used. For example, doses needed to achieve a 10-fold reduction in Salmonella are typically higher than those needed to achieve the same reduction in *E. coli* O157:H7. The actual effectiveness of any low-dose radiation treatment in pathogen control will, in addition, be strongly dependent on the load initially present.

#### 2.4 Cooling Operations

Various methods are available for cooling produce, including water, ice, and forced air. The method used depends on the fruit or vegetable and the resources of the operator. In most instances, cooling with air (such as vacuum coolers or fans) will pose the lowest risk.

Water and ice used in cooling operations should be considered a potential source of pathogenic contamination. Further, reuse of water to cool continuous loads of produce increases the risk of cross-contamination. For example, contaminated produce from a single container going through a cooling process may result in the build-up of pathogens over time in the cooling water supply. Operators should follow good management practices to ensure that chilling does not introduce food safety hazards. Practices may include the following.

#### • Maintain temperatures that promote optimum produce quality.

The benefits of chilling to remove field heat and the temperature requirements for optimum keeping quality vary for different types of produce. Adequate refrigeration, in conjunction with crop characteristics, such as pH, is an important safeguard against many pathogens. Further, good quality, intact produce is most resistant to microbial contamination and growth. Thus, maintaining temperatures that promote optimum product quality may reduce the risk of microbial hazards.

#### • Maintain air cooling equipment and cooling areas.

Air cooling equipment and cooling areas should be periodically cleaned and inspected. Potential sources of contamination should not be located near air intakes.

#### • Consider the use of antimicrobial chemicals in cooling water.

Antimicrobial chemicals in cooling water may reduce the potential for microbial contamination of produce.

#### • Keep water and ice clean and sanitary.

Consider periodic microbial testing of chilling water and water used to make ice. Operators should contact ice suppliers for information about the source and quality of their ice. Water in hydrocoolers should be changed as needed to maintain quality.

#### Manufacture, transport, and store ice under sanitary conditions.

#### • Equipment should be clean and sanitary.

Chilling equipment, such as hydrocoolers, and containers holding produce during chilling operations should be clean and sanitary. Field soil should be removed as much as possible from produce and containers prior to chilling. Interiors of hydrocoolers should routinely be cleaned and sanitized.

#### III. MANURE AND MUNICIPAL BIOSOLIDS

Growers should follow good agricultural practices for handling animal manure or biosolids to minimize microbial hazards.

Properly treated manure or biosolids can be an effective and safe fertilizer. Untreated, improperly treated, or recontaminated manure or biosolids used as a fertilizer, used to improve soil structure, or that enters surface or ground waters through runoff, may contain pathogens of public health significance that can contaminate produce. Crops in or near the soil are most vulnerable to pathogens which may survive in the soil. Low growing crops that may be splashed with soil during irrigation or heavy rainfall are also at risk if pathogens in manure persist in the soil. Produce where the edible portion of the crop generally does not contact soil is less at risk of contamination provided that produce that does contact the ground (e.g., windfalls) is not harvested. As with agricultural water, physical characteristics of produce that foster entrapment or attachment also affect risk.

Growers using manure or biosolids need to follow good agricultural practices to minimize microbial hazards. Growers also need to examine their specific growing environment to identify obvious sources of fecal matter that could be a source of contamination.

#### A. Microbial Hazard

Animal manure and human fecal matter represent a significant source of human pathogens. A particularly dangerous pathogen, *Escherichia coli* O157:H7, is known to originate primarily from ruminants such as cattle, sheep and deer, which shed it through their feces. In addition, animal and human fecal matter are known to harbor *Salmonella*, *Cryptosporidium*, and other pathogens. Therefore, the use of biosolids and manures, including solid manure, manure slurries, and manure tea, must be closely managed to limit the potential for pathogen contamination. Growers must also be alert to the presence of human or animal fecal matter that may be unwittingly introduced into the produce growing and handling environments. Potential sources of contamination include use of untreated or improperly treated manure; nearby composting or manure storage areas, livestock, or poultry operations; nearby municipal wastewater or biosolids storage, treatment, or disposal areas; and high concentrations of wildlife in the growing and harvesting environment (such as nesting birds in a packing shed or heavy concentrations of migratory birds, bats, or deer in fields). (See also Sections IV and V regarding worker hygiene and sanitary facilities in produce growing and packing environments.)

#### **B.** Control of Potential Hazards

Good agricultural practices for the use of animal manure or biosolids include treatments to reduce pathogens and maximizing the time between application to production areas and harvest of the crops.

#### 1.0 Municipal Biosolids

On July 18, 1991, the Environmental Protection Agency (EPA) published a notice in the Federal Register outlining the U.S. policy statements on the beneficial use of biosolids on Federal land, including its use on food crops (56 FR 33186). Requirements for the use of biosolids are set out in Title 40 of the Code of Federal Regulations, part 503 (40 CFR part 503). Part 503 requires either elimination of pathogens or significant reduction of pathogens along with certain restrictions (such as minimum times between the application of biosolids and the harvest of different food or feed crops). Some states also have requirements for the use of biosolids. Growers using biosolids must first meet the requirements of Part 503 and then comply with any additional state requirements. Since animal manure may contain equal or higher levels of certain pathogens, some of which are infectious to humans, growers may want to consider some of the principles behind the Part 503 requirements and consider the appropriateness of adapting these practices to the land application of manure. (See Appendix for information on obtaining 40 CFR part 503.) The use of biosolids on fields used to produce food crops involves a number of concerns in addition to microbial risk factors (e.g., potentially toxic heavy metals and organic compounds) that are beyond the scope of this document (which focuses on microbial hazards). However, these concerns are addressed in the Part 503 regulation. Growers may obtain guidance on proper agronomic methods for the use of biosolids from USDA's Natural Resources Conservation Service (NRCS) (formerly the Soil Conservation Service), and Cooperative State Research, Education, and Extension Service (CSREES). For additional technical information on the use of biosolids or manure in crop production, including fruits and vegetables, growers may consult the resources at the end of this section.

#### 2.0 Good Agricultural Practices for Manure Management

Growers should follow good agricultural practices for handling animal manure to reduce the introduction of microbial hazards to produce. Such practices include processes, like composting, that are designed to reduce possible levels of pathogens in manure. Good agricultural practices may also include minimizing direct or indirect manure-to-produce contact, especially close to harvest.

Examples of good agricultural practices for growers to consider are discussed below.

#### 2.1 Treatments to Reduce Pathogen Levels

A variety of treatments may be used to reduce pathogens in manure and other organic materials. Treatment may be performed by the grower using organic materials generated on the farm or by a supplier. Choice of treatment will

depend on the needs and resources of an individual grower or supplier. Treatments may be divided into two groups, passive and active.

#### 2.1.1 Passive treatments

Passive treatments rely primarily on the passage of time, in conjunction with environmental factors, such as natural temperature and moisture fluctuations and ultraviolet (UV) irradiation, to reduce pathogens. To minimize microbial hazards, growers relying on passive treatments should ensure manure is well aged and decomposed before applying to fields. Holding time for passive treatments will vary depending on regional and seasonal climatic factors and on the type and source of manure. Passive treatments such as aging should not be confused with actively managed treatments such as composting.

#### 2.1.2 Active treatments

Active treatments generally involve a greater level of intentional management and a greater input of resources compared with passive treatments. Active treatments include pasteurization, heat drying, anaerobic digestion, alkali stabilization, aerobic digestion, or combinations of these.

Composting is an active treatment commonly used to reduce the microbial hazards of raw manure. It is a controlled and managed process in which organic materials are digested, aerobically or anaerobically, by microbial action. When composting is carefully controlled and managed, and the appropriate conditions are achieved, the high temperature generated can kill most pathogens in a number of days. Thus, the risk of microbial contamination from composted manure is reduced compared to untreated manure.

Composting should not be confused with simpler passive treatments such as aging. In general, passive treatments, such as aging, will require a significantly longer period of time to reduce microbial hazards compared to active treatments which expose pathogens to lethal conditions, such as high temperature or high pH. In addition, much of the research on the composting of manure and application of manure to field crops has focused on the effects of different practices on soil fertility and crop quality. Research on pathogen survival in untreated manure, treatments to reduce pathogen levels in manure, and assessing the risk of cross-contamination of food crops from manure under varying conditions is largely just beginning. Some pathogens tolerate higher temperatures than others. In addition, management practices required to achieve the time and temperature necessary to eliminate or reduce microbial hazards in manure or other organic materials may vary depending on seasonal and regional climatic factors (such as ambient temperature and rainfall) and on the specific management practices of an individual operation.

While the agencies do not have sufficient data to make specific time and temperature recommendations that would apply to all composting or other manure treatment operations, good agricultural practices, as discussed below, may reduce the risk of microbial contamination of fresh produce by manure.

#### 2.2 Handling and Application

Review existing practices and conditions to identify potential sources of contamination.

### • Manure storage and treatment sites should be situated as far as practicable from fresh produce production and handling areas.

Minimize contamination of produce from manure in open fields, compost piles, or storage areas. Manure storage or treatment sites close to fresh produce fields or packinghouses increase the risk of microbial contamination. Thus, manure storage and treatments sites should be situated as far as practicable from fresh produce production and handling areas. The minimum distance necessary will depend on many factors, including farm layout and the slope of the land, what runoff controls are in place, the likelihood of wind-spread or heavy rainfall, and the quantity of manure and how it is contained.

- Consider barriers or physical containment to secure manure storage or treatment areas where contamination from runoff, leaching, or wind spread is a concern.
  - Physical containment may include concrete block, soil berms, pits, or lagoons. Practices such as storage on concrete slabs or in clay lined lagoons may reduce the potential of leachate entering groundwater.
- Consider good agricultural practices to minimize leachate from manure storage or treatment areas contaminating produce.

Rainfall onto a manure pile can result in leachate, potentially containing pathogens. Growers may want to consider covering manure piles, such as storing manure under a roof or covering piles with an appropriate covering. Alternatively, growers may consider collecting water that leaches through manure that is being stored or treated. Collecting leachate allows the grower to control its disposal (e.g., on a vegetative grassway) or use (e.g., to control moisture during composting). Leachate may pose a microbial hazard similar to the manure from which it originates. Growers using manure leachate or manure tea in fresh produce production areas should follow good agricultural practices, such as maximizing time between application and harvest, to minimize microbial hazards.

- Consider practices to minimize the potential of recontaminating treated manure.
  - -Treated manure can be recontaminated by birds and rodents. Covered storage and reducing nearby harborage, like tall grass and debris, may reduce the potential for recontamination.
  - -Equipment, such as tractors, that come into contact with untreated or partially treated manure and are then used in produce fields can be a source of contamination. Equipment used to turn compost, and other

multiple use equipment that contacts manure, should be cleaned (such as with high pressure water or steam sprays) before it contacts fresh produce. Growers should also be aware of other factors, such as farm layout and traffic flow, that may allow a tractor to drive through manure before entering a produce field.

#### 2.2.1 Untreated Manure

Use of untreated (raw) manure on food crops carries a greater risk of contamination compared with the use of manure that has been treated to reduce pathogens. Growers using untreated manure may need to consider the following good agricultural practices:

- Consider incorporating manure into the soil prior to planting.

  Competition with soil microorganisms may reduce pathogens. Incorporating manure into the soil (e.g., prior to planting) may reduce microbial hazards.
- Applying raw manure, or leachate from raw manure, to produce fields during the growing season prior to harvest is not recommended.
- Maximize the time between application of manure to produce production areas and harvest.
  - In general, the shorter the time between application of raw manure to a production area and harvest of the crop, the greater the risk of pathogens being present in manure or soil and contaminating the crop. Although no one knows for sure how long pathogens can survive in the field or on produce, some researchers have reported that, depending on conditions, pathogens may survive in raw manure for as much as a year or longer (Ref. 11 and 12). Growers should maximize, to the greatest extent possible, the time between application of manure to produce production areas and harvest.
  - Good agricultural practices to maximize the time between manure application and harvest of produce for the fresh market include, but are not limited to, post-harvest application and incorporation, applying raw manure to a fall cover crop to minimize nutrient loss, planning crop rotations where manure is applied to agronomic crops, or to fields planted with crops that are to be cooked or properly heat-processed prior to being delivered to consumers.
  - Additional research is needed to determine how pathogens in manure may spread in the field. However, for some operations, drift, flooding, or runoff from adjacent fields may result in microbial hazards. Growers may consider scheduling application of raw manure on adjacent fields to maximize the time between manure application to those fields and harvest of fresh market produce. Growers may also consider establishing field plans where the fields closest to fresh produce crops are planted with crops that do not receive raw manure.
- Where it is not possible to maximize the time between application and harvest, such as for fresh produce crops which are harvested throughout most of the year, raw manure should not be used.

#### 2.2.2 Treated Manure

Natural fertilizers, such as composted manure, and fertilizers containing natural components, should be processed and handled in a manner to reduce the likelihood of introducing pathogens into produce production areas. Composting, appropriate aging, and other treatments may reduce but might not eliminate pathogens in manure. Furthermore, it is unknown to what extent pathogens that survive treatment may regrow in treated manure that is stored before use. Therefore, growers using treated manure may want to consider some of the recommendations made for untreated manure, such as maximizing time between application and harvest. Additional good agricultural practices for handling and application of treated manure follow.

- Avoid contamination of fresh produce from manure that is in the process of being composted or otherwise treated.
- Apply good agricultural practices that ensure that all materials receive an adequate treatment.
  - The specific requirements of any treatment to reduce pathogens depend on many factors, including types of organic materials being treated, pH, moisture content, process management, the carbon/nitrogen balance of the organic materials, and even climatic factors such as rainfall and temperature.
  - Whatever parameters are selected, growers and manure suppliers should apply good agricultural practices that ensure that all materials receive an adequate treatment, such as thorough mixing and turning outside edges into the center of a compost pile. Cold spots or other pockets that do not receive an adequate treatment can recontaminate the rest of the batch.
- Growers purchasing manure should obtain a specification sheet from the manure supplier for each shipment of manure containing information about the method of treatment.
- Growers should contact state or local manure handling experts for advice specific to their individual operations and regions.

Assistance may be available through agricultural colleges or cooperative extension services.

#### 3.0 Animal Feces

Animal feces is a known source of pathogens that can cause foodborne illness.

While it is not possible to completely exclude all animal life from all fresh produce production areas, many field programs include elements to protect crops from animal damage. Growers should review existing practices and

conditions to assess the prevalence and likelihood of significant amounts of uncontrolled deposits of animal feces coming into contact with crops. Good agricultural practices for minimizing hazards from livestock include:

- Domestic animals should be excluded from fresh produce fields, vineyards, and orchards during the growing season.
  - Depending on the operation, good management practices may include keeping livestock confined (e.g., in pens or yards) or preventing their entry into fields by using physical barriers such as fences.
- Where necessary, growers should consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas.
  Growers should determine whether surrounding fields and farms are used for animal production. Growers may need to consider measures to ensure that animal waste from adjacent fields or waste storage facilities does not contaminate the produce production areas during heavy rains, especially if fresh produce is grown in low-lying fields or orchards. Measures might include physical barriers, such as ditches, mounds, grass/sod waterways, diversion berms, and vegetative buffer areas.

In addition, high concentrations of wildlife (such as deer or waterfowl in a field) may increase the potential for microbial contamination. Control of wild animal populations in the field may be difficult, especially where crop production areas are adjacent to wooded areas, open meadows, and waterways. Federal, state, or local animal protection requirements must also be considered. However, to the extent possible, where high concentrations of wildlife are a concern, growers should consider establishing good agricultural practices to deter or redirect wildlife to areas with crops that are not destined for the fresh produce market. Helpful Resources:

The NRCS Conservation Practice Standard 317, "Composting Facility" sets out standards for on-farm composting (USDA, SCS, December 1990) (202) 720-5157; <a href="http://www.ncg.nrcs.usda.gov/nhcp\_2.html">http://www.ncg.nrcs.usda.gov/nhcp\_2.html</a>.

NRCS AWMFH 651.1004(F), Rynk et al., "On Farm Composting Handbook," NRAES-54 Natural Resource, Agriculture, and Engineering Service, Cooperative Extension, 152 Riley-Robb Hall, Ithaca, NY 14853-5701 (607) 255-7654.

R.T. Haug, 1993, "The Practical Handbook of Compost Engineering," Tachnomics Publishing Co., Inc, Lancaster, PA.

"Domestic Septage Regulatory Guidance - A Guide to the EPA 503 Rule," EPA 832-B-92-005, September, 1993. US EPA, "A Plain English Guide to the EPA Part 503 Biosolids Rule," EPA 1832-R-93-003, Washington DC, 1994. Environmental Regulation and Technology Control of Pathogens and Vector Attraction Reduction, EPA 1625/1-92/013, December 1992.

#### IV. WORKER HEALTH AND HYGIENE

Be aware of existing state and Federal regulations regarding standards for worker health, hygiene and sanitation practices during the growing, packing, holding, and transport of human food.

Operators should be aware of and follow applicable standards for protecting worker health established under the Occupational Safety and Health Act. In addition, the U.S. Code of Federal Regulations (CFR) Title 21, Section 110.10 (21 CFR 110.10) prescribes worker health and hygienic practices within the context of GMPs in the manufacturing, packing, or holding of human food. The standards in this section should be considered when establishing hygienic practices appropriate for the agricultural environment (field, packing facility, and transport operations). Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws for protecting worker health.

#### A. Microbial Hazards

# Infected employees who work with fresh produce increase the risk of transmitting foodborne illnesses.

Past outbreaks of foodborne illness associated with fresh and minimally processed produce have usually been the result of produce becoming contaminated with fecal material. Therefore, operators should place a high priority on ensuring the use of agricultural and management practices that minimize the potential for direct or indirect contact between fecal material and fresh fruits and vegetables. In addition, infectious diseases, accompanied by diarrhea or open lesions, that include boils, sores, or infected wounds, are a source of disease-causing microorganisms.

The importance of food workers understanding and practicing proper hygiene cannot be overemphasized. Workers can unintentionally contaminate fresh produce, water supplies, and other workers, and transmit foodborne illness if they do not understand and follow basic hygienic principles. For example, in 1994, there was a community hepatitis A outbreak in New York among individuals who had consumed bakery foods (Ref. 13). The source of the infection was a baker who contaminated baked goods while applying sugar glaze. In 1995, a foodborne outbreak, culture-confirmed for *Salmonella typhimurium*, occurred in a Minnesota nursing home (Ref. 14). Data from the investigation indicated that the *Salmonella* was likely transmitted by the consumption of mechanically softened foods, possibly contaminated by an infected employee.

#### **B.** Control of Potential Hazards

### Train all employees to follow good hygienic practices.

#### 1.0 Personal Health and Hygiene

It is important to ensure that all personnel, including those indirectly involved in fresh produce operations, such as equipment operators, potential buyers and pest control operators, comply with established hygienic practices. Operators should consider the following practices.

#### • Establish a training program.

- All employees, including supervisors, full time, part time and seasonal personnel, should have a good working knowledge of basic sanitation and hygiene principles. The level of understanding needed will vary as determined by the type of operation, the task, and the assigned responsibilities.
- Each producer should develop a sanitation training program for their employees. Depending on the situation, formal presentations, one-on-one instruction, or demonstrations (example, handwashing) may be appropriate. Depending on the workers' job requirements, periodic refresher or follow-up training sessions may be needed. (Also, see section 2.0 below on training.)
- If a formalized training program is not practical, such as for part time and seasonal field personnel, the operator or the supervisor should verbally instruct and demonstrate to newly hired workers proper health and hygiene practices, such as proper handwashing techniques.

#### • Become familiar with typical signs and symptoms of infectious diseases.

- The pathogens *Salmonella typhi*, *Shigella* species, *E. coli* O157:H7, and hepatitis A virus have a high infectivity, which is the ability to invade and multiply in the body, and virulence, which is the ability to produce severe disease. Any worker showing symptoms of an active case of illness that may be caused by any of these pathogens should be excluded from work assignments that involve direct or indirect contact with fresh produce. Workers with diarrheal disease and symptoms of other infectious diseases should not work with fresh produce or the sorting and packing equipment in the packing facility. See the Appendix 1 for more information on symptoms of infectious diseases that can contaminate food. Operators may also want to consult FDA's Food Code (Ref. 4).
- Operators should instruct employees to report any active case of illness to their supervisor before beginning work. Supervisors should be familiar with the symptoms of infectious diseases so that if symptoms are evident, the supervisor can take appropriate steps.

#### • Provide protection from a lesion.

A lesion that contains pus, such as a boil or infected wound that is open or draining and that is located on parts of the body that might have contact with produce or produce harvesting, sorting, or packing equipment, increases the risk of contaminating fresh produce. If a worker has a lesion that cannot be effectively covered in such a way to prevent contact with fresh produce or related equipment, the employee should not be working in any aspect with fresh produce, utensils, or other food contact surfaces of equipment.

#### • Consider alternative good hygienic practices.

Single-service disposable gloves can be an important and effective hygienic practice in combination with handwashing in some circumstances. If gloves are used, be sure they are used properly and do not become another vehicle for spreading pathogens. The use of gloves in no way lessens the need or importance of handwashing and proper hygienic practices.

### • Ensure good hygienic practices are followed by visitors to the farm, packing, or transport facilities whenever they come into contact with fresh produce.

Operators should require that product inspectors, buyers, and other visitors comply with established hygienic practices when inspecting produce.

#### 2.0 Training

When providing training for employees, the requirements under the Occupational Safety and Health Act (29 CFR 1910.141, subpart J, and 29 CFR 1928.110) that are applicable to worker health and training should be considered. See Appendix 2 for information on how to obtain a copy of these regulations. Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws for protecting worker health. Other areas of training to consider include, but are not limited to, the following:

#### • The importance of good hygiene.

All personnel should understand the impact of poor personal cleanliness and unsanitary practices on food safety. Good hygiene not only protects the worker from illness, but it reduces the potential for contaminating fresh produce which, if consumed by the public, could cause a large number of illnesses.

#### • The importance of handwashing.

Thorough handwashing before commencing work with produce and after using the toilet is very important. Many of the diseases that are transmissible through food may be harbored in the employee's intestinal tract and shed in the feces. Contaminated hands can also transmit infectious diseases.

#### • The importance of proper handwashing techniques.

Don't assume that workers know how to wash their hands properly. Teach proper handwashing techniques which include the following:

- Handwashing with water. Warm water is more effective than cold water for washing hands;
- Use of soap; and
- Thorough scrubbing (including cleaning under fingernails and between fingers), rinsing, and drying of the hands. Common, or shared, towels should be not be used.

#### • The importance of using toilet facilities.

Teach all employees the importance of using toilet facilities connected to a sewage disposal system, or properly constructed on-site sanitary pit privies, or latrines to reduce the potential for contaminating fields, produce, other workers, and water supplies. See section V. (Sanitary Facility) for additional information about toilet facilities.

#### 3.0 Customer-Pick Operations and Road-Side Produce Stands

Growers who have a customer-pick operation should consider the good agricultural practices presented in this guide regarding water quality and the use of manure. Growers who allow the public to pick their own fruits or vegetables in the field or who sell their own produce directly to customers should also consider the following good agricultural practices.

#### Promote good hygienic practices.

Encourage customers to wash hands. Provide convenient, properly equipped handwashing stations in the field. Handwashing stations should be equipped with a basin, water, liquid soap, sanitary hand drying devices (such as single-use paper towels), and a waste container.

### • Provide clean, properly supplied, and convenient toilets for customer use.

Provide an adequate supply of toilet paper.

#### Promote good handling/processing practices.

Encourage all customers to thoroughly wash all fruits and vegetables to be eaten raw.

#### V. SANITARY FACILITIES

#### A. Microbial Hazards

Operations with poor management of human and other wastes in the field or packing facility can significantly increase the risk of contaminating produce.

#### **B.** Control of Potential Hazards

Operators should operate their facilities or farms in accordance with the laws and regulations that describe field and facility sanitation practices. The field sanitation laws prescribed under the Occupational Safety and Health Act 29 CFR 1928.110, subpart I, describe the appropriate number of toilets to the number of workers, proper handwashing facilities, maximum worker-to-restroom distance, and how often such facilities should be cleaned. Good field sanitation helps reduce the potential for contaminating produce and ensures that employees and consumers are protected from foodborne diseases.

OSHA standards under 29 CFR 1910.141, subpart J, provide regulations relative to toilet facilities and other sanitation issues. Enclosed packing facilities come under these regulations.

In addition, the CFR prescribes current good manufacturing practices for buildings and facilities, equipment, and production and process controls for foods (21 CFR 110.20 to 110.93), and is a good resource to guide the development of mitigation programs. Packers should also consider application of food service type standards, such as found in FDA's Food Code (Ref. 4), in packing facility environments.

Operators outside of the U.S. should follow corresponding or similar standards, regulations, or laws regarding field and facility sanitation practices. See appendix 2 for information on how to obtain copies of OSHA and FDA regulations.

#### 1.0 Toilet Facilities and Handwashing Stations

#### Toilet facilities should be accessible.

The more accessible the facilities, the greater the likelihood that they will be used. Workers should always have the opportunity to use the facilities when they need to, not only when they are on break. This helps reduce the incidence of workers in the field or outside packing areas relieving themselves elsewhere (such as in fields).

#### Toilet facilities should be properly located.

Toilet facilities in the field should not be located near a water source used in irrigation or in a location that would subject such facilities to potential runoff in the event of heavy rains. Runoff from improperly constructed and located toilet facilities has the potential to contaminate soil, water sources, produce, animals, and workers.

#### • Toilet facilities and handwashing stations should be well supplied.

Provide an adequate supply of toilet paper. Handwashing stations should be equipped with a basin, water, liquid soap, sanitary hand drying devices (such as disposable paper towels), and a waste container.

#### • All facilities should be kept clean.

Toilets and handwashing stations, whether attached to the toilet facility or located near it, should be cleaned on a regular basis. Containers used to transport or store water for handwashing should, on a routine basis, be emptied and thoroughly cleaned, sanitized, and refilled with potable water.

#### 2.0 Sewage Disposal

Improper disposal of human waste from toilets could lead to water, soil, animal, crop, or worker contamination. Systems and practices should be in place to ensure safe management and disposal of waste from permanently installed or portable toilets to prevent drainage into the field. Operators should follow EPA regulations for the use or disposal of sewage sludge, 40 CFR Part 503, or refer to EPA's "Domestic Septage Regulatory Guidance: A Guide to the EPA Part 503 Rule," or corresponding or similar standards, regulations, or laws for international operators. See Appendix 2 for information on how to obtain a copy of U.S. regulations. Examples of good practices to consider are as follows:

#### • Use caution when servicing portable toilets.

Waste water from portable toilet facilities that may drain into a field can contaminate fresh produce. Sewage transport trucks need direct access to toilet facilities to ensure proper collection and disposal of wastes through a municipal sewage system or a sub-surface septic tank system.

• Have a plan for containment and treatment of any effluent in the event of leakage or a spill. Operators should be made aware and be prepared in the event of any incidence of leakage or spillage of effluent in a field. Refer to 40 CFR Part 503 for additional guidance.

#### VI. FIELD SANITATION

Poor management of human and other wastes in the field can significantly increase the risk of contaminating produce.

#### A. Microbial Hazards

Microbial contamination or cross-contamination of fresh produce during pre-harvest and harvest activities may result from contact with soils, fertilizers, water, workers, and harvesting equipment. Any of these may be a source of pathogenic microorganisms.

Sections II. and III. of this guidance document address the concerns associated with water quality and use of manure and municipal biosolids. Sections IV. and V. address the importance of worker health and hygiene and sanitary facilities. Section VII. provides general guidance for packing facilities.

#### **B.** Control of Potential Hazards

#### 1.0 General Harvest Considerations

- Clean harvest storage facilities prior to use.
  - Facilities used to store fresh produce should be cleaned and, as necessary, disinfected prior to harvest. These facilities should also be inspected for evidence of pests, such as rodents, birds, and insects. (See section VII. B. 3.0 for guidance on pest control.)
- Discard damaged containers that are no longer cleanable in an effort to reduce possible microbial contamination of fresh produce.
- Clean containers or bins before using to transport fresh produce.
   Containers used to transport ready-to-eat produce should be routinely cleaned and sanitized.
- Ensure that produce that is washed, cooled, or packaged in the field is not contaminated in the process.
  - Contact with manure or biosolids, poor quality water, workers with poor hygiene, and unclean packaging or packing boxes greatly increases the risk of contaminating fresh produce with pathogenic microorganisms.
- Remove as much dirt and mud as practicable from the produce before it leaves the field.

  Removing mud from fresh produce when fields are muddy may not be practical. At such times, adhering mud would have to be removed at the packing facility prior to sorting, grading, and packing.

#### 2.0 Equipment Maintenance

Field equipment, such as harvesting machinery, knives, containers, tables, baskets, packaging materials, brushes, buckets, etc., can easily spread microorganisms to fresh produce. Operators should consider the following guidelines:

- Use harvesting and packing equipment appropriately and keep it as clean as practicable.

  Any equipment used to haul garbage, manure, or other debris should not be used to haul fresh produce or contact the containers or pallets that are used to haul fresh produce without first being carefully cleaned and sanitized.
- Keep harvest containers clean to prevent cross-contamination of fresh produce
  Harvest containers used repeatedly during a harvest should be cleaned after each load is delivered and prior
  to reuse. If the containers are stored outside, they should be cleaned and sanitized before being used to haul
  fresh produce.
- Assign responsibility for equipment to the person in charge.

  The person with assigned responsibility needs to know how equipment is being used during the day, ensure that it is functioning properly, and take steps to ensure proper cleaning and sanitizing of equipment when needed.

#### VII. PACKING FACILITY SANITATION

It is important to maintain buildings, fixtures, and other physical facilities, and their grounds, in good condition to reduce the potential for microbial contamination of produce.

#### A. Microbial Hazard

Operations with poor sanitation in the packing environment can significantly increase the risk of contaminating fresh produce and water used on produce. Pathogenic microorganisms may be found on the floors and in the drains in the packing facility and on the surfaces of sorting, grading, and packing equipment. Without good sanitary practices, any of these surfaces that come in contact with fresh produce could be a potential source of microbial contamination. Packers should employ good sanitation practices as a standard operating procedure to maintain control throughout the packing operation.

#### **B.** Control of Potential Hazards

#### 1.0 General Packing Considerations

 Remove as much dirt and mud as practicable from fresh produce outside of packing facilities or packing areas.

Take additional care to protect fresh field-packed produce from possible contamination because of possible exposure to manure and animal fecal material in the soil. Operators of open packing facilities should also be aware of potential contamination from airborne contaminants from any nearby livestock or poultry areas or manure storage or treatment facilities.

- Repair or discard damaged containers.
  - Inspect containers for damage on a regular basis. Because damaged container surfaces may harbor pathogenic microorganisms and cause damage to the surface of fresh produce, they should not be used.
- Clean pallets, containers or bins before using to transport fresh produce.
   Operators might set aside an area in the receiving yard to clean pallets and containers used for whole fresh fruits and vegetables. Containers used for ready-to-eat fresh produce should be cleaned and sanitized. Care must be taken when packing produce in the field not to contaminate containers or bins by exposure to soil and manure.
- Protect unused cleaned and new packing containers from contamination when in storage.
   Packing containers and other packing materials that are not used right away should be stored in a way that protects them from contamination by pests (such as rodents), dirt, and water condensing from overhead equipment and structures. If packing containers are stored outside the packing facility, they should be cleaned and sanitized before use.

#### 2.0 General Considerations for Facility Maintenance

Packing and storage facilities should always be maintained in a clean condition. Equipment used in sorting, grading, and packing fresh produce should be of such material and workmanship as to be adequately cleanable. The design, construction, use, and general cleanliness of equipment can help reduce the risk of cross contamination of produce. Operators or growers should consider the following practices:

- Keep equipment or machinery that comes in contact with fresh produce as clean as practicable. All sorting, grading, and packing equipment that makes contact with fresh produce may serve as a vehicle for spreading microbial contamination. Remove mud and debris from processing equipment daily. Equipment such as knives, saws, blades, boots, gloves, smocks, and aprons should be cleaned, inspected for defects that make them uncleanable on a regular basis, and replaced as needed.
- Clean packing areas at end of each day.
  - As necessary, clean and sanitize the washing, grading, sorting, and packing lines to reduce the potential for microbial contamination of fresh produce.
- Maintain the cooling system to ensure proper functioning of the equipment.

  Inspect all cooling equipment daily, remove all debris, and clean as necessary when in use.
- Clean product storage areas regularly.
  - Remove, as much as practicable, all visible debris, soil, dirt, and unnecessary items from product storage areas on an ongoing basis. Clean these areas on a regularly scheduled and "as needed" basis and take steps to minimize free-floating dust and other airborne contaminants.

#### 3.0 Pest Control

All animals, including mammals, birds, reptiles, and insects, are potential sources of contamination in produce environments because they harbor, or could be a vector for, a variety of pathogenic agents, such as *Salmonella*. In general, pest problems can be minimized by taking precautions, such as:

• Establish a pest control system.

For all facilities, establish a pest control program to reduce the risk of contamination by rodents and other animals. The program should include regular and frequent monitoring of affected and treated areas to accurately assess the program's effectiveness.

#### • Maintain the grounds in good condition.

- Grounds in the immediate vicinity of all packing areas should be kept clear of waste, litter, and improperly stored garbage. Keep all grasses cut to discourage the breeding, harboring, and feeding of pests, such as rodents and reptiles.
- Remove any unnecessary articles, including old and inoperative equipment that is no longer used, to eliminate areas that harbor rodents and insects.
- Clean daily to remove product or product remnants that attract pests in and around the packing facility and any other packing facility where product is handled or stored.
- Maintain adequate surface drainage to reduce breeding places for pests.

#### • Monitor and maintain facilities regularly.

- Regularly inspect all facilities to check for evidence of pest populations or animal contamination. Minimize the availability of food and water to pests.
- Remove dead or trapped birds, insects, rodents, and other pests promptly to ensure clean and sanitary facilities and to avoid attracting additional pests.
- As much as practicable, ensure that potential nesting or hiding places for pests have been eliminated.
- Clean surfaces soiled by birds or other wildlife.

#### • Block access of pests into enclosed facilities.

Exclude pests by blocking areas, such as holes in walls, doors, flooring, etc., and vents that allow entrance into the facility. Consider the use of screens, wind curtains, and traps.

#### • Use a pest control log.

Maintain a pest control log that includes dates of inspection, inspection report, and steps taken to eliminate any problems. Establish frequent monitoring of affected and treated areas to determine the effectiveness of the treatment applied.

#### VIII. TRANSPORTATION

# The proper transport of fresh produce from farm to market will help reduce the potential for microbial contamination.

Operators and others involved in the transport of fresh produce are encouraged to scrutinize product transportation at each level in the system, which includes transportation from the field to the cooler, packing facility, and on to distribution and wholesale terminal markets or retail centers. The proper transport of fresh produce helps reduce the potential for microbial contamination. An active and ongoing discussion with personnel responsible for transportation is essential for ensuring the success of any management program designed to deliver safe foods to the consumer.

#### A. Microbial Hazard

Microbial cross-contamination from other foods and nonfood sources and contaminated surfaces may occur during loading, unloading, storage, and transportation operations.

#### **B.** Control of Potential Hazards

Wherever produce is transported and handled, the sanitation conditions should be evaluated. Transporters should separate fresh produce from other food and nonfood sources of pathogens in order to prevent contamination of the produce during transport operations.

#### 1.0 General Considerations

- Workers involved in the loading and unloading of fresh produce during transport should practice good hygiene and sanitation practices.
  - See Section IV for more information about good hygienic practices.
- Product inspectors, buyers, and other visitors should comply with established hygienic practices, such as thoroughly washing their hands before inspecting produce.

#### 2.0 General Transport Considerations

Growers, packers, shippers, brokers, exporters, importers, retailers, wholesalers and others involved in the transport of fresh produce should help ensure that sanitation requirements for trucks or other carriers are met at the different steps within the transportation chain. Some specifics to consider are:

- Inspect trucks or transport cartons for cleanliness, odors, obvious dirt or debris before beginning the loading process.
- Keep transportation vehicles clean to help reduce the risk of microbial contamination of fresh produce.
  - Operators should be aware of prior loads carried in a transport vehicle and take this information into consideration when determining use of a vehicle. Trucks that were recently used to transport animals or animal products, for example, would increase the risk of contaminating fresh produce if the trucks were not cleaned before loading produce. Consult local or state agencies or universities to determine the most appropriate cleaning and sanitization methods for individual operations.
- Maintain proper temperatures to help ensure both the quality and safety of fresh produce.

  Operators should work with transporters to ensure adequate control of transport temperatures from the loading dock to the receiving dock. Transporters should be aware of temperature requirements for produce being hauled and avoid delivery of mixed loads with incompatible refrigeration requirements.
- Load produce in trucks or transport cartons in a manner that will minimize damage.

  All fresh produce should be carefully loaded in trucks or transport cartons in a manner designed to minimize physical damage to the produce and to reduce the potential for contamination during transport. Produce should also be loaded so as to allow proper refrigerated air circulation.

#### IX. TRACEBACK

The ability to identify the source of a product can serve as an important complement to good agricultural and management practices intended to minimize liability and prevent the occurrence of food safety problems.

Traceback is the ability to track food items, including fresh produce, back to their source (growers, packers, etc.). A system to identify the source of fresh produce cannot prevent the occurrence of a microbiological hazard that may lead to an initial outbreak of foodborne disease. However, the ability to identify the source of a product through traceback can serve as an important complement to good agricultural and management practices intended to prevent the occurrence of food safety problems. Information gained from traceback investigation may also be useful in identifying and eliminating a hazardous pathway.

#### Overview of the traceback process

Food items suspected of causing outbreaks of illness are typically identified through epidemiological studies. Once an outbreak is suspected, public health officials begin scientific studies to determine common food items consumed during the period of infection for the pathogen. If these epidemiological studies implicate a particular food product and hazard analysis shows that other contributing causes were not to blame (for example, cross-contamination, ill food workers, other sources of infectious agent, etc.), health officials attempt to obtain the following information:

- At the Point of Service establishment (where the product was sold or prepared), pertinent product identifying information, including product types, packaging, labeling, and lot numbers, if applicable, is obtained. Health officials also determine when the product was purchased or prepared, and determine receiving, stock rotation, inventory, handling and shipping procedures. Records are collected about suppliers and shipments of the implicated product to the Point of Service over the shelf life of the implicated product.
- 2. Data relating to distribution of the implicated product is charted and analyzed. This analysis is accomplished either by tracing lot numbers, if they are available; or using a Shipment Delivery Time Line to identify suspect shipments, based on knowledge about the time period when the implicated product is useable and salable during the infection period.
- 3. Distributor interview, data collection, and analysis are repeated for each level of distribution until health officials identify the source of the product.

Depending on the pathogen involved, and the suspected food source, there can be wide variations in the reliability of the data obtained from such studies. In most instances in the fresh produce industry, lot numbers/grower identifications are not commonly used or recorded on receipt/shipping records. Public health investigators must rely on record review and interviews. This method increases the time and resources necessary to trace an implicated product back to its source. Further, review of records that may not be complete and interviews with people whose memories may be imperfect make it more difficult to narrow down the cause(s) of an outbreak.

#### Challenges facing the produce industry

Fresh produce with a relatively short shelf life is often gone by the time an outbreak is reported, making it extremely difficult to identify the item causing foodborne illness. If fresh produce is linked to an outbreak, current industry practices in the marketing and distribution systems, such as using recycled shipping crates and co-mingling during distribution or at retail, make a direct identification of the source of a product very difficult. If an implicated source (for example, a field or packing facility) is identified, the source of contamination may no longer be present when investigators arrive on the scene. This variability and lack of a direct determination of cause have resulted in a high degree of uncertainty, and, in some cases, false associations. The economic burden of a false association is especially troublesome for those industry segments that may later be proven not to have been involved in the actual outbreak.

#### Advantages of an effective traceback system

Despite the best of efforts by food industry operators, food may never be completely free of microbial hazards. However, an effective traceback system, even if only some items carry identification, can give investigators clues that may lead to a specific region, packing facility, even field, rather than an entire commodity group. Narrowing the potential scope of an outbreak could lessen the economic burden on those industry operators not responsible for the problem.

From a public health perspective, improving the speed and accuracy of tracing implicated food items back to their source may help limit the population at risk in an outbreak. Rapid and effective traceback can also minimize the unnecessary expenditure of valuable public health resources and reduce consumer anxiety. Tracing implicated food items may also help public health officials to determine potential causes of contamination, thereby providing data for growers, shippers, and others for identifying and minimizing microbial hazards.

#### **Instituting effective traceback systems**

Because of the diversity of handling practices throughout the produce distribution and marketing chain, a traceback system may be more easily implemented for some commodities. For example, traceback systems may be more

easily implemented for larger operations that have more direct control over a greater number of steps in the growing/packing/distribution chain. However, industry associations, growers, and operators are encouraged to consider ways to provide this capability, where feasible.

Operators should examine current company procedures and develop procedures to track individual containers from the farm, to the packer, distributor, and retailer, in as much detail as possible. At a minimum, an effective traceback system should have documentation to indicate the source of a product and a mechanism for marking or identifying the product that can follow the product from the farm to the consumer. Documentation should include:

- a. Date of harvest,
- b. Farm identification, and
- c. Who handled the produce from grower to receiver.

Many growers, especially smaller operations, have little control over what happens to produce after it enters the distribution and marketing chain. Therefore, it is critical that growers, packers, and shippers work with their partners in transportation, distribution, and retail to develop technologies that allow grower/packing facility identification to follow fresh produce from the grower to the retailer and consumer. Some industry trade groups are developing technologies (such as bar codes, stamps, stickers, tags, etc.) to identify the source of produce and software to assist retailers in providing more accurate traceback to the grower/packer level.

#### X. CONCLUSION

## Once good agricultural practices are in place, it is important to ensure that the process is working correctly.

Protecting the safety of the U.S. food supply requires a comprehensive and coordinated effort throughout the food production and transportation system. The responsibility to safeguard our food supply is shared by everyone involved, from the grower to the consumer. This includes growers, farm workers, packers, shippers, transporters, importers, wholesalers, retailers, government agencies, and consumers.

This guidance document provides some basic principles and recommended practices for operators to consider that will help minimize microbial food safety hazards in the production, packing, and transport of fresh fruits and vegetables. While research is ongoing and will continue to provide new information and improved technologies, the industry is urged to take a proactive role to minimize those microbial hazards over which they have control. Operators are encouraged to utilize this guide to evaluate their own operations and assess site-specific hazards so they can develop and implement reasonable and cost effective agricultural and management practices to minimize microbial food safety hazards.

As outlined in this guide, analyzing the risk of microbial contamination includes a review of five major areas of concern. These involve: 1) water quality, 2) manure/municipal biosolids, 3) worker hygiene, 4) field, facility, and transport sanitation, and 5) traceback. Growers, packers, and shippers should consider the variety of physical characteristics of produce and practices that affect the potential sources of microbial contamination associated with their operation, and decide on which combination of good agricultural and management practices are most cost effective for them.

Once good agricultural and manufacturing practices are in place, it is important that the operator ensure that the process is working correctly. Operators should followup with supervisors or the person in charge to be sure that regular monitoring takes place, equipment is working, and good agricultural and management practices are being followed. Without accountability to ensure the process is working, the best attempts to minimize microbial food safety hazards in fresh fruits and vegetables are subject to failure.

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### Appendix 1

A wide range of communicable disease and infections may be transmitted by infected employees to consumers through food or food utensils. An important part of an on-going program to ensure the safety of fresh produce is to institute a system of identifying employees who present a risk of transmitting foodborne pathogens to fresh produce or to other employees. Below is a partial list of infectious and communicable diseases that are transmitted through

#### Pathogens Often Transmitted by Food Contaminated by Infected Employees\*

1. Hepatitis A virus Fever, Jaundice

2. Salmonella typhi Fever

3. Shigella species Diarrhea, Fever, Vomiting 4. Norwalk and Norwalk-like viruses Diarrhea, Fever, Vomiting

Diarrhea, Vomiting 5. Staphylococcus aureus

The symptoms of diarrhea, fever, and vomiting are also symptoms of several other pathogens occasionally transmitted by food contaminated by infected employees.

Fever, Sore throat with fever

\*1997 Food Code (Ref. 4)

6. Streptococcus pyogenes

#### Appendix 2

#### **Helpful Information**

Copies of Federal regulations in the Code of Federal Regulations (CFR) may be purchased from the U.S. Government Printing Office or by telephone purchase at (202) 512-1800.

The CFR is also available at local branches of the U.S. Government Printing Office Bookstores. Information on location of regional branches is available on the WWW at the following address: <a href="http://wm.cfsan.fda.gov/~lrd/ob-reg.html">http://wm.cfsan.fda.gov/~lrd/ob-reg.html</a>

Sections of the CFR that are referenced in the guide can be viewed and printed from the WWW at the following address: http://www.access.gpo.gov/nara/cfr/index.html.

#### 1. How to obtain FDA regulations

Title 21, Code of Federal Regulations: 21 CFR 100-169 and 21 CFR 170-199

Sections of Title 21, such as 21 CFR 110.10, that are referenced in the guide can be viewed and printed from the WWW at the following address: <a href="http://www.access.gpo.gov/nara/cfr/">http://www.access.gpo.gov/nara/cfr/</a>.

You may purchase 21 CFR 100-169 or 21 CFR 170-199 from the U.S. Government Printing Office or by telephone purchase at (202) 512-1800. FDA regulations may also be purchased at local branches of the U.S. Government Printing Office Bookstores.

#### 2. How to obtain OSHA standards

OSHA General Industry standards, Title 29 CFR 1910, and OSHA Agricultural Industry standards, Title 29 CFR 1928, may be purchased through a U.S. Government Printing Office or by telephone purchase at (202) 512-1800. 29 CFR 1910.141 and 29 CFR 1928.110, that are referenced in the guide may be viewed and printed from the WWW at the following address: <a href="http://www.osha-slc.gov/OshStd\_toc/OSHA\_Std\_toc.html">http://www.osha-slc.gov/OshStd\_toc/OSHA\_Std\_toc.html</a>.

#### 3. How to obtain EPA regulations

EPA regulations may be obtained by contacting the U.S. EPA/NCEPI, P.O. Box 42419, Cincinnati, OH 45242-2419. Telephone: 1-800-490-9198; FAX (513) 489-8695. You must give the EPA catalog number for the publication.

Electronic versions of additional EPA documents, such as criteria and supporting documents, are available at <a href="http://www.epa.gov">http://www.epa.gov</a>.

#### **Additional Helpful Information**

- 1. U.S. EPA. Ambient Water Quality Criteria for Bacteria, EPA Office of Water Regulations and Standards, EPA 832-B-92-005, January 1986.
- 2. USDA. List of Proprietary Substances and Nonfood Compounds Authorized for Use Under USDA Inspection and Grading Programs.
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- 5. USDA Agricultural Marketing Service program "Qualified Through Verification for Fresh Cut Produce" is available from: Branch Chief, Processed Products Branch, Fruit and Vegetable Programs, Agricultural Marketing Service, USDA, P.O. Box 96456, Rm. 0726, South Building, Washington, DC, 20090-6456. (202) 720-4693.

Analysis of Comments to the Proposed Guide

April 13, 1998 Federal Register Notice

April 13, 1998 Draft Guide

November 25, 1997 Working Draft Guide

Food Safety Initiative